DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 412, 416, and 419

[CMS–1633–P]

RIN 0938–AS42

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2016 to implement applicable statutory requirements and changes arising from our continuing experience with these systems. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Further, this proposed rule includes certain proposals relating to the hospital inpatient prospective payment system: proposed changes to the 2-midnight rule under the short inpatient hospital stay policy, as well as a discussion of the related −0.2 percent payment adjustment; and a proposed transition for Medicare-dependent, small rural hospitals located in all-urban States.

DATES: *Comment Period:* To be assured consideration, comments on all sections of this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on August 31, 2015.

ADDRESSES: In commenting, please refer to file code CMS–1633–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–1633–P, P.O. Box 8013, 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–1633–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:

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact Carol Schwartz at (410) 786–0576.

Ambulatory Surgical Center (ASC) Payment System, contact Erick Chuang at (410) 786–1816.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia at (410) 786–7236.

Ambulatory Surgical Center Quality Reporting (ASCQR) Data Measures, contact Vinitha Meyyur at (410) 786–8819.

Blood and Blood Products, contact Lela Strong at (410) 786–3213.

Cancer Hospital Payments, contact David Rice at (410) 786–6004.

Chronic Care Management (CCM) Services, contact Twi Jackson at (410) 786–1159.

CPT and Level II Alphanumeric HCPCS Codes, contact Marjorie Baldo at (410) 786–4617.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver at (410) 786–9379.

Composite APCs (Extended Assessment and Management, Low Dose Brachytherapy, Multiple Imaging), contact Twi Jackson at (410) 786–1159.

Comprehensive APCs, contact Elisabeth Daniel at (410) 786–0237.

Hospital Observation Services, contact Twi Jackson at (410) 786–1159.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Elizabeth Bainger at (410) 786–0529.

Hospital Outpatient Quality Reporting (OQR) Program and Data Issues, contact Vinitha Meyyur at (410) 786–8819.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Twi Jackson at (410) 786–1159.

Inpatient Only Procedures List, contact Lela Strong at (410) 786–3213.

New Technology Intraocular Lenses (NTIOLs), contact John McInnes at (410) 786–0791.

No Cost/Full Credit and Partial Credit Devices, contact Carol Schwartz at (410) 786–0576.

OPPS Brachytherapy, contact Elisabeth Daniel at (410) 786–0237.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact David Rice at (410) 786–6004.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Elisabeth Daniel at (410) 786–0237.

OPPS Exceptions to the Two Times Rule, contact Marjorie Baldo at (410) 786–4617.

OPPS Packaged Items/Services, contact Elisabeth Daniel at (410) 786–0237.

OPPS Pass-Through Devices and New Technology Procedures/Services, contact Carol Schwartz at (410) 786–0576.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova at (410) 786–2682.

Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact Dexter Dickey at (410) 786–6856.

Rural Hospital Payments, contact David Rice at (410) 786–6004.

Stereotactic Radiosurgery Services (SRS), contact Elisabeth Daniel at (410) 786–0237.

Transition for Medicare-Dependent, Small Rural Hospitals in All-Urban States, contact Shevi Marciano at (410) 786–4487.

Two-Midnight Policy—General Issues, contact Twi Jackson at (410) 786–1159.

Two-Midnight Policy—Medical Review, contact Steven Rubio at (410) 786–1782.

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Marjorie Baldo at (410) 786–4617.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection, generally beginning approximately 3 weeks after publication of the rule, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Addenda Available Only Through the Internet on the CMS Web site

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS Web site. The Addenda relating to the OPPS are available at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* The Addenda relating to the ASC payment system are available at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html.*

Alphabetical List of Acronyms Appearing in This Federal Register Document

AHA American Hospital Association
AMA American Medical Association
AMI Acute myocardial infarction
APC Ambulatory Payment Classification
APU Annual payment update
ASC Ambulatory surgical center
ASCQR Ambulatory Surgical Center Quality Reporting
ASP Average sales price
AWP Average wholesale price
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 Benefits Improvement and Protection Act of 2000, Public Law 106–554
BLS Bureau of Labor Statistics
CAH Critical access hospital
CAHPS Consumer Assessment of Healthcare Providers and Systems
CAP Competitive Acquisition Program
C–APC Comprehensive Ambulatory Payment Classification
CASPER Certification and Survey Provider Enhanced Reporting
CAUTI Catheter-associated urinary tract infection
CBSA Core-Based Statistical Area
CCM Chronic care management
CCN CMS Certification Number
CCR Cost-to-charge ratio
CDC Centers for Disease Control and Prevention
CED Coverage with Evidence Development
CERT Comprehensive Error Rate Testing
CFR Code of Federal Regulations
CI Comment indicator
CLABSI Central Line [Catheter] Associated Blood Stream Infection
CLFS Clinical Laboratory Fee Schedule
CMHC Community mental health center
CMS Centers for Medicare & Medicaid Services
CoP Condition of participation
CPI–U Consumer Price Index for All Urban Consumers
CPT Current Procedural Terminology (copyrighted by the American Medical Association)
CR Change request
CRC Colorectal cancer
CSAC Consensus Standards Approval Committee
CT Computed tomography
CV Coefficient of variation
CY Calendar year
DFO Designated Federal Official
DIR Direct or indirect remuneration
DME Durable medical equipment
DMEPOS Durable Medical Equipment, Prosthetic, Orthotics, and Supplies
DRA Deficit Reduction Act of 2005, Public Law 109–171
DSH Disproportionate share hospital
EACH Essential access community hospital
EAM Extended assessment and management
EBRT External beam radiotherapy
ECG Electrocardiogram
ED Emergency department
EDTC Emergency department transfer communication
EHR Electronic health record
E/M Evaluation and management
ESRD End-stage renal disease
ESRD QIP End-Stage Renal Disease Quality Improvement Program
FACA Federal Advisory Committee Act, Public Law 92–463
FDA Food and Drug Administration
FFS [Medicare] Fee-for-service
FY Fiscal year
GAO Government Accountability Office
GI Gastrointestinal
HAI Healthcare-associated infection
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCERA Health Care and Education Reconciliation Act of 2010, Public Law 111–152
HCP Health care personnel
HCPCS Healthcare Common Procedure Coding System
HCRIS Healthcare Cost Report Information System
HCUP Healthcare Cost and Utilization Project
HEU Highly enriched uranium
HH QRP Home Health Quality Reporting Program
HHS Department of Health and Human Services
HIE Health information exchange
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HOP Hospital Outpatient Payment [Panel]
HOPD Hospital outpatient department
HOP QDRP Hospital Outpatient Quality Data Reporting Program
HPMS Health Plan Management System
IBD Inflammatory bowel disease
ICC Interclass correlation coefficient

ICD Implantable cardioverter defibrillator
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10 International Classification of Diseases, Tenth Revision
ICH In-center hemodialysis
IDTF Independent diagnostic testing facility
IGI IHS Global Insight, Inc.
IHS Indian Health Service
I/OCE Integrated Outpatient Code Editor
IOL Intraocular lens
IORT Intraoperative radiation treatment
IPFQR Inpatient Psychiatric Facility Quality Reporting
IPPS [Hospital] Inpatient Prospective Payment System
IQR [Hospital] Inpatient Quality Reporting
IRF Inpatient rehabilitation facility
IRF QRP Inpatient Rehabilitation Facility Quality Reporting Program
IT Information technology
LCD Local coverage determination
LDR Low dose rate
LTCH Long-term care hospital
LTCHQR Long-Term Care Hospital Quality Reporting
MAC Medicare Administrative Contractor
MACRA Medicare Access and CHIP Reauthorization Act of 2015, Public Law 114–10
MAP Measure Application Partnership
MDH Medicare-dependent, small rural hospital
MedPAC Medicare Payment Advisory Commission
MEG Magnetoencephalography
MFP Multifactor productivity
MGCRB Medicare Geographic Classification Review Board
MIEA–TRHCA Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006, Public Law 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275
MLR Medical loss ratio
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173
MPFS Medicare Physician Fee Schedule
MR Medical review
MRA Magnetic resonance angiography
MRgFUS Magnetic Resonance Image Guided Focused Ultrasound
MRI Magnetic resonance imaging
MRSA Methicillin-Resistant Staphylococcus Aures
MS–DRG Medicare severity diagnosis-related group
MSIS Medicaid Statistical Information System
MUC Measure under consideration
NCCI National Correct Coding Initiative
NDC National Drug Code
NEMA National Electrical Manufacturers Association
NHSN National Healthcare Safety Network
NOS Not otherwise specified
NPI National Provider Identifier
NPWT Negative Pressure Wound Therapy
NQF National Quality Forum
NQS National Quality Strategy
NTIOL New technology intraocular lens
NUBC National Uniform Billing Committee
OACT [CMS] Office of the Actuary
OBRA Omnibus Budget Reconciliation Act of 1996, Public Law 99–509
OIG [HHS] Office of the Inspector General
OMB Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
OPD [Hospital] Outpatient Department
OPO Organ Procurement Organization
OPPS [Hospital] Outpatient Prospective Payment System
OPSF Outpatient Provider-Specific File
OQR [Hospital] Outpatient Quality Reporting
OT Occupational therapy
PAMA Protecting Access to Medicare Act of 2014, Public Law 113–93
PCHQR PPS-Exempt Cancer Hospital Quality Reporting
PCR Payment-to-cost ratio
PDC Per day cost
PDE Prescription Drug Event
PE Practice expense
PEPPER Program Evaluation Payment Patterns Electronic Report
PHP Partial hospitalization program
PHSA Public Health Service Act, Public Law 96–88
PMA Premarket approval
PN Pneumonia
POS Place of service
PPI Producer Price Index
PPS Prospective payment system
PQRI Physician Quality Reporting Initiative
PQRS Physician Quality Reporting System
QDC Quality data code
QIO Quality Improvement Organization
RFA Regulatory Flexibility Act
RHQDAPU Reporting Hospital Quality Data for Annual Payment Update
RTI Research Triangle Institute, International
RVU Relative value unit
SAD Self-administered drug
SAMS Secure Access Management Services
SCH Sole community hospital
SCOD Specified covered outpatient drugs
SES Socioeconomic status
SI Status indicator
SIR Standardized infection ratio
SNF Skilled nursing facility
SRS Stereotactic radiosurgery
SSA Social Security Administration
SSI Surgical site infection
TEP Technical Expert Panel
TIP Transprostatic implant procedure
TOPs Transitional Outpatient Payments
USPSTF United States Preventive Services Task Force
VBP Value-based purchasing
WAC Wholesale acquisition cost

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I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this proposed rule, we are proposing to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) beginning January 1, 2016. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i) of the Act, we annually review and update the ASC payment rates. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Further, we are proposing certain changes relating to the hospital inpatient prospective payment system (IPPS): Proposed changes to the 2-midnight rule under the short inpatient hospital stay policy and a discussion of the related −0.2 percent payment adjustment; and a proposed transition for Medicare-dependent, small rural hospitals (MDHs) in all-urban States.

2. Summary of the Major Provisions

• *OPPS Update:* For CY 2016, we are proposing to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.9 percent. This proposed increase is based on the proposed hospital inpatient market basket percentage increase of 2.7 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.6 percentage point, and minus a 0.2 percentage point adjustment required by the Affordable Care Act. In addition, we are proposing to apply a 2.0 percent reduction to the conversion factor to redress the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests that are excepted from our final CY 2014 laboratory packaging policy, as discussed in section II.B. of this proposed rule. Under this proposed rule, we estimate that total payments for CY 2016, including beneficiary cost-sharing, to the approximate 3,800 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers (CMHCs)), would decrease by approximately $43 million compared to CY 2015 payments, excluding our

estimated changes in enrollment, utilization, and case-mix.

We are proposing to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a proposed reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.

• *Rural Adjustment:* We are proposing to continue the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This proposed adjustment would apply to all services paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to cost.

• *Cancer Hospital Payment Adjustment:* For CY 2016, we are proposing to continue to provide additional payments to cancer hospitals so that the cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. Based on those data, a proposed target PCR of 0.90 would be used to determine the CY 2016 cancer hospital payment adjustment to be paid at cost report settlement. That is, the proposed payment adjustments would be the additional payments needed to result in a PCR equal to 0.90 for each cancer hospital.

• *Payment of Drugs, Biologicals, and Radiopharmaceuticals:* For CY 2016, proposed payment for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status are set at the statutory default of average sales price (ASP) plus 6 percent.

• *Payment of Biosimilar Biological Products:* For CY 2016, we are proposing to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act. We also are proposing to extend pass-through payment eligibility to biosimilar biological products and to set payment at the difference between the amount paid under section 1842(o) of the Act (that is, the payment allowance of the product as determined under section 1847A of the Act) and the otherwise applicable HOPD fee schedule amount.

• *Packaging Policies:* In CY 2015, we conditionally packaged certain ancillary services when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service. For CY 2016, we are proposing to expand the set of conditionally packaged ancillary services to include three new APCs.

• *Conditionally Packaged Outpatient Laboratory Tests:* For CY 2016, we are proposing to conditionally package laboratory tests (regardless of the date of service) on a claim with a service that is assigned status indicator ''S,'' ''T,'' or ''V'' unless an exception applies or the laboratory test is ''unrelated'' to the other HOPD service or services on the claim. We are proposing to establish a new status indicator ''Q4'' for this purpose. When laboratory tests are the only services on the claim, a separate payment at CLFS payment rates would be made. The ''L1'' modifier would still be used for ''unrelated'' laboratory tests.

• *Comprehensive APCs:* We implemented the comprehensive APCs (C–APCs) policy for CY 2015 with a total of 25 C–APCs. In CY 2016, we are not proposing extensive changes to the already established methodology used for C–APCs. However, we are proposing to create nine new C–APCs that meet the previously established criteria.

• *APC Restructuring:* Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. For CY 2016, we conducted a comprehensive review of the structure of the APCs and codes and are proposing to restructure the OPPS APC groupings for nine APC clinical families based on the following principles: (1) Improved clinical homogeneity; (2) improved resource homogeneity; (3) reduced resource overlap in longstanding APCs; and (4) greater simplicity and improved understandability of the OPPS APC structure.

• *New Process for Device Pass-Through Payment:* Beginning in CY 2016, we are proposing to add a rulemaking component to the current quarterly device pass-through payment application process. Specifically, we are proposing to supplement the quarterly process by including a description of applications received (whether they are approved or denied) as well as our rationale for approving or denying the application in the next applicable OPPS proposed rule. This proposed change would help achieve the goals of increased transparency and stakeholder input. In addition, the proposal would align a portion of the OPPS device pass-through payment application process with the already established IPPS application process for new medical services and new technology add-on payments. We also are proposing that a device that requires FDA premarket approval or clearance is eligible to apply for device pass-through payment only if it is ''new,'' meaning that the pass-through payment application is submitted within 3 years from the date of the applicable FDA premarket approval, clearance, or investigational device exemption.

• *Two-Midnight Rule:* The 2-midnight rule was adopted effective October 1, 2013. Under the 2-midnight rule, 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 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 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. In this proposed rule, we are proposing to modify our existing ''rare and unusual'' exceptions policy under which the only exceptions to the 2-midnight benchmark were cases involving services designated by CMS as inpatient only, and those rare and unusual circumstances published on the CMS Web site or other subregulatory guidance, to also allow exceptions to the 2-midnight benchmark to be determined on a case-by-case basis by the physician responsible for the care of the beneficiary, subject to medical review. However, we continue to expect that stays under 24 hours would rarely qualify for an exception to the 2-midnight benchmark. In addition, we are revising our medical review strategy and announcing that no later than October 1, 2015, we are changing the medical review strategy and have Quality Improvement Organization (QIO) contractors conduct reviews of short inpatient stays rather than the Medicare administrative contractors (MACs).

• *Chronic Care Management (CCM):* For CY 2016, we are proposing additional requirements for hospitals to bill and receive OPPS payment for CCM services described by CPT code 99490. These requirements include scope of service elements analogous to the scope of service elements finalized as

requirements in the CY 2015 Medicare Physician Fee Schedule (MPFS) final rule with comment period (79 FR 6715 through 67728).

• *National Electrical Manufacturers Association (NEMA) Modifier:* Effective for services furnished on or after January 1, 2016, section 218(a) of the PAMA amended section 1834 of the Act by establishing a new subsection 1834(p), which reduces payment for the technical component (TC) (and the TC of the global fee) under the MPFS and the OPPS (5 percent in 2016 and 15 percent in 2017 and subsequent years) for applicable computed tomography (CT) services identified by certain CPT HCPCS codes furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013, entitled ''Standard Attributes on CT Equipment Related to Dose Optimization and Management.'' The provision requires that information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable CT service was furnished that was not consistent with the NEMA CT equipment standard. To implement this provision, we are proposing to establish a new modifier that would be reported with specific CPT codes, effective January 1, 2016.

• *New Process for Requesting Comments on New and Revised Category I and III CPT Codes:* In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66842 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, we stated that we would include the proposed APC and status indicator assignments for the vast majority of new and revised CPT codes before they are used for payment purposes under the OPPS if the AMA provides CMS with the codes in time for the OPPS/ASC proposed rule. For the CY 2016 OPPS update, we received the CY 2016 CPT codes from AMA in time for inclusion to this CY 2016 OPPS/ASC proposed rule. The new and revised CY 2016 Category I and III CPT codes can be found in OPPS Addendum B and assigned to new comment indicator ''NP'' to indicate that the code is a new code for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed APC assignment and that comments will be accepted on the proposed APC assignment and status indicator.

• *Ambulatory Surgical Center Payment Update:* For CY 2016, we are proposing to increase payment rates under the ASC payment system by 1.1 percent. This proposed increase is based on a projected CPI–U update of 1.7 percent minus a multifactor productivity adjustment required by the Affordable Care Act that is projected to be 0.6 percentage point. Based on this proposed update, we estimate that proposed total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2016 would be approximately $4.293 billion, an increase of approximately $186 million compared to estimated CY 2015 Medicare payments. In addition, we are proposing a revised process of assigning ASC payment indicators for new and revised Category I and III CPT codes that would be effective January 1, similar to the OPPS process we finalized in the CY 2015 OPPS/ASC final rule with comment period. Specifically, we are proposing to include the proposed ASC payment indicator assignments in the OPPS/ASC proposed rule for the vast majority of new and revised CPT codes before they are used for payment purposes under the ASC payment system if the American Medical Association (AMA) provides CMS with the codes in time for the OPPS/ASC proposed rule.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are making proposals for the CY 2017 payment determination and subsequent years, the CY 2018 payment determination and subsequent years, and the CY 2019 payment determination and subsequent years. For CY 2017 and subsequent years, we are proposing to: (1) Remove the OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache measure, effective January 1, 2016 (no data for this measure will be used for any payment determination); (2) change the deadline for withdrawing from the Hospital OQR Program from November 1 to August 31; (3) shift the quarters on which we base payment determinations; (4) change the data submission timeframe for measures submitted via the CMS Web-based tool (QualityNet Web site) from July 1 through November 1 to January 1 through May 15; (5) rename our extension and exception policy to extension and exemption policy; (6) change the deadline for submitting a reconsideration request from the first business day of the month of February of the affected payment year to the first business day on or after March 17 of the affected payment year; and (7) amend 42 CFR 419.46(f)(1) and 42 CFR 419.46(e)(2) to replace the term ''fiscal year'' with the term ''calendar year.''

For CY 2018 and subsequent years, we are proposing a new measure: OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF # 1822). For CY 2019 and subsequent years, we also are proposing a new measure: OP–34: Emergency Department Transfer Communication (EDTC) (NQF # 0291). In addition, we are exploring electronic clinical quality measures (eCQMs) and whether, in future rulemaking, we would propose that hospitals have the option to voluntarily submit data for OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients electronically beginning with the CY 2019 payment determination.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are proposing to align data submission end dates for data submitted using a Web-based tool, to align policies regarding paid claims to be included in the calculation for all claims-based measures, to modify the submission date for reconsideration requests, to modify our policy for the facility identifier for public reporting of ASCQR Program data, and to not consider IHS hospital outpatient departments that bill as ASCs to be ASCs for purposes of the ASCQR Program. We also are proposing to codify a number of existing and proposed policies and are soliciting public comments on the possible inclusion of two measures in the ASCQR Program measure set in the future.

3. Summary of Costs and Benefits

In sections XX. and XXI. of this proposed rule, we set forth a detailed analysis of the regulatory and federalism impacts that the proposed changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of the Proposed OPPS Update

(1) Impacts of All OPPS Proposed Changes

Table 65 in section XX. of this proposed rule displays the distributional impact of all the proposed OPPS changes on various groups of hospitals and CMHCs for CY 2016 compared to all estimated OPPS payments in CY 2015. We estimate that the proposed policies in this proposed rule would result in a 0.2 percent overall decrease in OPPS payments to providers. We estimate that proposed

total OPPS payments for CY 2016, including beneficiary cost-sharing, to the approximate 3,800 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would decrease by approximately $43 million compared to CY 2015 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our proposed OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure that we adopted beginning in CY 2011 and basing payment fully on the type of provider furnishing the service, we estimate a 14.8 percent increase in CY 2016 payments to CMHCs relative to their CY 2015 payments.

(2) Impacts of the Proposed Updated Wage Indexes

We estimate that our proposed update of the wage indexes based on the FY 2016 IPPS proposed rule wage indexes results in a 0.1 percent increase for urban hospitals and a −0.4 percent decrease for rural hospitals under the OPPS. These wage indexes include the continued implementation of the OMB labor market area delineations based on 2010 Decennial Census data.

(3) Impacts of the Proposed Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our proposed CY 2016 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not proposing to make any change in policies for determining the rural and cancer hospital payment adjustments, and the adjustment amounts do not significantly impact the budget neutrality adjustments for these policies.

(4) Impacts of the Proposed OPD Fee Schedule Increase Factor

As a result of the proposed OPD fee schedule increase factor, the proposed 2.0 percent reduction to the conversion factor to redress the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests that are excepted from our final CY 2014 laboratory packaging policy, and other proposed budget neutrality adjustments, we estimate that urban and rural hospitals would experience decreases of approximately 0.1 percent for urban hospitals and 0.3 percent for rural hospitals. Classifying hospitals by teaching status or type of ownership suggests that these hospitals would receive similar decreases.

b. Impacts of the Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The proposed percentage change in estimated total payments by specialty groups under the proposed CY 2016 payment rates compared to estimated CY 2015 payment rates ranges between 5 percent for auditory system services and -5 percent for hematologic and lymphatic system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our proposed CY 2016 policies to significantly affect the number of hospitals that do not receive a full annual payment update.

d. Impacts of the ASCQR Program

We do not expect our proposed CY 2016 policies to significantly affect the number of ASCs that do not receive a full annual payment update.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Social Security Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93), enacted on March 27, 2014; and the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015.

Under the OPPS, we pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this proposed rule. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and

with respect to resource use (section 1833(t)(2)(B) of the Act). In accordance with section 1833(t)(2) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments,'' for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals include: Critical access hospitals (CAHs); hospitals located in Maryland and paid under the Maryland All-Payer Model; hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an external advisory panel of experts to annually review the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act and section 222 of the Public Health Service (PHS) Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the PHS Act which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel, or the Panel). The Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the HOP Panel, and at that time named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise), reviews clinical data, and advises CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that: The Panel continues to be technical in nature; is governed by the provisions of the FACA; may convene up to three meetings per year; has a Designated Federal Official (DFO); and is chaired by a Federal Official designated by the Secretary. The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add Critical Access Hospital (CAH) representation to its membership. The current charter was renewed on November 6, 2014 (80 FR 23009) and the number of panel members was revised from up to 19 to up to 15 members.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*.

3. Panel Meetings and Organizational Structure

The Panel has held multiple meetings, with the last meeting taking place on March 9, 2015. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting and, when necessary, to solicit nominations for Panel membership and to announce new members.

The Panel has established an operational structure that, in part, currently includes the use of three subcommittees to facilitate its required review process. The three current subcommittees are the Data Subcommittee, the Visits and Observation Subcommittee, and the Subcommittee for APC Groups and Status Indicator (SI) Assignments.

The Data Subcommittee is responsible for studying the data issues confronting the Panel and for recommending options for resolving them. The Visits and Observation Subcommittee reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS (for example, APC configurations and APC relative payment weights). The Subcommittee for APC Groups and SI Assignments advises the Panel on the following issues: The appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid; and the appropriate APC placement of HCPCS codes regarding services for which separate payment is made.

Each of these subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the March 9, 2015 meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the March 9, 2015 Panel meeting are included in the sections of this proposed rule that are specific to each recommendation. For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS Web site mentioned earlier in this section, and the FACA database at: *http://facadatabase.gov/*.

F. Public Comments Received on the CY 2015 OPPS/ASC Final Rule With Comment Period

We received approximately 38 timely pieces of correspondence on the CY 2015 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 10, 2014 (79 FR 66770), as well as in the correction notice that was published on February 24, 2015 (80 FR 9629), some of which contained comments on the interim APC assignments and/or status indicators of new or replacement HCPCS codes (identified with comment indicator ''NI'' in Addenda B, AA, and BB to that final rule). Summaries of the public comments on new or replacement codes will be set forth in the CY 2016 OPPS/ASC final rule with comment period under the appropriate subject-matter headings.

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

For this CY 2016 OPPS/ASC proposed rule, we are proposing to recalibrate the APC relative payment weights for services furnished on or after January 1, 2016, and before January 1, 2017 (CY 2016), using the same basic methodology that we described in the CY 2015 OPPS/ASC final rule with comment period. That is, we are proposing to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights. Therefore, for the purpose of recalibrating the proposed APC relative payment weights for CY 2016, we used approximately 151 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for hospital outpatient department services furnished on or after January 1, 2014, and before January 1, 2015. For exact counts of claims used, we refer readers to the claims accounting narrative under supporting documentation for this CY 2016 OPPS/ASC proposed rule on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Of the approximately151 million final action claims for services provided in hospital outpatient settings used to calculate the CY 2016 OPPS payment rates for this proposed rule, approximately 117 million claims were the type of bill potentially appropriate for use in setting rates for OPPS services (but did not necessarily contain services payable under the OPPS). Of the approximately 117 million claims, approximately 4 million claims were not for services paid under the OPPS or were excluded as not appropriate for use (for example, erroneous cost-to-charge ratios (CCRs) or no HCPCS codes reported on the claim). From the remaining approximately 113 million claims, we created approximately 88 million single records, of which approximately 38 million were ''pseudo'' single or ''single session'' claims (created from approximately 16 million multiple procedure claims using the process we discuss later in this section). Approximately 3 million claims were trimmed out on cost or units in excess of +/− 3 standard deviations from the geometric mean or other trims, yielding approximately 85 million single bills for ratesetting. As described in section II.A.2. of this proposed rule, our data development process is designed with the goal of using appropriate cost information in setting the APC relative payment weights. The bypass process is described in section II.A.1.b. of this proposed rule. This section discusses how we develop ''pseudo'' single procedure claims (as defined below), with the intention of using more appropriate data from the available claims. In some cases, the bypass process allows us to use some portion of the submitted claim for cost estimation purposes, while the remaining information on the claim continues to be unusable. Consistent with the goal of using appropriate information in our data development process, we only use claims (or portions of each claim) that are appropriate for ratesetting purposes.

The proposed APC relative weights and payments for CY 2016 in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) were calculated using

claims from CY 2014 that were processed through December 31, 2014. While prior to CY 2013 we historically based the payments on median hospital costs for services in the APC groups, beginning with the CY 2013 OPPS, we established the cost-based relative payment weights for the OPPS using geometric mean costs, as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271). For the CY 2016 OPPS, we are proposing to use this same methodology, basing payments on geometric mean costs. Under this methodology, we select claims for services paid under the OPPS and match these claims to the most recent cost report filed by the individual hospitals represented in our claims data. We continue to believe that it is appropriate to use the most current full calendar year claims data and the most recently submitted cost reports to calculate the relative costs underpinning the APC relative payment weights and the CY 2016 payment rates.

b. Proposed Use of Single and Multiple Procedure Claims

For CY 2016, in general, we are proposing to continue to use single procedure claims to set the costs on which the APC relative payment weights are based. We generally use single procedure claims to set the estimated costs for APCs because we believe that the OPPS relative weights on which payment rates are based should be derived from the costs of furnishing one unit of one procedure and because, in many circumstances, we are unable to ensure that packaged costs can be appropriately allocated across multiple procedures performed on the same date of service.

It is generally desirable to use the data from as many claims as possible to recalibrate the APC relative payment weights, including those claims for multiple procedures. As we have for several years, we are proposing to continue to use date of service stratification and a list of codes to be bypassed to convert multiple procedure claims to ''pseudo'' single procedure claims. Through bypassing specified codes that we believe do not have significant packaged costs, we are able to use more data from multiple procedure claims. In many cases, this enables us to create multiple ''pseudo'' single procedure claims from claims that were submitted as multiple procedure claims spanning multiple dates of service, or claims that contained numerous separately paid procedures reported on the same date on one claim. We refer to these newly created single procedure claims as ''pseudo'' single procedure claims. The history of our use of a bypass list to generate ''pseudo'' single procedure claims is well-documented, most recently in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66780 through 66783). In addition, for CY 2008 (72 FR 66614 through 66664), we increased packaging and created the first composite APCs, and continued those policies through CY 2015. Increased packaging and creation of composite APCs also increased the number of bills that we were able to use for ratesetting by enabling us to use claims that contained multiple major procedures that previously would not have been usable. Further, for CY 2009, we expanded the composite APC model to one additional clinical area, multiple imaging services (73 FR 68559 through 68569), which also increased the number of bills we were able to use in developing the OPPS relative weights on which payments are based. We have continued the composite APCs for multiple imaging services through CY 2015, and we are proposing to continue this policy for CY 2016. We refer readers to section II.A.2.f. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66810 through 66816) for a discussion of the use of claims in modeling the costs for composite APCs and to section II.A.3. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817 through 66823) for a discussion of our packaging policies for CY 2015. In addition, we are proposing to establish additional packaging policies for the CY 2016 OPPS, as discussed in section II.A.3. of this proposed rule.

We are proposing to continue to apply these processes to enable us to use as much claims data as possible for ratesetting for the CY 2016 OPPS. This methodology enabled us to create, for this proposed rule, approximately 38 million ''pseudo'' single procedure claims, including multiple imaging composite ''single session'' bills (we refer readers to section II.A.2.f.(4) of this proposed rule for further discussion), to add to the approximately 49 million ''natural'' single procedure claims.

In addition, we are proposing to continue our broader initiative to review, revise, and reorganize APCs across the OPPS to collectively group services that are clinically similar and have similar resource costs within the same APC. The proposed restructuring of APCs are discussed in the applicable sections of this proposed rule. In conjunction with this initiative, we are proposing to renumber the APCs (except for the composite APCs) primarily to achieve consecutive numbering of APCs within each clinical family of APCs, as discussed in section III.D. of this proposed rule. We are providing a crosswalk from the existing APC numbers to the proposed new APC renumber in Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site).

For CY 2016, we are proposing to bypass 178 HCPCS codes that are identified in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site). Since the inception of the bypass list, which is the list of codes to be bypassed to convert multiple procedure claims to ''pseudo'' single procedure claims, we have calculated the percent of ''natural'' single bills that contained packaging for each HCPCS code and the amount of packaging on each ''natural'' single bill for each code. Each year, we generally retain the codes on the previous year's bypass list and use the updated year's data (for CY 2016, data available for the March 9, 2015 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) from CY 2014 claims processed through September 30, 2014) to determine whether it would be appropriate to add additional codes to the previous year's bypass list. For CY 2016, we are proposing to continue to bypass all of the HCPCS codes on the CY 2015 OPPS bypass list, with the exception of HCPCS codes that we are proposing to delete for CY 2016, which are listed in Table 1 of this proposed rule. (We refer readers to Addendum N to the CY 2015 OPPS/ASC final rule with comment period for the CY 2015 OPPS bypass list. Addendum N is available via the Internet on the CMS Web site.) We also are proposing to remove HCPCS codes that are not separately paid under the OPPS because the purpose of the bypass list is to obtain more data for those codes relevant to ratesetting. Some of the codes we are proposing to remove from the CY 2016 bypass list are affected by the CY 2016 proposed packaging policy, discussed in section II.A.3. of this proposed rule. Some of the codes we are proposing to remove have packaged cost patterns associated with their natural single major claims that would no longer meet the bypass list criterion of 5 percent or fewer of the single major claims having packaged costs on the claim. In addition, we are proposing to add to the bypass list for CY 2016 HCPCS codes that are not on the CY 2015 bypass list that, using the March 9, 2015 Panel data (first 9 months of CY 2014 claims), met the empirical criteria for the bypass list that are summarized

below. Finally, to remain consistent with the CY 2016 proposal to continue to develop OPPS relative payment weights based on geometric mean costs, we also are proposing that the packaged cost criterion continue to be based on the geometric mean cost. The entire list proposed for CY 2016 (including the codes that remain on the bypass list from prior years) is open to public comment in this CY 2016 OPPS/ASC proposed rule. Because we must make some assumptions about packaging in the multiple procedure claims in order to assess a HCPCS code for addition to the bypass list, we assumed that the representation of packaging on ''natural'' single procedure claims for any given code is comparable to packaging for that code in the multiple procedure claims. The proposed criteria for the bypass list are:

- There are 100 or more ''natural'' single procedure claims for the code. This number of single procedure claims ensures that observed outcomes are sufficiently representative of packaging that might occur in the multiple claims.
- Five percent or fewer of the ''natural'' single procedure claims for the code have packaged costs on that single procedure claim for the code. This criterion results in limiting the amount of packaging being redistributed to the separately payable procedures remaining on the claim after the bypass code is removed and ensures that the costs associated with the bypass code represent the cost of the bypassed service.
- The geometric mean cost of packaging observed in the ''natural'' single procedure claims is equal to or less than $55. This criterion also limits the amount of error in redistributed costs. During the assessment of claims against the bypass criteria, we do not know the dollar value of the packaged cost that should be appropriately attributed to the other procedures on the claim. Therefore, ensuring that redistributed costs associated with a bypass code are small in amount and volume protects the validity of cost estimates for low cost services billed with the bypassed service.

We note that, as we did for CY 2015, we are proposing to continue to establish the CY 2016 OPPS relative payment weights based on geometric mean costs. To remain consistent in the metric used for identifying cost patterns, we are proposing to use the geometric mean cost of packaging to identify potential codes to add to the bypass list.

In response to public comments on the CY 2010 OPPS/ASC proposed rule requesting that the packaged cost threshold be updated, we considered whether it would be appropriate to update the $50 packaged cost threshold for inflation when examining potential bypass list additions. As discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60328), the real value of this packaged cost threshold criterion has declined due to inflation, making the packaged cost threshold more restrictive over time when considering additions to the bypass list. Therefore, adjusting the threshold by the market basket increase would prevent continuing decline in the threshold's real value. Based on the same rationale described for the CY 2015 OPPS/ASC final rule with comment period (79 FR 66781), we are proposing for CY 2016 to continue to update the packaged cost threshold by the market basket increase. By applying the final CY 2015 market basket increase of 2.2 percent (79 FR 66825) to the prior nonrounded dollar threshold of $55.66 (79 FR 66781), we determined that the proposed threshold would remain for CY 2016 at $55 ($56.88 rounded to $55, the nearest $5 increment). Therefore, we are proposing to set the geometric mean packaged cost threshold on the CY 2014 claims at $55 for a code to be considered for addition to the CY 2016 OPPS bypass list.

For inclusion on the bypass list, a code cannot be a code for an unlisted service. Unlisted codes do not describe a specific service, and therefore their costs would not be appropriate for bypass list purposes.

In addition, we are proposing to continue to include on the bypass list HCPCS codes that we believe have minimal associated packaging, based on our clinical assessment of the complete CY 2016 OPPS proposal. Some of these codes were identified by CMS, and some were identified in prior years by commenters with specialized knowledge of the packaging associated with specific services. We also are proposing to continue to include certain HCPCS codes on the bypass list in order to purposefully direct the assignment of packaged costs to a companion code where services always appear together and where there would otherwise be few single procedure claims available for ratesetting. For example, we have previously discussed our reasoning for adding HCPCS code G0390 (Trauma response team associated with hospital critical care service) to the bypass list (73 FR 68513).

As a result of the multiple imaging composite APCs that we established in CY 2009, the program logic for creating ''pseudo'' single procedure claims from bypassed codes that are also members of multiple imaging composite APCs changed. When creating the set of ''pseudo'' single procedure claims, claims that contain ''overlap bypass codes'' (those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs) were identified first. These HCPCS codes were then processed to create multiple imaging composite ''single session'' bills, that is, claims containing HCPCS codes from only one imaging family, thus suppressing the initial use of these codes as bypass codes. However, these ''overlap bypass codes'' were retained on the bypass list because, at the end of the ''pseudo'' single processing logic, we reassessed the claims without suppression of the ''overlap bypass codes'' under our longstanding ''pseudo'' single process to determine whether we could convert additional claims to ''pseudo'' single procedure claims. (We refer readers to section II.A.2.b. of this proposed rule for further discussion of the treatment of ''overlap bypass codes.'') This process also created multiple imaging composite ''single session'' bills that could be used for calculating composite APC costs. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site).

Addendum N to this proposed rule includes the proposed list of bypass codes for CY 2016. The proposed list of bypass codes contains codes that were reported on claims for services in CY 2014 and, therefore, includes codes that were in effect in CY 2014 and used for billing but were deleted for CY 2015. We are retaining these deleted bypass codes on the proposed CY 2016 bypass list because these codes existed in CY 2014 and were covered OPD services in that period, and CY 2014 claims data are used to calculate CY 2016 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we are proposing to add for CY 2016 are identified by asterisks (*) in the fourth column of Addendum N.

Table 1 below contains the list of codes that we are proposing to remove from the CY 2016 bypass list.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2016 BYPASS LIST

HCPCS Code	HCPCS Short descriptor
11057	Trim skin lesions over 4.
57454	Bx/curett of cervix w/scope.
88348	Electron microscopy.
92240	Icg angiography.
92546	Sinusoidal rotational test.

c. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2016, we are proposing to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 2016 APC payment rates are based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2014 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2013. For the CY 2016 OPPS proposed rates, we used the set of claims processed during CY 2014. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. That crosswalk is available for review and continuous comment on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2014 (the year of claims data we used to calculate the proposed CY 2016 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2014 Data Specifications Manual.

In accordance with our longstanding policy, we calculated CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculated CCRs was the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPPS/ASC final rule with comment period and discussed further in section II.A.2.d.(1) of this proposed rule.

For the CCR calculation process, we used the same general approach that we used in developing the final APC rates for CY 2007 and thereafter, using the revised CCR calculation that excluded the costs of paramedical education programs and weighted the outpatient charges by the volume of outpatient services furnished by the hospital. We refer readers to the CY 2007 OPPS/ASC final rule with comment period for more information (71 FR 67983 through 67985). We first limited the population of cost reports to only those hospitals that filed outpatient claims in CY 2014 before determining whether the CCRs for such hospitals were valid.

We then calculated the CCRs for each cost center and the overall ancillary CCR for each hospital for which we had claims data. We did this using hospital-specific data from the Hospital Cost Report Information System (HCRIS). We used the most recent available cost report data, which, in most cases, were from cost reports with cost reporting periods beginning in CY 2013. For this proposed rule, we used the most recently submitted cost reports to calculate the CCRs to be used to calculate costs for the proposed CY 2016 OPPS payment rates. If the most recently available cost report was submitted but not settled, we looked at the last settled cost report to determine the ratio of submitted to settled cost using the overall ancillary CCR, and we then adjusted the most recent available submitted, but not settled, cost report using that ratio. We then calculated both an overall ancillary CCR and cost center-specific CCRs for each hospital. We used the overall ancillary CCR referenced above for all purposes that require use of an overall ancillary CCR. We are proposing to continue this longstanding methodology for the calculation of costs for CY 2016.

Since the implementation of the OPPS, some commenters have raised concerns about potential bias in the OPPS cost-based weights due to ''charge compression,'' which is the practice of applying a lower charge markup to higher cost services and a higher charge markup to lower cost services. As a result, the cost-based weights may reflect some aggregation bias, undervaluing high-cost items and overvaluing low-cost items when an estimate of average markup, embodied in a single CCR, is applied to items of widely varying costs in the same cost center. This issue was evaluated in a report by the Research Triangle Institute, International (RTI). The RTI final report can be found on RTI's Web site at: *http://www.rti.org/reports/cms/HHSM–500–2005–0029I/PDF/Refining_Cost_to_Charge_ratios_200807_Final.pdf*. For a complete discussion of the RTI recommendations, public comments, and our responses, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527).

We addressed the RTI finding that there was aggregation bias in both the IPPS and the OPPS cost estimation of expensive and inexpensive medical supplies in the FY 2009 IPPS final rule (73 FR 48458 through 45467). Specifically, we created one cost center for ''Medical Supplies Charged to Patients'' and one cost center for ''Implantable Devices Charged to Patients,'' essentially splitting the then current cost center for ''Medical Supplies Charged to Patients'' into one cost center for low-cost medical supplies and another cost center for high-cost implantable devices in order to mitigate some of the effects of charge compression. In determining the items that should be reported in these respective cost centers, we adopted commenters' recommendations that hospitals should use revenue codes established by the AHA's NUBC to determine the items that should be reported in the ''Medical Supplies Charged to Patients'' and the ''Implantable Devices Charged to Patients'' cost centers. For a complete discussion of the rationale for the creation of the new cost center for ''Implantable Devices Charged to Patients,'' a summary of public comments received, and our responses to those public comments, we refer readers to the FY 2009 IPPS final rule.

The cost center for ''Implantable Devices Charged to Patients'' has been available for use for cost reporting periods beginning on or after May 1, 2009. In the CY 2013 OPPS/ASC final rule with comment period, we determined that a significant volume of hospitals were utilizing the ''Implantable Devices Charged to Patients'' cost center. Because a sufficient amount of data from which to generate a meaningful analysis was available, we established in the CY 2013 OPPS/ASC final rule with comment period a policy to create a distinct CCR using the ''Implantable Devices Charged to Patients'' cost center (77 FR 68225). We retained this policy through CY 2015, and we are proposing to continue this practice for the CY 2016 OPPS.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create new standard cost centers for ''Computed Tomography (CT),'' ''Magnetic Resonance Imaging (MRI),'' and ''Cardiac Catheterization,'' and to require that hospitals report the costs and charges for these services under these new cost centers on the revised Medicare cost report Form CMS 2552–10. As we discussed in the FY 2009 IPPS and CY 2009 OPPS/ASC proposed and final rules, RTI also found that the costs and charges of CT scans, MRIs, and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI concluded that both the IPPS and the OPPS relative payment weights would better estimate the costs of those services if CMS were to add standard costs 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 cost from charges on claims data. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a more detailed discussion on the reasons for the creation of standard cost centers for CT scans, MRIs, and cardiac catheterization. The new standard cost centers for CT scans, MRIs, and cardiac catheterization were effective for cost report periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10.

Using the December 2014 HCRIS update to estimate costs in the proposed CY 2016 OPPS ratesetting process, we were able to calculate a valid implantable device CCR for 2,940 hospitals, a valid MRI CCR for 1,978 hospitals, a valid CT scan CCR for 2,069 hospitals, and a valid Cardiac Catheterization CCR for 1,429 hospitals.

In our CY 2014 OPPS/ASC proposed rule discussion (78 FR 43549), we noted that, for CY 2014, the estimated changes in geometric mean estimated APC cost of using data from the new standard cost centers for CT scans and MRIs appeared consistent with RTI's analysis of cost report and claims data in the July 2008 final report (pages 5 and 6). RTI concluded that ''in hospitals that aggregate data for CT scanning, MRI, or nuclear medicine services with the standard line for Diagnostic Radiology, costs for these services all appear substantially overstated, while the costs for plain films, ultrasound and other imaging procedures are correspondingly understated.'' We also noted that there were limited additional impacts in the implantable device-related APCs from adopting the new cost report Form CMS 2552–10 because we had used data from the standard cost center for implantable medical devices beginning in CY 2013 OPPS ratesetting, as discussed above.

As we indicated in prior rulemaking (77 FR 68223 through 68225), once we determined that cost report data for the new standard cost centers were sufficiently available, we would analyze that data and, if appropriate, we would propose to use the distinct CCRs for new standard cost centers described above in the calculation of the OPPS relative payment weights. As stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74847), we conducted our analysis and concluded that we should develop distinct CCRs for each of the new cost centers and use them in ratesetting. Therefore, we began in the CY 2014 OPPS, continued in the CY 2015 OPPS, and we are proposing to retain this practice for the CY 2016 OPPS, to calculate the OPPS relative payment weights using distinct CCRs for cardiac catheterization, CT scan, MRI, and implantable medical devices. Section XIX. of this proposed rule includes the impacts of calculating the proposed CY 2016 OPPS relative payment weights using these standard cost centers that were adopted in CY 2014.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74847), we finalized a policy to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CCRs used to estimate costs associated with the CT and MRI APCs. This change allows hospitals additional time to use one of the more accurate cost allocation methods, and thereby improve the accuracy of the CCRs on which the OPPS relative payment weights are developed. In Table 2 below, we display CCR values for providers based on various cost allocation methods.

TABLE 2—CCR STATISTICAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost allocation method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0451	0.0589	0.0890	0.1124
Square Feet Only	0.0364	0.0493	0.0787	0.1019
Direct Assign	0.0641	0.0732	0.1078	0.1286
Dollar Value	0.0536	0.0692	0.1001	0.1235
Direct Assign and Dollar Value	0.0534	0.0690	0.1004	0.1237

As part of this transitional policy to estimate the CT and MRI APC relative payment weights using only cost data from providers that do not use ''square feet'' as the cost allocation statistic, we adopted a policy in the CY 2014 OPPS/ASC final rule with comment period that we will sunset this policy in 4 years once the updated cost report data become available for ratesetting purposes. We stated that we believe 4 years is sufficient time for hospitals that have not done so to transition to a more accurate cost allocation method and for the related data to be available for ratesetting purposes. Therefore, in CY 2018, we will estimate the CT and MRI APC relative payment weights using cost data from all providers, regardless of the cost allocation statistic employed. In Table 3 below, we display the impact of excluding claims based on the ''square feet'' cost allocation method from estimates of CT and MRI costs in CY 2016.

TABLE 3—PERCENTAGE CHANGE IN ESTIMATED COST FOR CT AND MRI APCS WHEN EXCLUDING CLAIMS FROM PROVIDERS USING ''SQUARE FEET'' AS THE COST ALLOCATION METHOD

Proposed CY 2016 APC	Proposed CY 2016 APC descriptor	Percent change
5570 *	Computed Tomography without Contrast	13.2
5571 *	Level 1 Computed Tomography with Contrast and Computed Tomography Angiography	9.3
5581 *	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast	7.6
5582 *	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast	6.2
8005	CT & CTA without Contrast Composite	12.1
8006	CT & CTA with Contrast Composite	9.0
8007	MRI & MRA without Contrast Composite	7.1
8008	MRI & MRA with Contrast Composite	6.8

* Proposed renumbered APC. We refer readers to Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) for a crosswalk of the existing APCs to the proposed renumbered APCs.

In summary, we are proposing to continue to use data from the ''Implantable Devices Charged to Patients'' and ''Cardiac Catheterization'' cost centers to create distinct CCRs for use in calculating the OPPS relative payment weights for the CY 2016 OPPS. For the ''Magnetic Resonance Imaging (MRI)'' and ''Computed Tomography (CT) Scan'' APCs identified in Table 3 of this proposed rule, we are proposing to continue our policy of removing claims from cost modeling for those providers using ''square feet'' as the cost allocation statistic for CY 2016.

2. Proposed Data Development Process and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the proposed OPPS payment rates for CY 2016. The Hospital OPPS page on the CMS Web site on which this proposed rule is posted (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, below in this section we discuss the file of claims that comprises the data set that is available for purchase under a CMS data use agreement. The CMS Web site, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*, includes information about purchasing the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–9–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2014 claims that were used to calculate the proposed payment rates for the CY 2016 OPPS.

In the history of the OPPS, we have traditionally established the scaled relative weights on which payments are based using APC median costs, which is a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same, under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost. For CY 2016, we are proposing to continue to use geometric mean costs to calculate the relative weights on which the proposed CY 2016 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.f. of this proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the proposed OPPS payment rates for CY 2016 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

a. Claims Preparation

For this proposed rule, we used the CY 2014 hospital outpatient claims processed through December 31, 2014, to calculate the geometric mean costs of APCs that underpin the proposed relative payment weights for CY 2016. To begin the calculation of the proposed relative payment weights for CY 2016, we pulled all claims for outpatient services furnished in CY 2014 from the national claims history file. This is not the population of claims paid under the OPPS, but all outpatient claims (including, for example, critical access hospital (CAH) claims and hospital claims for clinical laboratory tests for persons who are neither inpatients nor outpatients of the hospital).

We then excluded claims with condition codes 04, 20, 21, and 77 because these are claims that providers submitted to Medicare knowing that no payment would be made. For example, providers submit claims with a condition code 21 to elicit an official denial notice from Medicare and document that a service is not covered. We then excluded claims for services furnished in Maryland, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands because hospitals in those geographic areas are not paid under the OPPS, and, therefore, we do not use claims for services furnished in these areas in ratesetting.

We divided the remaining claims into the three groups shown below. Groups 2 and 3 comprise the 117 million claims that contain hospital bill types paid under the OPPS.

1. Claims that were not bill types 12X (Hospital Inpatient (Medicare Part B only)), 13X (Hospital Outpatient), 14X (Hospital—Laboratory Services Provided to Nonpatients), or 76X (Clinic—Community Mental Health Center). Other bill types are not paid under the OPPS; therefore, these claims were not used to set OPPS payment.

2. Claims that were bill types 12X, 13X or 14X. Claims with bill types 12X and 13X are hospital outpatient claims. Claims with bill type 14X are laboratory specimen claims.

3. Claims that were bill type 76X (CMHC).

To convert charges on the claims to estimated cost, we multiplied the charges on each claim by the appropriate hospital-specific CCR associated with the revenue code for the charge as discussed in section II.A.1.c. of this proposed rule. We then flagged

and excluded CAH claims (which are not paid under the OPPS) and claims from hospitals with invalid CCRs. The latter included claims from hospitals without a CCR; those from hospitals paid an all-inclusive rate; those from hospitals with obviously erroneous CCRs (greater than 90 or less than 0.0001); and those from hospitals with overall ancillary CCRs that were identified as outliers (that exceeded +/− 3 standard deviations from the geometric mean after removing error CCRs). In addition, we trimmed the CCRs at the cost center (that is, departmental) level by removing the CCRs for each cost center as outliers if they exceeded +/− 3 standard deviations from the geometric mean. We used a four-tiered hierarchy of cost center CCRs, which is the revenue code-to-cost center crosswalk, to match a cost center to every possible revenue code appearing in the outpatient claims that is relevant to OPPS services, with the top tier being the most common cost center and the last tier being the default CCR. If a hospital's cost center CCR was deleted by trimming, we set the CCR for that cost center to ''missing'' so that another cost center CCR in the revenue center hierarchy could apply. If no other cost center CCR could apply to the revenue code on the claim, we used the hospital's overall ancillary CCR for the revenue code in question as the default CCR. For example, if a visit was reported under the clinic revenue code but the hospital did not have a clinic cost center, we mapped the hospital-specific overall ancillary CCR to the clinic revenue code. The revenue code-to-cost center crosswalk is available for inspection on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Revenue codes that we do not use in establishing relative costs or to model impacts are identified with an ''N'' in the revenue code-to-cost center crosswalk.

We applied the CCRs as described above to claims with bill type 12X, 13X, or 14X, excluding all claims from CAHs and hospitals in Maryland, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands and excluding all claims from hospitals for which CCRs were flagged as invalid.

We identified claims with condition code 41 as partial hospitalization services of hospitals and moved them to another file. We note that the separate file containing partial hospitalization claims is included in the files that are available for purchase as discussed above.

We then excluded claims without a HCPCS code. We moved to another file claims that contained only influenza and pneumococcal pneumonia (PPV) vaccines. Influenza and PPV vaccines are paid at reasonable cost; therefore, these claims are not used to set OPPS rates.

We next copied line-item costs for drugs, blood, and brachytherapy sources to a separate file (the lines stay on the claim, but are copied onto another file). No claims were deleted when we copied these lines onto another file. These line-items are used to calculate a per unit arithmetic and geometric mean and median cost and a per day arithmetic and geometric mean and median cost for drugs and nonimplantable biologicals, therapeutic radiopharmaceutical agents, and brachytherapy sources, as well as other information used to set payment rates, such as a unit-to-day ratio for drugs.

Prior to CY 2013, our payment policy for nonpass-through separately paid drugs and biologicals was based on a redistribution methodology that accounted for pharmacy overhead by allocating cost from packaged drugs to separately paid drugs. This methodology typically would have required us to reduce the cost associated with packaged coded and uncoded drugs in order to allocate that cost. However, for CY 2013, we paid for separately payable drugs and biologicals under the OPPS at ASP+6 percent, based upon the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. Under that policy, we did not redistribute the pharmacy overhead costs from packaged drugs to separately paid drugs. We retained the CY 2013 payment policy for separately payable drugs and biologicals through CY 2015, and we are proposing to continue this payment policy for CY 2016. We refer readers to section V.B.3. of this proposed rule for a complete discussion of our CY 2016 proposed payment policy for separately paid drugs and biologicals.

We then removed line-items that were not paid during claims processing, presumably for a line-item rejection or denial. The number of edits for valid OPPS payment in the Integrated Outpatient Code Editor (I/OCE) and elsewhere has grown significantly in the past few years, especially with the implementation of the full spectrum of National Correct Coding Initiative (NCCI) edits. To ensure that we are using valid claims that represent the cost of payable services to set payment rates, we removed line-items with an OPPS status indicator that were not paid during claims processing in the claim year, but have a status indicator of ''S,'' ''T,'' and ''V'' in the prospective year's payment system. This logic preserves charges for services that would not have been paid in the claim year but for which some estimate of cost is needed for the prospective year, such as services newly removed from the inpatient list for CY 2015 that were assigned status indicator ''C'' in the claim year. It also preserves charges for packaged services so that the costs can be included in the cost of the services with which they are reported, even if the CPT codes for the packaged services were not paid because the service is part of another service that was reported on the same claim or the code otherwise violates claims processing edits.

For CY 2016, we are proposing to continue the policy we implemented for CY 2013 and retained in subsequent years to exclude line-item data for pass-through drugs and biologicals (status indicator ''G'' for CY 2013) and nonpass-through drugs and biologicals (status indicator ''K'' for CY 2013) where the charges reported on the claim for the line were either denied or rejected during claims processing. Removing lines that were eligible for payment but were not paid ensures that we are using appropriate data. The trim avoids using cost data on lines that we believe were defective or invalid because those rejected or denied lines did not meet the Medicare requirements for payment. For example, edits may reject a line for a separately paid drug because the number of units billed exceeded the number of units that would be reasonable and, therefore, is likely a billing error (for example, a line reporting 55 units of a drug for which 5 units is known to be a fatal dose). As with our trimming in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66788) of line-items with a status indicator of ''S,'' ''T,'' or ''V,'' we believe that unpaid line-items represent services that are invalidly reported and, therefore, should not be used for ratesetting (we note that the deletion of status indicator ''X'' was finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66821)). We believe that removing lines with valid status indicators that were edited and not paid during claims processing increases the accuracy of the data used for ratesetting purposes.

For the CY 2016 OPPS, as part of our proposal to continue packaging of clinical diagnostic laboratory tests, we also are proposing to apply the line item trim to these services if they did not receive payment in the claims year. Removing these lines ensures that, in establishing the CY 2016 OPPS relative

payment weights, we appropriately allocate the costs associated with packaging these services.

b. Splitting Claims and Creation of ''Pseudo'' Single Procedure Claims

(1) Splitting Claims

For the CY 2016 OPPS, we then split the remaining claims into five groups: single majors; multiple majors; single minors; multiple minors; and other claims. (Specific definitions of these groups are presented below.) We note that, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66819 through 66821), we deleted status indicator ''X'' and revised the title and description of status indicator ''Q1'' to reflect that deletion. We also finalized the creation of status indicator ''J1'' in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66800 through 66809) to reflect the comprehensive APCs (C–APCs). For CY 2016, we are proposing to define major procedures as any HCPCS code having a status indicator of ''J1,'' ''J2,'' ''S,'' ''T,'' or ''V,'' to define minor procedures as any code having a status indicator of ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N,'' and to classify ''other'' procedures as any code having a status indicator other than one that we have classified as major or minor. For CY 2016, we are proposing to continue to assign status indicator ''R'' to blood and blood products; status indicator ''U'' to brachytherapy sources; status indicator ''Q1'' to all ''STV-packaged codes;'' status indicator ''Q2'' to all ''T-packaged codes;'' and status indicator ''Q3'' to all codes that may be paid through a composite APC based on composite-specific criteria or paid separately through single code APCs when the criteria are not met.

As discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68709), we established status indicators ''Q1,'' ''Q2,'' and ''Q3'' to facilitate identification of the different categories of codes. We are proposing to treat these codes in the same manner for data purposes for CY 2016 as we have treated them since CY 2008. Specifically, we are continuing to evaluate whether the criteria for separate payment of codes with status indicator ''Q1'' or ''Q2'' are met in determining whether they are treated as major or minor codes. Codes with status indicator ''Q1'' or ''Q2'' are carried through the data either with status indicator ''N'' as packaged or, if they meet the criteria for separate payment, they are given the status indicator of the APC to which they are assigned and are considered as ''pseudo'' single procedure claims for major codes. Codes assigned status indicator ''Q3'' are paid under individual APCs unless they occur in the combinations that qualify for payment as composite APCs and, therefore, they carry the status indicator of the individual APC to which they are assigned through the data process and are treated as major codes during both the split and ''pseudo'' single creation process. The calculation of the geometric mean costs for composite APCs from multiple procedure major claims is discussed in section II.A.2.f. of this proposed rule.

Specifically, we are proposing to divide the remaining claims into the following five groups:

1. *Single Procedure Major Claims:* Claims with a single separately payable procedure (that is, status indicator ''S,'' ''T,'' or ''V'' which includes codes with status indicator ''Q3''); claims with status indicator ''J1'' or ''J2,'' which receive special processing for C–APCs, as discussed in section II.A.2.e. of this proposed rule; claims with one unit of a status indicator ''Q1'' code (''STV-packaged'') where there was no code with status indicator ''S,'' ''T,'' or ''V'' on the same claim on the same date; or claims with one unit of a status indicator ''Q2'' code (''T-packaged'') where there was no code with a status indicator ''T'' on the same claim on the same date.

2. *Multiple Procedure Major Claims:* Claims with more than one separately payable procedure (that is, status indicator ''S,'' ''T,'' or ''V'' which includes codes with status indicator ''Q3''), or multiple units of one payable procedure. These claims include those codes with a status indicator ''Q2'' code (''T-packaged'') where there was no procedure with a status indicator ''T'' on the same claim on the same date of service but where there was another separately paid procedure on the same claim with the same date of service (that is, another code with status indicator ''S'' or ''V''). We also include in this set claims that contained one unit of one code when the bilateral modifier was appended to the code and the code was conditionally or independently bilateral. In these cases, the claims represented more than one unit of the service described by the code, notwithstanding that only one unit was billed.

3. *Single Procedure Minor Claims:* Claims with a single HCPCS code that was assigned status indicator ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N'' and not status indicator ''Q1'' (''STV-packaged'') or status indicator ''Q2'' (''T-packaged'') code.

4. *Multiple Procedure Minor Claims:* Claims with multiple HCPCS codes that are assigned status indicator ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N;'' claims that contain more than one code with status indicator ''Q1'' (''STV-packaged'') or more than one unit of a code with status indicator ''Q1'' but no codes with status indicator ''S,'' ''T,'' or ''V'' on the same date of service; or claims that contain more than one code with status indicator ''Q2'' (T-packaged), or ''Q2'' and ''Q1,'' or more than one unit of a code with status indicator ''Q2'' but no code with status indicator ''T'' on the same date of service.

5. *Non-OPPS Claims:* Claims that contain no services payable under the OPPS (that is, all status indicators other than those listed for major or minor status). These claims were excluded from the files used for the OPPS. Non-OPPS claims have codes paid under other fee schedules, for example, durable medical equipment, and do not contain a code for a separately payable or packaged OPPS service. Non-OPPS claims include claims for therapy services paid sometimes under the OPPS but billed, in these non-OPPS cases, with revenue codes indicating that the therapy services would be paid under the Medicare Physician Fee Schedule (MPFS).

The claims listed in numbers 1, 2, 3, and 4 above are included in the data file that can be purchased as described above. Claims that contain codes to which we have assigned status indicators ''Q1'' (''STV-packaged'') and ''Q2'' (''T-packaged'') appear in the data for the single major file, the multiple major file, and the multiple minor file used for ratesetting. Claims that contain codes to which we have assigned status indicator ''Q3'' (composite APC members) appear in both the data of the single and multiple major files used in this proposed rule, depending on the specific composite calculation.

In this CY 2016 proposed rule, we are proposing to adjust the claims sorting process to determine whether a claim has a bilateral procedure modifier (Modifier 50) before claims are assigned to one of the five claims categories. This proposed adjustment shifts some claims that might otherwise be considered a single major procedure claim to the multiple major procedure claim category due to the presence of the bilateral modifier. We believe that this proposed adjustment more accurately sorts claims that have a bilateral modifier.

(2) Creation of ''Pseudo'' Single Procedure Claims

To develop ''pseudo'' single procedure claims for this proposed rule, we examined both the multiple procedure major claims and the multiple procedure minor claims. We first examined the multiple major procedure claims for dates of service to determine if we could break them into ''pseudo'' single procedure claims using the dates of service for all lines on the claim. If we could create claims with single major procedures by using dates of service, we created a single procedure claim record for each separately payable procedure on a different date of service (that is, a ''pseudo'' single procedure claim).

We also are proposing to use the bypass codes listed in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site) and discussed in section II.A.1.b. of this proposed rule to remove separately payable procedures which we determined contained limited or no packaged costs or that were otherwise suitable for inclusion on the bypass list from a multiple procedure bill. As discussed above, we ignore the ''overlap bypass codes,'' that is, those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs, in this initial assessment for ''pseudo'' single procedure claims. The proposed CY 2016 ''overlap bypass codes'' are listed in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site). When one of the two separately payable procedures on a multiple procedure claim was on the bypass list, we split the claim into two ''pseudo'' single procedure claim records. The single procedure claim record that contained the bypass code did not retain packaged services. The single procedure claim record that contained the other separately payable procedure (but no bypass code) retained the packaged revenue code charges and the packaged HCPCS code charges. We also removed lines that contained multiple units of codes on the bypass list and treated them as ''pseudo'' single procedure claims by dividing the cost for the multiple units by the number of units on the line. If one unit of a single, separately payable procedure code remained on the claim after removal of the multiple units of the bypass code, we created a ''pseudo'' single procedure claim from that residual claim record, which retained the costs of packaged revenue codes and packaged HCPCS codes. This enabled us to use claims that would otherwise be multiple procedure claims and could not be used.

We then assessed the claims to determine if the proposed criteria for the multiple imaging composite APCs, discussed in section II.A.2.f.(3) of this proposed rule, were met. If the criteria for the imaging composite APCs were met, we created a ''single session'' claim for the applicable imaging composite service and determined whether we could use the claim in ratesetting. For HCPCS codes that are both conditionally packaged and are members of a multiple imaging composite APC, we first assessed whether the code would be packaged and, if so, the code ceased to be available for further assessment as part of the composite APC. Because the packaged code would not be a separately payable procedure, we considered it to be unavailable for use in setting the composite APC costs on which the proposed CY 2016 OPPS relative payment weights are based. Having identified ''single session'' claims for the imaging composite APCs, we reassessed the claim to determine if, after removal of all lines for bypass codes, including the ''overlap bypass codes,'' a single unit of a single separately payable code remained on the claim. If so, we attributed the packaged costs on the claim to the single unit of the single remaining separately payable code other than the bypass code to create a ''pseudo'' single procedure claim. We also identified line-items of overlap bypass codes as a ''pseudo'' single procedure claim. This allowed us to use more claims data for ratesetting purposes.

We also are proposing to examine the multiple procedure minor claims to determine whether we could create ''pseudo'' single procedure claims. Specifically, where the claim contained multiple codes with status indicator ''Q1'' (''STV-packaged'') on the same date of service or contained multiple units of a single code with status indicator ''Q1,'' we selected the status indicator ''Q1'' HCPCS code that had the highest CY 2015 relative payment weight, and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q1.'' We then packaged all costs for the following into a single cost for the ''Q1'' HCPCS code that had the highest CY 2015 relative payment weight to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q1'' HCPCS code with the highest CY 2015 relative payment weight; other codes with status indicator ''Q1;'' and all other packaged HCPCS codes and packaged revenue code costs. We changed the status indicator for the selected code from the data status indicator of ''N'' to the status indicator of the APC to which the selected procedure was assigned for further data processing and considered this claim as a major procedure claim. We used this claim in the calculation of the APC geometric mean cost for the status indicator ''Q1'' HCPCS code.

Similarly, if a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') or multiple units of a single code with status indicator ''Q2,'' we selected the status indicator ''Q2'' HCPCS code that had the highest CY 2015 relative payment weight and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q2.'' We then packaged all costs for the following into a single cost for the ''Q2'' HCPCS code that had the highest CY 2015 relative payment weight to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2015 relative payment weight; other codes with status indicator ''Q2''; and other packaged HCPCS codes and packaged revenue code costs. We changed the status indicator for the selected code from a data status indicator of ''N'' to the status indicator of the APC to which the selected code was assigned, and we considered this claim as a major procedure claim.

If a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') and status indicator ''Q1'' (''STV-packaged''), we selected the T-packaged status indicator ''Q2'' HCPCS code that had the highest relative payment weight for CY 2015 and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q2.'' We then packaged all costs for the following into a single cost for the selected (''T-packaged'') HCPCS code to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2015 relative payment weight; other codes with status indicator ''Q2;'' codes with status indicator ''Q1'' (''STV-packaged''); and other packaged HCPCS codes and packaged revenue code costs. We selected status indicator ''Q2'' HCPCS codes instead of ''Q1'' HCPCS codes because ''Q2'' HCPCS codes have higher CY 2015 relative payment weights. If a status indicator ''Q1'' HCPCS code had a higher CY 2015 relative payment

weight, it became the primary code for the simulated single bill process. We changed the status indicator for the selected status indicator ''Q2'' (''T-packaged'') code from a data status indicator of ''N'' to the status indicator of the APC to which the selected code was assigned and we considered this claim as a major procedure claim.

We then applied our proposed process for creating ''pseudo'' single procedure claims to the conditionally packaged codes that do not meet the criteria for packaging, which enabled us to create single procedure claims from them, if they met the criteria for single procedure claims. Conditionally packaged codes are identified using status indicators ''Q1'' and ''Q2,'' and are described in section XI.A. of this proposed rule.

Lastly, we excluded those claims that we were not able to convert to single procedure claims even after applying all of the techniques for creation of ''pseudo'' single procedure claims to multiple procedure major claims and to multiple procedure minor claims. As has been our practice in recent years, we also excluded claims that contained codes that were viewed as independently or conditionally bilateral and that contained the bilateral procedure modifier (Modifier 50) because the line-item cost for the code represented the cost of two units of the procedure, notwithstanding that hospitals billed the code with a unit of one.

We are proposing to continue to apply the methodology described above for the purpose of creating ''pseudo'' single procedure claims for the CY 2016 OPPS.

c. Completion of Claim Records and Geometric Mean Cost Calculations

(1) General Process

We then packaged the costs of packaged HCPCS codes (codes with status indicator ''N'' listed in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) and the costs of those lines for codes with status indicator ''Q1'' or ''Q2'' when they are not separately paid), and the costs of the services reported under packaged revenue codes in Table 4 below that appeared on the claim without a HCPCS code into the cost of the single major procedure remaining on the claim. For a more complete discussion of our proposed CY 2016 OPPS packaging policy, we refer readers to section II.A.3. of this proposed rule.

As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66606), for the CY 2008 OPPS, we adopted an APC Panel recommendation that CMS should review the final list of packaged revenue codes for consistency with OPPS policy and ensure that future versions of the I/OCE edit accordingly. As we have in the past, we are proposing to continue to compare the final list of packaged revenue codes that we adopt for CY 2016 to the revenue codes that the I/OCE will package for CY 2016 to ensure consistency.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68531), we replaced the NUBC standard abbreviations for the revenue codes listed in Table 2 of the CY 2009 OPPS/ASC proposed rule with the most current NUBC descriptions of the revenue code categories and subcategories to better articulate the meanings of the revenue codes without changing the list of revenue codes. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60362 through 60363), we finalized changes to the packaged revenue code list based on our examination of the updated NUBC codes and public comment on the CY 2010 proposed list of packaged revenue codes.

For CY 2016, as we did for CY 2015, we reviewed the changes to revenue codes that were effective during CY 2014 for purposes of determining the charges reported with revenue codes but without HCPCS codes that we would propose to package for CY 2016. We believe that the charges reported under the revenue codes listed in Table 4 below continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes. Therefore, for CY 2016, we are proposing to continue to package the costs that we derive from the charges reported without HCPCS codes under the revenue codes displayed in Table 4 below for purposes of calculating the geometric mean costs on which the proposed CY 2016 OPPS/ASC payment rates are based.

TABLE 4—PROPOSED CY 2016 PACKAGED REVENUE CODES

Revenue code	Description
250	Pharmacy; General Classification
251	Pharmacy; Generic Drugs
252	Pharmacy; Non-Generic Drugs
254	Pharmacy; Drugs Incident to Other Diagnostic Services
255	Pharmacy; Drugs Incident to Radiology
257	Pharmacy; Non-Prescription
258	Pharmacy; IV Solutions
259	Pharmacy; Other Pharmacy
260	IV Therapy; General Classification
261	IV Therapy; Infusion Pump
262	IV Therapy; IV Therapy/Pharmacy Svcs
263	IV Therapy; IV Therapy/Drug/Supply Delivery
264	IV Therapy; IV Therapy/Supplies
269	IV Therapy; Other IV Therapy
270	Medical/Surgical Supplies and Devices; General Classification
271	Medical/Surgical Supplies and Devices; Non-sterile Supply
272	Medical/Surgical Supplies and Devices; Sterile Supply
275	Medical/Surgical Supplies and Devices; Pacemaker
276	Medical/Surgical Supplies and Devices; Intraocular Lens
278	Medical/Surgical Supplies and Devices; Other Implants
279	Medical/Surgical Supplies and Devices; Other Supplies/Devices
280	Oncology; General Classification
289	Oncology; Other Oncology
331	Radiology—Therapeutic and/or Chemotherapy Administration; Chemotherapy Admin—Injected
332	Radiology—Therapeutic and/or Chemotherapy Administration; Chemotherapy Admin—Oral
335	Radiology—Therapeutic and/or Chemotherapy Administration; Chemotherapy Admin—IV
343	Nuclear Medicine; Diagnostic Radiopharmaceuticals
344	Nuclear Medicine; Therapeutic Radiopharmaceuticals
360	Operating Room Services; General Classification
361	Operating Room Services; Minor Surgery
362	Operating Room Services; Organ Transplant- Other than Kidney
369	Operating Room Services; Other OR Services
370	Anesthesia; General Classification
371	Anesthesia; Anesthesia Incident to Radiology
372	Anesthesia; Anesthesia Incident to Other DX Services
379	Anesthesia; Other Anesthesia
390	Administration, Processing and Storage for Blood and Blood Components; General Classification
392	Administration, Processing and Storage for Blood and Blood Components; Processing and Storage
399	Administration, Processing and Storage for Blood and Blood Components; Other Blood Handling
410	Respiratory Services; General Classification
412	Respiratory Services; Inhalation Services
413	Respiratory Services; Hyperbaric Oxygen Therapy
419	Respiratory Services; Other Respiratory Services

TABLE 4—PROPOSED CY 2016 PACKAGED REVENUE CODES—Continued

Revenue code	Description
621	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Radiology
622	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Other DX Services
623	Medical Supplies—Extension of 027X, Surgical Dressings
624	Medical Surgical Supplies—Extension of 027X; FDA Investigational Devices
630	Pharmacy—Extension of 025X; Reserved
631	Pharmacy—Extension of 025X; Single Source Drug
632	Pharmacy—Extension of 025X; Multiple Source Drug
633	Pharmacy—Extension of 025X; Restrictive Prescription
681	Trauma Response; Level I Trauma
682	Trauma Response; Level II Trauma
683	Trauma Response; Level III Trauma
684	Trauma Response; Level IV Trauma
689	Trauma Response; Other
700	Cast Room; General Classification
710	Recovery Room; General Classification
720	Labor Room/Delivery; General Classification
721	Labor Room/Delivery; Labor
722	Labor Room/Delivery; Delivery Room
724	Labor Room/Delivery; Birthing Center
729	Labor Room/Delivery; Other Labor Room/Delivery
732	EKG/ECG (Electrocardiogram); Telemetry
760	Specialty Services; General Classification
761	Specialty Services; Treatment Room
762	Specialty services; Observation Hours
769	Specialty Services; Other Specialty Services
770	Preventive Care Services; General Classification
801	Inpatient Renal Dialysis; Inpatient Hemodialysis
802	Inpatient Renal Dialysis; Inpatient Peritoneal Dialysis (Non-CAPD)
803	Inpatient Renal Dialysis; Inpatient Continuous Ambulatory Peritoneal Dialysis (CAPD)
804	Inpatient Renal Dialysis; Inpatient Continuous Cycling Peritoneal Dialysis (CCPD)
809	Inpatient Renal Dialysis; Other Inpatient Dialysis
810	Acquisition of Body Components; General Classification
819	Acquisition of Body Components; Other Donor
821	Hemodialysis–Outpatient or Home; Hemodialysis Composite or Other Rate

TABLE 4—PROPOSED CY 2016 PACKAGED REVENUE CODES—Continued

Revenue code	Description
824	Hemodialysis–Outpatient or Home; Maintenance—100%
825	Hemodialysis–Outpatient or Home; Support Services
829	Hemodialysis–Outpatient or Home; Other OP Hemodialysis
942	Other Therapeutic Services (also see 095X, an extension of 094x); Education/Training
943	Other Therapeutic Services (also see 095X, an extension of 094X), Cardiac Rehabilitation
948	Other Therapeutic Services (also see 095X, an extension of 094X), Pulmonary Rehabilitation

In accordance with our longstanding policy, we are proposing to continue to exclude: (1) Claims that had zero costs after summing all costs on the claim; and (2) claims containing packaging flag number 3. Effective for services furnished after July 1, 2014, the I/OCE assigned packaging flag number 3 to claims on which hospitals submitted token charges less than $1.01 for a service with status indicator ''S'' or ''T'' (a major separately payable service under the OPPS) for which the Medicare Administrative Contractor (MAC) was required to allocate the sum of charges for services with a status indicator equaling ''S'' or ''T'' based on the relative payment weight of the APC to which each code was assigned. We do not believe that these charges, which were token charges as submitted by the hospital, are valid reflections of hospital resources. Therefore, we deleted these claims. We also deleted claims for which the charges equaled the revenue center payment (that is, the Medicare payment) on the assumption that, where the charge equaled the payment, to apply a CCR to the charge would not yield a valid estimate of relative provider cost. We are proposing to continue these processes for the CY 2016 OPPS.

For the remaining claims, we are proposing to then standardize 60 percent of the costs of the claim (which we have previously determined to be the labor-related portion) for geographic differences in labor input costs. We made this adjustment by determining the wage index that applied to the hospital that furnished the service and dividing the cost for the separately paid HCPCS code furnished by the hospital by that wage index. The claims accounting that we provide for the proposed rule and final rule with comment period contains the formula we use to standardize the total cost for the effects of the wage index. As has been our policy since the inception of the OPPS, we are proposing to use the pre-reclassified wage indices for standardization because we believe that they better reflect the true costs of items and services in the area in which the hospital is located than the post-reclassification wage indices and, therefore, would result in the most accurate unadjusted geometric mean costs. We are proposing to use these pre-reclassified wage indices for standardization using the new OMB labor market area delineations described in section II.C. of this proposed rule.

In accordance with our longstanding practice, we also are proposing to exclude single and ''pseudo'' single procedure claims for which the total cost on the claim was outside 3 standard deviations from the geometric mean of units for each HCPCS code on the bypass list (because, as discussed above, we used claims that contain multiple units of the bypass codes).

After removing claims for hospitals with error CCRs, claims without HCPCS codes, claims for immunizations not covered under the OPPS, and claims for services not paid under the OPPS, approximately 113 million claims were left. Using these approximately 113 million claims, we created approximately 105 million single and ''pseudo'' single procedure claims, of which we used approximately 88 million single bills (after trimming out approximately 17 million claims as discussed in section II.A.1.a. of this proposed rule) in the CY 2016 geometric mean cost development and ratesetting.

As discussed above, the OPPS has historically developed the relative weights on which APC payments are based using APC median costs. For the CYs 2013, 2014, and 2015 OPPS, we calculated the APC relative payment weights using geometric mean costs, and we are proposing to continue this practice for CY 2016. Therefore, the following discussion of the 2 times rule violation and the development of the relative payment weight refers to geometric means. For more detail about the CY 2016 OPPS/ASC proposed policy to calculate relative payment weights based on geometric means, we refer readers to section II.A.2.c. of this proposed rule.

We are proposing to use these claims to calculate the CY 2016 geometric mean costs for each separately payable HCPCS code and each APC. The comparison of HCPCS code-specific and APC geometric mean costs determines the applicability of the 2 times rule. Section 1833(t)(2) of the Act provides

that, subject to certain exceptions, the items and services within an APC group shall not be treated as comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the same group (the 2 times rule). While we have historically applied the 2 times rule based on median costs, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68270), as part of the CY 2013 policy to develop the OPPS relative payment weights based on geometric mean costs, we also applied the 2 times rule based on geometric mean costs. For the CY 2016 OPPS, we are proposing to continue to develop the APC relative payment weights based on geometric mean costs.

We note that, for purposes of identifying significant HCPCS codes for examination in the 2 times rule, we consider codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC geometric mean cost to be significant. This longstanding definition of when a HCPCS code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 88 million single procedure or single session claims we use for establishing geometric mean costs. Similarly, a HCPCS code for which there are fewer than 99 single bills and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC geometric mean. We note that this method of identifying significant HCPCS codes within an APC for purposes of the 2 times rule was used in prior years under the median-based cost methodology. Under our proposed CY 2016 policy to continue to base the relative payment weights on geometric mean costs, we believe that this same consideration for identifying significant HCPCS codes should apply because the principles are consistent with their use in the median-based cost methodology. Unlisted codes are not used in establishing the percent of claims contributing to the APC, nor are their costs used in the calculation of the APC geometric mean. Finally, we reviewed the geometric mean costs for the services for which we are proposing to pay separately under this proposed rule, and we reassigned HCPCS codes to different APCs where it was necessary to ensure clinical and resource homogeneity within the APCs. The proposed APC geometric means were recalculated after we reassigned the affected HCPCS codes. Both the HCPCS code-specific geometric means and the APC geometric means were weighted to account for the inclusion of multiple units of the bypass codes in the creation of ''pseudo'' single procedure claims.

As we discuss in sections II.A.2.d., II.A.2.f., and VIII.B. of this proposed rule, in some cases, APC geometric mean costs are calculated using variations of the process outlined above. Specifically, section II.A.2.d. of this proposed rule addresses the proposed calculation of single APC criteria-based geometric mean costs. Section II.A.2.f. of this proposed rule discusses the proposed calculation of composite APC criteria-based geometric mean costs. Section VIII.B. of this proposed rule addresses the methodology for calculating the proposed geometric mean costs for partial hospitalization services.

(2) Recommendations of the Panel Regarding Data Development

At the March 9, 2015 meeting of the Panel, we discussed our standard analysis of APCs, and specifically, those APCs for which geometric mean costs in the Panel run of CY 2014 claims data varied significantly from the CY 2013 claims data used for the CY 2015 OPPS/ASC final rule with comment period. We also discussed the claims accounting process for the CY 2015 OPPS/ASC final rule with comment period.

At the March 9, 2015 Panel meeting, the Panel made two recommendations related to the data process. The Panel's data-related recommendations and our responses follow.

Recommendation: The Panel recommends that the work of the Data Subcommittee continue.

CMS Response: We are accepting this recommendation.

Recommendation: The Panel recommends that CMS provide the Panel with a list of APCs fluctuating significantly in costs at the next Panel meeting.

CMS Response: We are accepting this recommendation.

d. Proposed Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

For CY 2016, we are proposing to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, in order to address the differences in CCRs and to better reflect hospitals' costs, we are proposing to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We also are proposing to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports in order to simulate blood-specific CCRs for those hospitals. We are proposing to calculate the costs upon which the proposed CY 2016 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific simulated blood-specific CCR methodology better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated

costs for these products. We continue to believe that this methodology in CY 2016 would result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that, as discussed in section II.A.2.e. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66798 through 66810), we defined a comprehensive APC (C–APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these C–APCs. We are proposing to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C–APCs (79 FR 66796). Because the costs of blood and blood products will be reflected in the overall costs of the C–APCs (and, as a result, in the final payment rates of the C–APCs), we are proposing to not make separate payments for blood and blood products when they appear on the same claims as services assigned to the C–APCs (79 FR 66796).

We are inviting public comments on these proposals. We refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for the proposed CY 2016 payment rates for blood and blood products (which are identified with status indicator ''R''). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) (''brachytherapy sources'') separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS payment methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS prospective payment methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66796 through 66798) for further discussion of the history of OPPS payment for brachytherapy sources.

In this proposed rule, for CY 2016, we are proposing to use the costs derived from CY 2014 claims data to set the proposed CY 2016 payment rates for brachytherapy sources, as we are proposing to use to set the proposed payment rates for most other items and services that would be paid under the CY 2016 OPPS. We based the proposed payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology proposed for other items and services paid under the OPPS, as discussed in section II.A.2. of this proposed rule. We also are proposing to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We are proposing to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per source basis (as opposed to, for example, a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). For CY 2016 and subsequent years, we also are proposing to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010 by section 142 of Pub. L. 110–275). That policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals.

The proposed CY 2016 payment rates for brachytherapy sources are included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) and are identified with status indicator ''U.''

We are inviting public comments on this proposed policy. We also are requesting recommendations for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources. Such recommendations should be directed to the Division of Outpatient Care, Mail Stop C4–03–27, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

e. Proposed Comprehensive APCs (C–APCs) for CY 2016

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014, but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C–APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C–APC policy (79 FR 66798 through 66810).

A C–APC is defined as a classification for the provision of a primary service and all adjunctive services provided to

support the delivery of the primary service. We established C–APCs as a category broadly for OPPS payment and implemented 25 C–APCs beginning in CY 2015 (79 FR 66809 through 66810).

Under this policy, we designated a HCPCS code assigned to a C–APC as the primary service (identified by a new OPPS status indicator ''J1''). When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as ''adjunctive services'') and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

Services excluded from the C–APC policy include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute that must be separately paid. This includes certain mammography and ambulance services that are not ever covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act, and certain preventive services (78 FR 74865 and 79 FR 66800 through 66801).

The C–APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period for the C–APCs and modified and implemented in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C–APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator ''J1,'' excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. HCPCS codes assigned to status indicator ''J1'' are assigned to C–APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

Services included under the C–APC payment packaging policy, that is, services that are typically adjunctive to the primary service, provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service, except the excluded services that are described below (78 FR 74865 and 79 FR 66800).

In addition, payment for outpatient department services that are similar to therapy services and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and not therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are outpatient department services and not therapy services. Therefore, the requirement for functional reporting under the regulations at 42 CFR 410.59(a)(4) and 42 CFR 410.60(a)(4) does not apply.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and those drugs that are usually self-administered (SADs), unless they function as packaged supplies (78 FR 74868 through 74869 and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.

Items and services excluded from the C–APC payment policy include: SADs that are not considered supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; services excluded from the OPPS according to section 1833(t)(1)(B) of the Act, including recurring therapy services, which we considered unrelated to the comprehensive service (defined as therapy services reported on a separate facility claim for recurring services), ambulance services, diagnostic and screening mammography, the annual wellness visit providing personalized prevention plan services, and pass-through drugs and devices that are paid according to section 1833(t)(6) of the Act.

We also excluded preventive services. For a description of the preventive services that are excluded from the C–APC payment policy, we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66800 through 66801) and the list below in Table 5, which also includes any new preventive services added for CY 2016.

Other exclusions include brachytherapy services and pass-through drugs, biologicals, and devices that are required by statute to be separately payable (78 FR 74868 and 74909 and 79 FR 66801). In addition, we also excluded services assigned to OPPS status indicator ''F,'' which are services not paid under the OPPS and are instead paid on a reasonable cost basis (that is, certain certified registered nurse assistant (CRNA) services, Hepatitis B vaccines, and corneal tissue acquisition, which is not part of a comprehensive service for CY 2015). In Table 5 below, we list the services that are excluded from the C–APC payment policy.

TABLE 5—COMPREHENSIVE APC PAYMENT POLICY EXCLUSIONS FOR CY 2016

Ambulance services;
Brachytherapy;
Diagnostic and mammography screenings;
Physical therapy, speech-language pathology and occupational therapy services—Therapy services reported on a separate facility claim for recurring services;
Pass-through drugs, biologicals, and devices;
Preventive services defined in 42 CFR410.2:
• Annual wellness visits providing personalized prevention plan services
• Initial preventive physical examinations
• Pneumococcal, influenza, and hepatitis B vaccines and administrations
• Mammography Screenings
• Pap smear screenings and pelvic examination screenings
• Low Dose Computed Tomography
• Prostate cancer screening tests
• Colorectal cancer screening tests
• Diabetes outpatient self-management training services
• Bone mass measurements
• Glaucoma screenings
• Medical nutrition therapy services
• Cardiovascular screening blood tests
• Diabetes screening tests
• Ultrasound screenings for abdominal aortic aneurysm
• Additional preventive services (as defined in section 1861(ddd)(1) of the Act);
Self-administered drugs (SADs)—Drugs that are usually self-administered and do not function as supplies in the provision of the comprehensive service;
Services assigned to OPPS status indicator ''F'' (certain CRNA services, Hepatitis B vaccines and corneal tissue acquisition);
Services assigned to OPPS status indicator ''L'' (influenza and pneumococcal pneumonia vaccines); and
Certain Part B inpatient services—Ancillary Part B inpatient services payable under Part B when the primary ''J1'' service for the claim is not a payable Medicare Part B inpatient service (for example, exhausted Medicare Part A benefits, beneficiaries with Part B only).

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator ''J1'' as a single ''J1'' unit procedure claim (78 FR 74871 and 79 FR 66801). We sum all line item charges for services included on the C–APC claim, convert the charges to costs, and calculate the ''comprehensive'' geometric mean cost of one unit of each service assigned to status indicator ''J1.'' (We note that we use the term ''comprehensive'' to describe the geometric mean cost of a claim reporting ''J1'' service(s) or the geometric mean cost of a C–APC, inclusive of all of the items and services included in the C–APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, excluding claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C–APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator ''J1'' according to their comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator ''J1'' or units thereof (approximately 20 percent of CY 2014 claims), we identify one ''J1'' service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple ''J1'' procedure claims to the C–APC to which the service designated as the primary service is assigned. If the reported ''J1'' services reported on a claim map to different C–APCs, we designate the ''J1'' service assigned to the C–APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple ''J1'' services on a claim map to the same C–APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator ''J1'' to the most appropriate C–APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying ''J1'' service code combinations or code combinations of ''J1'' services and certain add-on codes (as described further below) from the originating C–APC (the C–APC to which the designated primary service is first assigned) to a higher paying C–APC in the same clinical family of C–APCs, if reassignment is clinically appropriate and the reassignment would not create a violation of the 2 times rule in the receiving APC (the higher paying C–APC in the same clinical family of C–APCs). We implement this type of complexity adjustment when the code combination represents a complex, costly form or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule (cost threshold).

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator ''J1'' (or certain add-on codes) to determine if they meet the complexity adjustment criteria. For new HCPCS codes, we determine initial C–APC assignments and complexity adjustments using the best data available, crosswalking the new HCPCS codes to predecessor codes wherever possible.

Once we have determined that a particular code combination of ''J1'' services (or combinations of ''J1'' services reported in conjunction with certain add-on codes) represents a complex version of the primary service

because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the complex version of the primary service as described by the code combination to the next higher cost C–APC within the clinical family, unless the APC reassignment is not clinically appropriate, the reassignment would create a violation of the 2 times rule in the receiving APC, or the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C–APC. However, certain primary service-add-on combinations may qualify for a complexity adjustment. First, the add-on code must be an eligible add-on code. The list of add-on codes that are eligible for complexity adjustment evaluation was included in Table 8 of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66810), and also is identified as Addendum J to this proposed rule (which is available via the Internet on the CMS Web site). For CY 2016, we are not proposing to add any add-on codes to the list of add-on codes that are evaluated for a complexity adjustment when performed in conjunction with a primary C–APC procedure.

To determine which combinations of primary service codes reported in conjunction with an eligible add-on code may qualify for a complexity adjustment for CY 2016, we apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator ''J1'' and any number of units of a single add-on code. If the frequency and cost criteria thresholds for a complexity adjustment are met, and reassignment to the next higher cost APC in the clinical family is appropriate, we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the eligible add-on code combination to a higher cost C–APC within the same clinical family of C–APCs. If any add-on code combination reported in conjunction with the primary service code does not qualify for a complexity adjustment, payment for these services is packaged within the payment for the complete comprehensive service. We list the complexity adjustments proposed for add-on code combinations for CY 2016, along with all of the other proposed complexity adjustments, in Addendum J to this proposed rule (which is available via the Internet on the CMS Web site).

We are providing in Addendum J to this proposed rule a breakdown of cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this proposed rule also contains summary cost statistics for each of the code combinations that describe a complex code combination that would qualify for a complexity adjustment and are proposed to be reassigned to the next higher cost C–APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the last 4 digits of the designated primary service followed by ''A'' (indicating ''adjustment''). For example, the proposed geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3208A, which is assigned to proposed renumbered C–APC 5223 (Level 3 Pacemaker and Similar Procedures) (existing APC 0089), includes all code combinations that are proposed to be reassigned to proposed renumbered C–APC 5223 when CPT code 33208 is the primary code. Providing the information contained in Addendum J in this proposed rule allows stakeholders the opportunity to better assess the impact associated with the proposed reassignment of each of the code combinations eligible for a complexity adjustment.

(2) Proposed C–APCs to be Paid under the C–APC Payment Policy for CY 2016

(a) Proposed CY 2016 C–APCs

For CY 2016, we are proposing to continue to implement the C–APC payment policy methodology made effective in CY 2015, as described in detail below. We are proposing to continue to define the services assigned to C–APCs as primary services, and to define a C–APC as a classification for the provision of a primary service and all adjunctive services and supplies provided to support the delivery of the primary service. We also are proposing to continue to follow the C–APC payment policy methodology of including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator ''J1,'' excluding services that are not covered OPD services or that cannot by statute be paid under the OPPS.

After our annual review of the OPPS, we are proposing nine additional C–APCs to be paid under the existing C–APC payment policy beginning in CY 2016. All C–APCs, including those effective in CY 2016 and those being proposed for CY 2016, are displayed in Table 6 below with the proposed new C–APCs denoted with an asterisk. Addendum J to this proposed rule (which is available via the Internet on the CMS Web site) contains all of the data related to the C–APC payment policy methodology, including the list of proposed complexity adjustments.

TABLE 6—PROPOSED CY 2016 C–APCS

Proposed CY 2016 C–APC+	Proposed CY 2016 APC descriptor	Clinical family	New C–APC
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5165	Level 5 ENT Procedures	ENTXX	*
5166	Level 6 ENT Procedures	ENTXX	
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	

TABLE 6—PROPOSED CY 2016 C–APCS—Continued

Proposed CY 2016 C–APC+	Proposed CY 2016 APC descriptor	Clinical family	New C–APC
5492	Level 2 Intraocular Procedures	EYEXX	*
5493	Level 3 Intraocular Procedures	EYEXX	
5494	Level 4 Intraocular Procedures	EYEXX	
5331	Complex GI Procedures	GIXXX	
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	*
5361	Level 1 Laparoscopy	LAPXX	*
5362	Level 2 Laparoscopy	LAPXX	*
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5123	Level 3 Musculoskeletal Procedures	ORTHO	*
5124	Level 4 Musculoskeletal Procedures	ORTHO	
5471	Implantation of Drug Infusion Device	PUMPS	
5631	Single Session Cranial Stereotactic Radiosurgery	RADTX	
5375	Level 5 Urology and Related Services	UROXX	*
5376	Level 6 Urology and Related Services	UROXX	
5377	Level 7 Urology and Related Services	UROXX	
5191	Level 1 Endovascular Procedures	VASCX	
5192	Level 2 Endovascular Procedures	VASCX	
5193	Level 3 Endovascular Procedures	VASCX	
5881	Ancillary Outpatient Services When Patient Expires	N/A	*
8011	Comprehensive Observation Services	N/A	*

+ We refer readers to section III.D. of this proposed rule for a discussion of the proposed overall restructuring and renumbering of APCs and to Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) for a complete crosswalk of the existing APC numbers to the proposed new APC numbers.

* Proposed New C–APC for CY 2016.

Clinical Family Descriptor Key:
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices
BREAS = Breast Surgery
ENTXX = ENT Procedures
EPHYS = Cardiac Electrophysiology
EYEXX = Ophthalmic Surgery
GIXXX = Gastrointestinal Procedures
GYNXX = Gynecologic Procedures
LAPXX = Laparoscopic Procedures
NSTIM = Neurostimulators
ORTHO = Orthopedic Surgery
PUMPS = Implantable Drug Delivery Systems
RADTX = Radiation Oncology
UROXX = Urologic Procedures
VASCX = Vascular Procedures

(b) Proposed Observation Comprehensive APC

As part of our proposed expansion of the C–APC payment policy methodology, we have identified an instance where we believe that comprehensive payments are appropriate, that is, when a claim contains a specific combination of services performed in combination with each other, as opposed to the presence of a single primary service identified by status indicator ''J1.'' To recognize such instances, for CY 2016, we are proposing to create a new status indicator ''J2'' to designate specific combinations of services that, when performed in combination with each other and reported on a hospital Medicare Part B outpatient claim, would allow for all other OPPS payable services and items reported on the claim (excluding all preventive services and certain Medicare Part B inpatient services) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim. Additional information about the proposed new status indicator ''J2'' and its proposed C–APC assignment is provided below.

It has been our longstanding policy to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur (79 FR 66811 through 66812). Currently, payment for all qualifying extended assessment and management encounters is provided through APC 8009 (Extended Assessment and Management (EAM) Composite) (79 FR 66811 through 66812). Under this policy, we allow services identified by the following to qualify for payment through EAM composite APC 8009: a clinic visit HCPCS code G0463; a Level 4 or 5 Type A ED visit (CPT code 99284 or 99285); a Level 5 Type B ED visit (HCPCS code G0384); a direct referral for observation (G0379), or critical care (CPT code 99291) provided by a hospital in conjunction with observation services of substantial duration (8 or more hours) (provided the observation was not furnished on the same day as surgery or postoperatively) (79 FR 66811 through 66812).

For CY 2016, we are proposing to pay for all qualifying extended assessment and management encounters through a newly created ''Comprehensive Observation Services'' C–APC (C–APC 8011) and to assign the services within this APC to proposed new status indicator ''J2,'' as described earlier in this section. Specifically, we are proposing to make a C–APC payment through the proposed new C–APC 8011 for claims that meet the following criteria:

- The claims do not contain a HCPCS code to which we have assigned status

indicator ''T'' that is reported with a date of service on the same day or 1 day earlier than the date of service associated with HCPCS code G0378;

- The claims contain 8 or more units of services described by HCPCS code G0378 (Observation services, per hour);
- The claims contain one of the following codes: HCPCS code G0379 (Direct referral of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) provided on the same date of service or 1 day before the date of service for HCPCS code G0378;
- The claims do not contain a HCPCS code to which we have assigned status indicator ''J1.''

We are proposing to utilize all claims that meet the above criteria in ratesetting for the proposed new C–APC 8011, and to develop the geometric mean costs of the comprehensive service based on the costs of all reported OPPS payable services reported on the claim (excluding all preventive services and certain Medicare Part B inpatient services). The proposed CY 2016 geometric mean cost resulting from this methodology is approximately $2,111, based on 1,191,120 claims used for ratesetting.

With the proposal to establish a new C–APC 8011 to capture qualifying extended assessment and management encounters that currently are paid using composite APC 8009, we are correspondingly proposing to delete APC 8009, as it would be replaced with proposed new C–APC 8011 (Comprehensive Observation Services).

As stated earlier, we are proposing to assign certain combinations of procedures within proposed new C–APC 8011 to the proposed new status indicator ''J2,'' to distinguish the new C–APC 8011 from the other C–APCs. Comprehensive payment would be made through the new ''Comprehensive Observation Services'' C–APC when a claim contains a specific combination of services performed in combination with each other, as opposed to the presence of a single primary service identified by status indicator ''J1.'' We believe that a distinction in the status indicator is necessary to distinguish between the logic required to identify when a claim qualifies for payment through a C–APC because of the presence of a status indicator ''J1'' procedure being present on the claim versus when a claim qualifies for payment through a C–APC because of the presence of a specific combination of services on the claim. Specifically, for proposed new C–APC 8011, we believe the assignment of certain combinations of services that qualify under proposed new C–APC 8011 to the new proposed status indicator ''J2'' is necessary as claims containing status indicator ''T'' procedures on the same day or day before observation care is provided would not be payable through the proposed new C–APC 8011 and the initial ''J1'' logic would not exclude claims containing status indicator ''T'' procedures from qualifying for payment.

For claims reporting services qualifying for payment through a C–APC assigned to status indicator ''J1'' and qualifying for payment through a C–APC with a status indicator of ''J2,'' we are proposing that payment would be made through the C–APC with status indicator ''J1'' and all the OPPS payable services would be deemed adjunctive services to the primary status indicator ''J1'' service, including the specific combination of services performed in combination with each other that would otherwise qualify for payment through a C–APC with a status indicator of ''J2.'' We are proposing that the presence of the specific combination of services performed in combination with each other that would otherwise qualify the service for payment through a C–APC because it is assigned to status indicator ''J2'' on a hospital outpatient claim would not result in a complexity adjustment for the service qualifying for payment through a C–APC because it is assigned to status indicator ''J1.''

Under the C–APC payment policy, we note that, instead of paying copayments for a number of separate services that are generally, individually subject to the copayment liability cap at section 1833(t)(8)(C)(i) of the Act, beneficiaries can expect to pay a single copayment for the comprehensive service that would be subject to the copayment liability cap. As a result, we expect that this policy likely reduces the possibility that the overall beneficiary liability exceeds the cap for most of these types of claims.

(3) Proposed CY 2016 Policies for Specific C–APCs

(a) Stereotactic Radiosurgery (SRS)

With the advent of C–APCs, the OPPS consists of a wide array of payment methodologies, ranging from separate payment for a single service to a C–APC payment for an entire outpatient encounter with multiple services. As described above, our C–APC payment policy generally provides payment for a primary service and all adjunctive services provided to support the delivery of the primary service, with certain exceptions, billed on the same claim regardless of the date of service. Since implementation of the C–APC policy and subsequent claims data analyses, we have observed circumstances in which necessary services that are appropriately included in an encounter payment are furnished prior to a primary service and billed separately. That is, our analysis of billing patterns associated with certain procedures assigned status indicator ''J1'' indicates providers are reporting planning services, imaging tests, and other ''planning and preparation'' services that are integrally associated with the direct provision of the ''J1'' procedure on a separate claim. The physician practice patterns associated with various stereotactic radiosurgery (SRS) treatments presents an example of this issue.

Section 634 of the American Taxpayer Relief Act (ATRA) of 2012 (Pub. L. 112–240) amended section 1833(t)(16) of the Act by adding a new subparagraph (D) to require that OPPS payments for Cobalt-60 based SRS (also referred to as gamma knife) be reduced to equal that of payments for robotic linear accelerator-based (LINAC) SRS, for covered OPD services furnished on or after April 1, 2013. This payment reduction does not apply to hospitals in rural areas, rural referral centers, or SCHs. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66809), we created C–APC 0067 (proposed to be renumbered to C–APC 5631 for CY 2016) for single-session cranial stereotactic radiosurgery (SRS). Because section 1833(t)(16)(D) of the Act requires equal payment for SRS delivered by Cobalt-60 based or LINAC based technology, proposed renumbered C–APC 5631 includes two types of SRS delivery instruments, which are described by HCPCS code 77371 (Radiation treatment delivery, stereotactic radiosurgery [SRS], complete course of treatment cranial lesion(s) consisting of 1 session; multi-source Cobalt 60-based) and HCPCS code 77372 (Linear accelerator based) (79 FR 66862).

Based on our analysis of CY 2014 claims data (the data used to develop the proposed CY 2016 payment rates), we identified differences in billing patterns between SRS procedures delivered using Cobalt-60 based and LINAC based technologies. In particular,

our claims data analysis results revealed that SRS delivered by Cobalt-60 based technologies (as described by HCPCS code 77371) typically included SRS treatment planning services (for example, imaging studies, radiation treatment aids, and treatment planning) and the actual SRS treatment on the same date of service and reported on the same claim. In contrast, claims data analysis results revealed that SRS delivered by LINAC based technologies (as described by HCPCS code 77372) frequently included services related to SRS treatment (for example, imaging studies, radiation treatment aids, and treatment planning) that were provided and reported on different dates of services and billed on claims separate from the actual SRS treatment. Because Cobalt-60 based and LINAC based technologies are assigned to proposed renumbered C–APC 5631, the costs of both technologies are reflected in the APC payment rate.

The policy intent of C–APCs is to bundle payment for all services related and adjunctive to the primary ''J1'' procedure. In light of this, we believe that all essential planning and preparation services should be paid through the C–APC. For clean payment, we would make a single payment through the C–APC that would include these essential planning and preparation services, and we would not pay separately for C–APC services when furnished prior to delivery of the ''J1'' procedure and reported on separate claims. SRS services are just one example of where this may be occurring under our C–APC policy.

As a result of our SRS claims data findings, for CY 2016, we are proposing to change payment for SRS treatment under proposed renumbered C–APC 5631 by identifying any services that are differentially billed for HCPCS codes 77371 and 77372 on the same claim and on claims 1 month prior to delivery of SRS services in proposed renumbered C–APC 5631, including planning and preparation services, and removing them from our C–APC geometric mean calculation for CY 2016 and CY 2017 while we collect data using a modifier, which is discussed in greater detail below. For any codes that we remove from the C–APC bundle, we are proposing that those codes would receive separate payment even when appearing with a ''J1'' procedure code (HCPCS code 77371 or 77372) on the same claim for both CY 2016 and CY 2017. Specifically, we are proposing this treatment for the following codes for planning and preparation services:

- CT localization (HCPCS codes 77011 and 77014);
- MRI imaging (HCPCS codes 70551, 70552, and 70553);
- Clinical treatment planning (HCPCS codes 77280, 77285, 77290, and 77295); and
- Physics consultation (HCPCS code 77336).

We are inviting public comments on our proposal to remove planning and preparation service from our calculation of the CY 2016 and CY 2017 payment rate for proposed renumbered C–APC 5631 and to allow for separate payment of these same services during CY 2016 and CY 2017 using either modality. As discussed in detail below, our long-term goal is to create a single encounter payment for C–APC services by packaging all planning and preparation services that occur prior to the primary ''J1'' procedure.

(b) Proposed Data Collection for Nonprimary Services in C–APCs

As mentioned above, provider practice patterns can create a need for hospitals to perform services that are integral, ancillary, supportive, dependent, and adjunctive, hereinafter collectively referred to as ''adjunctive services'', to a comprehensive service prior to delivery of that service—for example, testing leads for a pacemaker insertion or planning for radiation treatment. As the C–APC policy continues to expand, we need a mechanism to identify these adjunctive services that are furnished prior to the associated primary service so that payments under the encounter-based C–APC will be more accurate.

To meet this objective, for CY 2016, we are proposing to establish a HCPCS modifier to be reported with every code that is adjunctive to a comprehensive service, but is billed on a different claim. The modifier would be reported on UB–04 form (CMS Form 1450) for hospital outpatient services. Specifically, hospitals would report this modifier for services that are adjunctive to a primary procedure HCPCS code with status indicator ''J1'' and that are billed on a different claim than the primary ''J1'' service. The collection of this information would allow us to begin to assess the accuracy of the claims data used to set payment rates for C–APC services. This information would be useful in refining our C–APC ratesetting process. Based on the collection of these data, we envision creating a single encounter payment for the primary ''J1'' services that reflects resources of all the primary services. Further, we also would discontinue separate payment for any of these packaged adjunctive services, even when furnished prior to delivery of the primary service. As noted above, we are proposing to use the modifier to identify planning and preparation services for SRS primary procedures with this goal in mind. We are seeking additional public comment on whether to adopt a condition code as early as CY 2017, which would replace this modifier to be used for CY 2016 data collection, for collecting this service-level information.

(c) Proposed Policy Regarding Payment for Claims Reporting Inpatient Only Services Performed on a Patient Who Dies Before Admission

Currently, composite APC 0375 packages payment for all services provided on the same date as an inpatient only procedure that is performed emergently on an outpatient who dies before admission represented by the presence of modifier ''–CA'' on the claim. We are proposing to renumber APC 0375 to APC 5881 for CY 2016. For CY 2016, we are proposing to provide comprehensive payment through proposed renumbered C–APC 5881 for all services reported on the same claim as an inpatient only procedure billed with modifier ''–CA.'' This proposal provides for all services provided on the same claim as an inpatient only procedure billed with modifier ''–CA'' to be paid through a single prospective payment for the comprehensive service.

f. Proposed Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for extended assessment and management services, low dose rate (LDR) prostate brachytherapy, mental health services,

and multiple imaging services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for a full discussion of the development of the composite APC methodology (72 FR 66611 through 66614 and 66650 through 66652) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) for more recent background.

In this CY 2016 OPPS/ASC proposed rule, for CY 2016, we are proposing to continue our composite APC payment policies for LDR prostate brachytherapy services, mental health services, and multiple imaging services, as discussed below. For CY 2016, we are proposing to discontinue our composite APC payment policies for qualifying extended assessment and management services (APC 8009) and to pay for these services through proposed new C–APC 8011 (Comprehensive Observation Services), as presented in a proposal included under section II.A.2.e. of this proposed rule. As a result, we are proposing to delete APC 8009 for CY 2016.

We note that we finalized a policy to discontinue our composite APC payment policies for cardiac electrophysiologic evaluation and ablation services (APC 8000), and to pay for these services through C–APC 0086 (Level III Electrophysiologic Procedures), as presented in a proposal included under section II.A.2.e. of the CY 2015 OPPS/ASC proposed rule (79 FR 66800 through 66810). As a result, in the CY 2015 OPPS/ASC final rule with comment period, we deleted APC 8000 for CY 2015 (79 FR 66810). For CY 2016, we are proposing to continue to pay for cardiac electrophysiologic evaluation and ablation services through existing C–APC 0086 (proposed to be renumbered C–APC 5213).

(1) Low Dose Rate (LDR) Prostate Brachytherapy Composite APC

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through the needles/catheters. At least two CPT codes are used to report the composite treatment service because there are separate codes that describe placement of the needles/catheters and the application of the brachytherapy sources: CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and CPT code 77778 (Interstitial radiation source application; complex), which are generally present together on claims for the same date of service in the same operative session. In order to base payment on claims for the most common clinical scenario, and to further our goal of providing payment under the OPPS for a larger bundle of component services provided in a single hospital encounter, beginning in CY 2008, we began providing a single payment for LDR prostate brachytherapy when the composite service, reported as CPT codes 55875 and 77778, is furnished in a single hospital encounter. We base the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the geometric mean cost derived from claims for the same date of service that contain both CPT codes 55875 and 77778 and that do not contain other separately paid codes that are not on the bypass list. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66652 through 66655) for a full history of OPPS payment for LDR prostate brachytherapy services and a detailed description of how we developed the LDR prostate brachytherapy composite APC. (We note that, for CY 2016, we are not proposing to change the existing number for composite APC 8001 as part of our overall APC restructuring and renumbering discussed in section III.D. of this proposed rule.)

In this proposed rule, for CY 2016, we are proposing to continue to pay for LDR prostate brachytherapy services using the composite APC payment methodology proposed and implemented for CY 2008 through CY 2015. That is, we are proposing to use CY 2014 claims reporting charges for both CPT codes 55875 and 77778 on the same date of service with no other separately paid procedure codes (other than those on the bypass list) to calculate the proposed payment rate for composite APC 8001. Consistent with our CY 2008 through CY 2015 practice, in this proposed rule, we are proposing not to use the claims that meet these criteria in the calculation of the geometric mean costs of procedures or services assigned to APC 0163 (Level IV Cystourethroscopy and Other Genitourinary Procedures) (proposed to be renumbered APC 5375 in this proposed rule) and APC 0651 (Complex Interstitial Radiation Source Application) (proposed to be renumber APC 5641 in this proposed rule), the APCs to which CPT codes 55875 and 77778 are assigned, respectively. We are proposing to continue to calculate the proposed geometric mean costs of procedures or services assigned to proposed renumbered APCS 5375 and 5641 using single and ''pseudo'' single procedure claims. We continue to believe that composite APC 8001 contributes to our goal of creating hospital incentives for efficiency and cost containment, while providing hospitals with the most flexibility to manage their resources. We also continue to believe that data from claims reporting both services required for LDR prostate brachytherapy provide the most accurate geometric mean cost upon which to base the proposed composite APC payment rate.

Using a partial year of CY 2014 claims data available for this CY 2016 proposed rule, we were able to use 226 claims that contained both CPT codes 55875 and 77778 to calculate the proposed geometric mean cost of approximately $3,807 for these procedures upon which the proposed CY 2016 payment rate for composite APC 8001 is based.

(2) Mental Health Services Composite APC

In this proposed rule, for CY 2016, we are proposing to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

Specifically, we are proposing that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on one date of service based on the payment rates associated with the APCs for the individual services exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be assigned to proposed renumbered APC 8010 (Mental Health Services Composite) (existing APC 0034). We also are proposing to continue to set the payment rate for proposed renumbered APC 8010 (existing APC 0034) at the same payment rate that we are proposing to establish for proposed renumbered APC 5862 (Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs) (existing APC 0176), which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid one unit of proposed renumbered APC 8010. Under

this policy, the I/OCE would continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for proposed renumbered APC 5862 (existing APC 0176) for all of the specified mental health services furnished by the hospital on that single date of service. We continue to believe that the costs associated with administering a partial hospitalization program at a hospital represent the most resource-intensive of all outpatient mental health services. Therefore, we do not believe that we should pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

(3) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital bills more than one imaging procedure within an imaging family on the same date of service, in order to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) Ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 12 of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74920 through 74924).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included in the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

(We note that we are not proposing to renumber these composite APCs as part of our overall restructuring and renumbering of APCs as discussed in section III.D. of this proposed rule.)

We define the single imaging session for the ''with contrast'' composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment for APC 8008, the ''with contrast'' composite APC.

We make a single payment for those imaging procedures that qualify for composite APC payment, as well as any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

In this proposed rule, for CY 2016, we are proposing to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy will reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

The proposed CY 2016 payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) are based on proposed geometric mean costs calculated from a partial year of CY 2014 claims available for this proposed rule that qualified for composite payment under the current policy (that is, those claims with more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we used to calculate the final CY 2014 and CY 2015 geometric mean costs for these composite APCs, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this CY 2016 proposed rule (which is available via the Internet on the CMS Web site) and are discussed in more detail in section II.A.1.b. of this proposed rule.

For this CY 2016 proposed rule, we were able to identify approximately 584,194 ''single session'' claims out of an estimated 1.5 million potential composite APC cases from our ratesetting claims data, approximately 39 percent of all eligible claims, to calculate the proposed CY 2016 geometric mean costs for the multiple imaging composite APCs.

Table 7 of this proposed rule lists the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2016.

TABLE 7—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1—Ultrasound	
CY 2016 APC 8004 (Ultrasound Composite)	CY 2016 Approximate Proposed APC Geometric Mean Cost = $296
76604	Us exam, chest.
76700	Us exam, abdom, complete.
76705	Echo exam of abdomen.
76770	Us exam abdo back wall, comp.
76775	Us exam abdo back wall, lim.
76776	Us exam k transpl w/Doppler.
76831	Echo exam, uterus.
76856	Us exam, pelvic, complete.

TABLE 7—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

76870	Us exam, scrotum.
76857	Us exam, pelvic, limited.
Family 2—CT and CTA with and without Contrast	
CY 2016 APC 8005 (CT and CTA without Contrast Composite) *	CY 2016 Approximate Proposed APC Geometric Mean Cost = $325
70450	Ct head/brain w/o dye.
70480	Ct orbit/ear/fossa w/o dye.
70486	Ct maxillofacial w/o dye.
70490	Ct soft tissue neck w/o dye.
71250	Ct thorax w/o dye.
72125	Ct neck spine w/o dye.
72128	Ct chest spine w/o dye.
72131	Ct lumbar spine w/o dye.
72192	Ct pelvis w/o dye.
73200	Ct upper extremity w/o dye.
73700	Ct lower extremity w/o dye.
74150	Ct abdomen w/o dye.
74261	Ct colonography, w/o dye.
74176	Ct angio abd & pelvis.
CY 2016 APC 8006 (CT and CTA with Contrast Composite)	CY 2016 Approximate Proposed APC Geometric Mean Cost = $548
70487	Ct maxillofacial w/dye.
70460	Ct head/brain w/dye.
70470	Ct head/brain w/o & w/dye.
70481	Ct orbit/ear/fossa w/dye.
70482	Ct orbit/ear/fossa w/o & w/dye.
70488	Ct maxillofacial w/o & w/dye.
70491	Ct soft tissue neck w/dye.
70492	Ct sft tsue nck w/o & w/dye.
70496	Ct angiography, head.
70498	Ct angiography, neck.
71260	Ct thorax w/dye.
71270	Ct thorax w/o & w/dye.
71275	Ct angiography, chest.
72126	Ct neck spine w/dye.
72127	Ct neck spine w/o & w/dye.
72129	Ct chest spine w/dye.
72130	Ct chest spine w/o & w/dye.
72132	Ct lumbar spine w/dye.
72133	Ct lumbar spine w/o & w/dye.
72191	Ct angiograph pelv w/o & w/dye.
72193	Ct pelvis w/dye.
72194	Ct pelvis w/o & w/dye.
73201	Ct upper extremity w/dye.
73202	Ct uppr extremity w/o & w/dye.
73206	Ct angio upr extrm w/o & w/dye.
73701	Ct lower extremity w/dye.
73702	Ct lwr extremity w/o & w/dye.
73706	Ct angio lwr extr w/o & w/dye.
74160	Ct abdomen w/dye.
74170	Ct abdomen w/o & w/dye.
74175	Ct angio abdom w/o & w/dye.
74262	Ct colonography, w/dye.
75635	Ct angio abdominal arteries.
74177	Ct angio abd & pelv w/contrast.
74178	Ct angio abd & pelv 1+ regns.

* If a ''without contrast'' CT or CTA procedure is performed during the same session as a ''with contrast'' CT or CTA procedure, the I/OCE would assign APC 8006 rather than APC 8005.

Family 3—MRI and MRA with and without Contrast	
CY 2016 APC 8007 (MRI and MRA without Contrast Composite) *	CY 2016 Approximate Proposed APC Geometric Mean Cost = $631
70336	Magnetic image, jaw joint.
70540	Mri orbit/face/neck w/o dye.
70544	Mr angiography head w/o dye.
70547	Mr angiography neck w/o dye.
70551	Mri brain w/o dye.

TABLE 7—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

70554	Fmri brain by tech.
71550	Mri chest w/o dye.
72141	Mri neck spine w/o dye.
72146	Mri chest spine w/o dye.
72148	Mri lumbar spine w/o dye.
72195	Mri pelvis w/o dye.
73218	Mri upper extremity w/o dye.
73221	Mri joint upr extrem w/o dye.
73718	Mri lower extremity w/o dye.
73721	Mri jnt of lwr extre w/o dye.
74181	Mri abdomen w/o dye.
75557	Cardiac mri for morph.
75559	Cardiac mri w/stress img.
C8901	MRA w/o cont, abd.
C8904	MRI w/o cont, breast, uni.
C8907	MRI w/o cont, breast, bi.
C8910	MRA w/o cont, chest.
C8913	MRA w/o cont, lwr ext.
C8919	MRA w/o cont, pelvis.
C8932	MRA, w/o dye, spinal canal.
C8935	MRA, w/o dye, upper extr.
CY 2016 APC 8008 (MRI and MRA with Contrast Composite)	CY 2016 Approximate Proposed APC Geometric Mean Cost = $945
70549	Mr angiograph neck w/o & w/dye.
70542	Mri orbit/face/neck w/dye.
70543	Mri orbt/fac/nck w/o & w/dye.
70545	Mr angiography head w/dye.
70546	Mr angiograph head w/o & w/dye.
70547	Mr angiography neck w/o dye.
70548	Mr angiography neck w/dye.
70552	Mri brain w/dye.
70553	Mri brain w/o & w/dye.
71551	Mri chest w/dye.
71552	Mri chest w/o & w/dye.
72142	Mri neck spine w/dye.
72147	Mri chest spine w/dye.
72149	Mri lumbar spine w/dye.
72156	Mri neck spine w/o & w/dye.
72157	Mri chest spine w/o & w/dye.
72158	Mri lumbar spine w/o & w/dye.
72196	Mri pelvis w/dye.
72197	Mri pelvis w/o & w/dye.
73219	Mri upper extremity w/dye.
73220	Mri uppr extremity w/o & w/dye.
73222	Mri joint upr extrem w/dye.
73223	Mri joint upr extr w/o & w/dye.
73719	Mri lower extremity w/dye.
73720	Mri lwr extremity w/o & w/dye.
73722	Mri joint of lwr extr w/dye.
73723	Mri joint lwr extr w/o & w/dye.
74182	Mri abdomen w/dye.
74183	Mri abdomen w/o & w/dye.
75561	Cardiac mri for morph w/dye.
75563	Card mri w/stress img & dye.
C8900	MRA w/cont, abd.
C8902	MRA w/o fol w/cont, abd.
C8903	MRI w/cont, breast, uni.
C8905	MRI w/o fol w/cont, brst, un.
C8906	MRI w/cont, breast, bi.
C8908	MRI w/o fol w/cont, breast.
C8909	MRA w/cont, chest.
C8911	MRA w/o fol w/cont, chest.
C8912	MRA w/cont, lwr ext.
C8914	MRA w/o fol w/cont, lwr ext.
C8918	MRA w/cont, pelvis.
C8920	MRA w/o fol w/cont, pelvis.
C8931	MRA, w/dye, spinal canal.
C8933	MRA, w/o&w/dye, spinal canal.
C8934	MRA, w/dye, upper extremity.
C8936	MRA, w/o&w/dye, upper extr.

* If a ''without contrast'' MRI or MRA procedure is performed during the same session as a ''with contrast'' MRI or MRA procedure, the I/OCE would assign APC 8008 rather than APC 8007.

3. Proposed Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular patient. The OPPS packages payment for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more profitable than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which often results if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. Over the last 15 years, as we have refined our understanding of the OPPS as a prospective payment system, we have packaged numerous services that were originally paid separately. As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b), including the two packaging policies that were added in CY 2015 (79 FR 66819 through 66823). Our overarching goal is to make OPPS payments for all services paid under the OPPS more consistent with those of a prospective payment system and less like those of a per service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

For CY 2016, we have examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment of the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies. In this proposed rule, for CY 2016, we are proposing to package the costs of selected newly identified ancillary services into payment with a primary service where we believe that the proposed packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code. Below we discuss the items and services that we are proposing to package beginning in CY 2016. For an extensive discussion of the history and background of the OPPS packaging policy, we refer readers to the CY 2000 OPPS final rule (65 FR 18434), the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817).

b. Proposed Packaging Policies for CY 2016

(1) Ancillary Services

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66819 through 66822), we conditionally packaged payment for ancillary services assigned to APCs with a geometric mean cost of less than or equal to $100 (prior to application of the conditional packaging status indicator). The ancillary services that we identified are primarily minor diagnostic tests and procedures that are often performed with a primary service, although there are instances where hospitals provide such services alone and without another primary service during the same encounter. Under this policy, we assigned the conditionally packaged services to status indicator ''Q1,'' which indicates that the service is separately payable when not billed on the same date of service as a HCPCS code assigned status indicator ''S,'' ''T,'' or ''V.'' Exclusions to this ancillary service packaging policy include preventive services, certain psychiatric and counseling-related services, and certain low-cost drug administration services. The policy adopted in CY 2015 was proposed in response to public comments on the CY 2014 ancillary packaging proposal, which expressed concern that certain low volume but relatively costly ancillary services would have been packaged into high volume but relatively inexpensive primary services (for example, a visit) (74 FR 74945). We noted in the CY 2015 OPPS/ASC final rule with comment period that the $100 geometric mean cost limit target was a selection criterion for the initial set of services in conditionally packaged ancillary service APCs under this packaging policy. The $100 geometric mean cost target was not intended to be a threshold above which ancillary services will not be packaged, but was a basis for selecting the initial set of APCs under the conditional packaging policy for ancillary services, which would likely be updated and expanded upon in the future. An increase in the geometric mean cost of any of those packaged APCs to above $100 in future years does not change the conditionally packaged status of services assigned to the APCs selected in CY 2015 in a future year. When we finalized this policy, we stated that we would continue to consider services in these APCs to be conditionally packaged and would review the conditionally packaged status of ancillary services annually. The ancillary services packaging policy is codified in the regulations at 42 CFR 419.2(b)(7).

For CY 2016, as we did in CY 2015, we examined categories of ancillary services that are integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment of the primary services that they support. As previously stated, the $100 geometric mean cost target we adopted in CY 2015 was not intended to be a threshold above which ancillary services will not be packaged, but was a basis for selecting the initial set of APCs under the conditional packaging policy for ancillary services, which would likely be updated and expanded upon in the future. Accordingly, for CY 2016, we are proposing to not limit our examination to ancillary service APCs with a geometric mean cost of $100 or less. We believe there are some ancillary services that are assigned to APCs with a geometric mean cost above $100, but for which conditional packaging is appropriate, given the context in which the service is performed. For CY 2016, we are proposing to evaluate categories of ancillary services by considering the clinical similarity of such categories of services to the currently conditionally packaged ancillary services that have already been determined to be integral, ancillary, supportive, dependent, or adjunctive to a primary service. Under this proposal, we identified services in certain APCs that meet these criteria, and we did not apply the $100 geometric mean cost threshold that we applied for CY 2015. Specifically, for CY 2016, we are proposing to expand the set of conditionally packaged ancillary services to include services in the three APCs listed in Table 8 below. Ancillary services in the APCs in Table 8 are typically furnished with a higher paying, separately payable primary procedure.

However, to avoid packaging a subset of high-cost pathology services into lower cost and nonprimary services (for example, low-cost imaging services) frequently billed with some of the services assigned to Level 3 and Level 4 pathology APCs, we are proposing to package Level 3 and 4 pathology services only when they are billed with a surgical service. We believe that pathology services are routine tests that are typically performed ancillary or adjunctive to another primary service, most commonly surgery. For the Level 3 and 4 pathology APCs listed below, we are proposing that the assigned status indicator would be ''Q2'' (''T packaging'').

The HCPCS codes that we are proposing to conditionally package as ancillary services for CY 2016 are displayed in Addendum B to this CY 2016 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site). The supporting documents for the proposed rule are available at the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

TABLE 8—PROPOSED APCS FOR CONDITIONALLY PACKAGED ANCILLARY SERVICES FOR CY 2016

Proposed renumbered CY 2016 APC*	Proposed CY 2016 APC title	Proposed CY 2016 OPPS status indicator	Proposed CY 2016 payment rate
5734	Level 4 Minor Procedures	Q1	$119.58
5673	Level 3 Pathology	Q2	229.13
5674	Level 4 Pathology	Q2	459.96

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed APC renumbers for CY 2016.

In addition, we are proposing to continue to exclude certain services from this ancillary services packaging policy. As established in CY 2015, preventive services, certain psychiatric and counseling-related services, and certain low-cost drug administration services are separately payable under the OPPS (79 FR 66819). Preventable services that would continue to be exempted from the ancillary service packaging policy for CY 2016 are listed in Table 9 below.

TABLE 9—PROPOSED PREVENTIVE SERVICES EXEMPTED FROM THE ANCILLARY SERVICES PACKAGING POLICY

HCPCS code	Short descriptor	Proposed renumbered CY 2016 APC*
76977	Us bone density measure.	5732
77078	Ct bone density axial.	5521
77080	Dxa bone density axial.	5522

TABLE 9—PROPOSED PREVENTIVE SERVICES EXEMPTED FROM THE ANCILLARY SERVICES PACKAGING POLICY—Continued

HCPCS code	Short descriptor	Proposed renumbered CY 2016 APC*
77081	Dxa bone density/peripheral.	5521
G0117	Glaucoma scrn hgh risk direc.	5732
G0118	Glaucoma scrn hgh risk direc.	5732
G0130	Single energy x-ray study.	5521
G0389	Ultrasound exam aaa screen.	5531
G0404	Ekg tracing for initial prev.	5731

TABLE 9—PROPOSED PREVENTIVE SERVICES EXEMPTED FROM THE ANCILLARY SERVICES PACKAGING POLICY—Continued

HCPCS code	Short descriptor	Proposed renumbered CY 2016 APC*
Q0091	Obtaining screen pap smear.	5731

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed APC renumbers.

(2) Drugs and Biologicals That Function as Supplies When Used in a Surgical Procedure

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74930 through 74939), we finalized our policy at 42 CFR 419.2(b)(16) to unconditionally package all drugs and biologicals that function as supplies when used in a surgical procedure. As noted in that final rule with comment period, supplies are a large category of items that typically are either for single

patient use or have a shorter life span in use than equipment. Supplies can be anything that is not equipment and include not only minor, inexpensive, or commodity-type items but also include a wide range of products used in the hospital outpatient setting, including certain implantable medical devices, drugs, biologicals, or radiopharmaceuticals (78 FR 74390). When evaluating whether a particular drug may meet the criteria for packaging under this policy, we do not consider low drug product utilization and/or drug product cost that exceeds the primary service APC payment to be factors in our determination (79 FR 66875). We unconditionally package all drugs and biologicals that function as supplies in a surgical procedure (79 FR 74930).

For CY 2016, we conducted a comprehensive review of CY 2015 separately payable OPPS drugs; that is, drugs with either a status indicator of ''G'' or ''K.'' For each separately payable drug, we reviewed the FDA-approved label and conducted a clinical review to determine whether a drug is indicated for use in a surgical procedure. Based on our clinical review, for CY 2016, we are proposing to package payment for the four drugs that are listed in Table 10 below based on their primary function as a supply in a surgical procedure, which typically means that the drug or biological is integral to, dependent on, or supportive of a surgical procedure. We note that one drug, described by HCPCS code C9447, that would otherwise be packaged in CY 2016 currently has pass-through payment status. Therefore, we are not proposing to package HCPCS code C9447 for CY 2016. Instead, we are proposing to package this drug for CY 2018, after its drug pass-through payment status has expired.

TABLE 10—SEPARATELY PAYABLE DRUGS PROPOSED FOR UNCONDITIONAL PACKAGING

HCPCS code	Descriptor	CY 2015 status indicator	Primary use in surgical procedure	Proposed first calendar year to be packaged
J0583	Injection, bivalirudin, 1 mg	K	Percutaneous Coronary Intervention[PCI]/PCTA [percutaneous transluminal coronary angioplasty] procedures.	2016
J7315	Mitomycin, ophthalmic, 0.2 mg	G	Glaucoma surgery	2016
C9447	Injection, phenylephrine and ketorolac, 4 ml vial.	G	Cataract surgery	2018
J0130	Injection abciximab, 10 mg	K	PCI procedure	2016

(3) Clinical Diagnostic Laboratory Tests

(a) Background

In CY 2014, we finalized a policy to package certain clinical diagnostic laboratory tests in the OPPS (78 FR 74939 through 74942 and 42 CFR 419.2(b)(17)). Under current policy, certain clinical diagnostic laboratory tests that are listed on the Clinical Laboratory Fee Schedule (CLFS) are packaged in the OPPS as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting on the same date of service as the laboratory test. Specifically, we conditionally package laboratory tests and only pay separately for a laboratory test when (1) it is the only service provided to a beneficiary on a given date of service; or (2) it is conducted on the same date of service as the primary service, but is ordered for a different purpose than the primary service ordered by a practitioner different than the practitioner who ordered the other OPPS services. Also excluded from this conditional packaging policy are molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 (78 FR 74939 through 74942), which are assigned status indicator ''A'' in Addendum B to this proposed rule (which is available at the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*). When laboratory tests are not packaged under the OPPS and are listed on the CLFS, they are paid at the CLFS payment rates outside the OPPS under Medicare Part B.

To implement our packaging policy in CY 2014, we assigned status indicator ''N,'' which describes unconditionally packaged items and services, to all laboratory tests paid at the CLFS rates except molecular pathology tests. We indicated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74939) that hospitals should use the 14X bill type for laboratory tests to bill and receive separate payment for unrelated laboratory tests excluded from the packaging proposal (except molecular pathology tests, which would still be reported on the 13X bill type), including both: (1) Those laboratory tests that are the only service provided on a date of service, and (2) laboratory tests provided on the same date of service as another OPPS service but ordered for a different purpose than the primary service and by a different practitioner than the practitioner who ordered the primary service. Therefore, under our final policy, we relied on hospitals to identify when laboratory tests should be separately paid and bill those laboratory tests on a 14X bill type.

Upon implementation of this final policy in January 2014, the National Uniform Billing Committee (NUBC) expressed concern that the 14X bill type was not an appropriate choice of bill type for billing for laboratory tests other than for laboratory tests on referred specimens and requested that CMS find another mechanism for hospitals to bill for separately payable laboratory tests. (We refer readers to our Medicare Learning Network article on this issue on the CMS Web site at: *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1412.pdf*.) In Transmittal 2971, Change Request 8776, July 2014 Update of the Hospital Outpatient Prospective Payment System (OPPS), which is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2971CP.pdf*, we implemented modifier ''L1'' (Separately payable laboratory test) to be used in lieu of the 14X bill type. Specifically, we stated that hospitals should use the ''L1'' modifier to indicate when laboratory tests meet either of the two exceptions for separate payment described above.

(b) CY 2016 Laboratory Test Packaging Proposals

For CY 2016 and subsequent years, we are proposing a few revisions to our

current laboratory packaging policy. First, with regard to the particular molecular pathology tests in the code range expressly excluded from the current policy, we are proposing to expand this exclusion to exclude all molecular pathology tests from our packaging policy, including any new codes that also describe molecular pathology tests. In our rationale for excluding these laboratory tests from our final packaging policy in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74939), we stated that we did not propose to package molecular pathology laboratory tests because we believed that these relatively new tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we proposed to package. We believe that this rationale remains applicable and may be appropriately extended to any new molecular pathology tests. Therefore, for CY 2016, we are proposing to assign all laboratory tests that describe molecular pathology tests status indicator ''A'' in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site), which means that they are separately paid at the CLFS rates outside of the OPPS.

Second, we are proposing for CY 2016 to make separate payment for preventive laboratory tests and assign them a status indicator ''A'' in Addendum B to this proposed rule. Laboratory tests that are considered preventive appear in Section 1.2, Chapter 18 of the Medicare Claims Processing Manual (Pub. 100–04). We currently make an exception to conditional packaging of ancillary services for ancillary services that are also preventive services (79 FR 66819). For consistency, we believe that such an exception should also apply to laboratory tests that are classified as preventive services.

Finally, for CY 2016, we are proposing to modify our current conditional packaging policy that laboratory tests are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting when those services are provided on the same date of service as the primary service and when they are ordered for the same purpose and by the same practitioner as the practitioner who ordered the primary service. Specifically, we are proposing to expand our current conditional packaging policy and consider laboratory tests provided during the same outpatient stay (rather than specifically provided on a same date of service as the primary service) as integral, ancillary, supportive, dependent, or adjunctive to a primary service or services, except when a laboratory test is ordered for a different purpose and by a different practitioner than the practitioner who ordered the other OPPS services. In some cases, outpatient hospital stays span more than a single date. For laboratory tests reported on a claim with a primary service, we do not believe that a different date of service for the laboratory test affects whether that test is integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the HOPD. Further, in reviewing our CY 2014 claims data, we observed hospitals indicating separate payment by reporting the ''L1'' modifier for only a few laboratory tests reported on different days than an OPPS service. We conclude that hospitals generally do not view laboratory tests occurring on a different day than a primary service during an outpatient stay as a reason for separate payment. Therefore, we are proposing to package laboratory tests that are reported on the same claim with a primary service, regardless of the date of service.

This proposal does not affect our existing policy to provide separate payment for laboratory tests: (1) If they are the only services furnished to an outpatient and are the only services on a claim and have a payment rate on the CLFS; or (2) if they are ordered for a different purpose than another OPPS service by a practitioner different than the practitioner who ordered the primary service (78 FR 74942). We also plan to continue to have hospitals report the ''L1'' modifier to identify any clinically ''unrelated'' laboratory tests that are furnished on the same claim as OPPS services, but are ordered by a different practitioner and for a different purpose than the primary OPPS services. However, as we discuss below, for ease of administration, we also are proposing to implement claims processing edits through a new conditional packaging status indicator ''Q4'' that would identify 13X bill type claims where there are only laboratory HCPCS codes that appear on the CLFS; automatically change their status indicator to ''A''; and pay them separately at the CLFS payment rates. For such claims, the ''L1'' modifier would not be used.

Proposed status indicator ''Q4'' is defined as ''packaged APC payment if billed on the same claim as a HCPCS code assigned status indicator ''J1,'' ''J2,'' ''S,'' ''T,'' ''V,'' ''Q1,'' ''Q2,'' or ''Q3,'' otherwise separately paid, and would apply to conditionally packaged laboratory tests. In our CY 2014 claims data, we observe some claims reporting laboratory services and no other OPPS services that were not paid because the hospital did not appropriately report the ''L1'' modifier. We further believe that the status indicator ''N'' for unconditional packaging does not accurately reflect the payment status of these laboratory tests. These tests may be eligible to receive separate payment at the CLFS payment rates in several circumstances as discussed above. Assigning a ''QX'' modifier generally indicates conditional packaging, where services are packaged, except in certain circumstances where separate payment can occur. Proposing a distinct ''Q4'' modifier allows for more precise categorization of the payment status of laboratory services. With the assignment of the proposed ''Q4'' modifier to laboratory tests, we are proposing that modifier ''L1'' would only be used to identify ''unrelated'' laboratory tests that are ordered for a different purpose and by a different practitioner than the other OPPS services on the claim.

We are inviting public comments on these proposals.

4. Proposed Calculation of OPPS Scaled Payment Weights

In this CY 2016 proposed rule, we are proposing to calculate the relative payment weights for each APC shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) using the APC costs discussed in sections II.A.1. and II.A.2. of this proposed rule. Prior to CY 2007, we standardized all of the relative payment weights to APC 0601 (Mid-Level Clinic Visit) because mid-level clinic visits were among the most frequently performed services in the hospital outpatient setting. We assigned APC 0601 a relative payment weight of 1.00 and divided the median cost for each APC by the median cost for APC 0601 to derive an initial unscaled relative payment weight for each APC.

Beginning with the CY 2007 OPPS (71 FR 67990), we standardized all of the relative payment weights to the median cost of APC 0606 (Level 3 Clinic Visits) because we deleted APC 0601 as part of the reconfiguration of the clinic visit APCs. We selected APC 0606 as the base because it was the mid-level clinic visit APC (that is, Level 3 of 5 levels). We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs rather than median-based APC costs to calculate relative payment weights. We are

proposing to continue this policy for CY 2016 and subsequent years.

As noted earlier for CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a new policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing any and all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For the CY 2014 and CY 2015 OPPS final rules with comment period, we standardized all of the relative payment weights to the geometric mean cost of APC 0634 as discussed in section VII. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66823). As noted in section VII. of this proposed rule, for CY 2016, we are proposing to delete APC 0634 and to move the outpatient clinic visit HCPCS code G0463 to APC 0632 (Level 2 Examinations and Related Services). Accordingly, for CY 2016 and subsequent years, we are proposing to standardize all of the relative payment weights to APC 0632. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For CY 2016, we are proposing to renumber APC 0632 as APC 5012 (Level 2 Examination and Related Services). For CY 2016, we are proposing to assign proposed renumbered APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the proposed geometric mean cost for proposed renumbered APC 5012 to derive the proposed unscaled relative payment weight for each APC. The choice of the APC on which to standardize the proposed relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2016 is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To comply with this requirement concerning the APC changes, we are proposing to compare the estimated aggregate weight using the CY 2015 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2016 unscaled relative payment weights.

For CY 2015, we multiplied the CY 2015 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2014 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2016, we are proposing to apply the same process using the estimated CY 2016 unscaled relative payment weights rather than scaled relative payment weights. We are proposing to calculate the weight scaler by dividing the CY 2015 estimated aggregate weight by the unscaled CY 2016 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Click on the CY 2016 OPPS proposed rule link and open the claims accounting document link at the bottom of the page.

In this CY 2016 proposed rule, we are proposing to compare the estimated unscaled relative payment weights in CY 2016 to the estimated total relative payment weights in CY 2015 using CY 2014 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we are proposing to adjust the calculated CY 2016 unscaled relative payment weights for purposes of budget neutrality. We are proposing to adjust the estimated CY 2016 unscaled relative payment weights by multiplying them by a weight scaler of 1.3823 to ensure that the proposed CY 2016 relative payment weights are scaled to be budget neutral. The proposed CY 2016 relative payment weights listed in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this proposed rule.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.3. of this proposed rule) is included in the budget neutrality calculations for the CY 2016 OPPS.

B. Proposed Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24477), consistent with current law, based on IHS Global Insight, Inc.'s first quarter 2015 forecast of the FY 2016 market basket increase, the proposed FY 2016 IPPS market basket update is 2.7 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(iv) of the Act, as added by section 3401(i) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) and as amended by section 10319(g) of that law and further amended by section 1105(e) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), provide adjustments to the OPD fee schedule increase factor for CY 2016.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending

with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). 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. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24478), we discussed the calculation of the proposed MFP adjustment for FY 2016, which is −0.6 percentage point reduction.

We are proposing that if more recent data become subsequently available after the publication of this CY 2016 OPPS/ASC proposed rule (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such updated data, if appropriate, to determine the CY 2016 market basket update and the MFP adjustment, components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in the CY 2016 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that, for each of years 2010 through 2019, the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act be reduced by the adjustment described in section 1833(t)(3)(G) of the Act. For CY 2016, section 1833(t)(3)(G)(iv) of the Act provides a −0.2 percentage point reduction to the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act. Therefore, in accordance with sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(iv) of the Act, we are proposing to apply a −0.2 percentage point reduction to the OPD fee schedule increase factor for CY 2016.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year, and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we are proposing to apply an OPD fee schedule increase factor of 1.9 percent for the CY 2016 OPPS (which is 2.7 percent, the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.6 percentage point MFP adjustment, and less the 0.2 percentage point additional adjustment).

Hospitals that fail to meet the Hospital OQR Program reporting requirements are subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. For further discussion of the Hospital OQR Program, we refer readers to section XIII. of this proposed rule.

In this CY 2016 OPPS/ASC proposed rule, we are proposing to amend 42 CFR 419.32(b)(1)(iv)(B) by adding new paragraph (*7*) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2016, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS, and to reflect the requirement in section 1833(t)(3)(G)(iv) of the Act, as required by section 1833(t)(3)(F)(ii) of the Act, that we reduce the OPD fee schedule increase factor by an additional 0.2 percentage point for CY 2016.

To set the OPPS conversion factor for CY 2016, we are proposing to increase the CY 2015 conversion factor of $74.173 by 1.9 percent. In accordance with section 1833(t)(9)(B) of the Act, we are proposing to further adjust the conversion factor for CY 2016 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We are proposing to calculate an overall proposed budget neutrality factor of 0.9993 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2016 IPPS wage indexes to those payments using the FY 2015 IPPS wage indexes, as adopted on a calendar year basis for the OPPS.

For CY 2016, we are proposing to maintain the current rural adjustment policy, as discussed in section II.E. of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment would be 1.0000.

For CY 2016, we are proposing to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this proposed rule. We are proposing to calculate a CY 2016 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2016 payments under section 1833(t) of the Act, including the proposed CY 2016 cancer hospital payment adjustment, to estimated CY 2016 total payments using the CY 2015 final cancer hospital payment adjustment as required under section 1833(t)(18)(B) of the Act. The CY 2016 proposed estimated payments applying the proposed CY 2016 cancer hospital payment adjustment are identical to estimated payments applying the CY 2015 final cancer hospital payment adjustment. Therefore, we are proposing to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment.

For this proposed rule, we estimate that proposed pass-through spending for drugs, biologicals, and devices for CY 2016 would equal approximately $136.8 million, which represents 0.25 percent of total projected CY 2016 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.13 percent estimate of pass-through spending for CY 2015 and the 0.25 percent estimate of proposed pass-through spending for CY 2016, resulting in a proposed adjustment for CY 2016 of −0.12 percent. Proposed estimated payments for outliers would be 1.0 percent of total OPPS payments for CY 2016. We currently estimate that outlier payments will be 0.95 percent of total OPPS payments in CY 2015; the 1.0 percent for proposed outlier payments in CY 2016 would constitute a 0.05 percent increase in payment in CY 2016 relative to CY 2015.

We also are proposing to exercise our authority in section 1833(t)(3)(C)(iii) of the Act to further adjust the conversion factor to eliminate the effect of coding and classification changes that we believe resulted in a change in aggregate payments that do not reflect real changes in service-mix related to our final policy to package certain clinical diagnostic laboratory tests in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74939 through 74942). Below we discuss our proposed adjustment to the conversion factor to redress the inflation in the OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests that we now understand continue to be paid separately outside the OPPS.

The current clinical diagnostic laboratory test packaging policy packages payment for laboratory tests in the OPPS when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting. Under current policy, payment for a laboratory test is not packaged when: (1) A laboratory test is the only service provided to the beneficiary on that date of service; or (2) a laboratory test is conducted on the same date of service as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service. The laboratory tests falling under these two exceptions continue to

be paid separately at the CLFS payment rates outside the OPPS.

In addition, we exclude payment for molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81404, and 81479 from packaging (78 FR 74939). In section II.A.3.b.(3) of this proposed rule, we are proposing to expand this exclusion to exclude all molecular pathology tests from our packaging policy, including any new codes that also describe molecular pathology tests. Finally, we continue to pay separately for referred specimens billed on a 14X bill type because these services will always consist only of laboratory services. We also make separate (that is, not packaged) payment for laboratory tests billed on a 12X (inpatient Part B) bill type claim when billed for reasons other than rebilling for a denied Part A claim, such as inpatient Part B coverage following exhausted Part A benefits. We refer readers to section II.A.3.b.(3) of this proposed rule for a detailed discussion of our laboratory test packaging policy exceptions and to review our proposals to modify our laboratory test packaging policy in light of current experience with this policy.

In monitoring aggregate payments for CY 2014, we observed that OPPS spending for hospital outpatient services experienced double digit growth in 2014 compared to typical growth of 6 to 8 percent, due to our CY 2014 final policy to package laboratory services, without a comparable reduction in spending for laboratory services paid at the CLFS payment rates outside the OPPS. As part of our CY 2014 final policy to package certain clinical diagnostic laboratory tests, we both revised the OPPS relative payment weights to reflect packaged laboratory services, and we increased the OPPS relative weight scaler to reflect the estimated total cost of packaged laboratory services. In calculating the appropriate increase to the weight scaler for CY 2014, we estimated that we spent approximately $2.4 billion on laboratory services on 13X type bill claims, and we incorporated this aggregate amount of weight into our estimate of the 2013 relative weight when calculating the budget neutral weight scaler to scale all relative weights for CY 2014, except those with a fixed payment amount such as drugs paid at ASP+6 percent (78 FR 74948 through 74949). An adjustment to the overall weight scaler has a comparable effect on final payment as an adjustment to the conversion factor. We also assumed that separate payment would continue for laboratory services billed on 14X bill type claims for referred specimens and for select inpatient Part B claims billed on a 12X bill type claim. Thus, we expect to experience an increase in OPPS spending due to our final packaging policy and a commensurate reduction in overall payment for Medicare Part B laboratory tests paid at the CLFS rates outside the OPPS.

However, upon reviewing actual claims for CY 2014, we observed an unexpectedly high volume of laboratory tests associated with $1 billion in spending for exceptions to our packaging policy for laboratory tests that continued to receive separate payment at the CLFS payment rates outside the OPPS. We did not observe a significant change in the overall volume of laboratory services being furnished. Specifically, we observed a pronounced shift in volume from billing on the 13X bill type claims to the 14X bill type claims beginning January 1, 2014, consistent with our final rule policy and then shifting back to the 13X bill type claims with an ''L1'' modifier when our instructions on billing for laboratory tests that are excepted from our laboratory packaging policy were implemented in July 2014. (We refer readers to Transmittal 2971, Change Request 8776, July 2014 Update of the Hospital Outpatient Prospective Payment System (OPPS), which is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2971CP.pdf.*) Because we do not observe a significant change in the number of laboratory services in our claims data, we conclude that the changes in aggregate payments under the OPPS are a result of changes in pricing alone and do not reflect real changes in service-mix.

Therefore, we overestimated the adjustment necessary to account for the new policy to package laboratory tests and underestimated the amount of spending that would continue for laboratory tests paid at the CLFS rates outside the OPPS by approximately $1 billion. This $1 billion effectively resulted in inflation in the OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests for all OPPS services and duplicate payments for certain laboratory tests because we are paying the laboratory tests through packaged payment incorporated into the OPPS payment rates as well as through separate payment at the CLFS payment rates outside the OPPS.

Section 1833(t)(3)(C)(iii) of the Act specifies that if the Secretary determines the adjustments for service-mix for a previous year (or estimates that such adjustments for a future year) did (or are likely to) result in a change in aggregate payments during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service-mix, the Secretary may adjust the conversion factor for subsequent years so as to eliminate the effect of such coding or classification changes. Based on this authority, we are proposing a reduction of 2.0 percentage points to the proposed CY 2016 conversion factor to redress inappropriate inflation in the OPPS payment rates and remove the $1 billion in excess packaged payment. We also used the ''L1'' modifier information on the CY 2014 claims data that we use to model the OPPS to identify which laboratory services should be packaged into the associated OPPS services when establishing the proposed CY 2016 relative weights. We are proposing this reduction in order to eliminate the effect of the coding and classification changes for payment for laboratory tests that resulted in changes in aggregate payments, but which did not result in real changes in service-mix under the OPPS. If we had been able to accurately forecast the amount of continued spending on separately payable laboratory tests that would continue in CY 2014 at the CLFS rates outside the OPPS, we would have incorporated a reduced amount of estimated spending into our CY 2014 OPPS budget neutrality calculations in CY 2014 rulemaking.

We conducted several analyses to better understand the derivation of the overestimated adjustment made in CY 2014. These efforts included an attempt to determine how much spending at the CLFS payment rates outside the OPPS should have been packaged in CY 2014 with full knowledge of the actual volume for exceptions to our final laboratory tests packaging policy now that CY 2014 claims data are available for review. This assessment required some assumptions about what payment would have been at the CY 2014 CLFS payment amounts using the CLFS national limitation amount (NLA) price or the mode price among jurisdictions where an NLA did not exist for all laboratory services in 12X, 13X, and 14X bill type claims less actual payments for those same services and the $2.4 billion in packaged payments. We adjusted our total estimates for incomplete claims data because the data that we use to model the proposed rule are data from CY 2014 claims processed as of December 31, 2014, estimated at 90 percent based on historical claims data.

As a result of this analysis, we estimated that we included a gross estimate of roughly $1.1 billion in excess packaged payment in the CY 2014 OPPS payment rates for laboratory tests that were paid separately, as demonstrated by actual CY 2014 claims data. We also did a more straightforward analysis assessing total payment for our exceptions policy, in which we looked at the change in payment on 14X bill type claims for the first part of CY 2014 along with any payment for laboratory services billed with the ''L1'' modifier. This analysis resulted in a similar estimate of roughly $1.003 billion. Because both analyses resulted in an approximate $1 billion estimate of spending at the CLFS rates outside the OPPS that was packaged into the OPPS, we believe that a prospective adjustment to remove this $1 billion from the OPPS realigns total aggregate OPPS payments to reflect the resources associated with OPPS services. When we calculate the $1 billion as a percent of actual total spending for OPPS services in CY 2014 (approximately $50 billion), we determined an estimated 2.0 percent reduction to total spending to be applied to the conversion factor. Therefore, we are proposing to apply a 2.0 percent adjustment to the proposed CY 2016 conversion factor to redress the inflation in the OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests we now understand continue to be paid at the CLFS rates outside the OPPS for CY 2016 and subsequent years.

For the CY 2017 OPPS rulemaking, we plan to review actual CY 2015 claims data and assess whether our proposed adjustment for CY 2016 accurately adjusted for the inflation in the OPPS payment rates under current policy.

We provide a summary file of our analysis of separate payment at the CLFS rates outside the OPPS for laboratory services that are exceptions to our packaging policy which is available in the ''Downloads'' section of the CMS Web site accompanying this proposed rule (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*). We note that the ''OPPS limited data set'' that we make available to accompany each proposed and final rule is not a complete set of institutional Part B claims, containing only the 12X, 13X, and 14X bill types that we use to model the OPPS rates and excluding claims weeded or trimmed as discussed in our claims accounting document (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*).

For this proposed rule, we also are proposing that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we are proposing to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of −0.1 percent (that is, the proposed OPD fee schedule increase factor of 1.9 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2016 of $72.478 for hospitals that fail to meet the Hospital OQR requirements (a difference of −1.451 in the conversion factor relative to hospitals that meet the requirements).

In summary, for CY 2016, we are proposing to amend § 419.32(b)(1)(iv)(B) by adding a new paragraph (*7*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2016 to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(iv) of the Act. We are proposing to use a reduced conversion factor of $72.478 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.451 in the conversion factor relative to hospitals that meet the requirements).

For CY 2016, we are proposing to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this proposed rule.

As a result of these proposed policies, the proposed OPD fee schedule increase factor for the CY 2016 OPPS is 1.9 percent (which is 2.7 percent, the estimate of the hospital inpatient market basket percentage increase, less the proposed 0.6 percentage point MFP adjustment, and less the 0.2 percentage point additional adjustment). For CY 2016, we are proposing to use a conversion factor of $73.929 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs. That is, the proposed OPD fee schedule increase factor of 1.9 percent for CY 2016, the required wage index budget neutrality adjustment of approximately 0.9993, the proposed cancer hospital payment adjustment of 1.0000, the proposed −2.0 percent adjustment to the conversion factor to redress the inflation in the OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests we now understand continue to be paid at the CLFS rates outside the OPPS, and the proposed adjustment of −0.12 percentage point of projected OPPS spending for the difference in the pass-through spending result in a proposed conversion factor for CY 2016 of $73.929.

C. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B. of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). Therefore, we are proposing to continue this policy for the CY 2016 OPPS. We refer readers to section II.H. of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in section II.A.2.c. of this proposed rule, for estimating APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same proposed FY 2016 pre-reclassified wage index that the IPPS uses to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the original OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market

differences. Therefore, the wage index that applies to a particular acute care short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add new paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements in § 419.43(c)(2) and (c)(3) of our regulations. For the CY 2016 OPPS, we are proposing to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, rural and imputed floor, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the following sections in the FY 2011 through FY 2015 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of ''frontier States'' as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: for FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 through 53370; for FY 2014, 78 FR 50590 through 50591; and for FY 2015, 79 FR 49971.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2016 IPPS wage indexes continue to reflect a number of adjustments implemented over the past few years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural and imputed floor provisions, an adjustment for occupational mix, and an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment). We refer readers to the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24463 through 24472) for a detailed discussion of all proposed changes to the FY 2016 IPPS wage indexes. In addition, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65842 through 65844) and subsequent OPPS rules for a detailed discussion of the history of these wage index adjustments as applied under the OPPS.

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) and the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24463 through 24469), the Office of Management and Budget (OMB) issued revisions to the labor market area delineations on February 28, 2013 (based on 2010 Decennial Census data), that included a number of significant changes such as new Core Based Statistical Areas (CBSAs), urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart (OMB Bulletin 13–01). This bulletin can be found at: *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b13-01.pdf*. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49950 through 49985), we adopted the use of the OMB labor market area delineations that were based on the 2010 Decennial Census data.

For the CY 2016 OPPS/ASC proposed rule, we are proposing to use the proposed FY 2016 hospital IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2016. Thus, any adjustments that were proposed for the FY 2016 IPPS post-reclassified wage index would be reflected in the proposed CY 2016 OPPS wage index. (We refer readers to the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24463 through 24477) and the proposed FY 2016 hospital wage index files posted on the CMS Web site.)

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments. We are proposing to continue this policy for CY 2016. The following is a brief summary of the major proposed FY 2016 IPPS wage index policies and adjustments that we are proposing to apply to these hospitals under the OPPS for CY 2016. We further refer readers to the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24463 through 24477) for a detailed discussion of the proposed changes to the FY 2016 wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they would be eligible for the out-migration wage adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that would apply if the hospital were paid under the IPPS. For CY 2016, we are proposing to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA). The new Table 2 from the FY 2016 IPPS/LTCH PPS proposed rule (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) identifies counties eligible for the out-migration adjustment and IPPS hospitals that would receive the adjustment for FY 2016. (We note that the new FY 2016 proposed IPPS Table 2 consolidates information on counties eligible for the out-migration adjustment that was previously issued as Table 4J.) We are including the proposed out-migration adjustment information from the new consolidated Table 2 from the FY 2016 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule with the addition of non-IPPS hospitals that would receive the section 505 out-migration adjustment under the CY 2016 OPPS. Addendum L is available via the Internet on the CMS Web site.

As stated earlier, in the FY 2015 IPPS/LTCH PPS final rule, we adopted the OMB labor market area delineations issued by OMB in OMB Bulletin No. 13–01 on February 28, 2013, based on standards published on June 28, 2010 (75 FR 37246 through 37252) and the 2010 Census data to delineate labor market areas for purposes of the IPPS

wage index. For IPPS wage index purposes, for hospitals that were located in urban CBSAs in FY 2014 but were designated as rural under these revised OMB labor market area delineations, we generally assigned 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 (79 FR 49957 through 49960). To be consistent, we applied the same policy to hospitals paid under the OPPS but not under the IPPS so that such hospitals will maintain the wage index of the CBSA in which they were physically located for FY 2014 for 3 calendar years (until December 31, 2017). Thus, for the CY 2016 OPPS, consistent with the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24467 through 24468), this 3-year transition will continue for the second year in CY 2016. For CY 2015, we also finalized a 1-year blended wage index for all hospitals that experienced any decrease in their actual payment wage index exclusively due to the implementation of the new OMB delineations. In the CY 2015 OPPS/ASC proposed rule, for purposes of the OPPS, we finalized a policy to apply this 1-year 50-percent transition blend to hospitals paid under the OPPS but not under the IPPS. Therefore, this one-year transition blend does not apply for the CY 2016 OPPS wage index because it expires at the end of CY 2015.

In addition, for the FY 2016 IPPS, we proposed to extend the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2016 (80 FR 24469 through 24470). For purposes of the CY 2016 OPPS, we also are proposing to apply the imputed floor policy to hospitals paid under the OPPS but not under the IPPS so long as the IPPS continues an imputed floor policy.

For CMHCs, for CY 2016, we are proposing to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. As with OPPS hospitals and for the same reasons, in CY 2015, we applied a 1-year, 50/50 blended wage index to CMHCs that would receive a lower wage index due to the new OMB labor market area delineations. However, this blended wage index does not apply in CY 2016 because it expires at the end of CY 2015. In addition, as with OPPS hospitals and for the same reasons, for CMHCs previously located in urban CBSAs that were designated as rural under the new OMB labor market area delineations, we finalized a policy to maintain the urban wage index value of the CBSA in which they were physically located for CY 2014 for 3 calendar years (until December 31, 2017). Consistent with our current policy, the wage index that applies to CMHCs includes both the imputed floor adjustment and the rural floor adjustment, but does not include the out-migration adjustment because that adjustment only applies to hospitals.

With the exception of the proposed out-migration wage adjustment table (Addendum L to this proposed rule, which is available via the Internet on the CMS Web site), which includes non-IPPS hospitals paid under the OPPS, we are not reprinting the proposed FY 2016 IPPS wage indexes referenced in this discussion of the wage index. We refer readers to the CMS Web site for the OPPS at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At this link, readers will find a link to the proposed FY 2016 IPPS wage index tables.

D. Proposed Statewide Average Default CCRs

In addition to using CCRs to estimate costs from charges on claims for ratesetting, CMS uses overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. MACs cannot calculate a CCR for some hospitals because there is no cost report available. For these hospitals, CMS uses the statewide average default CCRs to determine the payments mentioned above until a hospital's MAC is able to calculate the hospital's actual CCR from its most recently submitted Medicare cost report. These hospitals include, but are not limited to, hospitals that are new, have not accepted assignment of an existing hospital's provider agreement, and have not yet submitted a cost report. CMS also uses the statewide average default CCRs to determine payments for hospitals that appear to have a biased CCR (that is, the CCR falls outside the predetermined ceiling threshold for a valid CCR) or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11). In this proposed rule, we are proposing to update the default ratios for CY 2016 using the most recent cost report data. We discuss our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009.

For CY 2016, we are proposing to continue to use our standard methodology of calculating the statewide average default CCRs using the same hospital overall CCRs that we use to adjust charges to costs on claims data for setting the proposed CY 2016 OPPS relative payment weights. Table 11 below lists the proposed CY 2016 default urban and rural CCRs by State and compares them to the CY 2015 default CCRs. These proposed CCRs represent the ratio of total costs to total charges for those cost centers relevant to outpatient services from each hospital's most recently submitted cost report, weighted by Medicare Part B charges. We also are proposing to adjust ratios from submitted cost reports to reflect the final settled status by applying the differential between settled to submitted overall CCRs for the cost centers relevant to outpatient services from the most recent pair of final settled and submitted cost reports. We then are proposing to weight each hospital's CCR by the volume of separately paid line-items on hospital claims corresponding to the year of the majority of cost reports used to calculate the overall CCRs. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66680 through 66682) and prior OPPS rules for a more detailed discussion of our established methodology for calculating the statewide average default CCRs, including the hospitals used in our calculations and our trimming criteria.

For Maryland, we used an overall weighted average CCR for all hospitals in the Nation as a substitute for Maryland CCRs. Few hospitals in Maryland are eligible to receive payment under the OPPS, which limits the data available to calculate an accurate and representative CCR. The weighted CCR is used for Maryland because it takes into account each hospital's volume, rather than treating each hospital equally. We refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65822) for further discussion and the rationale for our longstanding policy of using the national average CCR for Maryland. In general, observed changes in the statewide average default CCRs between CY 2015 and CY 2016 are modest and the few significant changes are associated with areas that have a small number of hospitals.

Table 11 below lists the proposed statewide average default CCRs for OPPS services furnished on or after January 1, 2016.

TABLE 11—PROPOSED CY 2016 STATEWIDE AVERAGE CCRS

State	Urban/Rural	Proposed CY 2016 default CCR	Previous default CCR (CY 2015 OPPS Final Rule)
ALABAMA	RURAL	0.226	0.235
ALABAMA	URBAN	0.172	0.186
ALASKA	RURAL	0.592	0.439
ALASKA	URBAN	0.286	0.294
ARIZONA	RURAL	0.224	0.228
ARIZONA	URBAN	0.176	0.181
ARKANSAS	RURAL	0.261	0.262
ARKANSAS	URBAN	0.222	0.239
CALIFORNIA	RURAL	0.180	0.178
CALIFORNIA	URBAN	0.196	0.196
COLORADO	RURAL	0.381	0.410
COLORADO	URBAN	0.212	0.219
CONNECTICUT	RURAL	0.337	0.339
CONNECTICUT	URBAN	0.267	0.273
DELAWARE	URBAN	0.316	0.314
DISTRICT OF COLUMBIA	URBAN	0.307	0.299
FLORIDA	RURAL	0.169	0.180
FLORIDA	URBAN	0.154	0.156
GEORGIA	RURAL	0.253	0.256
GEORGIA	URBAN	0.211	0.211
HAWAII	RURAL	0.339	0.337
HAWAII	URBAN	0.310	0.307
IDAHO	RURAL	0.357	0.353
IDAHO	URBAN	0.491	0.463
ILLINOIS	RURAL	0.251	0.252
ILLINOIS	URBAN	0.220	0.217
INDIANA	RURAL	0.332	0.334
INDIANA	URBAN	0.256	0.262
IOWA	RURAL	0.308	0.321
IOWA	URBAN	0.259	0.269
KANSAS	RURAL	0.302	0.300
KANSAS	URBAN	0.219	0.231
KENTUCKY	RURAL	0.223	0.231
KENTUCKY	URBAN	0.217	0.212
LOUISIANA	RURAL	0.264	0.272
LOUISIANA	URBAN	0.213	0.209
MAINE	RURAL	0.465	0.430
MAINE	URBAN	0.415	0.432
MARYLAND	RURAL	0.290	0.296
MARYLAND	URBAN	0.241	0.244
MASSACHUSETTS	RURAL	0.325	0.326
MASSACHUSETTS	URBAN	0.337	0.333
MICHIGAN	RURAL	0.339	0.371
MICHIGAN	URBAN	0.316	0.320
MINNESOTA	RURAL	0.473	0.485
MINNESOTA	URBAN	0.351	0.347
MISSISSIPPI	RURAL	0.240	0.247
MISSISSIPPI	URBAN	0.177	0.181
MISSOURI	RURAL	0.248	0.267
MISSOURI	URBAN	0.259	0.274
MONTANA	RURAL	0.459	0.501
MONTANA	URBAN	0.386	0.386
NEBRASKA	RURAL	0.280	0.290
NEBRASKA	URBAN	0.245	0.255
NEVADA	RURAL	0.221	0.241
NEVADA	URBAN	0.150	0.149
NEW HAMPSHIRE	RURAL	0.383	0.362
NEW HAMPSHIRE	URBAN	0.310	0.280
NEW JERSEY	URBAN	0.200	0.202
NEW MEXICO	RURAL	0.267	0.296
NEW MEXICO	URBAN	0.295	0.294
NEW YORK	RURAL	0.331	0.333
NEW YORK	URBAN	0.314	0.340
NORTH CAROLINA	RURAL	0.280	0.280
NORTH CAROLINA	URBAN	0.245	0.246
NORTH DAKOTA	RURAL	0.443	0.660
NORTH DAKOTA	URBAN	0.357	0.395
OHIO	RURAL	0.301	0.317
OHIO	URBAN	0.216	0.222

TABLE 11—PROPOSED CY 2016 STATEWIDE AVERAGE CCRS—Continued

State	Urban/Rural	Proposed CY 2016 default CCR	Previous default CCR (CY 2015 OPPS Final Rule)
OKLAHOMA	RURAL	0.252	0.282
OKLAHOMA	URBAN	0.198	0.203
OREGON	RURAL	0.267	0.287
OREGON	URBAN	0.366	0.352
PENNSYLVANIA	RURAL	0.282	0.283
PENNSYLVANIA	URBAN	0.195	0.197
PUERTO RICO	URBAN	0.596	0.577
RHODE ISLAND	URBAN	0.298	0.297
SOUTH CAROLINA	RURAL	0.193	0.191
SOUTH CAROLINA	URBAN	0.211	0.207
SOUTH DAKOTA	RURAL	0.366	0.286
SOUTH DAKOTA	URBAN	0.225	0.214
TENNESSEE	RURAL	0.203	0.203
TENNESSEE	URBAN	0.180	0.188
TEXAS	RURAL	0.249	0.251
TEXAS	URBAN	0.183	0.203
UTAH	RURAL	0.476	0.481
UTAH	URBAN	0.336	0.335
VERMONT	RURAL	0.437	0.439
VERMONT	URBAN	0.352	0.353
VIRGINIA	RURAL	0.205	0.219
VIRGINIA	URBAN	0.258	0.241
WASHINGTON	RURAL	0.351	0.300
WASHINGTON	URBAN	0.323	0.330
WEST VIRGINIA	RURAL	0.313	0.312
WEST VIRGINIA	URBAN	0.311	0.300
WISCONSIN	RURAL	0.325	0.328
WISCONSIN	URBAN	0.292	0.294
WYOMING	RURAL	0.441	0.429
WYOMING	URBAN	0.311	0.262

E. Proposed Adjustment for Rural SCHs and EACHs Under Section 1833(t)(13)(B) of the Act

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised § 419.43(g) of the regulations to clarify that EACHs also are eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Public Law 105–33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2015. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For the CY 2016 OPPS, we are proposing to continue our policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

F. Proposed OPPS Payment to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the Act

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient hospital services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act

of 1999 (Pub. L. 106–113), Congress established section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (often referred to as ''held harmless'').

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a ''pre-BBA amount.'' That is, cancer hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA amount'' is the product of the hospital's reasonable costs for covered outpatient services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The ''pre-BBA amount,'' including the determination of the base PCR, are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, respectively) as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are greater than other hospitals' costs, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recent submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. For CYs 2012 and 2013, the target PCR for purposes of the cancer hospital payment adjustment was 0.91. For CY 2014, the target PCR for purposes of the cancer hospital payment adjustment was 0.89. For CY 2015, the target PCR was 0.90, as discussed in the CY 2015 OPPS/ASC final rule with comment period correction notice (80 FR 9629).

2. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2016

For CY 2016, we are proposing to continue our policy to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals using the most recent submitted or settled cost report data that are available at the time of the development of this proposed rule. To calculate the proposed CY 2016 target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A. of this proposed rule, used to estimate costs for the CY 2016 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2014 claims data that we used to model the impact of the proposed CY 2016 APC relative payment weights (3,794 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2016 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2013 to 2014. We then removed the cost report data of the 47 hospitals located in Puerto Rico from our dataset because we do not believe that their cost structure reflects the costs of most hospitals paid under the OPPS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 18 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,729 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS are approximately 90 percent of reasonable cost (weighted average PCR of 0.90). Therefore, we are proposing that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.90 for each cancer hospital. Table 12 below indicates the proposed estimated percentage increase in OPPS payments to each cancer hospital for CY 2016 due to the cancer hospital payment adjustment policy.

The actual amount of the CY 2016 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2016 payments and costs. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 12—ESTIMATED CY 2016 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider number	Hospital name	Estimated percentage increase in OPPS payments for CY 2016
050146	City of Hope Comprehensive Cancer Center	19.0
050660	USC Norris Cancer Hospital	19.3
100079	Sylvester Comprehensive Cancer Center	22.3
100271	H. Lee Moffitt Cancer Center & Research Institute	24.5
220162	Dana-Farber Cancer Institute	47.8
330154	Memorial Sloan-Kettering Cancer Center	42.4
330354	Roswell Park Cancer Institute	19.2
360242	James Cancer Hospital & Solove Research Institute	32.5
390196	Fox Chase Cancer Center	21.0
450076	M.D. Anderson Cancer Center	47.7
500138	Seattle Cancer Care Alliance	53.9

G. Proposed Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain amount of dollars). In CY 2015, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus $2,775 (the fixed-dollar amount threshold) (79 FR 66834). If the cost of a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the proposed OPPS. Our current estimate of total outlier payments as a percent of total CY 2014 OPPS payment, using available CY 2014 claims and the OPPS expenditure estimate for the FY 2016 President's Budget, is approximately 0.9 percent of the total aggregated OPPS payments. Therefore, for CY 2014, we estimate that we paid 1.0 percent below the CY 2014 outlier target of 1.0 percent of total aggregated OPPS payments.

Using CY 2014 claims data and CY 2015 payment rates, we currently estimate that the aggregate outlier payments for CY 2015 will be approximately 0.95 percent of the total CY 2015 OPPS payments. The difference between 0.9 percent and the 1.0 percent target is reflected in the regulatory impact analysis in section XX. of this proposed rule. We provide estimated CY 2016 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts—Provider-Specific Data file on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

2. Proposed Outlier Calculation

For CY 2016, we are proposing to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We are proposing that a portion of that 1.0 percent, an amount equal to 0.49 percent of outlier payments (or 0.0049 percent of total OPPS payments) would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. As discussed in section VIII.D. of this proposed rule, for CMHCs, we are proposing to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under either proposed renumbered APC 5851 (Level 1 Partial Hospitalization (3 services) for CMHCs) (existing APC 0172) or proposed renumbered APC 5852 (Level 2 Partial Hospitalization (4 or more services) for CMHCs) (existing APC 0173), exceeds 3.40 times the payment rate for proposed renumbered APC 5852, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed renumbered APC 5852 payment rate. For further discussion of CMHC outlier payments, we refer readers to section VIII.D. of this proposed rule.

To ensure that the estimated CY 2016 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we are proposing that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus $3,650.

We calculated the proposed fixed-dollar threshold of $3,650 using the standard methodology most recently used for CY 2015 (79 FR 66833 through 66834). For purposes of estimating outlier payments for this proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2015 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are

maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years.

In order to estimate the CY 2016 hospital outlier payments for this proposed rule, we inflated the charges on the CY 2014 claims using the same inflation factor of 1.0985 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24632 through 24633). We used an inflation factor of 1.0481 to estimate CY 2015 charges from the CY 2014 charges reported on CY 2014 claims. The methodology for determining this charge inflation factor is discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24632). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors are appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we are proposing to apply the same CCR inflation adjustment factor that we are proposing to apply for the FY 2016 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2016 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2016, we are proposing to apply an adjustment factor of 0.9795 to the CCRs that were in the April 2015 OPSF to trend them forward from CY 2015 to CY 2016. The methodology for calculating this proposed adjustment is discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24633).

To model hospital outlier payments for this proposed rule, we applied the overall CCRs from the April 2015 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.9795 to approximate CY 2016 CCRs) to charges on CY 2014 claims that were adjusted (using the proposed charge inflation factor of 1.0985 to approximate CY 2016 charges). We simulated aggregated CY 2016 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2016 OPPS payments. We estimated that a proposed fixed-dollar threshold of $3,650, combined with the proposed multiple threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we are proposing that, if a CMHC's cost for partial hospitalization services, paid under either proposed renumbered APC 5851 (existing APC 0172) or proposed renumbered APC 5852 (existing APC 0173), exceeds 3.40 times the payment rate for proposed renumbered 5852, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed renumbered APC 5852 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that will apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we are proposing to continue the policy that we implemented in CY 2010 that the hospitals' costs will be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XIII. of this proposed rule.

H. Proposed Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2016 OPPS/ASC proposed rule, the proposed payment rate for most services and procedures for which payment is made under the OPPS is the product of the proposed conversion factor calculated in accordance with section II.B. of this proposed rule and the proposed relative payment weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) was calculated by multiplying the proposed CY 2016 scaled weight for the APC by the proposed CY 2016 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIII. of this proposed rule.

We demonstrate below the steps on how to determine the APC payments that will be made in a calendar year under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''J1,'' ''J2,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''U,'' or ''V'' (as defined in Addendum D1 to this proposed rule, which is available via the Internet on the CMS Web site), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We note that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program

requirements. We note that, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66799), we created new status indicator ''J1'' to reflect the comprehensive APCs discussed in section II.A.2.e. of this proposed rule. We also note that we deleted status indicator ''X'' as part of the CY 2015 packaging policy for ancillary services, discussed in section II.A.3. of this proposed rule. We are proposing to create new status indicator ''J2'' to reflect the new C–APC 8011 (Comprehensive Observation Services) proposed in this CY 2016 proposed rule, as discussed in section II.A.2.e.(2) of this proposed rule.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the proposed national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the proposed national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.980 times the ''full'' national unadjusted payment rate. The proposed national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements in order to receive the proposed full CY 2016 OPPS fee schedule increase factor of 1.9 percent.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

X = .60 * (national unadjusted payment rate).

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. We note that under the proposed CY 2016 OPPS policy for continuing to use the OMB labor market area delineations based on the 2010 Decennial Census data for the wage indexes used under the IPPS, a hold harmless policy for the wage index may apply, as discussed in section II.C. of this proposed rule. The proposed wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are proposed to be assigned for FY 2016 under the IPPS, reclassifications through the MGCRB, section 1886(d)(8)(B) ''Lugar'' hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in § 412.103 of the regulations, and hospitals designated as urban under section 601(g) of Pub. L. 98–21. (For further discussion of the proposed changes to the FY 2016 IPPS wage indexes, as applied to the CY 2016 OPPS, we refer readers to section II.C. of this proposed rule.) We are proposing to continue to apply a wage index floor of 1.00 to frontier States, in accordance with section 10324 of the Affordable Care Act of 2010.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Public Law 108–173. Addendum L to this proposed rule (which is available via the Internet on the CMS Web site) contains the qualifying counties and the proposed associated wage index increase developed for the FY 2016 IPPS, which are listed in Table 4J in the FY 2016 IPPS/LTCH PPS proposed rule and available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

Xa is the labor-related portion of the national unadjusted payment rate (wage adjusted).

X_a = .60 * (national unadjusted payment rate) * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

Y = .40 * (national unadjusted payment rate).

Adjusted Medicare Payment = $Y + Xa$.

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

We are providing examples below of the calculation of both the proposed full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined above. For purposes of this example, we used a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to proposed renumbered APC 5072 (Level 2 Excision/Biopsy/Incision and Drainage) (existing APC 0019). The proposed CY 2016 full national unadjusted payment rate for APC 5072 is approximately $486.16. The proposed reduced national unadjusted payment rate for proposed renumbered APC 5072 for a hospital

that fails to meet the Hospital OQR Program requirements is approximately $476.44. This proposed reduced rate is calculated by multiplying the proposed reporting ratio of 0.980 by the proposed full unadjusted payment rate for proposed renumbered APC 5072.

The proposed FY 2016 wage index for a provider located in CBSA 35614 in New York is 1.2998. The labor-related portion of the proposed full national unadjusted payment is approximately $379.15 (.60 * $486.16 * 1.2998). The labor-related portion of the proposed reduced national unadjusted payment is approximately $371.57 (.60 * $476.44* 1.2998). The nonlabor-related portion of the proposed full national unadjusted payment is approximately $194.46 (.40 * $486.16). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately $190.58 (.40 * $476.44). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately $573.61 ($379.15 + $194.46). The sum of the portions of the proposed reduced national adjusted payment is approximately $562.15 ($371.57 + $190.58).

I. Proposed Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in calendar years thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. Our discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, may be found in section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

2. Proposed OPPS Copayment Policy

For CY 2016, we are proposing to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we are proposing to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2016, are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). As discussed in section XIII.E. of this proposed rule, for CY 2016, the proposed Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.
- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.
- If HCPCS codes are added to or deleted from an APC, and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).
- If HCPCS codes are added to an APC, and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in that CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent.

We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which is consistent with the Congressional goal of achieving a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459). We believe the proposed reorganization of APCs discussed in section III.D. of this proposed rule hastens this movement toward copayments equal to 20 percent of an APC for reorganized APCs that previously had copayment percentages greater than 20 percent.

3. Proposed Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using proposed renumbered APC 5072 (existing APC 0019), $97.50 is approximately 20 percent of the proposed full national unadjusted payment rate of $486.16. For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of this proposed rule. Calculate the rural adjustment for eligible providers as indicated in Step 6 under section II.H. of this proposed rule.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of this proposed rule, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B.*

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B.*

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.980.

The proposed unadjusted copayments for services payable under the OPPS that would be effective January 1, 2016, are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the proposed full CY 2016 OPD fee schedule increase factor discussed in section II.B. of this proposed rule.

In addition, as noted above, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPPS Treatment of New CPT and Level II HCPCS Codes

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures and medical services;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

CPT codes are established by the American Medical Association (AMA) and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and HCPCS code changes that affect the OPPS are published both through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). CMS releases new Level II HCPCS codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new CPT and Level II HCPCS codes to interim status indicator (SI) and APC assignments. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that may more accurately describe items or services furnished and provides payment or more accurate payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on these new codes and finalize our proposals related to these codes through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. For those items, procedures, or services not paid separately under the hospital OPPS, they are assigned to appropriate status indicators. Section XI. of this proposed rule provides a discussion of the various status indicators used under the OPPS. Certain payment indicators provide separate payment while others do not.

In Table 13 below, we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the OPPS.

TABLE 13—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April I, 2015	Level II HCPCS Codes	April 1, 2015	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.
July 1, 2015	Level II HCPCS Codes	July 1, 2015	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2015	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.
October 1, 2015	Level II HCPCS Codes	October 1, 2015	CY 2016 OPPS/ASC final rule with comment period.	CY 2017 OPPS/ASC final rule with comment period.
January 1, 2016	Level II HCPCS Codes	January 1, 2016	CY 2016 OPPS/ASC final rule with comment period.	CY 2017 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes.	January 1, 2016	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.

This process is discussed in detail below. We have separated our discussion into two sections based on whether we are soliciting public comments in this CY 2016 OPPS/ASC proposed rule or whether we will be soliciting public comments in the CY 2016 OPPS/ASC final rule with comment period. We note that we sought public comments in the CY 2015 OPPS/ASC final rule with comment period on the interim APC and status assignments for new CPT and Level II HCPCS codes that were effective January 1, 2015. We also sought public comments in the CY 2015 OPPS/ASC final rule with comment period on the interim APC and status assignments for new Level II HCPCS codes that became effective October 1, 2014. These new and revised codes, with an effective date of October 1, 2014, or January 1, 2015, were flagged with comment indicator ''NI'' (New code, interim APC assignment; comments will be accepted on the interim APC assignment for the new code) in Addendum B to the CY 2015 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and an APC and payment rate, if applicable, and were subject to public comment following publication of the CY 2015 OPPS/ASC final rule with comment period. We will respond to public comments and finalize our interim OPPS treatment of these codes in the CY 2016 OPPS/ASC final rule with comment period.

1. Proposed Treatment of New CY 2015 Level II HCPCS and CPT Codes Effective April 1, 2015 and July 1, 2015 for Which We Are Soliciting Public Comments in This CY 2016 OPPS/ASC Proposed Rule

Through the April 2015 OPPS quarterly update CR (Transmittal 3217, Change Request 9097, dated March 13, 2015), and the July 2015 OPPS quarterly update CR (Transmittal 3280, Change Request 9205, dated June 5, 2015), we recognized several new HCPCS codes for separate payment under the OPPS.

Effective April 1, 2015, we made effective eight new Level II HCPCS codes and also assigned them to appropriate interim OPPS status indicators and APCs. Through the April 2015 OPPS quarterly update CR, we allowed separate payment for eight new Level II HCPCS codes. Specifically, as displayed in Table 14 below, we provided separate payment for HCPCS codes C2623, C9445, C9448, C9449, C9450, C9451, C9452, and Q9975. We note that HCPCS code C9448 was deleted on June 30, 2015, and replaced with HCPCS code Q9978, effective July 1, 2015.

TABLE 14—NEW LEVEL II HCPCS CODES IMPLEMENTED IN APRIL 2015

CY 2015 HCPCS Code	CY 2015 Long descriptor	Proposed CY 2016 Status indicator	Proposed CY 2016 APC**
C2623	Catheter, transluminal angioplasty, drug-coated, non-laser	H	2623
C9445	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	9445
C9448#	Netupitant 300mg and palonosetron 0.5 mg, oral	N/A	N/A
C9449	Injection, blinatumomab, 1 mcg	G	9449
C9450	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	G	9450
C9451	Injection, peramivir, 1 mg	G	9451
C9452	Injection, ceftolozane 50 mg and tazobactam, 25 mg	G	9452
Q9975*	Injection, Factor VIII, FC Fusion Protein (Recombinant), per iu	G	1656

HCPCS code C9448 was deleted on June 30, 2015, and replaced with HCPCS code Q9978, effective July 1, 2015.

*HCPCS code Q9975 was replaced with HCPCS code C9136 (Injection, factor viii, fc fusion protein, (recombinant), per i.u.), effective April 1, 2015.

**Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

In this CY 2016 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments, where applicable, for the Level II HCPCS codes implemented on April 1, 2015 and listed in Table 14 of this proposed rule. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

Effective July 1, 2015, we made effective several new CPT and Level II HCPCS codes and also assigned them to appropriate interim OPPS status indicators and APCs. Through the July 2015 OPPS quarterly update CR (Transmittal 3280, Change Request 9205, dated June 5, 2015), we assigned interim OPPS status indicators and APCs for two new Category III CPT codes and eight Level II HCPCS codes that were made effective July 1, 2015. Specifically, as displayed in Table 15 below, we made interim OPPS status indicators and APC assignments for Category III CPT codes 0392T and 0393T, and Level II HCPCS codes C2613, C9453, C9454, C9455, Q5101, Q9976, Q9977, and Q9978. Table 15 below lists the CPT and Level II HCPCS codes that were implemented on July 1, 2015, along with the proposed status indicators, proposed APC assignments, and proposed payment rates, where applicable, for CY 2016.

We note that HCPCS code Q9978 replaced HCPCS code C9448 (Netupitant 300 mg and palonosetron 0.5 mg, oral), beginning July 1, 2015. HCPCS code C9448 was made effective April 1, 2015, but the code was deleted June 30, 2015, because it was replaced with HCPCS code Q9978. HCPCS code C9448 was granted pass-through payment status when the code was implemented on April 1, 2015. Because HCPCS code Q9978 describes the same drug as HCPCS code C9448, we are proposing to continue the pass-through payment status for HCPCS code Q9978, and assign the HCPCS Q-code to the same APC and status indicator as its predecessor HCPCS C-code, as shown in Table 15. Specifically, we are proposing to assign HCPCS code Q9978 to APC 9448 (Netupitant Palonosetron Oral) and status indicator ''G.''

In addition, the CPT Editorial Panel established CPT codes 0392T and 0393T, effective July 1, 2015. We note that CPT code 0392T replaced HCPCS code C9737 (Laparoscopy, surgical, esophageal sphincter augmentation with device (*e.g.*, magnetic band)), beginning July 1, 2015. Because CPT code 0392T describes the same procedure as HCPCS code C9737, we are proposing to assign the CPT code to the same APC and status indicator as its predecessor HCPCS C-code, as shown in Table 15.

In this CY 2016 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments, where applicable, for the CPT and Level II HCPCS codes implemented on July 1, 2015 and listed in Table 15 of this proposed rule.

TABLE 15—NEW CATEGORY III CPT AND LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2015

CY 2015 CPT/ HCPCS Code	CY 2015 Long descriptor	Proposed CY 2016 Status indicator	Proposed CY 2016 APC****
C2613	Lung biopsy plug with delivery system	H	2613
C9453	Injection, nivolumab, 1 mg	G	9453
C9454	Injection, pasireotide long acting, 1 mg	G	9454
C9455	Injection, siltuximab, 10 mg	G	9455
Q5101*	Injection, Filgrastim (G–CSF), Biosimilar, 1 microgram	E	N/A
Q9976	Injection, Ferric Pyrophosphate Citrate Solution, 0.1 mg of iron	E	N/A
Q9977	Compounded Drug, Not Otherwise Classified	N	N/A
Q9978**	Netupitant 300 mg and Palonosetron 0.5 mg, oral	G	9448
0392T***	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (*i.e.*, magnetic band).	Q2	5362
0393T	Removal of esophageal sphincter augmentation device	Q2	5361

*HCPCS code Q5101, Zarxio, was approved by the FDA on March 6, 2015. As the biosimilar is currently not being marketed, pricing information is not yet available. Once Zarxio is marketed we will make pricing information available at the soonest possible date on the OPPS payment files and payment for Zarxio will be retroactive to the date the product is first marketed.

**HCPCS code C9448 (Netupitant 300 mg and palonosetron 0.5 mg, oral) was deleted June 30, 2015, and replaced with HCPCS code Q9978, effective July 1, 2015.

***HCPCS code C9737 (Laparoscopy, surgical, esophageal sphincter augmentation with device (*e.g.*, magnetic band) was deleted June 30, 2015 and replaced with CPT code 0392T, effective July 1, 2015.

****We refer readers to Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) for a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

In summary, we are soliciting public comments on the proposed CY 2016 status indicators, APC assignments, and payment rates for the Level II HCPCS codes and the Category III CPT codes that were made effective April 1, 2015, and July 1, 2015. These codes are listed in Tables 14 and 15 of this proposed rule. We also are proposing to finalize the status indicator and APC assignments and payment rates for these codes, if applicable, in the CY 2016 OPPS/ASC final rule with comment period. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

2. Proposed Process for New Level II HCPCS Codes That Will Be Effective October 1, 2015 and January 1, 2016 for Which We Will Be Soliciting Public Comments in the CY 2016 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the OPPS for the following calendar year. These codes are released to the public via the CMS HCPCS Web site, and also through the January OPPS quarterly update CRs. In the past, we also released new Level II HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period, thereby updating the OPPS for the following calendar year.

For CY 2016, we are proposing to continue our established policy of assigning comment indicator ''NI'' in Addendum B to the OPPS/ASC final

rule with comment period to those new Level II HCPCS codes that are effective October 1 and January 1 to indicate that we are assigning them an interim payment status which is subject to public comment. Specifically, the Level II HCPCS codes that will be effective October 1, 2015 and January 1, 2016 would be flagged with comment indicator ''NI'' in Addendum B to the CY 2016 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2016. We will be inviting public comments in the CY 2016 OPPS/ASC final rule with comment period on the status indicator, APC assignments, and payment rates for these codes, if applicable, that would be finalized in the CY 2017 OPPS/ASC final rule with comment period.

3. Proposed Treatment of New and Revised CY 2016 Category I and III CPT Codes That Will Be Effective January 1, 2016, for Which We Are Soliciting Public Comments in This CY 2016 OPPS/ASC Proposed Rule

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the MPFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid the resort to HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), solicit public comments, and finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2016 OPPS update, we received the CY 2016 CPT codes from AMA in time for inclusion in this CY 2016 OPPS/ASC proposed rule. The new and revised CY 2016 Category I and III CPT codes can be found in OPPS Addendum B and assigned to new comment indicator ''NP'' to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year with a proposed APC assignment and that comments will be accepted on the proposed APC assignment and status indicator. We refer readers to section XI.B. of this CY 2016 OPPS/ASC proposed rule for further discussion on the new proposed comment indicator ''NP.''

Further, we remind readers that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the long descriptors for the new and revised CY 2016 CPT codes in Addendum O to this proposed rule (which is available via the Internet on the CMS Web site) so that the public can adequately comment on our proposed APCs and status indicator assignments. Because CPT procedure codes are 5 alpha-numeric characters and CMS systems only utilize 5-character HCPCS codes, we have developed alternative 5-character placeholder codes for this proposed rule. The placeholder codes can be found in Addendum O, specifically under the column labeled ''CY 2016 OPPS/ASC Proposed Rule 5-Digit CMS Placeholder Code,'' to this proposed rule. The final CPT code numbers will be included in the CY 2016 OPPS/ASC final rule with comment period. We note that not every code listed in Addendum O is subject to comment. For the new/revised Category I and III CPT codes, we are requesting comments on only those codes that are assigned to comment indicator ''NP.'' Comments will not be accepted for new Category I CPT laboratory codes that are not assigned to ''NP'' comment indicator in Addendum O. Comments to these codes must be submitted at the Clinical Laboratory Fee Schedule (CLFS) Public Meeting, which is scheduled for July 16, 2015.

In summary, we are soliciting public comments on the proposed CY 2016 status indicators and APC assignments for the new and revised Category I and III CPT codes that will be effective January 1, 2016. The CPT codes are listed in Addendum B to this proposed rule with short descriptors only. We list them again in Addendum O to this proposed rule with long descriptors. We also are proposing to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2016 OPPS/ASC final rule with comment period. The proposed status indicator, and APC assignment and payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

B. Proposed OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in § 419.31 of the regulations. We use Level I and Level II HCPCS codes to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they

support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to the items and services listed in § 419.2(b) of the regulations. A further discussion of packaged services is included in section II.A.3. of this proposed rule.

Under the OPPS, we generally pay for hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2016, we are proposing that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in proposed renumbered APC 5012 (Level 2 Examinations and Related Services) (existing APC 0632). The APC relative payment weights are scaled to proposed renumbered APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting. We note that, historically, we have proposed APC relative payment weights relative to the hospital costs of services included in existing APC 0634. In this proposed rule, we are proposing to reassign HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) from existing APC 0634 to proposed renumbered APC 5012 (for CY 2015, this is existing APC 0632). Proposed new APC 5012 includes other services that are clinically similar with similar resource costs to the service described by HCPCS code G0463, such as HCPCS code G0402 (Initial preventive physical examination). Accordingly, for the CY 2016 OPPS update, we are proposing to delete existing APC 0634 and replace it with proposed renumbered APC 5012.

2. Application of the 2 Times Rule

In accordance with section 1833(t)(2) of the Act and § 419.31 of the regulations, we annually review the items and services within an APC group to determine, with respect to comparability of the use of resources, if the highest cost for an item or service in the APC group is more than 2 times greater than the lowest cost for an item or service within the same APC group (referred to as the ''2 times rule''). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims (or less than 1,000 claims) is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost. In this proposed rule, for CY 2016, we are proposing to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services.

For the CY 2016 OPPS, we have identified the APCs with violations of the 2 times rule. Therefore, we are proposing changes to the procedure codes assigned to these APCs in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this CY 2016 OPPS/ASC proposed rule. Rather, it is published and made available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. In these cases, to eliminate a violation of the 2 times rule or to improve clinical and resource homogeneity, we are proposing to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2016 included in this proposed rule are related to changes in costs of services that were observed in the CY 2014 claims data newly available for CY 2016 ratesetting. We also are proposing changes to the status indicators for some procedure codes that are not specifically and separately discussed in this proposed rule. In these cases, we are proposing to change the status indicators for these procedure codes because we believe that another status indicator would more accurately describe their payment status from an OPPS perspective based on the policies that we are proposing for CY 2016. In addition, we are proposing to rename existing APCs or create new clinical APCs to complement the proposed procedure code reassignments. Addendum B to this CY 2016 OPPS/ASC proposed rule identifies with a comment indicator ''CH'' those procedure codes for which we are proposing a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2015 OPPS Addendum B Update (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*).

3. Proposed APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we are proposing for CY 2016, we reviewed all of the APCs to determine which APCs would not meet the requirements of the 2 times rule. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

Based on the CY 2014 claims data available for this CY 2016 proposed rule, we found three APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs that we are proposing to make exceptions for under the 2 times rule for CY 2016, and identified three APCs that met the criteria for an exception to the 2 times rule based on the CY 2014 claims data available for this proposed rule. We did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as existing APC 0375 (proposed for CY 2016 to be renumbered APC 5881 (Ancillary Outpatient Services When Patient Dies)), which has an APC cost for a single service of $5,653.37. (We note that, in section II.A.2.e. of this proposed rule, we are proposing to convert proposed renumbered APC 5881 to a comprehensive APC for CY 2016. However, the APC cost is still not relevant to determine whether there is a

2 times rule violation in that comprehensive APC.)

Therefore, we only identified those APCs, including those with criteria-based costs, with violations of the 2 times rule. For a detailed discussion of these criteria, we refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18457 and 18458).

We note that, for cases in which a recommendation by the Panel appears to result in or allow a violation of the 2 times rule, we generally accept the Panel's recommendation because those recommendations are based on explicit consideration (that is, a review of the latest OPPS claims data and group discussion of the issue) of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 16 of this proposed rule lists the three APCs that we are proposing to make exceptions for under the 2 times rule for CY 2016 based on the criteria cited above and claims data submitted between January 1, 2014, and December 31, 2014, and processed on or before December 31, 2014. For the final rule with comment period, we intend to use claims data for dates of service between January 1, 2014, and December 31, 2014, that were processed on or before June 30, 2015, and updated CCRs, if available.

The geometric mean costs for hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.

TABLE 16—PROPOSED APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2016

Proposed CY 2016 APC*	Proposed CY 2016 APC Title
5221	Level 1 Pacemaker and Similar Procedures.
5673	Level 3 Pathology.
5731	Level 1 Minor Procedures.

* We refer readers to Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) for a crosswalk of the existing APC numbers to the proposed new APC numbers.

C. Proposed New Technology APCs

1. Background

In the November 30, 2001 final rule (66 FR 59903), we finalized changes to the time period a service was eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

Currently, there are 37 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0–$10)) through the highest cost band assigned to APC 1574 (New Technology—Level XXXVII ($9,500–$10,000)). In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs, one set with a status indicator of ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently. (We note that we are not proposing to renumber the New Technology APCs in this proposed rule.)

We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1574, vary with increments ranging from $10 to $500. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level VII ($500–$600)) is made at $550.

Every year we receive several requests for higher payment amounts under the New Technology APCs for specific procedures paid under the OPPS because they require the use of expensive equipment. We are taking this opportunity to reiterate our response in general to the issue of hospitals' capital expenditures as they relate to the OPPS and Medicare.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital inpatient market basket increase. We believe that our payment rates generally reflect the costs that are associated with providing care to Medicare beneficiaries, and we believe that our rates are adequate to ensure access to services.

For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the techniques and their clinical utility. Quite often, parties request that Medicare make higher payment amounts under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per use costs for which requesters believe Medicare should make full payment. However, we believe that it is most appropriate to set payment rates based on costs that are associated with providing care to Medicare beneficiaries. As claims data for new services become available, we use these data to establish payment rates for new technology.

2. Proposed Additional New Technology APC Groups

Currently, there are 37 levels of New Technology APC groups with two parallel status indicators; one set with a status indicator of ''S'' and the other set with a status indicator of ''T.'' To improve our ability to pay appropriately for new technology services and procedures, we are proposing to expand

the New Technology APC groups by adding 9 more levels, specifically, adding New Technology Levels 38 through 46. We are proposing this expansion to accommodate the assignment of the retinal prosthesis implantation procedure to a New Technology APC, which is discussed further below. Therefore, for the CY 2016 OPPS update, we are proposing to establish a new set of New Technology APCs 1575 through 1583 (for Levels 38 through 46) with OPPS status indicator ''S'' and a new set of New Technology APCs 1585 through 1593 (for Levels 38 through 46) with OPPS status indicator ''T.'' These two new sets of APCs have the same payment levels with one set subject to the multiple procedure payment reduction (T) and the other set not subject to the multiple procedure payment reduction (S). Each proposed set of new technology APC groups has identical group titles, payment rates, and minimum unadjusted copayments, but a different status indicator. Table 17 below includes the complete list of the proposed additional 18 New Technology APC groups for CY 2016.

TABLE 17—PROPOSED ADDITIONAL NEW TECHNOLOGY APC GROUPS FOR CY 2016

Proposed new CY 2016 APC	Proposed CY 2016 APC Group title	Status indicator
1575	New Technology—Level 38 ($10,000-$15,000)	S
1576	New Technology—Level 39 ($15,000-$20,000)	S
1577	New Technology—Level 40 ($20,000-$25,000)	S
1578	New Technology—Level 41 ($25,000-$30,000)	S
1579	New Technology—Level 42 ($30,000-$40,000)	S
1580	New Technology—Level 43 ($40,000-$50,000)	S
1581	New Technology—Level 44 ($50,000-$60,000)	S
1582	New Technology—Level 45 ($60,000-$70,000)	S
1583	New Technology—Level 46 ($70,000-$80,000)	S
1585	New Technology—Level 38 ($10,000-$15,000)	T
1586	New Technology—Level 39 ($15,000-$20,000)	T
1587	New Technology—Level 40 ($20,000-$25,000)	T
1588	New Technology—Level 41 ($25,000-$30,000)	T
1589	New Technology—Level 42 ($30,000-$40,000)	T
1590	New Technology—Level 43 ($40,000-$50,000)	T
1591	New Technology—Level 44 ($50,000-$60,000)	T
1592	New Technology—Level 45 ($60,000-$70,000)	T
1593	New Technology—Level 46 ($70,000-$80,000)	T

The proposed payment rates for New Technology APC groups 1575 through 1583 and 1585 through 1593 can be found in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site).

3. Proposed Procedures Assigned to New Technology APC Groups for CY 2016

As we explained in the CY 2002 OPPS final rule with comment period (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC. However, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2016, we are proposing to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for reassignment have not been obtained (66 FR 59902).

a. Transprostatic Urethral Implant Procedure

Currently, in CY 2015, there is one procedure that is receiving payment through a New Technology APC. Specifically, the procedure described by HCPCS code C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants) is assigned to New Technology APC 1564 (New Technology—Level XXVII ($4,500–$5,000)) with a payment rate of $4,750. This procedure was assigned to New Technology APC 1564 on April 1, 2014, when the HCPCS C-code was established.

For the CY 2016 OPPS update, based on our review of the claims data for HCPCS code C9740 from April through December 2014, we found 100 single claims (out of 128 total claims) with a geometric mean cost of approximately $5,648. Because there is not a full year of claims data and only 100 single claims are in our database for HCPCS code C9740, we are proposing to maintain the assignment of HCPCS code C9740 to New Technology APC 1564 for CY 2016. As described in section IV.B. of this proposed rule, we note that, based on the costs of the device relative to the procedure in this APC, the procedures assigned to APC 1564 would be device-intensive for CY 2016. The proposed CY 2016 payment rate for HCPCS code C9740 is included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

b. Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis. This surgical procedure is currently assigned to APC 0673 that has a CY 2015 payment rate of approximately $3,123. The retinal prosthesis device that is used in the procedure described by CPT code 0100T is described by HCPCS code C1841 (Retinal prosthesis, includes all internal

and external components). The first retinal prosthesis (Argus® II Retinal Prosthesis System) was approved by the FDA in 2013 for adult patients with advanced retinitis pigmentosa. Pass-through status was granted for HCPCS code C1841 beginning October 1, 2013, and is proposed to expire on December 31, 2015. We refer readers to section IV.A.1.b. of this proposed rule for the discussion of the expiration of pass-through for HCPCS code C1841.

After pass-through status expires for a medical device, the payment for the device is packaged into the payment for the associated surgical procedure. The surgical procedure in which the Argus device (HCPCS code C1841) is implanted is described by CPT code 0100T. Review of the CY 2014 OPPS claims data used for this CY 2016 OPPS/ASC proposed rule shows only one single claim for CPT code 0100T with HCPCS code C1841 on the claim. Due to the newness of this surgical procedure and its associated implantable device and the extremely low number of CY 2014 HOPD claims for this procedure, we are proposing to reassign CPT code 0100T from existing APC 0673 (Level III Intraocular Procedures) to proposed newly established New Technology APC 1593 (New Technology—Level 46 ($70,000–$80,000)). We are proposing a CY 2016 OPPS payment of approximately $75,000 for proposed new APC 1593, which would be the payment for CPT code 0100T (not including the retinal prosthesis), plus the proposed maximum FY 2016 IPPS new technology add-on payment for a case involving the Argus® II Retinal Prosthesis System of $72,028.75 (80 FR 24425). Therefore, we are proposing to reassign CPT code 0100T to proposed new APC 1593 with a payment of $75,000 for CY 2016. We refer readers to section III.C.2. of this proposed rule for a discussion of the proposed expansion of the New Technology APC levels. We believe that, given the newness of this procedure and the severe paucity of OPPS claims data, this approach provides a reasonable payment amount that is not significantly dissimilar to the payment for the same procedure provided in the hospital inpatient setting. Once we have more claims data, we will reassess the APC placement of the Argus® II Retinal Prosthesis System in light of our standard rate setting methodology. We are inviting public comments on this proposal.

D. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and to revise the groups, relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Therefore, every year we review and revise the APC assignments for many procedure codes and diagnosis codes based on our evaluation of these factors using the latest OPPS claims data. Although we do not discuss every APC change in the proposed and final rules, these changes are listed in the OPPS Addendum B of the proposed and final rules. Specifically, procedure and diagnosis codes with revised APC and/or status indicator assignments are identified by comment indicator ''CH'' (Active HCPCS code in current year and next calendar year, status indicator and/or APC assignment has changed) in the OPPS Addendum B payment file.

In our efforts to improve clinical and resource homogeneity among the APC groupings and update the hospital OPPS, we conducted a comprehensive review of the current structure of the APCs and codes assignments for CY 2015. Consequently, as part of our broader efforts to thoroughly review, revise, and consolidate APCs to improve both resource and clinical homogeneity, we proposed in the CY 2015 OPPS/ASC proposed rule (79 FR 40981 through 40983) to restructure the first set of clinical families, specifically the ophthalmology and gynecology APCs. We proposed to restructure the APCs for these clinical families based on the following principles:

- Improved clinical homogeneity;
- Improved resource homogeneity;
- Reduced resource overlap in APCs within a clinical family; and
- Greater simplicity and improved understanding of the structure of the APCs.

Based on our review, for CY 2015, we finalized the APC restructuring for the ophthalmology and gynecology APCs. For the complete discussion on the APC restructuring for the ophthalmology APCs, we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66857 through 66859). Similarly, for the complete discussion on the APC restructuring for the gynecology APCs, we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66849 through 66851).

For the CY 2016 update, as a part of our continued review of the structure of the APCs, we are proposing to restructure nine APC clinical families based on the same principles used for restructuring the ophthalmology and gynecology APCs for CY 2015. We discuss below our proposed restructuring for the nine APC clinical families. We note that, in conjunction with the proposed restructuring, we are proposing to renumber several families of APCs to provide consecutive APC numbers for consecutive APC levels within a clinical family for improved identification of APCs and ease of understanding the APC groupings. For example, the seven APC levels for urology procedures are proposed to be renumbered as APC 5371 (Level 1 Urology and Related Services), APC 5372 (Level 2 Urology and Related Services), APC 5373 (Level 3 Urology and Related Services), APC 5374 (Level 4 Urology and Related Services), APC 5375 (Level 5 Urology and Related Services), APC 5376 (Level 6 Urology and Related Services), and APC 5377 (Level 7 Urology and Related Services). We believe that consecutive numbering of the APCs will enhance the public understanding of the APC groups and will make it easier for them to communicate to the agency about issues concerning APCs. We note that, under this initiative, we are not proposing to change the numbering of the composite APCs or the New Technology APCs for CY 2016.

Existing CY 2015 APC numbers and their proposed new CY 2016 APC numbers can be found in Addendum Q (Crosswalk of CY 2015 APC Numbers to CY 2016 APC Numbers) to this proposed rule, which is available via the Internet on the CMS Web site.

1. Airway Endoscopy Procedures

As a part of our CY 2016 comprehensive review of the structure of the APCs and procedure code assignments, we examined the APCs that contain airway endoscopy procedures. For CY 2016, we are proposing to restructure the OPPS APC groupings for airway endoscopy procedures to more appropriately reflect the costs and clinical characteristics of the procedures within each APC grouping in the context of the OPPS. The current APCs for airway endoscopy procedures are divided into upper airway and lower airway endoscopy APC series. After reviewing these APCs, we believe that consolidating the current upper airway and lower airway APC series into a single APC series for airway endoscopy procedures would result in improved resource homogeneity for the various airway endoscopy procedures, while maintaining clinical homogeneity. Therefore, for CY 2016, we are proposing to restructure and consolidate the APCs that include airway endoscopy

procedures into a single APC series. Table 18 below lists the current CY 2015 APCs that contain airway endoscopy procedures, and Table 19 below lists the proposed CY 2016 APCs that result from our proposed consolidation and restructuring of the current airway endoscopy procedure APCs into a single APC series. The procedures assigned to each APC are listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 18—CY 2015 AIRWAY ENDOSCOPY APCS

CY 2015 APC	CY 2015 APC Group title
0071	Level I Endoscopy Upper Airway.
0072	Level II Endoscopy Upper Airway.
0073	Level III Endoscopy Upper Airway.
0074	Level IV Endoscopy Upper Airway.
0075	Level V Endoscopy Upper Airway.
0076	Level I Endoscopy Lower Airway.
0415	Level II Endoscopy Lower Airway.

TABLE 19—PROPOSED CY 2016 AIRWAY ENDOSCOPY APCS

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC Group title
5151	Level 1 Airway Endoscopy.
5152	Level 2 Airway Endoscopy.
5153	Level 3 Airway Endoscopy.
5154	Level 4 Airway Endoscopy.
5155	Level 5 Airway Endoscopy.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

2. Diagnostic Tests and Related Services

As a part of our CY 2016 comprehensive review of the structure of the APCs and procedure code assignments, we examined the APCs that contain diagnostic tests and related services. For CY 2016, we are proposing to restructure the OPPS APC groupings for diagnostic tests and related services to more appropriately reflect the costs and clinical characteristics of the services within each APC grouping in the context of the OPPS. The current APCs for diagnostic tests and related services are divided according to organ system or physiologic test type. After reviewing these APCs, we believe that the current APC structure is based on clinical categories that do not necessarily reflect significant differences in the delivery of these services in the HOPD. The current level of granularity for these APCs results in groupings that are unnecessarily narrow for the purposes of a prospective payment system. Therefore, for CY 2016, we are proposing to restructure and consolidate the APCs that include diagnostic tests and related services. We believe that this proposed restructuring and consolidation of APCs into larger APC groupings would more appropriately reflect a prospective payment system that is based on payment groupings and not code-specific payment rates, while maintaining clinical and resource homogeneity. Table 20 below lists the current CY 2015 APCs that contain nonimaging diagnostic tests, and Table 21 below lists the proposed CY 2016 APCs that result from our proposed consolidation and restructuring of the current diagnostic test and related services APCs. The procedures assigned to each APC are listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 20—CY 2015 APCS THAT CONTAIN DIAGNOSTIC TESTS AND RELATED SERVICES

CY 2015 APC	CY 2015 APC Group title
0360	Level I Alimentary Tests.
0361	Level II Alimentary Tests.
0100	Cardiac Stress Tests.
0099	Electrocardiograms/Cardiography.
0231	Level III Eye Tests & Treatments.
0213	Level I Extended EEG, Sleep, and Cardiovascular Studies.
0209	Level II Extended EEG, Sleep, and Cardiovascular Studies.
0435	Level III Extended EEG, Sleep, and Cardiovascular Studies.
0215	Level I Nerve and Muscle Services.
0218	Level II Nerve and Muscle Services.
0216	Level III Nerve and Muscle Services.
0446	Level IV Nerve and Muscle Services.
0373	Neuropsychological Testing.
0097	Level I Noninvasive Physiologic Studies.
0096	Level II Noninvasive Physiologic Studies.

TABLE 20—CY 2015 APCS THAT CONTAIN DIAGNOSTIC TESTS AND RELATED SERVICES—Continued

CY 2015 APC	CY 2015 APC Group title
0363	Otorhinolaryngologic and Related Tests.
0367	Level I Pulmonary Tests.
0369	Level II Pulmonary Tests.
0126	Level I Urinary and Anal Procedures.

TABLE 21—PROPOSED CY 2016 DIAGNOSTIC TESTS AND RELATED SERVICES APCS

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC Group title
5721	Level 1 Diagnostic Tests and Related Services.
5722	Level 2 Diagnostic Tests and Related Services.
5723	Level 3 Diagnostic Tests and Related Services.
5724	Level 4 Diagnostic Tests and Related Services.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

3. Excision/Biopsy and Incision and Drainage Procedures

As a part of our CY 2016 comprehensive review of the structure of the APCs and procedure code assignments, we examined the APCs for incision and drainage procedures as well as excision/biopsy procedures. The current APC structure for these procedures is organized into two series: incision and drainage procedures in one series and excision/biopsy procedures in another series.

Based on our evaluation of the current APC structure and the latest hospital outpatient claims data available for this proposed rule, we are proposing to revise these APCs by combining the incision and drainage procedures with the excision/biopsy procedures to more accurately reflect the resource costs and clinical characteristics of the procedures within each APC. Many of the procedures in these two series are clinically similar. Therefore, we believe that a single series encompassing incision and drainage procedures and excision/biopsy procedures groups clinically similar procedures without unnecessary granularity. We believe that the proposed consolidation and restructuring of these APCs would more appropriately reflect a prospective payment system that is based on

payment for APC groupings with clinically similar procedures while maintaining resource homogeneity. Moreover, we believe that the proposed APC groupings would more accurately accommodate and align new services under the hospital OPPS when assigned to clinical APCs with services with similar clinical attributes and resource costs. Therefore, for CY 2016, we are proposing to consolidate and restructure the APCs that describe incision and drainage procedures as well as the excision/biopsy procedures by combining these procedures into a single APC series.

Table 22 below lists the current CY 2015 APCs that contain incision and drainage as well as excision/biopsy procedures, and Table 23 below lists the proposed CY 2016 APCs that result from the proposed consolidating and restructuring of the APCs into a single APC series. The proposed payment rates for the specific CPT or Level II HCPCS codes for incision and drainage procedures as well as excision/biopsy procedures are included in Addendum B to this proposed rule, while the proposed payment rates for the specific APCs to which these procedures are assigned are included in Addendum A to this proposed rule. Both OPPS Addenda A and B are available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 22—CY 2015 APCS TO WHICH THE INCISION AND DRAINAGE AND EXCISION/BIOPSY PROCEDURES ARE ASSIGNED

CY 2015 APC	CY 2015 APC group title
0006	Level I Incision & Drainage.
0007	Level II Incision & Drainage.
0008	Level III Incision & Drainage.
0019	Level I Excision/Biopsy.
0020	Level II Excision/Biopsy.
0021	Level III Excision/Biopsy.
0022	Level IV Excision/Biopsy.

TABLE 23—PROPOSED CY 2016 APCS FOR EXCISION/BIOPSY/INCISION AND DRAINAGE PROCEDURES

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC group title
5071	Level 1 Excision/Biopsy/Incision and Drainage.
5072	Level 2 Excision/Biopsy/Incision and Drainage.
5073	Level 3 Excision/Biopsy/Incision and Drainage.
5074	Level 4 Excision/Biopsy/Incision and Drainage.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

4. Gastrointestinal (GI) Procedures

As a part of our comprehensive review of the structure of the APCs and procedure code assignments for CY 2016, we examined the APCs that contain gastrointestinal (GI) procedures. As explained below, as a result of our findings from this review, for CY 2016, we are proposing to restructure the APC groupings for GI procedures to more appropriately reflect the costs and the clinical characteristics of the procedures within each APC grouping in the context of the OPPS.

The current APCs for GI procedures are partially organized according to location in the GI tract and type of surgery performed (endoscopy versus incisional surgery). After reviewing these APCs for GI procedures, we believe that the current APC construction is based on clinical categories that do not appropriately represent a consistent set of clinical categories throughout the entire spectrum of GI-related procedures. The current level of granularity for some of the GI APCs results in groupings that are unnecessarily narrow for the purposes of a prospective payment system. Therefore, for CY 2016, we are proposing to restructure and consolidate the APCs that contain GI procedures. We believe that consolidating these procedures under broader APC groupings primarily based on separating upper and lower GI procedures into two series with additional APCs containing abdominal and peritoneal procedures would more appropriately reflect a prospective payment system that is based on payment for clinically consistent APC groupings rather than code-specific payment rates while maintaining resource homogeneity. Furthermore, we believe that the proposed APC groupings would more accurately accommodate and align new services within clinical APCs with similar resource costs.

Table 24 below lists the current CY 2015 APCs that contain GI procedures, and Table 25 below lists the proposed CY 2016 APCs that result from the proposed consolidation and restructuring of the current GI procedure APCs into a single APC series. The procedures assigned to each APC are listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 24—CY 2015 APCS THAT CONTAIN GASTROINTESTINAL PROCEDURES

CY 2015 APC	CY 2015 APC Group title
0148	Level I Anal/Rectal Procedures.
0155	Level II Anal/Rectal Procedures.
0149	Level III Anal/Rectal Procedures.
0150	Level IV Anal/Rectal Procedures.
0151	Endoscopic Retrograde Cholangio-Pancreaotography.
0384	GI Procedures with Stents.
0154	Hernia/Hydrocele Procedures.
0652	Insertion of Intraperitoneal and Pleural Catheters.
0143	Lower GI Endoscopy.
0152	Level I Percutaneous Abdominal and Biliary Procedures.
0423	Level II Percutaneous Abdominal and Biliary Procedures.
0153	Peritoneal and Abdominal Procedures.
0146	Level I Sigmoidoscopy and Anoscopy.
0147	Level II Sigmoidoscopy and Anoscopy.
0428	Level III Sigmoidoscopy and Anoscopy.
0142	Level I Small Intestine Endoscopy.
0424	Level II Small Intestine Endoscopy.

TABLE 24—CY 2015 APCS THAT CONTAIN GASTROINTESTINAL PROCEDURES—Continued

CY 2015 APC	CY 2015 APC Group title
0070	Thoracentesis/Lavage Procedures.
0121	Level I Tube or Catheter Changes or Repositioning.
0427	Level II Tube or Catheter Changes or Repositioning.
0141	Level I Upper GI Procedures.
0419	Level II Upper GI Procedures.
0422	Level III Upper GI Procedures.

TABLE 25—PROPOSED CY 2016 APCS FOR GASTROINTESTINAL PROCEDURES

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC Group title
5301	Level 1 Upper GI Procedures.
5302	Level 2 Upper GI Procedures.
5303	Level 3 Upper GI Procedures.
5311	Level 1 Lower GI Procedures.
5312	Level 2 Lower GI Procedures.
5313	Level 3 Lower GI Procedures.
5314	Level 4 Lower GI Procedures.
5331	Complex GI Procedures.
5341	Peritoneal and Abdominal Procedures.
5351	Level 1 Percutaneous Abdominal/Biliary Procedures and Related Procedures.
5352	Level 2 Percutaneous Abdominal/Biliary Procedures and Related Procedures.

TABLE 25—PROPOSED CY 2016 APCS FOR GASTROINTESTINAL PROCEDURES—Continued

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC Group title
5391	Level 1 Tube/Catheter Changes/Thoracentesis/Lavage.
5392	Level 2 Tube/Catheter Changes/Thoracentesis/Lavage.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

In addition, we are proposing to accept the Panel's recommendation with regard to the APC assignment for four lower endoscopy stent procedures described by HCPCS codes that were established in CY 2015. The Panel recommended that the four CPT codes listed in Table 26 below be moved from their currently assigned APC to C–APC 0384 (GI Procedures with Stents). The Panel's recommendation was based on an analysis of the similarities in clinical characteristics and resource utilization between the procedures described by these four CPT codes and the procedures described by other CPT codes within existing (CY 2015) APCs 0142, 0143 and 0147. (We note that, in section II.A.2.e. of the preamble of this proposed rule, we are proposing to renumber and retitle C–APC 0384 as ''C–APC 5331 (Complex GI Procedures)'' for CY 2016.)

TABLE 26—GASTROINTESTINAL PROCEDURES PROPOSED FOR REASSIGNMENT TO NEW C–APC 5331 IN CY 2016

CY 2015 CPT code	Procedure code description	CY 2015 APC	Proposed CY 2016 APC
44384	Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	APC 0142 (Level I Small Intestine APC).	C–APC 5331 (Complex GI Procedures).
44402	Colonoscopy through stoma; with endoscopic stent placement (including pre- and post-dilation and guide wire passage, when performed).	APC 0143 (Lower GI Endoscopy APC)	C–APC 5331 (Complex GI Procedures).
45347	Sigmoidoscopy, flexible; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	APC 0147 (Level II Sigmoidoscopy and Anoscopy).	C–APC 5331 (Complex GI Procedures).
45389	Colonoscopy, flexible; with endoscopic stent placement (includes pre- and post-dilation and guide wire passage, when performed).	APC 0143 (Lower GI Endoscopy APC)	C–APC 5331 (Complex GI Procedures).

5. Imaging Services

As a part of our CY 2016 comprehensive review of the structure of the APCs and procedure code assignments, we examined the APCs that contain imaging services. For CY 2016, we are proposing to restructure the OPPS APC groupings for imaging services to more appropriately reflect the costs and clinical characteristics of the procedures within each APC grouping in the context of the OPPS. The current APCs for imaging services are divided at the highest level between diagnostic radiology (for example, x-ray, CT, MRI, and ultrasound) and nuclear medicine imaging. After reviewing these APCs, we believe that the current APC structure is based on clinical categories that do not necessarily reflect significant differences in the delivery of these services in the HOPD. The current level of granularity for these APCs results in groupings that are unnecessarily narrow for the purposes of a prospective payment system. This excessive granularity is especially apparent with the APCs for x-ray based imaging services and nuclear medicine imaging services. Many of these APCs are currently structured according to organ or physiologic system that does not necessarily reflect either significant differences in resources or how these services are delivered in the HOPD.

Therefore, for CY 2016, we are proposing to restructure and consolidate the APCs that include radiology and nuclear medicine services. We believe that this proposed restructuring and consolidation would result in APC groupings that would more appropriately reflect a prospective payment system that is based on payment for clinically consistent APC groupings and not code-specific payment rates, while maintaining clinical and resource homogeneity. Furthermore, the proposed APC groupings would more accurately

accommodate and align new services into clinical APCs with similar resource costs. Table 27 below lists the current CY 2015 APCs that contain radiology and nuclear medicine services, and Table 28 below lists the proposed CY 2016 APCs that result from the proposed consolidation and restructuring of the current radiology and nuclear medicine services APCs. The procedures assigned to each APC are listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 27—CY 2015 IMAGING-RELATED PROCEDURES APCS

CY 2015 APC	CY 2015 APC Group title
0668	Level I Angiography and Venography.
0279	Level II Angiography and Venography.
0280	Level III Angiography and Venography.
0275	Arthrography.
0396	Bone Imaging.
0383	Cardiac Computed Tomographic Imaging.
0398	Level I Cardiac Imaging.
0377	Level II Cardiac Imaging.
0334	Combined Abdomen and Pelvis CT with Contrast.
0331	Combined Abdomen and Pelvis CT without Contrast.
0283	Computed Tomography with Contrast.
0332	Computed Tomography without Contrast.
0333	Computed Tomography without Contrast followed by Contrast.
8006	CT and CTA with Contrast Composite.
8005	CT and CTA without Contrast Composite.
0662	CT Angiography.
0265	Level I Diagnostic and Screening Ultrasound.
0266	Level II Diagnostic and Screening Ultrasound.
0267	Level III Diagnostic and Screening Ultrasound.
0278	Diagnostic Urography.
0276	Level I Digestive Radiology.
0277	Level II Digestive Radiology.
0388	Discography.
0177	Level I Echocardiogram with Contrast.
0178	Level II Echocardiogram with Contrast.
0269	Level I Echocardiogram Without Contrast.
0270	Level II Echocardiogram Without Contrast.
0390	Level I Endocrine Imaging.
0391	Level II Endocrine Imaging.
0272	Fluoroscopy and Other Radiology Services.
0395	Hepatobiliary Imaging.
0400	Hematopoietic Imaging.
0394	Hepatobiliary Imaging.

TABLE 27—CY 2015 IMAGING-RELATED PROCEDURES APCS—Continued

CY 2015 APC	CY 2015 APC Group title
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast.
0336	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast.
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast.
0263	Level I Miscellaneous Radiology Procedures.
0317	Level II Miscellaneous Radiology Procedures.
8008	MRI and MRA with Contrast Composite.
8007	MRI and MRA without Contrast Composite.
0274	Myelography.
0403	Level I Nervous System Imaging.
0402	Level II Nervous System Imaging.
0260	Level I Plain Film Including Bone Density Measurement.
0261	Level II Plain Film Including Bone Density Measurement.
0308	Positron Emission Tomography (PET) imaging.
0401	Level I Pulmonary Imaging.
0378	Level II Pulmonary Imaging.
0404	Renal and Genitourinary Studies.
0406	Level I Tumor/Infection Imaging.
0414	Level II Tumor/Infection Imaging.
0408	Level III Tumor/Infection Imaging.
8004	Ultrasound Composite.
0393	Hematologic Processing & Studies.

TABLE 28—PROPOSED CY 2016 IMAGING-RELATED PROCEDURES APCS

Proposed restructured/renumbered CY 2016 APC*	Proposed CY 2016 APC Group title
5521	Level 1 X-Ray and Related Services.
5522	Level 2 X-Ray and Related Services.
5523	Level 3 X-Ray and Related Services.
5524	Level 4 X-Ray and Related Services.
5525	Level 5 X-Ray and Related Services.
5526	Level 6 X-Ray and Related Services.
5531	Level 1 Ultrasound and Related Services.

TABLE 28—PROPOSED CY 2016 IMAGING-RELATED PROCEDURES APCS—Continued

Proposed restructured/renumbered CY 2016 APC*	Proposed CY 2016 APC Group title
5532	Level 2 Ultrasound and Related Services.
5551	Level 1 Echocardiogram Without Contrast.
5552	Level 2 Echocardiogram Without Contrast.
5561	Level 1 Echocardiogram with Contrast.
5562	Level 2 Echocardiogram with Contrast.
5570	Computed Tomography without Contrast.
5571	Level 1 Computed Tomography with Contrast and Computed Tomography Angiography.
5572	Level 2 Computed Tomography with Contrast and Computed Tomography Angiography.
5581	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast.
5582	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast.
5591	Level 1 Nuclear Medicine and Related Services.
5592	Level 2 Nuclear Medicine and Related Services.
5593	Level 3 Nuclear Medicine and Related Services.
8004	Ultrasound Composite.
8005	CT and CTA without Contrast Composite.
8006	CT and CTA with Contrast Composite.
8007	MRI and MRA without Contrast Composite.
8008	MRI and MRA with Contrast Composite.

*Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

6. Orthopedic Procedures

As a part of our CY 2016 comprehensive review of the structure of the APCs and procedure code assignments, we examined the APCs that contain orthopedic-related procedures. For CY 2016, we are proposing to restructure the OPPS APC groupings for orthopedic surgery procedures to more appropriately reflect similar costs and clinical characteristics of the procedures within each APC grouping in the context of the OPPS. The current APCs for orthopedic-related procedures are primarily divided according to anatomy and the type of

musculoskeletal procedure. After reviewing these APCs, we believe that the current APC structure is based on clinical categories that do not necessarily reflect significant differences in the delivery of these services in the HOPD. The current level of granularity for these APCs results in groupings that are unnecessarily narrow for the purposes of a prospective payment system. For example, we see no reason for purposes of OPPS payment to continue to separate musculoskeletal procedures that do not involve the hand or foot from procedures that do include the hand or foot.

Therefore, for CY 2016, we are proposing to restructure and consolidate the APCs for orthopedic surgery procedures. We believe that this proposed restructuring and consolidation would result in APC groupings that would more appropriately reflect a prospective payment system that is based on payment for clinically consistent APC groupings and not code-specific payment rates while maintaining clinical and resource homogeneity. Table 29 below lists the current CY 2015 APCs that contain orthopedic-related procedures, and Table 30 below lists the proposed CY 2016 APCs that result from the proposed restructuring and consolidation of the current orthopedic-related procedures APCs. The procedures assigned to each APC are listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 29—CY 2015 ORTHOPEDIC–RELATED PROCEDURES APCS

CY 2015 APC	CY 2015 APC Group title
0047	Arthroplasty.
0041	Level I Arthroscopy.
0042	Level II Arthroscopy.
0045	Bone/Joint Manipulation Under Anesthesia.
0057	Bunion Procedures.
0129	Level I Closed Treatment Fracture.
0138	Level II Closed Treatment Fracture.
0139	Level III Closed Treatment Fracture.
0431	Level IV Closed Treatment Fracture.
0055	Level I Foot Musculoskeletal Procedures.
0056	Level II Foot Musculoskeletal Procedures.
0053	Level I Hand Musculoskeletal Procedures.
0054	Level II Hand Musculoskeletal Procedures.

TABLE 29—CY 2015 ORTHOPEDIC–RELATED PROCEDURES APCS—Continued

CY 2015 APC	CY 2015 APC Group title
0208	Laminotomies and Laminectomies.
0049	Level I Musculoskeletal Procedures Except Hand and Foot.
0050	Level II Musculoskeletal Procedures Except Hand and Foot.
0051	Level III Musculoskeletal Procedures Except Hand and Foot.
0052	Level IV Musculoskeletal Procedures Except Hand and Foot.
0425	Level V Musculoskeletal Procedures Except Hand and Foot.
0058	Level II Strapping and Cast Application.
0059	Level I Strapping and Cast Application.
0062	Level I Treatment Fracture/Dislocation.
0063	Level II Treatment Fracture/Dislocation.
0064	Level III Treatment Fracture/Dislocation.

TABLE 30—PROPOSED CY 2016 ORTHOPEDIC-RELATED PROCEDURES APCS

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC group title
5101	Level 1 Strapping and Cast Application.
5102	Level 2 Strapping and Cast Application.
5111	Level 1 Closed Treatment Fracture and Related Services.
5112	Level 2 Closed Treatment Fracture and Related Services.
5113	Level 3 Closed Treatment Fracture and Related Services.
5121	Level1 Musculoskeletal Procedures.
5122	Level 2 Musculoskeletal Procedures.
5123	Level 3 Musculoskeletal Procedures.
5124	Level 4 Musculoskeletal Procedures.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

7. Skin Procedures

As a part of our CY 2016 comprehensive review of the structure of the APCs and procedure code assignments, we examined the APCs that describe skin procedures. Based on our evaluation of the latest hospital outpatient claims data available for this proposed rule, we are proposing to restructure all of the skin-related procedure APC assignments by combining the debridement and skin procedure APCs to more appropriately reflect the costs and clinical characteristics of the procedures within each APC. Clinically, the services assigned to the current debridement APC series are similar to the services assigned to the current skin procedures APCs. We believe that the services in these two APC series would be more appropriately represented in a single APC series described as skin procedures and related services. We believe that this proposed consolidation and restructuring of APCs more appropriately categorizes all of the skin procedures and related services within a series of APCs with different resources, such that the services within each proposed newly configured APC are comparable based on its clinical homogeneity and resource costs. Therefore, for CY 2016, we are proposing to consolidate and restructure the skin and debridement APCs into a single APC series. Table 31 below lists the current CY 2015 APCs that contain skin and debridement procedures, and Table 32 below lists the proposed CY 2016 APCs that result from the proposed consolidation and restructuring of the current skin-related procedure APCs into a single APC series. The proposed payment rates for the specific CPT or Level II HCPCS skin procedure codes are specified in Addendum B to this proposed rule. The proposed payment rates for the specific APCs to which the skin procedures are proposed to be assigned are specified in Addendum A to this proposed rule. Both OPPS Addenda A and B are available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 31—CY 2015 APCS TO WHICH DEBRIDEMENT AND SKIN PROCEDURES ARE ASSIGNED

CY 2015 APC	CY 2015 APC Group title
0012	Level I Debridement & Destruction.
0015	Level II Debridement & Destruction.
0016	Level III Debridement & Destruction.
0017	Level IV Debridement & Destruction.
0326	Level I Skin Procedures.
0327	Level II Skin Procedures.
0328	Level III Skin Procedures.

TABLE 31—CY 2015 APCS TO WHICH DEBRIDEMENT AND SKIN PROCEDURES ARE ASSIGNED—Continued

CY 2015 APC	CY 2015 APC Group title
0329	Level IV Skin Procedures.

TABLE 32—PROPOSED CY 2016 APCS ASSIGNMENT FOR SKIN PROCEDURES

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC Group title
5051	Level 1 Skin Procedures.
5052	Level 2 Skin Procedures.
5053	Level 3 Skin Procedures.
5054	Level 4 Skin Procedures.
5055	Level 5 Skin Procedures.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

8. Urology and Related Services Procedures

For the CY 2016 OPPS update, based on our evaluation of the latest hospital outpatient claims data used for this proposed rule, we are proposing to revise all of the urology and related services APCs to more appropriately reflect the resource costs and clinical characteristics of the procedures within each APC. Currently, several of the urology-related APCs are differentiated based on their resource costs rather than clinical similarity. We believe that establishing more inclusive categories of the urology and related procedures is more appropriate for future ratesetting under the hospital OPPS because the restructured APCs have a more clinically appropriate granularity, while improving resource similarity. Further, we believe that this proposed revision and consolidation of APCs would more appropriately categorize all of the urology procedures and services within an APC group such that the services within each proposed newly configured APC are comparable clinically and with respect to resource use. Therefore, for CY 2016, we are proposing to restructure and consolidate the urology and related APCs into a single APC series. Table 33 below shows the CY 2015 urology and related APCs and status indicator assignments, and Table 34 below lists the proposed CY 2016 APCs that result from the proposed consolidation and restructuring of the current urology and related APCs into a single APC series. The proposed payment rates for the specific CPT or Level II HCPCS urology and related procedure codes are included in Addendum B to this proposed rule. The proposed payment rates for the proposed specific APCs to which we are proposing to assign the urology and related procedures codes are included in Addendum A to this proposed rule. Both OPPS Addenda A and B are available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 33—CY 2015 APCS TO WHICH UROLOGY & RELATED SERVICES ARE ASSIGNED

CY 2015 APC	CY 2015 APC Group title
0160	Level I Cystourethroscopy and other Genitourinary Procedures.
0161	Level II Cystourethroscopy and other Genitourinary Procedures.
0162	Level III Cystourethroscopy and other Genitourinary Procedures.
0163	Level IV Cystourethroscopy and other Genitourinary Procedures.
0183	Level I Male Genital Procedures.
0181	Level II Male Genital Procedures.
0205	Level III Male Genital Procedures.
0184	Prostate Biopsy.
0166	Level I Urethral Procedures.
0168	Level II Urethral Procedures.
0126	Level I Urinary and Anal Procedures.
0164	Level II Urinary and Anal Procedures.
0156	Level III Urinary and Anal Procedures.
0165	Level IV Urinary and Anal Procedures.
0385	Level I Urogenital Procedures.
0386	Level II Urogenital Procedures.

TABLE 34—PROPOSED CY 2016 APCS ASSIGNED TO AL UROLOGY AND RELATED SERVICES

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC Group title
5371	Level 1 Urology and Related Services.
5372	Level 2 Urology and Related Services.
5373	Level 3 Urology and Related Services.
5374	Level 4 Urology and Related Services.
5375	Level 5 Urology and Related Services.

TABLE 34—PROPOSED CY 2016 APCS ASSIGNED TO AL UROLOGY AND RELATED SERVICES—Continued

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC Group title
5376	Level 6 Urology and Related Services.
5377	Level 7 Urology and Related Services.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

9. Vascular Procedures (Excluding Endovascular Procedures)

For the CY 2016 OPPS update, based on our evaluation of the latest hospital outpatient claims data available for this proposed rule, we are proposing to restructure all of the vascular procedure-related APCs (excluding endovascular procedures) to more appropriately reflect the costs and clinical characteristics of the procedures within each APC. We believe that this proposed restructuring of APCs for vascular procedures more accurately categorizes all of the vascular procedures within an APC group, such that the services within each proposed newly configured APC are more comparable clinically and with respect to resource use. Table 35 below shows the vascular procedures APCs for CY 2015, and Table 36 below shows the proposed vascular procedures APCs for CY 2016. The proposed payment rates for the vascular procedure codes are included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site). The proposed payment rates for the proposed specific APCs to which we are proposing to assign the urology and related procedures codes are included in Addenda A and B to this proposed rule. Both OPPS Addenda A and B are available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 35—CY 2015 VASCULAR PROCEDURE APCS

[Excluding Endovascular Procedures]

CY 2015 APC	CY 2015 APC Group title
0103	Miscellaneous Vascular Procedures.
0624	Phlebotomy and Minor Vascular Access Device.
0088	Thrombectomy.

TABLE 35—CY 2015 VASCULAR PROCEDURE APCS—Continued

[Excluding Endovascular Procedures]

CY 2015 APC	CY 2015 APC Group title
0621	Level I Vascular Access Procedures.
0622	Level II Vascular Access Procedures.
0093	Vascular Reconstruction/Fistula Repair.
0219	Vascular Ligation.

TABLE 36—PROPOSED CY 2016 VASCULAR PROCEDURES APCS

[Excluding Endovascular Procedures]

Proposed restructured/renumbered CY 2016 APC*	Proposed CY 2016 APC Group title
5181	Level 1 Vascular Procedures.
5182	Level 2 Vascular Procedures.
5183	Level 3 Vascular Procedures.

*Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

IV. Proposed OPPS Payment for Devices

A. Proposed Pass-Through Payments for Devices

1. Expiration of Transitional Pass-Through Payments for Certain Devices

a. Background

Section 1833(t)(6)(B)(iii) of the Act sets forth the period for which a device category eligible for transitional pass-through payments under the OPPS may be in effect. The implementing regulation at 42 CFR 419.66(g) provides that this pass-through payment eligibility period begins on the date CMS establishes a particular transitional pass-through category of devices. The eligibility period is for at least 2 years but no more than 3 years. We may establish a new device category for pass-through payment in any quarter. Under our established policy, we base the pass-through status expiration date for a device category on the date on which pass-through payment is effective for the category; that is, the date CMS establishes a particular category of devices eligible for transitional pass-through payments. We propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update.

We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763). Brachytherapy sources, which are now separately paid in accordance with section 1833(t)(2)(H) of the Act, are an exception to this established policy.

b. Proposed CY 2016 Policy

As stated earlier, section 1833(t)(6)(B)(iii) requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. There currently are four device categories eligible for pass-through payment: HCPCS code C1841 (Retinal prosthesis, includes all internal and external components) was established effective October 1, 2013. HCPCS code C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components) was established effective January 1, 2015. HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) was established effective April 1, 2015. HCPCS code C2613 (Lung biopsy plug with delivery system) was established effective July 1, 2015. The pass-through payment status of the device category for HCPCS code C1841 will end on December 31, 2015. Therefore, in accordance with our established policy, beginning with CY 2016, we are proposing to package the costs of the HCPCS code C1841 devices into the costs related to the procedures with which the device is reported in the hospital claims data.

If we create any new device categories for pass-through payment status during the remainder of CY 2015 or during CY 2016, we will propose future expiration dates in accordance with § 419.66(g).

2. Proposed Annual Rulemaking Process in Conjunction With Quarterly Review Process for Device Pass-Through Payment Applications

a. Background

Section 1833(t)(6)(B) of the Act requires payment to be made on a ''pass-through'' basis for designated medical devices. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations might be most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at 42 CFR 419.66(b)(1) through (b)(3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria: (1) If required by FDA, the device must have received FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA), or meet another FDA exemption from premarket approval or clearance; (2) the device must be determined reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as provided under section 1862(a)(1)(A) of the Act; and (3) the device must be an integral part of the service, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, whether or not it remains with the patient when the patient is released from the hospital. A device is not eligible if it is any of the following, as specified at § 419.66(b)(4): Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or a material or supply furnished incident a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a category of devices should be established: The device must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not ''insignificant'' relative to the payment amount for the procedure or service with which the device is associated as determined under § 416.66(d); and
- Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

More details on the requirements for device pass-through payment applications are included on the CMS Web site in the application form itself at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html,* in the ''Downloads'' section.

The current OPPS process for applying for a new device category for transitional pass-through payment is subregulatory; that is, device or implantable biological or skin substitute manufacturers, hospitals, or other interested parties may apply to the agency through an application process available online. The application determination process is handled outside of rulemaking. Applications are accepted by CMS on a rolling basis and determinations are made on a quarterly basis. Decisions by CMS to approve an application for a device for pass-through payment under the OPPS are announced quarterly through a subregulatory process via program transmittal and are communicated directly to the applicant. Approvals are then referenced in our annual rulemaking as a means to establish payment periods. Currently, denials of applications for devices for pass-through payment status under the OPPS are communicated directly to the applicant and not announced publicly through rulemaking, program transmittal, or other public forum. Applicants for pass-through payment for a device whose application is denied may submit a reconsideration request to CMS. The applicant must send a written letter that explains the reasons for the request for reconsideration of CMS' decision, along with any additional information or evidence that may not have been included with the original application that may further support the reconsideration request. Currently, reconsiderations of denials of devices for pass-through payment under the OPPS are handled similarly to initial denials through direct communication with the applicant.

Over the years, stakeholders have opined that the current OPPS device pass-through payment application process lacks transparency and consistent approval standards. That is, stakeholders have suggested that the unavailability to the public of specific information about application decisions makes it difficult to determine if there are consistent approval standards because there is no public knowledge regarding which applications are rejected and which criteria are not met. Likewise, for approved applications, there is a lack of the specific information available to the public that led to approval of the application. Some stakeholders have requested that CMS increase transparency in the device pass-through payment application process by notifying the public, through rulemaking, of the number of applications received each year in aggregate and, for each application, include in rulemaking the preliminary decision, any additional details included in follow-up with the applicant, and the final decision, including the rationale for the approval or denial of the application. Stakeholders also have requested that CMS consult with industry and other stakeholders during the application review process.

We agree with stakeholders that the current OPPS device pass-through payment application process could benefit from increased transparency and stakeholder input. Therefore, for CY 2016, we are proposing changes to the OPPS device pass-through payment application process to help achieve the goals of increased transparency and stakeholder input. We are proposing to align a portion of the OPPS device pass-through payment application process with the already established inpatient prospective payment system (IPPS) application process for new medical services and new technology add-on payments. (We refer readers to sections 1886(d)(5)(K) and (d)(5)(L) of the Act and 42 CFR 412.87 and 412.88 for additional information on the IPPS process for approval of new medical services and technologies for new technology add-on payment under the IPPS.) Frequently, an applicant will apply for both device pass-through payments under the OPPS and for new technology add-on payments under the IPPS. Both the OPPS and the IPPS require that the applicant demonstrate that the technology represents a substantial clinical improvement relative to existing technologies. Approvals and denials of applications for new technology add-on payments under the IPPS are finalized through annual rulemaking. We discuss the specific changes that we are proposing for the transitional medical device pass-through payment application process under the OPPS in the section below.

b. Proposed Revisions to the Application Process for Device Pass-Through Payments

Beginning in CY 2016, we are proposing to add a rulemaking component to the current quarterly device pass-through payment application process. That is, we are proposing to supplement the quarterly process by including a description of applications received (whether they are approved or denied) as well as our rationale for approving or denying the application in the next applicable OPPS proposed rule. This proposed revised process would include providing information related to the establishment of the new device category, the cost thresholds, and the substantial clinical improvement criterion. For applications that are approved during the quarterly review process, based on public comments received in response to proposed rulemaking, we would either continue to maintain device pass-through payment status or finalize a policy to discontinue pass-through payment status. In the rare case in which an applicant is approved during the quarterly process and then a decision is made in rulemaking to reverse the approval, the applicant could reapply with new information, in advance of the following year proposed rule. The application would be included in the proposed rule, along with a proposal to approve or deny device pass-through payment status and a final decision would be provided in the final rule after consideration of public comments.

For applications that we deny during the quarterly review process, we are proposing to include the same type of information that we include for approved devices in the next applicable OPPS proposed rule and, after consideration of public comments received, could revisit our decision and either uphold the original decision of denial or approve the application based on additional evidence submitted through the rulemaking process. The final decision would be published in the appropriate final rule. In lieu of the informal reconsideration process that is currently in place for denied applications; we would only provide opportunity to reconsider applications that are denied through the rulemaking process. We are proposing to allow applicants whose applications are denied through the quarterly review process to withdraw their applications if they do not wish to go through the rulemaking process. If such a decision is made, the quarterly review decision to deny device pass-through payment for the application would be considered final and there would be no further reconsideration process available. By providing an opportunity for public comment, we believe that we would not only make the device pass-through payment application and review process more transparent, but also would assure that applicants have the benefit of public input on the ultimate decision to

approve or deny an application for device pass-through payments under the OPPS.

Currently, the deadline for device pass-through payment applications is the first business day in March, June, September, and December of a year for consideration for the next quarter (at the earliest) of the calendar year. For example, under our proposal, CMS' decision on an application that is submitted by the first business day in March would likely be presented in that calendar year's OPPS proposed rule (assuming the application that is submitted is complete). Decisions on applications received after the first business day in March would be included in the OPPS proposed rule for the following calendar year.

In response to requests for more transparency and public input on the device pass-through payment application process, we considered moving entirely to a yearly process through rulemaking and eliminating quarterly submissions. However, in an effort to maintain flexibility under the OPPS process for device pass-through payment applications, we believe that maintaining the quarterly process in addition to adding the annual rulemaking process may be beneficial because applications approved on a quarterly basis would be granted access to pass-through payments as soon as possible for approved devices. In addition, all applications would be considered through the rulemaking process, which would provide increased transparency and allow public input that would be considered in making a final determination. We are inviting public comments on this proposed approach as well as on whether moving to a rulemaking process entirely would be more helpful to further increase transparency and further align the review of applications submitted under both the IPPS and the OPPS.

c. Criterion for Newness

Since the inception of transitional pass-through payments for new categories of medical devices on April 7, 2000, there has not been any specific criteria provided to evaluate the newness of the device for purposes of determining eligibility and receiving device pass-through payment under the OPPS. Section 1833(t)(6)(B)(ii)(I) of the Act requires that the Secretary shall establish criteria that will be used for creation of additional categories other than the initial categories described by section 1833(t)(6)(B)(i) of the Act through rulemaking. We believe that one prong of determining whether a new category should be established is whether or not the device seeking such new category status is itself new. We believe that the payment adjustment for transitional pass-through payments for devices under the OPPS was intended as an interim measure to allow for adequate payment of new innovative technology while we collected the necessary data to incorporate the costs for these devices into the base APC rate (66 FR 55861). Typically, there is a lag of 2 to 3 years from the point when a new device is first introduced on the U.S. market (generally on the date that the device receives FDA approval) until it is reflected in our claims data.

Existing regulations at § 419.66(b)(1) specify that, if required by the FDA, the device must have received FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215 of the regulations), or meet another appropriate FDA exemption from premarket approval or clearance. This existing regulatory provision does not address the issue of how dated these device approvals, clearances, or exemptions may be. As a result, a device that has received FDA approval, clearance, or exemption and has been available on the U.S. market for several years could apply for and possibly be approved for pass-through payments for a new device category if the device is not described by any of the existing (either currently active or expired) categories established for transitional device pass-through payments. Over the years, we have received applications for device pass-through payment for devices that have been on the market for several years. We do not believe that this is the intent of the regulation. Therefore, we are proposing to modify the medical device eligibility requirement at § 419.66(b)(1) to provide that not only must a device, if required, receive FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215 of the regulations) or meet another appropriate FDA exemption from premarket approval or clearance, but also that beginning with applications received on or after January 1, 2016, any such device must have received such approval or clearance, as applicable, within 3 years from the date of the application for transitional pass-through payment. That is, we are proposing to add a requirement to ensure that medical devices falling under § 419.66(b)(1) and seeking creation of a category for device pass-through payment must be ''new.'' We believe that the proposed adjustment is consistent with section 1833(t)(6)(B)(ii)(I) of the Act, which allows for establishing criteria that will be used for the creation of additional categories through rulemaking. This proposed adjustment also will further align the OPPS device pass-through process with the IPPS process for new medical services and new technology add-on payments (42 CFR 412.87(b)(2) and 78 FR 50570) by adding the requirement that the device be new. Specifically, we are proposing that, beginning with applications received on or after January 1, 2016, a device will only be eligible for transitional pass-through payment under the OPPS if, in cases where the device requires FDA approval, clearance, or exemption, the device meets the newness criterion; that is, the date of original FDA approval or clearance and U.S. market availability is within 3 years from the date of the application for transitional pass-through payment. We are proposing to revise § 419.66(b)(1) to reflect this proposal. We are inviting public comments on this proposal.

3. Proposed Provisions for Reducing Transitional Pass-Through Payments To Offset Costs Packaged Into APC Groups

a. Background

Section 1833(t)(6)(D)(ii) of the Act sets the amount of additional pass-through payment for an eligible device as the amount by which the hospital's charges for a device, adjusted to cost (the cost of the device), exceeds the portion of the otherwise applicable Medicare outpatient department fee schedule amount (the APC payment amount) associated with the device. We have an established policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of the associated devices that are eligible for pass-through payments (66 FR 59904) for purposes of estimating the portion of the otherwise applicable APC payment amount associated with pass-through devices. For eligible device categories, we deduct an amount that reflects the portion of the APC payment amount that we determine is associated with the cost of the device, defined as the device APC offset amount, from the charges adjusted to cost for the device, as provided by section 1833(t)(6)(D)(ii) of the Act, to determine the pass-through payment amount for the eligible device. We have consistently used an

established methodology to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of an associated device eligible for pass-through payment, using claims data from the period used for the most recent recalibration of the APC rates (72 FR 66751 through 66752). We establish and update the applicable device APC offset amounts for eligible pass-through device categories through the transmittals that implement the quarterly OPPS updates. In the unusual case where the device offset amount exceeds the device pass-through payment amount, the regular APC rate would be paid.

We published a list of all procedural APCs with the CY 2015 portions (both percentages and dollar amounts) of the APC payment amounts that we determined are associated with the cost of devices on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* The dollar amounts are used as the device APC offset amounts. In addition, in accordance with our established practice, the device APC offset amounts in a related APC are used in order to evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices, as specified in our regulations at § 419.66(d).

Beginning January 1, 2010, we include packaged costs related to implantable biologicals in the device offset calculations in accordance with our policy that the pass-through evaluation process and payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only (74 FR 60476). Beginning January 1, 2015, skin substitutes are evaluated for pass-through status and payment using the device pass-through evaluation process (79 FR 66888).

b. Proposed CY 2016 Policy

As we did for CY 2015, we are proposing to continue, for CY 2016, our established methodology to estimate the portion of each APC payment rate that could reasonably be attributed to (that is, reflect) the cost of an associated device eligible for pass-through payment, using claims data from the period used for the most recent recalibration of the APC payment rates. We also are proposing to continue our established policies for calculating and setting the device APC offset amounts for each device category eligible for pass-through payment. In addition, we are proposing to continue to review each new device category on a case-by-case basis to determine whether device costs associated with the new category are already packaged into the existing APC structure. If device costs packaged into the existing APC structure are associated with the new category, we are proposing to deduct the device APC offset amount from the pass-through payment for the device category. As stated earlier, these device APC offset amounts also would be used in order to evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices (§ 419.66(d)).

In addition, we are proposing to update the list of all procedural APCs with the final CY 2016 portions of the APC payment amounts that we determine are associated with the cost of devices on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html* so that this information is available for use by the public in developing potential CY 2016 device pass-through payment applications and by CMS in reviewing those applications.

B. Proposed Device-Intensive Procedures

1. Background

Under the OPPS, device-intensive APCs are defined as those APCs with a device offset greater than 40 percent (79 FR 66795). In assigning device-intensive status to an APC, the device costs of all procedures within the APC are calculated and the geometric mean device offset of all the procedures must exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilize devices, and the device costs for the associated HCPCS codes exceed the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive APCs and is discussed in detail in section IV.B.3. of this proposed rule. A related device policy is the requirement that procedures assigned to certain (formerly device-dependent) APCs require the reporting of a device code on the claim (79 FR 66795).

2. Proposed Changes to Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period, we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed below in Table 37 (the formerly device-dependent APCs) is reported on the claim (79 FR 66795).

TABLE 37—APCs THAT REQUIRE A DEVICE CODE TO BE REPORTED ON A CLAIM WHEN A PROCEDURE ASSIGNED TO ONE OF THESE APCs IS REPORTED FOR CY 2015

CY 2015 APC	CY 2015 APC title
0039	Level III Neurostimulator.
0061	Level II Neurostimulator.
0083	Level I Endovascular.
0084	Level I EP.
0085	Level II EP.
0086	Level III EP.
0089	Level III Pacemaker.
0090	Level II Pacemaker.
0107	Level I ICD.
0108	Level II ICD.
0202	Level V Gynecologic Procedures.
0227	Implantation of Drug Infusion.
0229	Level II Endovascular.
0259	Level VII ENT Procedures.
0293	Level IV Intraocular.
0318	Level IV Neurostimulator.
0319	Level III Endovascular.
0384	GI Procedures with Stents.
0385	Level I Urogenital.
0386	Level II Urogenital.
0425	Level V Musculoskeletal.
0427	Level II Tube/Catheter.
0622	Level II Vascular Access.
0648	Level IV Breast Surgery.
0652	Insertion of IP/Pl. Cath.
0655	Level IV Pacemaker.

There are 10 APCs listed in Table 37 that are not device-intensive APCs; that is, their device offsets do not exceed 40 percent. We do not believe that we should continue to require device codes on claims for procedures that are not assigned to device-intensive APCs, as the relative device costs do not exceed the device-intensive threshold of 40 percent. Unlike with device-intensive APCs, we believe it is not necessary to require the reporting of a device code for reporting device charges on a claim because the relative device costs are much less significant than those associated with device-intensive APCs. We believe that device code reporting requirements should only apply to the device-intensive APCs because these APCs have significant device costs that are associated with particular devices.

We note that, in CY 2015 (79 FR 66794 through 66795), we applied the device code reporting requirements to those formerly device-dependent APCs that also met the device-intensive APC definition. However, after further consideration, we no longer believe it is appropriate to restrict the application of this policy to only the subset of device-intensive APCs that were formerly device-dependent and now believe the device code reporting requirements should apply to all device-intensive APCs, regardless of whether or not the APC was formerly device-dependent. We believe that the device coding requirement should apply to procedures assigned to all device-intensive APCs because these are the APCs with significant device costs. Therefore, we are proposing for CY 2016 that only the procedures that require the implantation of a device that are assigned to a device-intensive APC would require a device code on the claim. The list of device-intensive APCs are listed in Table 38 below.

TABLE 38—PROPOSED CY 2016 DEVICE-INTENSIVE APCS

Proposed re-numbered CY 2016 APC *	Proposed CY 2016 APC title
0039	Level III Neurostimulator & Related Procedures.
0061	Level II Neurostimulator & Related Procedures.
0089	Level III Pacemaker & Similar Procedures.
0090	Level II Pacemaker & Similar Procedures.
0105	Level I Pacemaker & Similar Procedures.
0107	Level I ICD & Similar Procedures.
0108	Level II ICD & Similar Procedures.
0227	Implantation of Drug Infusion Device.
0229	Level II Endovascular Procedures.
0259	Level VI ENT Procedures.
0293	Level III Intraocular Procedures.
0318	Level IV Neurostimulator & Related Procedures.
0319	Level III Endovascular Procedures.
0351	Level IV Intraocular Procedures.
0386	Level VII Urology & Related Procedures.
0425	Level IV Musculoskeletal Procedures.
0655	Level IV Pacemaker & Similar Procedures.
1564	New Technology—Level 27.

TABLE 38—PROPOSED CY 2016 DEVICE-INTENSIVE APCS—Continued

Proposed re-numbered CY 2016 APC *	Proposed CY 2016 APC title
1593	New Technology—Level 46.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) provides a crosswalk of the existing APC numbers to the proposed APC renumbers.

We are proposing that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to an APC listed in Table 38, would satisfy the edit. Claims submitted with a procedure code requiring a device assigned to an APC listed in Table 38, but without any device code reported on the claim, would be returned to the provider.

3. Proposed Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit cases on the claim using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals are instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals are instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the ''FD'' value code appears on a claim. For CY 2015, we continued our existing policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873).

b. Proposed Policy for CY 2016

For CY 2016 and subsequent years, we are proposing to continue our existing policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Specifically, for CY 2016, we are proposing to continue to reduce the OPPS payment, for the device intensive APCs listed in Table 38 above, by the full or partial credit a provider receives for a replaced device. Under this proposed policy, hospitals would continue to be required to report on the claim the amount of the credit in the amount portion for value code ''FD'' when the hospital receives a credit for

a replaced device that is 50 percent or greater than the cost of the device. In CY 2015 and prior years, we specified a list of costly devices to which this APC payment adjustment would apply. Upon further consideration of our existing value code ''FD'' APC payment adjustment policy and the ability to deduct the actual amount of the device credit from the OPPS payment, regardless of the cost of the individual device, instead of a percentage of the device offset, we no longer believe it is necessary to restrict the application of this policy to a specific list of costly devices (most recently listed in Table 27 of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66873)) as was necessary under the ''FB''/''FC'' modifier payment adjustment policy, which made APC payment adjustments as a percentage of the applicable device offset amount. Under the current policy, the actual amount of the device credit can be appropriately reported in the amount portion of value code ''FD'' and deducted from OPPS payment for all no cost/full credit and partial credit devices furnished in conjunction with a procedure assigned to a device intensive APC. Therefore, for CY 2016 and subsequent years, we are proposing to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply. Instead, we are proposing to apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

For CY 2016 and subsequent years, we also are proposing to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which our proposed CY 2016 policy would apply (71 FR 68072 through 68077). Specifically: (1) All procedures assigned to the selected APCs must involve implantable devices that would be reported if device insertion procedures were performed; (2) the required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and (3) the APC must be device intensive; that is, the device offset amount must be significant, which is defined as exceeding 40 percent of the APC cost. We continue to believe these criteria are appropriate because no cost devices and device credits are likely to be associated with particular cases only when the device must be reported on the claim and is of a type that is implanted and remains in the body when the beneficiary leaves the hospital. We believe that the reduction in payment is appropriate only when the cost of the device is a significant part of the total cost of the APC into which the device cost is packaged, and that the 40-percent threshold is a reasonable definition of a significant cost. As noted earlier in this section, APCs with a device offset that exceed the 40-percent threshold are called device-intensive APCs.

We examined the offset amounts calculated from the CY 2016 proposed rule claims data and the clinical characteristics of the proposed CY 2016 APCs to determine which APCs meet the criteria for CY 2016. The full list of device-intensive APCs to which we are proposing that the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2016 is included in Table 38 above.

4. Proposed Adjustment to OPPS Payment for Discontinued Device-Intensive Procedures

It has been our longstanding policy to instruct hospitals to utilize an appropriate modifier on a claim to report when a procedure is discontinued, partially reduced, or cancelled. Specifically, when appropriate, hospitals are instructed to append modifiers 73, 74, and 52 to report and be paid for expenses incurred in preparing a patient for a procedure and scheduling a room for performing the procedure where the service is subsequently discontinued (Medicare Claims Processing Manual (Pub. 100–04, Chapter 4, Section 20.6.4). The circumstances identifying when it is appropriate to append modifier 73, 74, or 52 to a claim are detailed below.

Modifier 73 is used by the hospital to indicate that a procedure requiring anesthesia was terminated due to extenuating circumstances or to circumstances that threatened the well-being of the patient after the patient had been prepared for the procedure (including procedural pre-medication when provided), and been taken to the room where the procedure was to be performed, but prior to administration of anesthesia. For purposes of billing for services furnished in the HOPD, anesthesia is defined to include local, regional blocks(s), moderate sedation/analgesia (''conscious sedation''), deep sedation/analgesia, or general anesthesia. Modifier 73 was created so that the costs incurred by the hospital to prepare the patient for the procedure and the resources expended in the procedure room and recovery room (if needed) could be recognized for payment even though the procedure was discontinued. Modifier 73 results in a payment rate of 50 percent of the full OPPS payment for the procedure.

Modifier 74 is used by the hospital to indicate that a procedure requiring anesthesia was terminated after the induction of anesthesia or after the procedure was started (for example, the incision made, the intubation started, and the scope inserted) due to extenuating circumstances or to circumstances that threatened the well-being of the patient. This modifier may also be used to indicate that a planned surgical or diagnostic procedure was discontinued, partially reduced, or canceled at the physician's discretion after the administration of anesthesia. For purposes of billing for services furnished in the HOPD, anesthesia is defined to include local, regional blocks(s), moderate sedation/analgesia (''conscious sedation''), deep sedation/analgesia, or general anesthesia. Modifier 74 was created so that the costs incurred by the hospital to initiate the procedure (preparation of the patient, procedure room, and recovery room) could be recognized for payment even though the procedure was discontinued prior to completion. Modifier 74 results in a payment rate of 100 percent of the full OPPS payment for the procedure.

Modifier 52 was revised in CY 2012 and is used by the hospital to indicate partial reduction, cancellation, or discontinuation of services for which anesthesia is not planned. (We refer readers to the January 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS), Transmittal 2386, Change Request 7672, dated January 13, 2012.) The modifier provides a means for reporting reduced services without disturbing the identification of the basic service. Modifier 52 results in a payment rate of 50 percent of the full OPPS payment for the procedure.

When a procedure assigned to a device-intensive APC is discontinued either prior to administration of anesthesia or for a procedure that does not require anesthesia, we presume that, in the majority of cases, the device was not used and remains sterile such that it could be used for another case. In these circumstances, under current policy, hospitals could be paid twice by Medicare for the same device, once for the initial procedure that was discontinued and again when the device is actually used. Accordingly, for CY 2016, we are proposing that, for procedures involving implantable devices that are assigned to a device-

intensive APC (defined as those APCs with a device offset greater than 40 percent), we would reduce the APC payment amount for discontinued device-intensive procedures, where anesthesia has not been administered to the patient or the procedure does not require anesthesia, by 100 percent of the device offset amount prior to applying the additional payment adjustments that apply when the procedure is discontinued. We are proposing to restrict the policy to device-intensive APCs so that the adjustment would not be triggered by the use of an inexpensive device whose cost would not constitute a significant portion of the total payment rate for an APC. At this time, we are not proposing to deduct the device offset amount from a procedure that was discontinued after anesthesia was administered (modifier 74) because we believe that it may be more likely that devices involved with such procedures may no longer be sterile, such that they could be restocked and used for another case. However, we are soliciting public comments on how often the device becomes ineligible for use in a subsequent case and whether we should deduct the device offset amount from claims with modifier 74 as well.

V. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals. Throughout this proposed rule, the term ''biological'' is used because this is the term that appears in section 1861(t) of the Act. ''Biological'' as used in this proposed rule includes (but is not necessarily limited to) ''biological product'' or ''biologic'' as defined in the Public Health Service Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this provision requires the Secretary to make additional payments to hospitals for: Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to drugs or biologicals that are outpatient hospital services under Medicare Part B for which payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996 and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Proposed CY 2016 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this proposed rule, which are available via the Internet on the CMS Web site.

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. If the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, the pass-through payment amount is determined by the Secretary to be equal to the average price for the drug or biological for all competitive acquisition areas and the year established under such section as calculated and adjusted by the Secretary. However, we note that the Part B drug competitive acquisition program (CAP) has been postponed since CY 2009, and such a program has not been reinstated for CY 2016.

This methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological. Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this proposed rule, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

The pass-through application and review process for drugs and biologicals is explained on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*.

2. Proposed Drugs and Biologicals with Expiring Pass-Through Payment Status in CY 2015

We are proposing that the pass-through status of 12 drugs and biologicals would expire on December 31, 2015, as listed in Table 39 below. All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2015. These drugs and biologicals were approved for pass-through status on or before January 1, 2013. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure, our standard methodology for providing payment for drugs and biologicals with expiring pass-through status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed at $100 for CY 2016), as discussed further in section V.B.2. of this proposed rule. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we would provide separate payment at the applicable relative ASP-based payment amount

(which is proposed at ASP+6 percent for CY 2016, as discussed further in section V.B.3. of this proposed rule).

TABLE 39—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2015

CY 2015 HCPCS code	CY 2015 long descriptor	CY 2015 SI	CY 2015 APC
A9520	Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries	N	N/A
C9132	Prothrombin complex concentrate (human), Kcentra, per i.u. of Factor IX activity	K	9132
J1556	Injection, immune globulin (Bivigam), 500 mg	K	9130
J3060	Injection, taliglucerase alfa, 10 units	K	9294
J7315	Mitomycin, ophthalmic, 0.2 mg	N	N/A
J7316	Injection, Ocriplasmin, 0.125mg	K	9298
J9047	Injection, carfilzomib, 1 mg	K	9295
J9262	Injection, omacetaxine mepesuccinate, 0.01 mg	K	9297
J9354	Injection, ado-trastuzumab emtansine, 1 mg	K	9131
J9400	Injection, Ziv-Aflibercept, 1 mg	K	9296
Q4122	Dermacell, per square centimeter	N	N/A
Q4127	Talymed, per square centimeter	N	N/A

3. Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Payment Status in CY 2016

We are proposing to continue pass-through payment status in CY 2016 for 32 drugs and biologicals. None of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2015. These drugs and biologicals, which were approved for pass-through status between January 1, 2013, and July 1, 2015, are listed in Table 40 below. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through July 1, 2015 are assigned status indicator ''G'' in Addenda A and B to this proposed rule. Addenda A and B to this proposed rule are available via the Internet on the CMS Web site.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. Payment for drugs and biologicals with pass-through status under the OPPS is currently made at the physician's office payment rate of ASP+6 percent. We believe it is consistent with the statute to propose to continue to provide payment for drugs and biologicals with pass-through status at a proposed rate of ASP+6 percent in CY 2016, which is the amount that drugs and biologicals receive under section 1842(o) of the Act.

Therefore, for CY 2016, we are proposing to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2016. We are proposing that a $0.00 pass-through payment amount would be paid for most pass-through drugs and biologicals under the CY 2016 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: contrast agents; diagnostic radiopharmaceuticals; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs; and biologicals that function as supplies when used in a surgical procedure), we are proposing that their pass-through payment amount would be equal to ASP+6 percent for CY 2016 because, if not for their pass-through status, payment for these products would be packaged into the associated procedure.

In addition, we are proposing to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2016 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

In CY 2016, as is consistent with our CY 2015 policy for diagnostic and therapeutic radiopharmaceuticals, we are proposing to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated above, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2016, we are proposing to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we are proposing to provide pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information also is not available, we are proposing to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

As discussed in more detail in section II.A.3. of this proposed rule, we implemented a policy whereby payment for the following nonpass-through items is packaged into payment for the associated procedure: policy-packaged drugs which include contrast agents, stress agents, diagnostic radiopharmaceuticals, and anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure. As stated earlier, pass-through payment is the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug

or biological. Because payment for a drug that is policy-packaged would otherwise be packaged if the product did not have pass-through payment status, we believe the otherwise applicable OPPS payment amount would be equal to the policy-packaged drug APC offset amount for the associated clinical APC in which the drug or biological is utilized. The calculation of the policy-packaged drug APC offset amounts is described in more detail in section V.A.4. of this proposed rule. It follows that the copayment for the nonpass-through payment portion (the otherwise applicable fee schedule amount that we also would offset from payment for the drug or biological if a payment offset applies) of the total OPPS payment for those drugs and biologicals, therefore, would be accounted for in the copayment for the associated clinical APC in which the drug or biological is used.

According to section 1833(t)(8)(E) of the Act, the amount of copayment associated with pass-through items is equal to the amount of copayment that would be applicable if the pass-through adjustment was not applied. Therefore, as we did in CY 2015, we are proposing to continue to set the associated copayment amount to zero for CY 2016 for pass-through drugs and biologicals that would otherwise be packaged if the item did not have pass-through payment status. The 32 drugs and biologicals that we are proposing to continue to have pass-through payment status for CY 2016 or have been granted pass-through payment status as of July 2015 are shown in Table 40 below.

TABLE 40—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2016

CY 2015 HCPCS code	Proposed CY 2016 HCPCS code	CY 2016 Long descriptor	Proposed CY 2016 SI	Proposed new CY 2016 APC *
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	1664
C9025	C9025	Injection, ramucirumab, 5 mg	G	1488
C9026	C9026	Injection, vedolizumab, 1 mg	G	1489
C9027	C9027	Injection, pembrolizumab, 1 mg	G	1490
C9349	C9349	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter.	G	1657
C9442	C9442	Injection, belinostat, 10 mg	G	1658
C9443	C9443	Injection, dalbavancin, 10 mg	G	1659
C9444	C9444	Injection, oritavancin, 10 mg	G	1660
C9445	C9445	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	9445
C9446	C9446	Injection, tedizolid phosphate, 1 mg	G	1662
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	1663
C9449	C9449	Injection, blinatumomab, 1 mcg	G	9449
C9450	C9450	Injection, fluocinolone acetonide intravitreal implant, 0.19 mg	G	9450
C9451	C9451	Injection, peramivir, 1 mg	G	9451
C9452	C9452	Injection, ceftolozane 50 mg and tazobactam 25 mg	G	9452
C9453	C9453	Injection, nivolumab, 1 mg	G	9453
C9454	C9454	Injection, pasireotide long acting, 1 mg	G	9454
C9455	C9455	Injection, siltuximab, 10 mg	G	9455
C9497	C9497	Loxapine, inhalation powder, 10 mg	G	9497
C9022	J1322	Injection, elosulfase alfa, 1 mg	G	1480
Q9970	J1439	Injection, ferric carboxymaltose, 1 mg	G	9441
J1446	J1446	Injection, TBO-Filgrastim, 5 micrograms	G	1477
C9023	J3145	Injection, testosterone undecanoate, 1 mg	G	1487
C9134	J7181	Factor XIII (antihemophilic factor, recombinant), Tretten, per i.u	G	1746
C9133	J7200	Factor IX (antihemophilic factor, recombinant), Rixubus, per i.u	G	1467
C9135	J7201	Factor IX (antihemophilic factor, recombinant), Alprolix, per i.u	G	1486
J7508	J7508	Tacrolimus, Extended Release, Oral, 0.1 mg	G	1465
C9021	J9301	Injection, obinutuzumab, 10 mg	G	1476
J9371	J9371	Injection, Vincristine Sulfate Liposome, 1 mg	G	1466
Q4121	Q4121	Theraskin, per square centimeter	G	1479
C9136	Q9975	Injection, factor viii, fc fusion protein, (recombinant), per i.u.	G	1656
C9448	Q9978	Netupitant (300mg) and palonosetron (0.5 mg), oral	G	9448

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

4. Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals to Offset Costs Packaged into APC Groups

a. Background

Prior to CY 2008, diagnostic radiopharmaceuticals and contrast agents were paid separately under the OPPS if their mean per day costs were greater than the applicable year's drug packaging threshold. In CY 2008 (72 FR 66768), we began a policy of packaging payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents as ancillary and supportive items and services into their associated nuclear medicine and radiology procedures. Therefore, beginning in CY 2008, nonpass-through diagnostic radiopharmaceuticals and contrast agents were not subject to the annual OPPS drug packaging threshold to determine their packaged or separately payable payment status, and instead all non-pass-through diagnostic radiopharmaceuticals and contrast agents were packaged as a matter of policy.

Beginning in CY 2014, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), we finalized a policy to package nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. In addition, beginning in CY 2014, we finalized the packaging

of all drugs and biologicals that function as supplies when used in a surgical procedure (including but not limited to skin substitutes and implantable biologicals). These packaging policies are codified at 42 CFR 419.2(b).

b. Proposed Payment Offset Policy for Diagnostic Radiopharmaceuticals

As previously noted, radiopharmaceuticals are considered to be drugs for OPPS pass-through payment purposes. As described above, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for diagnostic radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor radiopharmaceuticals in order to ensure no duplicate radiopharmaceutical payment is made.

In CY 2009, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor diagnostic radiopharmaceuticals when considering a new diagnostic radiopharmaceutical for pass-through payment (73 FR 68638 through 68641). Specifically, we use the policy-packaged drug offset fraction for APCs containing nuclear medicine procedures, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy-packaged drugs divided by the cost from single procedure claims in the APC. To determine the actual APC offset amount for pass-through diagnostic radiopharmaceuticals that takes into consideration the otherwise applicable OPPS payment amount, we multiply the policy-packaged drug offset fraction by the APC payment amount for the nuclear medicine procedure with which the pass-through diagnostic radiopharmaceutical is used and, accordingly, reduce the separate OPPS payment for the pass-through diagnostic radiopharmaceutical by this amount. For CY 2016, as we did in CY 2015, we are proposing to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals. For CY 2016, there will be one diagnostic radiopharmaceutical with pass-through status under the OPPS, HCPCS code A9586 (Florbetapir f18, diagnostic, per study dose, up to 10 millicuries). We currently apply the established radiopharmaceutical payment offset policy to pass-through payment for this product.

Table 41 below displays the proposed APCs to which nuclear medicine procedures would be assigned in CY 2016 and for which we expect that an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

TABLE 41—PROPOSED APCS TO WHICH A DIAGNOSTIC RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2016

Proposed Restructured/ Renumbered CY 2016 APC *	Proposed CY 2016 APC title
5591	Level 1 Nuclear Medicine and Related Services.
5592	Level 2 Nuclear Medicine and Related Services.
5593	Level 3 Nuclear Medicine and Related Services.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

c. Proposed Payment Offset Policy for Contrast Agents

Section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for contrast agents an amount reflecting the portion of the APC payment associated with predecessor contrast agents in order to ensure no duplicate contrast agent payment is made.

In CY 2010, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor contrast agents when considering new contrast agents for pass-through payment (74 FR 60482 through 60484). Specifically, we use the policy-packaged drug offset fraction for procedural APCs, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy-packaged drugs divided by the cost from single procedure claims in the APC. To determine the actual APC offset amount for pass-through contrast agents that takes into consideration the otherwise applicable OPPS payment amount, we are proposing to multiply the policy packaged drug offset fraction by the APC payment amount for the procedure with which the pass-through contrast agent is used and, accordingly, reduce the separate OPPS payment for the pass-through contrast agent by this amount. For CY 2016, as we did in CY 2015, we are proposing to continue to apply our standard contrast agents offset policy to payment for any pass-through contrast agents (we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66879) for the final CY 2015 policy).

Although there are currently no contrast agents with pass-through payment status under the OPPS, we believe that a payment offset is necessary in the event that a new contrast agent is approved for pass-through status during CY 2016 to provide an appropriate transitional pass-through payment for new contrast agents. We are proposing to identify procedural APCs for which we expect a contrast offset could be applicable in the case of a pass-through contrast agent as any procedural APC with a policy-packaged drug amount greater than $20 that is not a nuclear medicine APC identified in Table 41 above, and these APCs are displayed in Table 42 below. The methodology used to determine a proposed threshold cost for application of a contrast agent offset policy is described in detail in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60483 through 60484). For CY 2016 and subsequent years, we are proposing to continue to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 42 of this proposed rule, a specific offset based on the procedural APC would be applied to payment for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

TABLE 42—PROPOSED APCS TO WHICH A CONTRAST AGENT PAYMENT OFFSET MAY BE APPLICABLE FOR CY 2016

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC title
5181	Level 1 Vascular Procedures and Related Services.
5182	Level 2 Vascular Procedures and Related Services.
5183	Level 3 Vascular Procedures and Related Services.

TABLE 42.—PROPOSED APCS TO WHICH A CONTRAST AGENT PAYMENT OFFSET MAY BE APPLICABLE FOR CY 2016—Continued

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC title
5188	Diagnostic Cardiac Catheterization.
5191	Level 1 Endovascular Procedures.
5192	Level 2 Endovascular Procedures.
5193	Level 3 Endovascular Procedures.
5351	Level 1 Percutaneous Abdominal/Biliary Procedures and Related Services.
5523	Level 3 X-Ray and Related Services.
5524	Level 4 X-Ray and Related Services.
5525	Level 5 X-Ray and Related Services.
5526	Level 6 X-Ray and Related Services.
5561	Level 1 Echocardiogram With Contrast.
5562	Level 2 Echocardiogram With Contrast.
5571	Computed Tomography With Contrast and Computed Tomography Angiography.
5582	Magnetic Resonance Imaging and Magnetic Resonance Angiography With Contrast.
5881	Ancillary Outpatient Service When Patient Expires.
8006	CT and CTA With Contrast Composite.
8008	MRI and MRA With Contrast Composite.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

d. Proposed Payment Offset Policy for Drugs, Biologicals, and Radiopharmaceuticals That Function as Supplies When Used in a Diagnostic Test or Procedure (Other Than Diagnostic Radiopharmaceuticals and Contrast Agents and Drugs and Biologicals That Function as Supplies When Used in a Surgical Procedure)

Section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), we finalized our policy to package drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure. As a part of this policy, we specifically finalized that skin substitutes and stress agents used in myocardial perfusion imaging (MPI) be policy packaged in CY 2014, in addition to diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs (78 FR 75019). Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we finalized a policy for CY 2014 to deduct from the pass-through payment for skin substitutes and stress agents an amount reflecting the portion of the APC payment associated with predecessor skin substitutes and stress agents in order to ensure no duplicate skin substitute or stress agent payment is made (78 FR 75019).

In CY 2014, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor skin substitutes or stress agents when considering a new skin substitute or stress agent for pass-through payment (78 FR 75019). Specifically, in the case of pass-through skin substitutes, we use the policy-packaged drug offset fraction for skin substitute procedural APCs, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy-packaged drugs divided by the cost from single procedure claims in the APC. Because policy-packaged radiopharmaceuticals also would be included in the drug offset fraction for the APC to which MPI procedures are assigned, in the case of pass-through stress agents, we use the policy-packaged drug offset fraction for the procedural APC, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy-packaged drugs excluding policy-packaged diagnostic radiopharmaceuticals divided by the cost from single procedure claims in the APC. To determine the actual APC offset amount for pass-through skin substitutes and pass-through stress agents that takes into consideration the otherwise applicable OPPS payment amount, we multiply the policy-packaged drug offset fraction by the APC payment amount for the procedure with which the pass-through skin substitute or pass-through stress agent is used and, accordingly, reduce the separate OPPS payment for the pass-through skin substitute or pass-through stress agent by this amount (78 FR 75019). For CY 2016, as we did in CY 2015, we are proposing to continue to apply the skin substitute and stress agent offset policy to payment for pass-through skin substitutes and stress agents.

For 2016, there will be two skin substitutes (HCPCS codes Q4121 and C9349) with pass-through payment status under the OPPS. We will apply the skin substitute payment offset policy to pass-through payment for these products. Table 43 below displays the proposed APCs to which skin substitute procedures would be assigned in CY 2016 and for which we expect that an APC offset could be applicable in the case of skin substitutes with pass-through status.

Although there are currently no stress agents with pass-through status under the OPPS, we believe that a payment offset is necessary in the event that a new stress agent is approved for pass-through status during CY 2016 in order to provide an appropriate transitional pass-through payment for new stress agents. Table 44 below displays the proposed APCs to which MPI procedures would be assigned in CY 2016 and for which we expect that an APC offset could be applicable in the case of a stress agent with pass-through status.

TABLE 43—PROPOSED APCS TO WHICH A SKIN SUBSTITUTE PAYMENT OFFSET MAY BE APPLICABLE FOR CY 2016

Proposed new CY 2016 APC *	Proposed CY 2016 APC title
5054	Level 4 Skin Procedures.
5055	Level 5 Skin Procedures.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

TABLE 44—PROPOSED APCS TO WHICH A STRESS AGENT PAYMENT OFFSET MAY BE APPLICABLE FOR CY 2016

Proposed new CY 2016 APC *	Proposed CY 2016 APC title
5722	Level 2 Diagnostic Tests and Related Services.
5593	Level 3 Nuclear Medicine and Related Services.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) for a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

We are proposing to continue to post annually on the CMS Web site at *http://*

www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPPS clinical APC.

B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Background

Under the policies that we established for the CY 2013 OPPS, we currently pay for drugs, biologicals, and radiopharmaceuticals that do not have pass-through payment status in one of two ways: (1) As a packaged payment included in the payment for the associated service, or (2) as a separate payment (individual APCs). We explained in the April 7, 2000 OPPS final rule with comment period (65 FR 18450) that we generally package the cost of drugs and radiopharmaceuticals into the APC payment rate for the procedure or treatment with which the products are usually furnished. Hospitals do not receive separate payment for packaged items and supplies, and hospitals may not bill beneficiaries separately for any packaged items and supplies whose costs are recognized and paid within the national OPPS payment rate for the associated procedure or service.

Packaging costs into a single aggregate payment for a service, procedure, or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility.

2. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Background

As indicated in section V.B.1. of this proposed rule, in accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $95 for CY 2015 (79 FR 66882).

Following the CY 2007 methodology, for this CY 2016 OPPS/ASC proposed rule, we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2016 and rounded the resulting dollar amount ($100.22) to the nearest $5 increment, which yielded a figure of $100. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics (BLS) series code WPUSI07003) from CMS' Office of the Actuary (OACT). We refer below to this series generally as the PPI for Prescription Drugs.

Based on the calculations described above, we are proposing a packaging threshold for CY 2016 of $100. For a more detailed discussion of the OPPS drug packaging threshold and the use of the PPI for Prescription Drugs, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086).

b. Proposed Cost Threshold for Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals (''Threshold-Packaged Drugs'')

To determine the proposed CY 2016 packaging status for all nonpass-through drugs and biologicals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals (collectively called ''threshold-packaged'' drugs) that had a HCPCS code in CY 2014 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2014 claims processed before January 1, 2015 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.2.c. of this proposed rule, or for the following policy-packaged items that we are proposing to continue to package in CY 2016: anesthesia drugs; contrast agents; stress agents; diagnostic radiopharmaceuticals; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2016, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we are proposing for separately payable drugs and biologicals for CY 2016, as discussed in more detail in section V.B.3.b. of this proposed rule) to calculate the CY 2016 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2014 (data that were used for payment purposes in the physician's office setting, effective April 1, 2015) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2016, we are proposing to use payment rates based on the ASP data from the fourth quarter of CY 2014 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) because these are the most recent data available for use at the time of development of this proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2015. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2014 hospital claims data to determine their per day cost.

We are proposing to package items with a per day cost less than or equal to $100, and identify items with a per day cost greater than $100 as separately payable. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2014

HCPCS codes that were reported to the CY 2015 HCPCS codes that we display in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for proposed payment in CY 2016.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in this CY 2016 OPPS/ASC proposed rule, we are proposing to use ASP data from the first quarter of CY 2015, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective July 1, 2015, along with updated hospital claims data from CY 2014. We note that we also are proposing to use these data for budget neutrality estimates and impact analyses for this CY 2016 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B to the final rule with comment period will be based on ASP data from the second quarter of CY 2015. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2015. These payment rates would then be updated in the January 2016 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2016. For items that do not currently have an ASP-based payment rate, we are proposing to recalculate their mean unit cost from all of the CY 2014 claims data and updated cost report information available for the CY 2016 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in this CY 2016 OPPS/ASC proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the CY 2016 OPPS/ASC final rule with comment period. Under such circumstances, we are proposing to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose cost fluctuates relative to the proposed CY 2016 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2015. Specifically, for CY 2016, consistent with our historical practice, we are proposing to apply the following policies to these HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2015 and that are proposed for separate payment in CY 2016, and that then have per day costs equal to or less than the CY 2016 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2016 final rule, would continue to receive separate payment in CY 2016.
- HCPCS codes for drugs and biologicals that were packaged in CY 2015 and that are proposed for separate payment in CY 2016, and that then have per day costs equal to or less than the CY 2016 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2016 final rule, would remain packaged in CY 2016.
- HCPCS codes for drugs and biologicals for which we are proposing packaged payment in CY 2016 but then have per day costs greater than the CY 2016 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2016 final rule, would receive separate payment in CY 2016.

c. Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to finalize the packaging of skin substitutes, we also finalized a methodology that divides the skin substitutes into a high cost group and a low cost group, in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933). For the CY 2014 update, assignment to the high cost or low cost skin substitute group depended upon a comparison of the July 2013 ASP+6 percent payment amount for each skin substitute to the weighted average payment per unit for all skin substitutes. The weighted average was calculated using the skin substitute utilization from the CY 2012 claims data and the July 2013 ASP+6 percent payment amounts. The high cost/low cost skin substitute threshold for CY 2014 was $32 per cm^2. Skin substitutes that had a July 2013 ASP+6 percent amount above $32 per cm^2 were classified in the high cost group, and skin substitutes that had a July 2013 ASP+6 percent amount at or below $32 per cm^2 were classified in the low cost group. Any new skin substitutes without pricing information were assigned to the low cost category until pricing information was available to compare to the $32 per cm^2 threshold for CY 2014. Skin substitutes with pass-through payment status were assigned to the high cost category, with an offset applied as described in section V.A.4.d. of the CY 2015 OPPS/ASC proposed rule (79 FR 40996).

As discussed in the CY 2015 OPPS/ASC proposed rule (79 FR 40998 through 40999) and final rule with comment period (79 FR 66882 through 66885), after the effective date of the CY 2014 packaging policy, some skin substitute manufacturers brought the following issues to our attention regarding the CY 2014 methodology for determining the high cost/low cost threshold:

- Using ASP to determine a product's placement in the high or low cost category may unfairly disadvantage the limited number of skin substitute products that are sold in large sizes (that is, above 150 cm^2). Large size skin substitute products are primarily used for burns that are treated on an inpatient basis. These manufacturers contended that nonlinear pricing for skin substitute products sold in both large and small sizes results in lower per cm^2 prices for large sizes. Therefore, the use of ASP data to categorize products into high and low cost categories can result in placement of products that have significant inpatient use of the large, lower-priced (per cm^2) sizes into the low cost category, even though these large size products are not often used in the hospital outpatient department.
- Using a weighted average ASP to establish the high/low cost categories, combined with the drug pass-through policy, will lead to unstable high/low cost skin substitute categories in the future. According to one manufacturer, under our CY 2014 policy, manufacturers with products on pass-

through payment status have an incentive to set a very high price because hospitals are price-insensitive to products paid with pass-through payments. As these new high priced pass-through skin substitutes capture more market share, the weighted average ASP high cost/low cost threshold could escalate rapidly, resulting in a shift in the assignment of many skin substitutes from the high cost category to the low cost category.

We agreed with stakeholder concerns regarding the potential instability of the high/low cost categories associated with the drug pass-through policy, as well as stakeholder concerns about the inclusion of large-sized products that are primarily used for inpatients in the ASP calculation, when ASP is used to establish the high cost/low cost categories. As an alternative to using ASP data, in the CY 2015 OPPS/ASC final rule with comment period, we established the high cost/low cost threshold using an alternative methodology (that is, the weighted average mean unit cost (MUC) for all skin substitute products from claims data) that we believed may provide more stable high/low cost categories and resolve the issue associated with large sized products because the MUC will be derived from hospital outpatient claims only. We indicated that the threshold was based on costs from hospital outpatient claims data instead of manufacturer reported sales prices that would not include larger sizes primarily used for inpatient burn cases.

As discussed in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66884), after consideration of the public comments we received on the CY 2015 OPPS/ASC proposed rule, we finalized a policy for CY 2015 to maintain the high cost/low cost APC structure for skin substitute procedures in CY 2015, and we revised the existing methodology used to establish the high/low cost threshold with the alternative MUC methodology. We also finalized for CY 2015 the policies that skin substitutes with pass-through payment status would be assigned to the high cost category, and that skin substitutes with pricing information but without claims data to calculate an MUC would be assigned to either the high cost or low cost category based on the product's ASP+6 percent payment rate. If ASP is not available, we stated we would use WAC+6 percent or 95 percent of AWP to assign a product to either the high cost or low cost category. We also finalized a policy for CY 2015 that any new skin substitutes without pricing information will be assigned to the low cost category until pricing information is available to compare to the CY 2015 threshold. We stated that new skin substitute manufacturers must submit pricing information to CMS no later than the 15th of the third month prior to the effective date of the next OPPS quarterly update. For example, for a new skin substitute with new pricing information to be included in the July 1, 2015 OPPS update and designated as included in the high cost group, verifiable pricing information must have been provided to CMS no later than April 15, 2015.

We stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66884) that we would evaluate the per day cost (PDC) methodology and compare it to the MUC methodology in CY 2016 once CY 2014 claims data were available. For CY 2016, we analyzed CY 2014 claims data to calculate a threshold using both the MUC and PDC methods. To calculate a per patient, per day cost for each skin substitute product, we multiplied the total units by the mean unit cost and divided the product by the total number of days. We have posted a file on the CMS Web site that provides details on the CY 2016 high/low cost status for each skin substitute product based on a MUC threshold (rounded to the nearest $1) of $25 per cm^2 and a PDC threshold (rounded to the nearest $1) of $1,050.

For CY 2016, based on these calculations, we are proposing to determine the high/low cost status for each skin substitute product based on either a product's MUC exceeding the MUC threshold or the product's PDC exceeding the PDC threshold. Skin substitutes that exceed either of these thresholds would be assigned to the high cost group and all other products would be assigned to the low cost group. As demonstrated in the aforementioned file that we posted on the CMS Web site, we note that the majority of high cost products remain high cost under both methodologies. Observing fairly consistent results with both methodologies, we believe that, together, both thresholds constitute a more robust methodology for identifying high cost skin substitute products.

We would continue to assign skin substitutes with pass-through payment status to the high cost category, and skin substitutes with pricing information but without claims data to calculate a MUC or PDC will be assigned to either the high cost or low cost category based on the product's ASP+6 percent payment rate as compared to the MUC threshold. If ASP is not available, we would use WAC+6 percent or 95 percent of AWP to assign a product to either the high cost or low cost category. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2016 MUC threshold.

For CY 2016, we also are proposing to remove all implantable biologicals from the skin substitute cost group list because these products are typically used in internal surgical procedures to reinforce or repair soft tissue, and are not typically used to promote healing of wounds on the skin. The implantable biologicals that we are proposing to remove for the skin cost group are identified in Table 45 below. Implantable biologicals are treated as packaged surgical supplies under the OPPS, which are captured under 42 CFR 419.2(b)(4).

TABLE 45—PROPOSED IMPLANTABLE BIOLOGICALS FOR REMOVAL FROM SKIN SUBSTITUTE COST GROUP LIST

Proposed CY 2016 HCPCS code	Proposed CY 2016 short descriptor	Proposed CY 2016 status indicator
C9358	SurgiMend, fetal	N
C9360	SurgiMend, neonatal	N
Q4107	Graft Jacket	N
Q4125	Arthroflex	N
Q4130	Strattice TM	N
Q4142	Xcm biologic tiss matrix 1cm	N

Table 46 below shows the CY 2015 high cost/low cost status for each product based on our combined threshold methodology. As noted earlier, we have posted a file on the CMS Web site that provides more information on the high cost/low cost disposition of each product for each threshold methodology. For the CY 2016 OPPS/ASC final rule with comment period, we will update the MUC and PDC threshold amounts using the most recently available CY 2014 claims data and CY 2015 pricing information.

We are proposing that a skin substitute that is assigned to the high cost group in CY 2015 and exceeds either the MUC or PDC in this proposed rule for CY 2016 would be assigned to the high cost group for CY 2016, even if it no longer exceeds the MUC or PDC CY 2016 thresholds based on updated claims data and pricing information used in the CY 2016 final rule with comment period.

TABLE 46—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2016

Proposed CY 2016 HCPCS code	CY 2016 Short descriptor	HCPCS Code dosage	Proposed CY 2016 SI	CY 2015 High/Low status based on weighted MUC	Proposed CY 2016 High/Low status based on proposed weighted MUC	Proposed CY 2016 High/Low status based on proposed weighted PDC
Q4100	Skin Substitute, NOS	N/A	N	Low	Low	Low
Q4102	Oasis Wound Matrix	1 cm^2	N	Low	Low	Low
Q4103	Oasis Burn Matrix	1 cm^2	N	Low	High	High
Q4111	Gammagraft	1 cm^2	N	Low	Low	Low
Q4115	Alloskin	1 cm^2	N	Low	Low	Low
Q4117**	Hyalomatrix	1 cm^2	N	Low	Low	Low
Q4119	Matristem Wound Matrix	1 cm^2	N	Low	Low	Low
Q4120	Matristem Burn Matrix	1 cm^2	N	Low	Low	Low
Q4124	Oasis Tri-layer Wound Matrix	1 cm^2	N	Low	Low	Low
Q4135	Mediskin	1 cm^2	N	Low	Low	Low
Q4136	Ezderm	1 cm^2	N	Low	Low	Low
Q4141	Alloskin ac, 1cm	1 cm^2	N	Low	Low	Low
Q4142	Xcm Biologic Tissue Matrix 1cm	1 cm^2	N	Low	Low	High
Q4143**	Repriza, 1cm	1 cm^2	N	Low	Low	Low
Q4146	Tensix, 1CM	1 cm^2	N	Low	Low	Low
Q4150**	Allowrap DS or Dry 1 sq cm	1 cm^2	N	High	Low	Low
Q4151**	AmnioBand, Guardian 1 sq cm	1 cm^2	N	Low	Low	Low
Q4153**	Dermavest 1 square cm	1 cm^2	N	High	Low	Low
Q4157**	Revitalon 1 square cm	1 cm^2	N	Low	Low	Low
Q4158**	MariGen 1 square cm	1 cm^2	N	Low	Low	Low
Q4159**	Affinity 1 square cm	1 cm^2	N	High	Low	Low
C9349*/**	PuraPly/PuraPly Antimicrobial	1 cm^2	G	High	High	High
C9363	Integra Meshed Bil Wound Mat	1 cm^2	N	High	High	Low
Q4101	Apligraf	1 cm^2	N	High	High	High
Q4104	Integra BMWD	1 cm^2	N	High	Low	Low
Q4105	Integra DRT	1 cm^2	N	High	Low	High
Q4106	Dermagraft	1 cm^2	N	High	High	Low
Q4108	Integra Matrix	1 cm^2	N	High	Low	Low
Q4110	Primatrix	1 cm^2	N	High	High	Low
Q4116	Alloderm	1 cm^2	N	High	Low	High
Q4121*	Theraskin	1 cm^2	G	High	High	High
Q4122**	Dermacell	1 cm^2	N	High	High	High
Q4123	Alloskin	1 cm^2	N	High	Low	High
Q4126	Memoderm/derma/tranz/ Integup	1 cm^2	N	High	High	High
Q4127	Talymed	1 cm^2	N	High	High	High
Q4128	Flexhd/Allopatchhd/Matrixhd	1 cm^2	N	High	High	High
Q4129**	Unite Biomatrix	1 cm^2	N	High	Low	Low
Q4131	Epifix	1 cm^2	N	High	High	High
Q4132	Grafix Core	1 cm^2	N	High	High	High
Q4133	Grafix Prime	1 cm^2	N	High	High	High
Q4134	hMatrix	1 cm^2	N	High	Low	Low
Q4137	Amnioexcel or Biodexcel, 1cm	1 cm^2	N	High	High	Low
Q4138	Biodfence DryFlex, 1cm	1 cm^2	N	High	High	High
Q4140	Biodfence 1cm	1 cm^2	N	High	High	High
Q4147**	Architect ecm, 1cm	1 mg	N	High	High	High
Q4148	Neox 1k, 1cm	1 cm^2	N	High	High	High
Q4152**	Dermapure 1 square cm	1 cm^2	N	High	High	High
Q4154**	Biovance 1 square cm	1 cm^2	N	High	High	High
Q4156**	Neox 100 1 square cm	1 cm^2	N	High	High	High
Q4160**	NuShield 1 square cm	1 cm^2	N	High	High	High

*Pass-through status in CY 2016.
**New HCPCS code. Claims data not available in CY 2014.

d. Proposed Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66776), we began recognizing, for OPPS payment purposes, multiple HCPCS codes reporting different dosages for the same covered Part B drugs or biologicals in order to reduce hospitals' administrative burden by permitting them to report all HCPCS codes for drugs and biologicals. In general, prior to CY 2008, the OPPS recognized for payment only the HCPCS code that described the lowest dosage of a drug or biological. During CYs 2008 and 2009, we applied a policy that assigned the status indicator of the previously recognized HCPCS code to the associated newly recognized code(s), reflecting the packaged or separately payable status of the new code(s).

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believed that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we are proposing to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2016.

For CY 2016, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2014 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for this CY 2016 OPPS/ASC proposed rule and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2014 claims data to make the proposed packaging determinations for these drugs: HCPCS code J3471 (Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)) and HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP+6 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to $100 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than $100 (so that all HCPCS codes for the same drug or biological would be separately payable).

The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2016 is displayed in Table 47 below.

TABLE 47—PROPOSED HCPCS CODES TO WHICH THE CY 2016 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY

Proposed CY 2016 HCPCS code	Proposed CY 2016 long descriptor	Proposed CY 2016 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1070	Injection, testosterone cypionate, up to 100 mg	N
J1080	Injection, testosterone cypionate, 1 cc, 200 mg	N
J1440	Injection, filgrastim (g-csf), 300 mcg	K
J1441	Injection, filgrastim (g-csf), 480 mcg	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	N
J1560	Injection, gamma globulin, intramuscular over 10 cc	N
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J2270	Injection, morphine sulfate, up to 10 mg	N
J2271	Injection, morphine sulfate, 100mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3120	Injection, testosterone enanthate, up to 100 mg	N
J3130	Injection, testosterone enanthate, up to 200 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7050	Infusion, normal saline solution , 250 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7030	Infusion, normal saline solution , 1000 cc	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	K
J8521	Capecitabine, oral, 500 mg	K

TABLE 47—PROPOSED HCPCS CODES TO WHICH THE CY 2016 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY—Continued

Proposed CY 2016 HCPCS code	Proposed CY 2016 long descriptor	Proposed CY 2016 SI
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

3. Proposed Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary. Most physician Part B drugs are paid at ASP+6 percent pursuant to section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.

It has been our longstanding policy to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In this CY 2016 OPPS/ASC proposed rule, we are proposing to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

Since CY 2006, we have attempted to establish a drug payment methodology that reflects hospitals' acquisition costs for drugs and biologicals while taking into account relevant pharmacy overhead and related handling expenses. We have attempted to collect more data on hospital overhead charges for drugs and biologicals by making several proposals that would require hospitals to change the way they report the cost and charges for drugs. None of these proposals were adopted due to significant stakeholder concern, including that hospitals stated that it would be administratively burdensome to report hospital overhead charges. We established a payment policy for separately payable drugs and biologicals, authorized by section 1833(t)(14)(A)(iii)(I) of the Act, based on an ASP+X amount that is calculated by comparing the estimated aggregate cost of separately payable drugs and biologicals in our claims data to the estimated aggregate ASP dollars for separately payable drugs and biologicals, using the ASP as a proxy for average acquisition cost (70 FR 68642 through 68643). We referred to this methodology as our standard drug payment methodology. Taking into consideration comments made by the pharmacy stakeholders and acknowledging the limitations of the reported data due to charge compression and hospitals' reporting practices, we added an ''overhead adjustment'' in CY 2010 (an internal adjustment of the data) by redistributing cost from coded and uncoded packaged drugs and biologicals to separately payable drugs in order to provide more appropriate payments for drugs and biologicals in the HOPD. We continued this methodology, and we further refined it in CY 2012 by finalizing a policy to update the redistribution amount for inflation and to keep the redistribution ratio constant between the proposed rule and the final rule. For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385).

Because of continuing uncertainty about the full cost of pharmacy overhead and acquisition cost, based in large part on the limitations of the submitted hospital charge and claims data for drugs, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386), we indicated our concern that the continued use of the standard drug payment methodology (including the overhead adjustment) still may not appropriately account for average acquisition and pharmacy overhead cost

and, therefore, may result in payment rates that are not as predictable, accurate, or appropriate as they could be. Section 1833(t)(14)(A)(iii)(II) of the Act requires an alternative methodology for determining payment rates for SCODS wherein, if hospital acquisition cost data are not available, payment shall be equal (subject to any adjustment for overhead costs) to payment rates established under the methodology described in section 1842(o), 1847A, or 1847B of the Act. We refer to this alternative methodology as the ''statutory default.'' In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386), we noted that section 1833(t)(14)(A)(iii)(II) of the Act authorizes the Secretary to calculate and adjust, as necessary, the average price for a drug in the year established under section 1842(o), 1847A, or 1847B of the Act, as the case may be, in determining payment for SCODs. Pursuant to sections 1842(o) and 1847A of the Act, Part B drugs are paid at ASP+6 percent when furnished in physicians' offices. We indicated that we believe that establishing the payment rates based on the statutory default of ASP+6 percent is appropriate as it yields increased predictability in payment for separately payable drugs and biologicals under the OPPS and, therefore, we finalized our proposal for CY 2013 to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We also finalized our proposal that the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals, that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payments for these separately paid drugs and biologicals for CY 2013 (77 FR 68389). We continued our final policy of paying the statutory default for both CY 2014 and CY 2015.

b. Proposed CY 2016 Payment Policy

For CY 2016 and subsequent years, we are proposing to continue our CY 2015 policy and pay for separately payable drugs and biologicals at ASP+6 percent pursuant to section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We are proposing that the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals. We also are proposing that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payments for these separately paid drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this proposed rule (available via the Internet on the CMS Web site), which illustrate the proposed CY 2016 payment of ASP+6 percent for separately payable non-pass-through drugs and biologicals and ASP+6 percent for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective April 1, 2015, or WAC, AWP, or mean unit cost from CY 2014 claims data and updated cost report information available for this proposed rule. In general, these published payment rates are not reflective of actual proposed January 2016 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2016 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of 2015 (July 1, 2015 through September 30, 2015) will be used to set the payment rates that are released for the quarter beginning in January 2016 near the end of December 2015. In addition, proposed payment rates for drugs and biologicals in Addenda A and B to this proposed rule for which there was no ASP information available for April 2015 are based on mean unit cost in the available CY 2014 claims data. If ASP information becomes available for payment for the quarter beginning in January 2016, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for this proposed rule (reflecting April 2015 ASP data) that do not have ASP information available for the quarter beginning in January 2016. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2014 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2016 payment purposes and are only illustrative of the proposed CY 2016 OPPS payment methodology using the most recently available information at the time of issuance of this proposed rule.

4. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

Beginning in CY 2010 and continuing for CY 2015, we established a policy to pay for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through separately payable therapeutic radiopharmaceuticals in CY 2016. Therefore, we are proposing for CY 2016 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also are proposing to rely on CY 2014 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information is available. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524).

The proposed CY 2016 payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

5. Proposed Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, is currently produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States would like to eliminate domestic reliance on these reactors, and is promoting the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, and conversion to such production has begun and is expected to be completed within a 3-year time period. We expect this change in the supply source for the radioisotope used for modern medical imaging will introduce new costs into the payment system that are not accounted for in the historical claims data.

Therefore, for CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources. The time period for this additional payment was not to exceed 5 years from January 1, 2013 (77 FR 68321).

We stated in our CY 2013 OPPS/ASC final rule with comment period (77 FR 68316) that our expectation was that the transition to non-HEU sourced Mo-99 would be completed within 4 to 5 years and that there might be a need to make differential payments for a period of 4 to 5 years. We further stated that we would reassess, and propose if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted. As discussed in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66892), we reassessed this payment for CY 2015 and did not identify any new information that would cause us to modify payment. We stated that we were continuing the policy of providing an additional $10 payment for radioisotopes produced by non-HEU sources for CY 2015. We also stated that although we will reassess this policy annually, consistent with the original policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321), we do not anticipate that this additional payment would extend beyond CY 2017.

We have reassessed this payment for CY 2016 and did not identify any new information that would cause us to modify payment. Therefore, for CY 2016, we are proposing to continue to provide an additional $10 payment for radioisotopes produced by non-HEU sources.

6. Proposed Payment for Blood Clotting Factors

For CY 2015, we provided payment for blood clotting factors under the same methodology as other non-pass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (79 FR 66893). That is, for CY 2015, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2015 updated furnishing fee was $0.197 per unit.

For CY 2016, we are proposing to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician office and inpatient hospital setting, and first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we are proposing to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

7. Proposed Payment for Non-Pass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes but Without OPPS Hospital Claims Data

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) did not address the OPPS payment in CY 2005 and subsequent years for drugs, biologicals, and radiopharmaceuticals that have assigned HCPCS codes, but that do not have a reference AWP or approval for payment as pass-through drugs or biologicals. Because there was no statutory provision that dictated payment for such drugs, biologicals, and radiopharmaceuticals in CY 2005, and because we had no hospital claims data to use in establishing a payment rate for them, we investigated several payment options for CY 2005 and discussed them in detail in the CY 2005 OPPS final rule with comment period (69 FR 65797 through 65799).

For CYs 2005 to 2007, we implemented a policy to provide separate payment for new drugs, biologicals, and radiopharmaceuticals with HCPCS codes (specifically those new drug, biological, and radiopharmaceutical HCPCS codes in each of those calendar years that did not crosswalk to predecessor HCPCS codes) but which did not have pass-through status, at a rate that was equivalent to the payment they received in the physician's office setting, established in accordance with the ASP methodology for drugs and biologicals, and based on charges adjusted to cost for radiopharmaceuticals. Beginning in CY 2008 and continuing through CY 2015, we implemented a policy to provide payment for new drugs and biologicals with HCPCS codes (except those that are policy-packaged), but which did not have pass-through status and were without OPPS hospital claims data, at an amount consistent with the final OPPS payment methodology for other separately payable non-pass-through drugs and biologicals for the given year.

For CY 2016, we are proposing to continue this policy and provide payment for new drugs, biologicals, and therapeutic radiopharmaceuticals that do not have pass-through status at

ASP+6 percent, consistent with the proposed CY 2016 payment methodology for other separately payable non-pass-through drugs, biologicals, and therapeutic radiopharmaceuticals, which is proposed to be ASP+6 percent as discussed earlier in this section. We believe this proposed policy would ensure that new nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals would be treated like other drugs, biologicals, and therapeutic radiopharmaceuticals under the OPPS.

For CY 2016, we also are proposing to continue to package payment for all new nonpass-through policy-packaged products (diagnostic radiopharmaceuticals; contrast agents; stress agents; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure) with HCPCS codes but without claims data (those new proposed CY 2016 HCPCS codes that do not replace predecessor HCPCS codes). This is consistent with the CY 2014 final packaging policy for all existing nonpass-through diagnostic radiopharmaceuticals; contrast agents; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in more detail in section II.A.3. of this proposed rule.

In accordance with the OPPS ASP methodology, in the absence of ASP data, for CY 2016 and subsequent years, we are proposing to continue our policy of using the WAC for the product to establish the initial payment rate for new nonpass-through drugs and biologicals with HCPCS codes, but which are without OPPS claims data. However, we note that if the WAC is also unavailable, we would make payment at 95 percent of the product's most recent AWP. We also are proposing to assign status indicator ''K'' (Separately paid nonpass-through drugs and biologicals, including therapeutic radiopharmaceuticals) to HCPCS codes for new drugs and biologicals without OPPS claims data and for which we have not granted pass-through status. With respect to new nonpass-through drugs and biologicals for which we do not have ASP data, we are proposing that once their ASP data become available in later quarterly submissions, their payment rates under the OPPS would be adjusted so that the rates would be based on the ASP methodology and set to the proposed ASP-based amount (proposed for CY 2016 at ASP+6 percent) for items that have not been granted pass-through status. This proposed policy, which utilizes the ASP methodology for new nonpass-through drugs and biologicals with an ASP, is consistent with prior years' policies for these items and would ensure that new nonpass-through drugs and biologicals would be treated like other drugs and biologicals under the OPPS, unless they are granted pass-through status.

Similarly, we are proposing to continue to base the initial payment for new therapeutic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and are without claims data, on the WACs for these products if ASP data for these therapeutic radiopharmaceuticals are not available. If the WACs also are unavailable, we are proposing to make payment for new therapeutic radiopharmaceuticals at 95 percent of the products' most recent AWP because we would not have mean costs from hospital claims data upon which to base payment. As we are proposing with new drugs and biologicals, we are proposing to continue our policy of assigning status indicator ''K'' to HCPCS codes for new therapeutic radiopharmaceuticals without OPPS claims data for which we have not granted pass-through status.

Consistent with other ASP-based payment, for CY 2016, we are proposing to announce any changes to the payment amounts for new drugs and biologicals in the CY 2016 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2016 if later quarter ASP submissions (or more recent WACs or AWPs) indicate that changes to the payment rates for these drugs and biologicals are necessary. The payment rates for new therapeutic radiopharmaceuticals also would be changed accordingly based on later quarter ASP submissions. We note that the new CY 2016 HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals were not available at the time of development of this proposed rule. However, these drugs, biologicals, and therapeutic radiopharmaceuticals will be included in Addendum B to the CY 2016 OPPS/ASC final rule with comment period (which will be available via the Internet on the CMS Web site), where they will be assigned comment indicator ''NI.'' This comment indicator reflects that their interim final OPPS treatment will be open to public comment in the CY 2016 OPPS/ASC final rule with comment period.

There are several nonpass-through drugs and biologicals that were payable in CY 2014 and/or CY 2015 for which we did not have CY 2014 hospital claims data available for this proposed rule and for which there are no other HCPCS codes that describe different doses of the same drug, but which have pricing information available for the ASP methodology. In order to determine the packaging status of these products for CY 2016, we are proposing to continue our policy to calculate an estimate of the per day cost of each of these items by multiplying the payment rate of each product based on ASP+6 percent, similar to other non-pass-through drugs and biologicals paid separately under the OPPS, by an estimated average number of units of each product that would typically be furnished to a patient during 1 day in the hospital outpatient setting. This rationale was first adopted in the CY 2006 OPPS/ASC final rule with comment period (70 FR 68666 through 68667).

We are proposing to package items for which we estimate the per day administration cost to be less than or equal to $100 and to pay separately for items for which we estimate the per day administration cost to be greater than $100 (with the exception of diagnostic radiopharmaceuticals; contrast agents; stress agents; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure, which we are proposing to continue to package regardless of cost) in CY 2016. We also are proposing that the CY 2016 payment for separately payable items without CY 2014 claims data would be ASP+6 percent, similar to payment for other separately payable nonpass-through drugs and biologicals under the OPPS. In accordance with the ASP methodology paid in the physician's office setting, in the absence of ASP data, we are proposing to use the WAC for the product to establish the initial payment rate and, if the WAC is also unavailable, we would make payment at 95 percent of the most recent AWP available. The proposed estimated units per day and status indicators for these items are displayed in Table 48 of this proposed rule.

Finally, there are 33 drugs and biologicals, shown in Table 49 of this proposed rule, that were payable in CY 2014 but for which we lacked CY 2014 claims data and any other pricing information for the ASP methodology for this CY 2016 OPPS/ASC proposed rule. For CY 2010, we finalized a policy

to assign status indicator ''E'' (Not paid by Medicare when submitted on outpatient claims [any outpatient bill type]) whenever we lacked claims data and pricing information and were unable to determine the per day cost of a drug or biological. In addition, we noted that we would provide separate payment for these drugs and biologicals if pricing information reflecting recent sales became available mid-year for the ASP methodology.

For CY 2016, as we finalized in CY 2015 (79 FR 66894), we are proposing to continue to assign status indicator ''E'' to drugs and biologicals that lack CY 2014 claims data and pricing information for the ASP methodology. All drugs and biologicals without CY 2014 hospital claims data or data based on the ASP methodology that are assigned status indicator ''E'' on this basis at the time of this proposed rule for CY 2016 are displayed in Table 49 of this proposed rule. We also are proposing to continue our policy to assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2016 if pricing information becomes available.

TABLE 48—DRUGS AND BIOLOGICALS WITHOUT CY 2014 CLAIMS DATA

Proposed CY 2016 HCPCS code	Proposed CY 2016 long descriptor	Estimated average number of units per day	Proposed CY 2016 SI	Proposed New CY 2016 APC *
90581	Anthrax vaccine, for subcutaneous or intramuscular use	1	N	N/A
C9293	Injection, glucarpidase, 10 units	400	K	9293
J0215	Injection, alefacept, 0.5 mg	29	K	1633
J0630	Injection, calcitonin salmon, up to 400 units	2	K	1433
J0717	Injection, certolizumab pegol, 1 mg	361	K	1474
J1324	Injection, enfuvirtide, 1 mg	169	K	1361
J3355	Injection, urofollitropin, 75 IU	2	K	1741
J3489	Injection, Zoledronic Acid, 1 mg	4	K	1356
J7196	Injection, antithrombin recombinant, 50 IU	268	K	1332
J8650	Nabilone, oral, 1 mg	4	K	1424
J9306	Injection, pertuzumab, 1 mg	450	K	1471
Q2050	Injection, Doxorubicin Hydrochloride, Liposomal, Not Otherwise Specified, 10 mg.	7	K	7046
Q3027	Injection, Interferon Beta-1a, 1 mcg for Intramuscular Use	3	K	1472

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

TABLE 49—DRUGS AND BIOLOGICALS WITHOUT CY 2014 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

Proposed CY 2016 HCPCS code	Proposed CY 2016 long descriptor	Proposed CY 2016 SI
90296	Diphtheria antitoxin, equine, any route	E
90477	Adenovirus vaccine, type 7, live, for oral use	E
90681	Rotavirus vaccine, human, attenuated, 2 dose schedule, live, for oral use	E
90704	Mumps virus vaccine, live, for subcutaneous use	E
90727	Plague vaccine for intramuscular use	E
J0190	Injection, biperiden lactate, per 5 mg	E
J0205	Injection, alglucerase, per 10 units	E
J0350	Injection, anistreplase, per 30 units	E
J0365	Injection, aprotonin, 10,000 kiu	E
J0395	Injection, arbutamine hcl, 1 mg	E
J0710	Injection, cephapirin sodium, up to 1 gm	E
J1180	Injection, dyphylline, up to 500 mg	E
J1435	Injection, estrone, per 1 mg	E
J1452	Injection, fomivirsen sodium, intraocular, 1.65 mg	E
J1562	Injection, immune globulin (vivaglobin), 100 mg	E
J1655	Injection, tinzaparin sodium, 1000 iu	E
J1835	Injection, itraconazole, 50 mg	E
J2513	Injection, pentastarch, 10% solution, 100 ml	E
J2670	Injection, tolazoline hcl, up to 25 mg	E
J2725	Injection, protirelin, per 250 mcg	E
J2940	Injection, somatrem, 1 mg	E
J3320	Injection, spectinomycin dihydrochloride, up to 2 gm	E
J3400	Injection, triflupromazine hcl, up to 20 mg	E
J7191	Factor viii (antihemophilic factor (porcine)), per i.u.	E
J7505	Muromonab-cd3, parenteral, 5 mg	E
J7513	Daclizumab, parenteral, 25 mg	E
J8562	Fludarabine phosphate, oral, 10 mg	E
J9160	Injection, denileukin diftitox, 300 micrograms	E
J9165	Injection, diethylstilbestrol diphosphate, 250 mg	E
J9213	Injection, interferon, alfa-2a, recombinant, 3 million units	E
J9215	Injection, interferon, alfa-n3, (human leukocyte derived), 250,000 iu	E
J9300	Injection, gemtuzumab ozogamicin, 5 mg	E
Q0515	Injection, sermorelin acetate, 1 microgram	E

C. Self-Administered Drugs (SADs) Technical Correction

Sections 1861(s)(2)(A) and (s)(2)(B) of the Act define covered ''medical and other health services'' to include both ''services and supplies'' and ''hospital services'', which both, in turn, include drugs and biologicals not usually self-administered by the patient. Our regulations at 42 CFR 410.29 set forth limitations on payment of drugs and biologicals under Medicare Part B, and capture the description of self-administered drugs noted in sections 1861(s)(2)(A) and (s)(2)(B) of the Act. In our review of § 410.29, which defines exclusions to Medicare Part B payment for drugs and biologicals, we noted that paragraph (a), as currently written, excludes payment for any drug or biological that can be self-administered. We are proposing to make a technical correction that would amend the description of these drugs and biologicals at § 410.29(a) to more appropriately reflect the statutory language. Specifically, we are proposing to delete the phrase ''any drug or biological that can be self-administered'' and replace it with the phrase ''any drug or biological which is usually self-administered by the patient''.

D. Proposed OPPS Payment for Biosimilar Biological Products

1. Background

The Affordable Care Act authorized an abbreviated pathway for the licensing of biosimilar biological products. Under this abbreviated pathway, a proposed biological product that is demonstrated to be biosimilar to a reference product can rely on certain existing scientific knowledge about the safety, purity, and potency of the reference product to support licensure. Section 3139 of the Affordable Care Act amended section 1847A of the Act to add the definition of biosimilar biological product and set forth a payment methodology for biosimilar biological products. In 2010, CMS published regulations for the payment for biosimilar biological products that are administered in a physician's office (75 FR 73393 through 73394). However, at that time, it was not clear how or when the new Food and Drug Administration (FDA) approval pathway would be implemented or when biosimilar products would be approved.

The FDA approved the first biosimilar under the new pathway on March 6, 2015. By the end of 2015, we anticipate that the FDA may approve several more biosimilar biological products, including products that have a common previously licensed reference product. Although we described our Medicare Part B payment policy for biosimilar biological products when administered in the physician office setting in the CY 2011 MPFS final rule with comment period, we did not describe how payment would be made for these products when administered in the hospital outpatient department.

2. Proposed Payment Policy for Biosimilar Biological Products

Section 1833(t)(14)(A)(iii) of the Act defines payment policy for separately covered outpatient drugs (SCODs), and currently, CMS pays for SCODs under the payment methodology set forth at section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). Through rulemaking, CMS adopted this payment methodology to apply to separately payable drugs and biologicals that are not SCODs. Under this authority, the payment rate for SCODs and applicable separately payable drugs and biologicals is determined in accordance with sections 1842(o) and 1847A of the Act, which generally equates to average sales price (ASP) plus 6 percent.

As noted above, the Affordable Care Act amended section 1847A of the Act to add the definition of biosimilar biological product and set forth a payment methodology for biosimilar biological products. Since the statutory authority under section 1833(t)(14)(A)(iii)(II) of the Act authorizes payment in accordance with section 1847A of the Act, and provides additional discretionary authority for such payments to be calculated and adjusted by the Secretary as necessary, we believe that it is reasonable to adopt a policy to pay for biosimilar biological products as provided under section 1847A(b)(8) of the Act. Therefore, we are proposing to extend the application of the methodology for determining the amount of payment applicable to SCODs authorized by section 1833(t)(14)(A)(iii)(II) of the Act, which, through rulemaking, is applicable separately paid drugs and biologicals, to biosimilar biological products provided under the OPPS. This equates to a payment determined under section 1847A of the Act. That is, we are proposing to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act. In addition, we are proposing that nonpass-through biosimilar biological products would be subject to our threshold-packaged policy as described in section V.B.2. of this proposed rule.

Consistent with our established OPPS drug, biological, and radiopharmaceutical payment policy, we are proposing that HCPCS coding and modifiers for biosimilar biological products will be based on policy established under the CY 2016 MPFS rule. Public comments on HCPCS codes and modifiers for biosimilar biological products should be submitted in response to the CY 2016 MPFS proposed rule.

3. Proposed OPPS Transitional Pass-Through Payment Policy for Biosimilar Biological Products

Section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable hospital outpatient department fee schedule amount. Because section 1842(o)(1)(C) of the Act cross references section 1847A of the Act, we believe that it is reasonable to infer that biosimilar biological products are eligible for transitional pass-through payment, and that such payment amount may be set as the difference between the amount paid under section 1842(o) of the Act (that is, the payment allowance of the product determined under section 1847A(b)(8) of the Act) and the otherwise applicable hospital outpatient department fee schedule amount. Therefore, we are proposing to extend pass-through payment eligibility to biosimilar biological products and to establish pass-through payment based on the difference between the amount paid under section 1842(o) of the Act (that is, the payment allowance of the product determined under section 1847A(b)(8) of the Act) and the otherwise applicable hospital outpatient department fee schedule amount.

We are soliciting public comments on our proposed payment policies for biosimilar biological products, including whether biosimilar biological products should be eligible for transitional pass-through payment, and the appropriate methodologies for determining payment for biosimilar biological products eligible for transitional pass-through payment.

VI. Proposed Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an ''applicable percentage,'' currently not

to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate prorata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing an estimate of pass-through spending in CY 2016 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2016. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2015 or beginning in CY 2016. The sum of the CY 2016 pass-through estimates for these two groups of device categories equals the total CY 2016 pass-through spending estimate for device categories with pass-through status. We base the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010 that are surgically inserted or implanted (through a surgical incision or a natural orifice) is the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in this proposed rule, for CY 2016, we are proposing to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 to 66888). Therefore, as we did beginning in CY 2015, for CY 2016, we also are proposing to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. We note that the Part B drug CAP program has been postponed since CY 2009, and such a program has not been proposed to be reinstated for CY 2016. Because, as we are proposing to pay for most non-pass-through separately payable drugs and biologicals under the CY 2016 OPPS at ASP+6 percent, as we discussed in section V.B.3. of this proposed rule, which represents the otherwise applicable fee schedule amount associated with most pass-through drugs and biologicals, and because, as we are proposing to pay for CY 2016 pass-through drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of this proposed rule, our estimate of drug and biological pass-through payment for CY 2016 for this group of items is $0, as discussed below.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through status, will always be packaged into payment for the associated procedures and these products will not be separately paid. In addition, we policy-package all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in section II.A.3. of this proposed rule. We are proposing that all of these policy-packaged drugs and biologicals with pass-through status would be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2016. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through status approved prior to CY 2016 is not $0, as discussed below. In section V.A.4. of this proposed rule, we discuss our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we are proposing to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we are proposing to reduce our estimate of pass-through payments for these drugs or biologicals by this amount.

Similar to pass-through estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2016. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible in the remaining quarters of CY 2015 or beginning in CY 2016. The sum of the proposed CY 2016 pass-through estimates for these two groups of drugs and biologicals equals the proposed total CY 2016 pass-through spending estimate for drugs and biologicals with pass-through status.

B. Proposed Estimate of Pass-Through Spending

We are proposing to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2016, consistent with section 1833(t)(6)(E)(ii)(II) of the Act, and our OPPS policy from CY 2004

through CY 2015 (79 FR 66897 through 66898).

For the first group, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2016, there are three active categories for CY 2016. For CY 2015, we established one new device category subsequent to the publication of the CY 2015 OPPS/ASC proposed rule, HCPCS code C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components), that was effective January 1, 2015. We estimate that HCPCS code C2624 will cost $50.5 million in pass-through expenditures in CY 2016. Effective Apri1 1, 2015, we established that HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) will be eligible for pass-through payment. We estimate that HCPCS code C2623 will cost $73 million in pass-through expenditures in CY 2016. Effective July 1, 2015, we established that HCPCS code C2613 (Lung biopsy plug with delivery system) will be eligible for pass-through payment. We estimate that HCPCS code C2613 will cost $3.3 million in pass-through expenditures in CY 2016. Based on the three device categories of HCPCS codes C2624, C2623, and C2613, we are proposing an estimate for the first group of devices of $126.8 million.

In estimating our proposed CY 2016 pass-through spending for device categories in the second group, we include: Device categories that we knew at the time of the development of this proposed rule will be newly eligible for pass-through payment in CY 2016; additional device categories that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2016; and contingent projections for new device categories established in the second through fourth quarters of CY 2016. We are proposing to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For this proposed rule, the estimate of CY 2016 pass-through spending for this second group of device categories is $10 million.

To estimate proposed CY 2016 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for CY 2016, we are proposing to use the most recent Medicare physician claims data regarding their utilization, information provided in the respective pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or biologicals to project the CY 2016 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2016, we estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-through drugs and biologicals that will be separately paid at ASP+6 percent, which is zero for this group of drugs. Because payment for policy-packaged drugs and biologicals is packaged if the product was not paid separately due to its pass-through status, we are proposing to include in the CY 2016 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment. For this proposed rule, using the proposed methodology described above, we calculated a CY 2016 proposed spending estimate for this first group of drugs and biologicals of approximately $5.2 million.

To estimate proposed CY 2016 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of this proposed rule are newly eligible for pass through payment in CY 2016, additional drugs and biologicals that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2016, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2016), we are proposing to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2016 pass-through payment estimate. We also are proposing to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2016 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $4.6 million.

In summary, in accordance with the methodology described above in this section, for this proposed rule, we estimate that proposed total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2016 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2016 would be approximately $146.6 million (approximately $136.8 million for device categories and approximately $9.8 million for drugs and biologicals), which represents 0.25 percent of total projected OPPS payments for CY 2016. Therefore, we estimate that proposed pass-through spending in CY 2016 would not amount to 2.0 percent of total projected OPPS CY 2016 program spending.

VII. Proposed OPPS Payment for Hospital Outpatient Visits

A. Proposed Payment for Hospital Outpatient Clinic and Emergency Department Visits

Since April 7, 2000, we have instructed hospitals to report facility resources for clinic and emergency department (ED) hospital outpatient visits using the CPT E/M codes and to develop internal hospital guidelines for reporting the appropriate visit level (65 FR 18451). Because a national set of hospital-specific codes and guidelines do not currently exist, we have advised hospitals that each hospital's internal guidelines that determine the levels of clinic and ED visits to be reported should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes.

While many hospitals have advocated for hospital-specific national guidelines for visit billing since the OPPS started in 2000, and we have signaled in past rulemaking our intent to develop

guidelines, this complex undertaking has proven challenging. Our work with interested stakeholders, such as hospital associations, along with a contractor, has confirmed that no single approach could consistently and accurately capture hospitals' relative costs. Public comments received on this issue, as well as our own knowledge of how clinics operate, have led us to conclude that it is not feasible to adopt a set of national guidelines for reporting hospital clinic visits that can accommodate the enormous variety of patient populations and service-mix provided by hospitals of all types and sizes throughout the country. Moreover, no single approach has been broadly endorsed by the stakeholder community.

With respect to outpatient clinic visits, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75045), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) for hospital use only, representing any and all clinic visits under the OPPS, and assigned HCPCS code G0463 to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits (five levels for new patient clinic visits and five levels for established patient clinic visits) previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

With respect to ED visits, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we also stated our policy that we would continue to use our existing methodology to recognize the existing CPT codes for Type A ED visits as well as the five HCPCS codes that apply to Type B ED visits, and to establish the OPPS payment under our established standard process. We refer readers to the CY 2014 OPPS/ASC final rule with comment period for a detailed discussion of the public comments and our rationale for the CY 2014 policies (78 FR 75036 through 75043).

In this proposed rule, for CY 2016, we are proposing to continue the current policy, adopted in CY 2014, for clinic and ED visits. HCPCS code G0463 (for hospital use only) will represent any and all clinic visits under the OPPS. As part of our broader initiative to restructure APCs across the OPPS to collectively group services that are clinically similar and have similar resource costs within the same APC, we are proposing to reassign HCPCS code G0463 from existing APC 0634 to proposed renumbered APC 5012 (Level 2 Examinations and Related Services), former APC 0632. Proposed renumbered APC 5012 includes other services that are clinically similar with similar resource costs to HCPCS code G0463, such as HCPCS code G0402 (Initial preventive physical examination). We are proposing to use CY 2014 claims data to develop the proposed CY 2016 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of HCPCS code G0463, as CY 2014 is the first year for which claims data are available for this code. Finally, as we established in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75042), there is no longer a policy to recognize a distinction between new and established patient clinic visits.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75040), we stated that additional study was needed to fully assess the most suitable payment structure for ED visits, including the particular number of visit levels that would not underrepresent resources required to treat the most complex patients, such as trauma patients, and that we believed it was best to delay any change in ED visit coding while we reevaluate the most appropriate payment structure for Type A and Type B ED visits. At this time, we continue to believe that additional study is needed to assess the most suitable payment structure for ED visits. Therefore, in this CY 2016 OPPS/ASC proposed rule, we are not proposing any change in ED visit coding. Rather, as we did for CY 2015 and prior years, for CY 2016, we are proposing to continue to use our existing methodology to recognize the existing five CPT codes for Type A ED visits as well as the five HCPCS codes that apply to Type B ED visits, and to establish the proposed CY 2016 OPPS payment rates using our established standard process. We may propose changes to the coding and APC assignments for ED visits in future rulemaking.

B. Proposed Payment for Critical Care Services

For the history of the payment policy for critical care services, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043). In the CY 2014 OPPS/ASC final rule with comment period, we continued to use the methodology established in the CY 2011 OPPS/ASC final rule with comment period for calculating a payment rate for critical care services that includes packaged payment of ancillary services, for example electrocardiograms, chest X-rays, and pulse oximetry. Critical care services are described by CPT codes 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) and 99292 (Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)).

Since CY 2013, we have stated that we would continue to monitor the hospital claims data for CPT code 99291 in order to determine whether revisions to our current payment policy for critical care services are warranted based on changes in hospitals' billing practices. Because the CY 2011 through CY 2014 claims data (used for CY 2013 through CY 2016 ratesetting, respectively) do not demonstrate any significant change in hospital billing practices for critical care services, we continue to believe that it would be inappropriate to pay separately for the ancillary services that hospitals typically report in addition to CPT codes for critical care services. Based on this pattern of billing practices, we continue to believe that packaging ancillary services into critical care services is appropriate. Therefore, for CY 2016 and subsequent years, we are proposing to continue our policy (that has been in place since CY 2011) to recognize the existing CPT codes for critical care services and establish a payment rate based on historical claims data. We also are proposing to continue to implement claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment.

C. Proposed Payment for Chronic Care Management Services

In the CY 2015 OPPS/ASC final rule with comment period, we assigned CPT code 99490 to APC 0631 (Level 1 Examinations and Related Services), with a payable status indicator of ''V,'' under general physician supervision. (In this proposed rule, for CY 2016 and subsequent years, we are proposing to renumber APC 0631 as APC 5011.) The current code descriptor for CPT code 99490 is ''Chronic care management services (CCM), at least 20 minutes of clinical staff time directed by a physician or other qualified health care

professional, per calendar month), with the following required elements:

- Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;
- Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; and
- Comprehensive care plan established, implemented, revised, or monitored.''

CPT code 99490 is a physician-directed service, where the physician is directing the clinical staff time spent on care management for a specific patient. As a physician-directed service, payment under the OPPS for CPT code 99490 is made to the hospital when the hospital's clinical staff furnishes the service at the direction of the physician (or other appropriate nonphysician practitioner) who meets all the requirements to bill CPT code 99490 under the MPFS. The billing physician or nonphysician practitioner directing the CCM services must meet the requirements to bill CPT code 99490 under the MPFS. These requirements are the same, regardless of whether the services described by CPT code 99490 are furnished in the office or in the HOPD.

While CPT code 99490 has been payable under the OPPS since January 1, 2015, we have received questions about specific requirements for hospitals to bill this code beyond those requirements discussed in the CY 2015 MPFS final rule with comment period. In response to these questions, we posted frequently asked questions (FAQs) and answers on the CMS Web site on May 8, 2015. These FAQs can be accessed on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/*. In reviewing the questions from hospitals on billing of CCM services, we identified several issues that we believe need to be clarified. Therefore, for CY 2016 and subsequent years, we are proposing additional requirements for hospitals to bill and receive OPPS payment for CPT code 99490. These proposed requirements, discussed below, are in addition to those already required under the OPPS for billing CPT code 99490 in CY 2015.

In accordance with the CPT code descriptor for CPT code 99490, a hospital can only bill CPT code 99490 and receive payment under the OPPS for furnishing clinical staff services under a physician's or other appropriate nonphysician practitioner's direction to a patient that has multiple (two or more) chronic conditions expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. While we have always expected the hospital furnishing the clinical staff portion of CCM services, as described by CPT code 99490, to have an established relationship with the patient and to provide care and treatment to the patient during the course of illness (that is, the chronic conditions that are expected to last at least 12 months), we have not previously specified through notice-and-comment rulemaking that the hospital must have an established relationship with the patient as a requirement for billing and OPPS payment for CPT code 99490. Therefore, for CY 2016 and subsequent years, we are proposing that a hospital would be able to bill CPT code 99490 for CCM services only when furnished to a patient who has been either admitted to the hospital as an inpatient or has been a registered outpatient of the hospital within the last 12 months and for whom the hospital furnished therapeutic services. Section 20.2, Chapter 4 of the Medicare Claims Processing Manual (Pub. 100–04) defines a hospital outpatient as a person who has not been admitted by the hospital as an inpatient but is registered on the hospital records as an outpatient and receives services (other than supplies alone) from the hospital. We believe that hospitals furnishing services described by CPT code 99490 are, in all likelihood, already meeting this requirement as they are providing CCM services described by CPT code 99490 to patients for whom they already provide care and treatment. However, we are proposing to adopt the relationship requirement as an explicit condition for billing and payment of CCM services under the OPPS.

As outlined in the CY 2015 MPFS final rule with comment period (79 FR 67721 through 67722), practitioners furnishing and billing CCM services as described by CPT code 99490 under the MPFS are required to (1) inform the beneficiary about the availability of the CCM services from the practitioner and obtain his or her written agreement to have the service(s) provided; (2) document in the beneficiary's medical record that all elements of the CCM service(s) were explained and offered to the beneficiary, noting the beneficiary's decision to accept or decline the service; and (3) inform the beneficiary that only one practitioner can furnish and be paid for these services during the calendar month service period. For CY 2016 and subsequent years, we are proposing to adopt analogous requirements for billing services described by CPT code 99490 under the OPPS. Specifically, we are proposing, for CY 2016 and subsequent years, that hospitals furnishing and billing services described by CPT code 99490 under the OPPS would be required to have documented in the hospital's medical record the patient's agreement to have the services provided, or alternatively, to have the patient's agreement to have the CCM services provided documented in a beneficiary's medical record that the hospital can access. In addition, for CY 2016 and subsequent years, we are proposing to require hospitals furnishing and billing for the CCM services described by CPT code 99490 under the OPPS to have documented in the hospital medical record (or beneficiary medical record that the hospital can access) that all elements of the CCM services were explained and offered to the beneficiary, including a notation of the beneficiary's decision to accept or decline the services. If the hospital is billing for the CCM services, we would expect the physician or practitioner under whose direction the services are furnished to have discussed with the beneficiary that hospital clinical staff will furnish the services and that the beneficiary could be liable for two separate copayments from both the hospital and physician. Consistent with the MPFS requirement that only one practitioner can furnish and be paid for services described by CPT code 99490 during the calendar month service period, we are proposing, for CY 2016 and subsequent years, that only one hospital can furnish and be paid for services described by CPT code 99490 during the calendar month service period. The physician or other appropriate nonphysician practitioner directing the CCM services should inform the beneficiary that only one hospital can furnish and be paid for these services during the calendar month service period. These proposed requirements are consistent with and support the MPFS requirements set forth in the CY 2015 MPFS final rule with comment period (79 FR 67728).

In addition, a number of scope of service elements for CCM services were finalized as requirements to bill for CCM services described by CPT code 99490 in the CY 2015 MPFS final rule with comment period (79 FR 67715 through 67728). For CY 2016 and subsequent years, we are proposing to require analogous scope of service elements for the CCM services, listed below, to be met in order for hospitals

to bill and receive OPPS payment for furnishing CCM services described by CPT code 99490. Specifically, we are proposing to require a hospital that bills and receives OPPS payment for their clinical staff furnishing CCM services described by CPT code 99490 under the direction of a physician or other appropriate nonphysician practitioner to provide—

- Structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary record. A full list of problems, medications, and medication allergies in the electronic health record (EHR) must inform the care plan, care coordination, and ongoing clinical care.
- Access to care management services 24 hours a day/7 days a week (providing the beneficiary with a means to make timely contact with health care providers to address his or her urgent chronic care needs, regardless of the time of day or day of the week).
- Continuity of care with a designated practitioner or member of the care team with whom the beneficiary is able to get successive routine appointments.
- Care management for chronic conditions, including systematic assessment of the beneficiary's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of beneficiary self-management of medications.
- Documentation of the creation of a patient-centered care plan based on a physical, mental, cognitive, psychosocial, functional, and environmental assessment or reassessment and an inventory of resources and supports (a comprehensive care plan for all health issues). Electronically capture care plan information, make this information available on a 24 hour/7 day a week basis to all practitioners furnishing CCM services, and electronically share, as appropriate, with other practitioners and providers.
- A written or electronic copy of the care plan provided to the beneficiary, and document its provision in the electronic medical record using certified information technology (IT).
- Management of care transitions between and among health care providers and settings, including referrals to other clinicians; follow-up after an emergency department visit; and follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities. Electronic transmission of a clinical summary created using certified health IT to support care transitions.
- Coordination with home- and community-based clinical service providers required to support the patient's psychosocial needs and functional deficits. Communication to and from home- and community-based providers regarding these patient needs must be documented in the patient's medical record.
- Enhanced opportunities for the beneficiary and any caregiver to communicate with the practitioner regarding the beneficiary's care through not only telephone access, but also through the use of secure messaging, internet, or other asynchronous non-face-to-face consultation methods.

Lastly, with respect to the EHR, for CY 2016 and subsequent years, we are proposing to adopt the requirements set forth in the CY 2015 MPFS final rule with comment period (79 FR 67723 through 67724) and detailed below for billing services described by CPT code 99490 under the OPPS. Specifically, for CY 2016 and subsequent years, we are proposing to require the use of EHR technology that has been certified under the ONC Health Information Technology (IT) Certification Program as requisite for hospitals furnishing and receiving payment under the OPPS for the clinical staff portion of CCM services, to ensure that hospitals have adequate capabilities to allow members of the interdisciplinary care team to have timely access to the most updated information informing the care plan. We are proposing, for hospital payment under the OPPS, that the CCM services as described by CPT code 99490 must be furnished using, at a minimum, the edition(s) of certification criteria that is acceptable for purposes of the EHR Incentive Programs as of December 31 of the calendar year preceding each MPFS payment year to meet the following core technology capabilities: Structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary. We also are proposing to require hospitals to use certified IT to fulfill the CCM scope of service requirements whenever the requirements reference a health or medical record. This would ensure that requirements for billing CCM services under the MPFS and OPPS are consistent throughout each MPFS and OPPS payment year, and are automatically updated according to the certification criteria required for the EHR Incentive Programs. For payment for CCM services under the OPPS in CY 2016, this policy would allow hospitals to use EHR technology certified to, at a minimum, the 2014 edition of certification criteria to meet the final core capabilities for CCM services and to fulfill the scope of service requirements for CCM services whenever the requirements reference a health or medical record. The CY 2015 MPFS final rule with comment period (79 FR 67728) includes a detailed table summarizing when certified health IT is required to support the scope of service requirements. We remind stakeholders that, for all electronic sharing of beneficiary information under our final CCM services policies, HIPAA standards apply in the usual manner.

VIII. Proposed Payment for Partial Hospitalization Services

A. Background

Partial hospitalization is an intensive outpatient program of psychiatric services provided to patients as an alternative to inpatient psychiatric care for individuals who have an acute mental illness. Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a partial hospitalization program (PHP) is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC) (as defined in subparagraph (B)), and which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care other than in an individual's home or in an inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a community mental health center for purposes of this benefit.

Section 1833(t)(1)(B)(i) of the Act provides the Secretary with the authority to designate the OPD services to be covered under the OPPS. The Medicare regulations that implement this provision specify, under 42 CFR 419.21, that payments under the OPPS will be made for partial hospitalization

services furnished by CMHCs as well as Medicare Part B services furnished to hospital outpatients designated by the Secretary, which include partial hospitalization services (65 FR 18444 through 18445).

Section 1833(t)(2)(C) of the Act, in pertinent part, requires the Secretary to establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs using data on claims from 1996 and data from the most recent available cost reports. In pertinent part, subparagraph (B) provides that the Secretary may establish groups of covered OPD services, within a classification system developed by the Secretary for covered OPD services, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we have developed the PHP APCs. Section 1833(t)(9)(A) of the Act requires the Secretary to review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

Because a day of care is the unit that defines the structure and scheduling of partial hospitalization services, we established a per diem payment methodology for the PHP APCs, effective for services furnished on or after July 1, 2000 (65 FR 18452 through 18455). Under this methodology, the median per diem costs have been used to calculate the relative payment weights for PHP APCs.

From CY 2003 through CY 2006, the median per diem costs for CMHCs fluctuated significantly from year to year, while the median per diem costs for hospital-based PHPs remained relatively constant. We were concerned that CMHCs may have increased and decreased their charges in response to Medicare payment policies. Therefore, we began efforts to strengthen the PHP benefit through extensive data analysis and policy and payment changes finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). We made two refinements to the methodology for computing the PHP median: The first remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers; and the second refined our methodology for computing the PHP median per diem cost by computing a separate per diem cost for each day rather than for each bill. We refer readers to a complete discussion of these refinements in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676).

In CY 2009, we implemented several regulatory, policy, and payment changes, including a two-tiered payment approach for PHP services under which we paid one amount for days with 3 services under APC 0172 (Level I Partial Hospitalization) and a higher amount for days with 4 or more services under APC 0173 (Level II Partial Hospitalization). We refer readers to section X.B. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68693) for a full discussion of the two-tiered payment system. In addition, for CY 2009, we finalized our policy to deny payment for any PHP claims submitted for days when fewer than 3 units of therapeutic services are provided (73 FR 68694).

Furthermore, for CY 2009, we revised the regulations at 42 CFR 410.43 to codify existing basic PHP patient eligibility criteria and to add a reference to current physician certification requirements under 42 CFR 424.24 to conform our regulations to our longstanding policy (73 FR 68694 through 68695). These changes have helped to strengthen the PHP benefit. We also revised the partial hospitalization benefit to include several coding updates. We refer readers to section X.C.3. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68695 through 68697) for a full discussion of these requirements.

For CY 2010, we retained the two-tiered payment approach for PHP services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based. We used only hospital-based PHP data because we were concerned about further reducing both PHP APC per diem payment rates without knowing the impact of the policy and payment changes we made in CY 2009. Because of the 2-year lag between data collection and rulemaking, the changes we made in CY 2009 were reflected for the first time in the claims data that we used to determine payment rates for the CY 2011 rulemaking (74 FR 60556 through 60559).

In CY 2011, in accordance with section 1301(b) of the Health Care and Education Reconciliation Act of 2010 (HCERA 2010), we amended the description of a PHP in our regulations to specify that a PHP must be a distinct and organized intensive ambulatory treatment program offering less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. In addition, in accordance with section 1301(a) of HCERA 2010, we revised the definition of a CMHC in the regulations to conform to the revised definition now set forth under section 1861(ff)(3)(B) of the Act. We discussed our finalized policies for these two provisions of HCERA 2010 in section X.C. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71990).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we also established four separate PHP APC per diem payment rates, two for CMHCs (for Level I and Level II services) and two for hospital-based PHPs (for Level I and Level II services), based on each provider's own unique data. As stated in the CY 2011 OPPS/ASC proposed rule (75 FR 46300) and the final rule with comment period (75 FR 71991), for CY 2011, using CY 2009 claims data, CMHC costs had significantly decreased again. We attributed the decrease to the lower cost structure of CMHCs compared to hospital-based PHP providers, and not the impact of the CY 2009 policies. CMHCs have a lower cost structure than hospital-based PHP providers, in part, because the data showed that CMHCs generally provide fewer PHP services in a day and use less costly staff than hospital-based PHPs. Therefore, it was inappropriate to continue to treat CMHCs and hospital-based providers in the same manner regarding payment, particularly in light of such disparate differences in costs. We also were concerned that paying hospital-based PHPs at a lower rate than their cost structure reflects could lead to hospital-based PHP closures and possible access problems for Medicare beneficiaries because hospital-based PHPs are located throughout the country and, therefore, offer the widest access to PHP services. Creating the four payment rates (two for CMHCs and two for hospital-based PHPs) based on each provider's data supported continued access to the PHP benefit, while also providing appropriate payment based on the unique cost structures of CMHCs and hospital-based PHPs. In addition, separation of data by provider type was supported by several hospital-based PHP commenters who responded to the CY 2011 OPPS/ASC proposed rule (75 FR 71992).

For CY 2011, we instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates based solely on CMHC data. For CY 2011, under the transition methodology,

CMHC PHP APCs Level I and Level II per diem costs were calculated by taking 50 percent of the difference between the CY 2010 final hospital-based PHP median costs and the CY 2011 final CMHC median costs and then adding that number to the CY 2011 final CMHC median costs. A 2-year transition under this methodology moved us in the direction of our goal, which is to pay appropriately for PHP services based on each provider type's data, while at the same time allowing providers time to adjust their business operations and protect access to care for beneficiaries. We also stated that we would review and analyze the data during the CY 2012 rulemaking cycle and, based on these analyses, we might further refine the payment mechanism. We refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994) for a full discussion.

After publication of the CY 2011 OPPS/ASC final rule with comment period, a CMHC and one of its patients filed an application for a preliminary injunction, challenging the OPPS payment rates for PHP services provided by CMHCs in CY 2011 as adopted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71995). We refer readers to the court case, *Paladin Cmty. Mental Health Ctr.* v. *Sebelius,* 2011 WL 3102049 (W.D.Tex. 2011), *aff'd,* 684 F.3d 527 (5th Cir. 2012) (*Paladin*). The plaintiffs in the *Paladin* case challenged the agency's use of cost data derived from both hospitals and CMHCs in determining the relative payment weights for the OPPS payment rates for PHP services furnished by CMHCs, alleging that section 1833(t)(2)(C) of the Act requires that such relative payment weights be based on cost data derived solely from hospitals. As discussed above, section 1833(t)(2)(C) of the Act requires CMS to establish relative payment weights for covered OPD services (and any groups of such services) based on hospital costs. Numerous courts have held that ''based on'' does not mean ''based exclusively on.'' On July 25, 2011, the District Court dismissed the plaintiffs' complaint and application for a preliminary injunction for lack of subject-matter jurisdiction, which the plaintiffs appealed to the United States Court of Appeals for the Fifth Circuit. On June 15, 2012, the Court of Appeals affirmed the District Court's dismissal for lack of subject-matter jurisdiction and found that the Secretary's payment rate determinations for PHP services are not a facial violation of a clear statutory mandate (*Paladin*, 684 F.3d at 533).

For CY 2012, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74348 through 74352), we determined the relative payment weights for PHP services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for hospital-based PHP services based exclusively on hospital data. The statute is reasonably interpreted to allow the relative payment weights for the OPPS payment rates for PHP services provided by CMHCs to be based solely on CMHC data and relative payment weights for hospital-based PHP services to be based exclusively on hospital data. Section 1833(t)(2)(C) of the Act requires the Secretary to establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on hospital costs. In pertinent part, subparagraph (B) provides that the Secretary may establish groups of covered OPD services so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with subparagraph (B), we developed the PHP APCs, as set forth in § 419.31 of the regulations (65 FR 18446 and 18447; 63 FR 47559 through 47562 and 47567 through 47569). As discussed above, PHP services are grouped into APCs.

Based on section 1833(t)(2)(C) of the Act, we believe that the word ''establish'' can be interpreted as applying to APCs at the inception of the OPPS in 2000 or whenever a new APC is added to the OPPS. In creating the original APC for PHP services (APC 0033), we did ''establish'' the initial relative payment weight for PHP services, provided in both hospital-based and CMHC-based settings, only on the basis of hospital data. Subsequently, from CY 2003 through CY 2008, the relative payment weights for PHP services were based on a combination of hospital and CMHC data. For CY 2009, we established new APCs for PHP services based exclusively on hospital data. Specifically, we adopted a two-tiered APC methodology (in lieu of the original APC 0033) under which CMS paid one rate for days with 3 services (APC 0172) and a different payment rate for days with 4 or more services (APC 0173). These two new APCs were established using only hospital data. For CY 2011, we added two new APCs (APCs 0175 and 0176) for PHP services provided by hospitals and based the relative payment weights for these APCs solely on hospital data. APCs 0172 and 0173 were designated for PHP services provided by CMHCs and were based on a mixture of hospital and CMHC data. As the Secretary argued in the *Paladin* case, the courts have consistently held that the phrase ''based on'' does not mean ''based exclusively on.'' Thus, the relative payment weights for the two APCs for PHP services provided by CMHCs in CY 2011 were ''based on'' hospital data, no less than the relative payment weights for the two APCs for hospital-based PHP services.

Although we used hospital data to establish the relative payment weights for APCs 0033, 0172, 0173, 0175, and 0176 for PHP services, we believe that we have the authority to discontinue the use of hospital data in determining the OPPS relative payment weights for PHP services provided by CMHCs. Other parts of section 1833(t)(2)(C) of the Act make plain that the data source for the relative payment weights is subject to change from one period to another. Section 1833(t)(2)(C) of the Act provides that, in establishing the relative payment weights, the Secretary shall use data on claims from 1996 and use data from the most recent available cost reports. We used 1996 data (in addition to 1997 data) in determining only the original relative payment weights for 2000. In the ensuing calendar year updates, we continually used more recent cost report data.

Moreover, section 1833(t)(9)(A) of the Act requires the Secretary to review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. For purposes of the CY 2012 update, we exercised our authority under section 1833(t)(9)(A) of the Act to change the data source for the relative payment weights for PHP services provided by CMHCs based on new cost data, and other relevant information and factors.

In the CY 2014 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs, on geometric mean costs rather than on the median costs. For CY 2014, we established the four PHP APC per diem payment rates based on geometric mean cost levels calculated using the most recent claims and cost data for each provider type. We refer readers to the CY 2014 OPPS/ASC final rule with comment period for a more detailed discussion (78 FR 75047 through 75050).

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on PHP APC geometric mean per diem costs using the most recent claims and cost data for each provider type.

B. Proposed PHP APC Update for CY 2016

1. Proposed PHP APC Geometric Mean Per Diem Costs

For CY 2016, we are proposing to continue to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. We are proposing to compute proposed CMHC PHP APC geometric mean per diem costs for Level 1 (3 services per day) and Level 2 (4 or more services per day) PHP services using only CY 2014 CMHC claims data and the most recent cost data, and proposed hospital-based PHP APC geometric mean per diem costs for Level 1 and Level 2 PHP services using only CY 2014 hospital-based PHP claims data and the most recent cost data. These proposed geometric mean per diem costs are shown in Tables 50 and 51 of this proposed rule. To prevent confusion, we refer to the per diem information listed in Tables 50 and 51 of this proposed rule as the proposed PHP APC per diem costs or the proposed PHP APC geometric mean per diem costs, and the per diem information listed in Addendum A to this proposed rule as the proposed PHP APC per diem payment rates or the proposed PHP APC geometric mean per diem payment rates. The PHP APC per diem costs are the provider-specific costs derived from the most recent claims and cost data. The PHP APC per diem payment rates are the national unadjusted payment rates calculated after applying the OPPS budget neutrality adjustments described in sections II.A.4. and II.B. of this proposed rule.

As part of the effort to increase the accuracy of the PHP per diem costs, we completed an extensive analysis of the claims and cost data, which included provider service usage, coding practices, and the ratesetting methodology. As part of our analysis, we also identified aberrant data from several providers that are impacting the calculation of the proposed PHP geometric mean per diem costs. Aberrant data are claims and/or cost data that are so abnormal that they skew the resulting geometric mean per diem costs. For example, we found claims with excessive CMHC charges resulting in CMHC geometric mean costs per day that are approximately the same as or more than the daily payment for inpatient psychiatric facility services. For an outpatient program like PHP, because it does not incur room and board costs such as an inpatient stay would, these costs per day are excessive. In addition, we found some CMHCs had very low costs per day (less than $25 per day). Without using a trimming process, the data from these providers will inappropriately skew the geometric mean per diem cost for Level 2 CMHC PHP services. Without the trim, the CMHC PHP APC geometric mean per diem cost is $172.62 for Level 2 services, which significantly diverges from the median cost per day of $148.14. When data are not skewed and are normally distributed, measures of central tendency such as the median and geometric mean will be very similar to each other. The differences between these two measures suggest skewing, and as previously noted, examination of the data confirmed that there are a few providers with extreme cost per day values. Level 1 CMHC geometric mean per diem costs were $103.10 before any trim is performed. Our proposed trim on total CMHC costs per day is performed before stratifying the data by payment tiers (Level 1 and Level 2 CMHC PHP services), and would affect both CMHC payment tiers.

During our claims and cost data analysis, we also found aberrant data from some hospital-based PHP providers. Nearly all hospital-based PHPs recorded their costs using cost center 9000 (''Clinic'') as the source for the CCR for individual or group therapy services, psychiatric testing, and education/training services. These services comprise the majority of the PHP services provided. The existing OPPS ±3 standard deviation trim removed very extreme CCRs for cost center 9000, which were less than 0.0206 or greater than 28.3446, by defaulting two providers that failed this trim to their overall hospital ancillary CCR. However, the calculation of the ±3 standard deviations used to define the trim for cost center 9000 was influenced by these two providers, which had very extreme CCRs of 178.0224 and 272.4451. Because these two hospital-based PHP providers remained in the data when we calculated the boundaries of the OPPS ±3 standard deviation trim, the upper limit of the trim boundaries was fairly high, at 28.3446. As such, some aberrant CCRs for cost center 9000 were not trimmed out, and still had high values ranging from 6.3840 to 19.996. We note in section II.D. of this proposed rule that OPPS defines a biased CCR as one that falls outside the predetermined ceiling threshold for a valid CCR; using CY 2014 cost report data, that threshold is 1.5. The hospital CCR ceiling thresholds or upper limits are available online at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files-Items/2015-Annual-Policy-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*.

We are concerned that including aberrant data in the calculation of the proposed hospital-based PHP per diem payment rates would inappropriately skew these payment rates. When we included these aberrant CCRs, which ranged from 6.3840 to 19.996, in hospital-based PHP cost modeling, the geometric mean per diem costs were $267.04 for Level 1 services and $223.39 for Level 2 services. We note that the geometric mean per diem cost of the hospital-based PHP Level 1 APC was greater than that of the hospital-based PHP Level 2 APC, despite fewer services being provided. This occurred because a relatively higher share of high-CCR service days was reported for hospital-based PHP Level 1 services compared to hospital-based PHP Level 2 services. Due to the low volume of hospital-based PHP Level 1 services, the effect of the high-CCR service days on the resulting proposed geometric mean per diem costs is relatively greater than the effect of the high-CCR service days on the resulting proposed Level 2 geometric mean per diem costs. As such, the hospital-based Level 1 PHP APC geometric mean per diem costs are higher than the proposed geometric mean per diem costs for the hospital-based Level 2 PHP APC.

In order to reduce or eliminate the impact of including aberrant data received from a few CMHCs and hospital-based PHP providers in the claims data used for ratesetting, we are proposing to use a ±2 standard deviation trim for CMHCs and to apply a CCR greater than five (CCR>5) hospital service day trim for hospital-based PHP providers for CY 2016 and subsequent years.

Under the ±2 standard deviation trim proposal, we would exclude any CMHC when the CMHC's cost per day is more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. For example, based on our CY 2014 claims data used for CY 2016 ratesetting, the geometric mean cost per day for all CMHCs before trimming is $168.16. Using the ± 2 standard deviation trim, three providers with geometric mean costs per day ranging

from as low as $23.50 to as high as $996.71 were excluded from the ratesetting for CY 2016. Excluding providers with extremely low or extremely high costs per day protects CMHCs from having those extreme costs per day inappropriately skew the CMHC PHP APC geometric mean per diem costs. In addition, we are proposing to use a ±2 standard deviation trim because, when we used this methodology, it aligned the geometric mean and median per diem costs for the CMHC Level 2 PHP APC payment tier, which also indicates that the trim removed the skewing in the data caused by the inclusion of aberrant data received from the three providers. We believe that the ±2 standard deviation trim would exclude CMHCs with aberrant data from the ratesetting process while allowing for the use of as much data as possible. In addition, implementing a ±2 standard deviation trim on CMHCs would target these aberrancies without limiting overall per diem cost increases. A ±2 standard deviation trim also is an accepted statistical approach for objectively mitigating extreme data. For normally distributed data, ±2 standard deviations from the mean capture approximately 95 percent of the data.

We are proposing to apply the ±2 standard deviation trim to the geometric mean cost per day at the CMHC level. This application would exclude those CMHCs with costs per day ±2 standard deviations from the geometric mean cost per day for all CMHCs. Under this proposal, three CMHCs with aberrant data would be removed from the ratesetting calculations. The exclusion of these three CMHCs removed from modeling 2,296 CMHC claims out of 25,383 total CMHC claims, in order to prevent inappropriate fluctuations in the payment rates. The resulting CMHC Level 2 PHP APC geometric mean per diem costs would be $147.51. The CMHC Level 1 PHP APC geometric mean per diem costs actually increased slightly when the trim was applied, from $103.10 to $105.82.

We determined that proposing to use a higher trim level, such as ±2.5 or ±3 standard deviations from the geometric mean, did not reduce the skewing caused by the inclusion of data from a few CMHC providers. In other words, using a higher trim level did not remove the CMHCs with aberrant data from the ratesetting process. Further, we believe that using a trim level lower than ±2 standard deviations would remove too much data. If a data distribution is approximately normally distributed, approximately 68 percent of the data fall within ±1 standard deviation of the mean, and approximately 95 percent of the data fall within ±2 standard deviations of the mean. Our goal was to remove outliers while using as much of the CMHC data as possible.

We did not consider the CCR >5 service day trim for CMHCs, because longstanding PHP OPPS methodology defaults any CMHC CCR >1 to the statewide hospital ancillary CCR (we refer readers to the following section for a review of the PHP OPPS ratesetting methodology). Hospital statewide CCRs have been less than 1 and are available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files-Items/2015-Annual-Policy-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*. In our CY 2016 ratesetting process, we identified only one CMHC that had a CCR >1. That CMHC's CCR was 1.019, and was defaulted to its appropriate hospital statewide CCR for CY 2016 ratesetting purposes.

We considered applying the ±2 standard deviation trim to hospital-based PHP providers as well. However, the ±2 standard deviation trim would have removed 25 hospital-based PHP providers with aberrant data out of 387 hospital-based PHP providers. We were concerned about removing data from that many providers, and sought an alternative that allowed for use of more of the data. Therefore, we are proposing a trim on CCRs, which we believe would be more effective in removing aberrant data and allowing the use or retention of more data. Trims on hospital and CMHC CCRs are already used with the OPPS system, but due to the two very extreme outlier CCRs for cost center 9000 previously mentioned, the OPPS ±3 standard deviation trim on hospital cost center 9000 CCRs had a higher upper limit than usual, and therefore did not trim all the claims with aberrant CCRs. As such, claims with aberrant data remain for some hospital-based PHPs. Therefore, for hospital-based PHPs, we are proposing to apply a trim on hospital service days when the CCR is greater than five (CCR>5) at the cost center level.

Under our proposal, the CCR>5 hospital service day trim would remove hospital-based PHP service days that use a CCR>5 to calculate costs for at least one of their component services. Unlike the ±2 standard deviation trim, which excludes CMHC providers that fail the trim, the CCR>5 trim would exclude any hospital-based PHP service day where any of the services on that day are associated with a CCR > 5. For example, assume a hospital-based PHP had a claim with a service day with one individual therapy service, two group therapy services, and one occupational therapy service. Assume that the hospital-based PHP's cost center CCRs associated with these services were 0.6, 0.6, 0.6, and 6.7, respectively. Because the CCR associated with the occupational therapy service is greater than 5, this particular day, and all other days for this provider where occupational therapy services were provided, would be excluded from the data used in ratesetting. Applying this trim removed service days from seven hospital-based PHP providers. After applying the CCR>5 trim, the Level 1 hospital-based PHP APC geometric mean per diem cost changed from $267.04 to $195.73, and the Level 2 hospital-based PHP geometric mean per diem cost changed from $223.39 to $218.93. As expected, without including the aberrant CCR service days in the data used to calculate the proposed hospital-based PHP APC geometric mean per diem costs, the Level 1 hospital-based PHP APC geometric mean per diem cost is less than the Level 2 hospital-based PHP APC geometric mean per diem cost.

As an alternative to these proposals for CMHCs and hospital-based PHPs, we considered proposing a 15-percent cap on changes in the geometric mean per diem costs. This cap would limit the increase or the decrease in the geometric mean per diem costs from one year to the next by capping the change at 15 percent. This cap also would protect providers from fluctuations in PHP APC per diem payment rates due to large increases or declines in the geometric mean per diem costs. However, we are not proposing this alternative because we believe that establishing such a cap would not specifically target aberrant data from a minority of providers, which is the purpose of our proposals.

Targeting aberrant data is important in order to help stabilize the PHP APC geometric mean per diem costs for both CMHCs and hospital-based PHP services. As we receive updated claims and cost files, and as we continue analyzing PHP data, it is possible that the PHP trims that we are proposing may need refinement. We would propose any changes to the methodology that we finalize later this year through future notice-and-comment rulemaking.

Therefore, for CY 2016 and subsequent years, we are proposing to exclude any CMHC when the CMHC's costs per day are more than ±2 standard deviations from the geometric mean cost per day for all CMHCs (Level 1 and Level 2), and to exclude hospital-based PHP service days when a CCR>5 is used

to calculate costs for at least one of their component services (Level 1 and Level 2).

The CY 2016 proposed PHP APC geometric mean per diem costs for CMHCs calculated under the proposed CY 2016 methodology using CY 2014 claims data and the most recent cost data are $105.82 for Level 1 (3 services per day) CMHC PHP services, and are $147.51 for Level 2 (4 or more services per day) CMHC PHP services.

The CY 2016 proposed PHP APC geometric mean per diem costs for hospital-based PHPs calculated under the proposed CY 2016 methodology using CY 2014 claims data and the most recent cost report data are $195.73 for Level 1 (3 services per day) hospital-based PHP services, and are $218.93 for Level 2 (4 or more services per day) hospital-based PHP services.

We recognize that several factors may cause a fluctuation in the PHP APC per diem payment rates, including direct changes to the PHP APC per diem costs (for example, establishing separate APCs and associated per diem payment rates for CMHCs and hospital-based providers based on the provider type's costs), changes to the OPPS (for example, basing the relative payment weights on geometric mean costs), and provider-driven changes (for example, a provider's decision to change its mix of services or to change its charges and clinical practice for some services). We refer readers to a more complete discussion of this issue in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75049).

The proposed CY 2016 PHP APC geometric mean per diem costs for the CMHC and hospital-based PHP APCs are shown in Tables 50 and 51 of this proposed rule. We note that Tables 50 and 51 below display the proposed PHP APC renumbering that is part of the proposed reorganization of OPPS APCs described in section III.D. of this proposed rule. Specifically, we are proposing to renumber the four PHP APCs, that is, APCs 0172, 0173, 0175, and 0176, as APCs 5851, 5852, 5861, and 5862, respectively. As noted earlier in this section, we refer readers to Addendum A to this proposed rule (which is available via the Internet on the CMS Web site) for the proposed PHP APC payment rates.

TABLE 50—PROPOSED CY 2016 PHP APC GEOMETRIC MEAN PER DIEM COSTS FOR CMHC PHP SERVICES

Proposed renumbered CY 2016 APC	Group title	Proposed PHP APC geometric mean per diem costs
5851	Level 1 Partial Hospitalization (3 services) for CMHCs	$105.82
5852	Level 2 Partial Hospitalization (4 or more services) for CMHCs	147.51

TABLE 51—PROPOSED CY 2016 PHP APC GEOMETRIC MEAN PER DIEM COSTS FOR HOSPITAL-BASED PHP SERVICES

Proposed renumbered CY 2016 APC	Group title	Proposed PHP APC geometric mean per diem costs
5861	Level 1 Partial Hospitalization (3 services) for hospital-based PHPs	$195.73
5862	Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs	218.93

We are inviting public comments on these proposals.

2. PHP Ratesetting Process

While the PHP is part of the OPPS, PHP ratesetting has some unique aspects. To foster understanding and transparency, we are providing the following detailed explanation of the PHP APC ratesetting process. The OPPS ratesetting process includes various steps as part of its data development process, such as CCR determination and calculation of geometric mean per diem costs, identification of allowable charges, development of the APC relative payment weights, calculation of the APC payment rates, and establishment of outlier thresholds. We refer readers to section II. of this proposed rule and encourage readers to review these discussions to increase their overall understanding of the entire OPPS ratesetting process. We also refer readers to the OPPS Claims Accounting narrative, which is a supporting document to this proposed rule available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html;* click on the link to this proposed rule to find the Claims Accounting narrative. We encourage CMHCs and hospital-based PHPs to review their accounting and billing processes to ensure that they are following these procedures, which should result in greater accuracy in setting the PHP rates.

We limit our discussion here primarily to the data development process and calculation of PHP APC geometric mean per diem costs used for PHP ratesetting. Our discussions focus on five major phases in modeling the data, which result in the development of PHP APC geometric mean per diem costs, and on the importance of correct coding and reasonable charges for PHPs, and include: (a) Development of PHP claims; (b) determination of CCRs for CMHCs and hospital-based PHPs; (c) identification of PHP allowable charges; (d) determination of PHP APC per diem costs; (e) development of service days and cost modeling; and (f) issues regarding correct coding and reasonable charges.

a. Development of PHP Claims

We use outpatient claims from the national claims history file for the most recent available calendar year that were processed through December 31 of that year (that is, the calendar year that is 2 years before the calendar year at issue) to calculate the geometric mean costs of APCs that underpin the relative payment weights for the calendar year at issue. It is important to note that this is not the population of claims paid under the OPPS, but all outpatient claims as

explained in further detail in section II.A.2.a. of this proposed rule.

We then exclude the following claims from OPPS ratesetting. These are claims where:

- No payment is made;
- There are more than 300 lines; or
- Services were furnished in Maryland, Guam, the U.S. Virgin Islands, American Samoa, or the Northern Mariana Islands (these providers are not paid under the OPPS).

From these outpatient claims, we extract all hospital outpatient PHP claims and all CMHC claims. PHP claims are extracted based on their specific bill types: 12X or 13X, with condition code 41, for hospital-based PHPs; and 76X for CMHCs. For example, for this proposed rule, we used data from the CY 2014 hospital outpatient PHP and CMHC PHP claims from the national claims history file that were processed through December 31, 2014, to calculate the PHP APC geometric mean per diem costs that underpin the proposed PHP APC relative payment weights for CY 2016.

As noted in section II.A.2.c. of this proposed rule and in the Claims Accounting narrative, we exclude hospital-based PHP claims if—

- They were submitted by critical access hospitals;
- They reported obviously erroneous units (for example, more than 100,000 units for a single service);
- They reported charge amounts equal to the payment received;
- They did not report at least one HCPCS code, because OPPS APCs are based upon HCPCS codes; or
- They only contained flu or pneumonia vaccine services, which are paid separately outside of OPPS.

At the end of this process, we have identified the PHP claims that are appropriate and available to use to calculate PHP APC geometric mean per diem costs. These claims include dates of service, revenue codes, HCPCS codes for services provided, charges, and the payments Medicare made (the PHP APC per diem rates).

b. Determination of CCRs for CMHCs and Hospital-Based PHPs

Next, we determine and assess each provider's CCR. This ratio, along with the charges from the claims, is used to estimate the costs, which are then used to determine the geometric mean per diem costs. There are specific policies we follow in determining which CCR to use in estimating costs, which differ for CMHCs and for hospital-based PHPs, largely due to differences in the cost reports for these two types of PHPs. PHPs should review section II.A.1.c. of this proposed rule and section 10.11, Chapter 4, of the Medicare Claims Processing Manual (internet-only manual (IOM), Pub. 100–04), which is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf*) for more specific discussion of CCRs used in PHP ratesetting.

(1) Calculation and Assessment of CMHC CCRs

As noted in section VIII.A. of this proposed rule and section 10.11.9, Chapter 4 of the Medicare Claims Processing Manual (Pub. 100–04), the CMHC CCR is calculated using the provider's most recent full year cost report, Form CMS 2088–92, and Medicare cost and charges from Worksheet C, Page 2. We divide costs from line 39.01, Column 3 by charges from line 39.02, Column 3 to calculate an overall CMHC CCR. The CMHC cost report forms and cost reporting instructions are available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.html?DLPage=1&DLSort=0&DLSortDir=ascending*.

The most recent CMHC CCRs are posted to the Outpatient Provider Specific File (OPSF). We assess those CMHC CCRs within that file in preparation for use in cost estimation in the following manner:

- We use the most recent CMHC-specific CCR from the OPSF. If the CCR is not available (for example, the CMHC is a new provider with less than 12 months data), we use the hospital ancillary CCR associated with the provider's urban/rural designation and their state location. The statewide urban and rural hospital CCRs are available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html*.
- As described in Section 10.11.9, Chapter 4, of the Medicare Claims Processing Manual, for any CMHC with a CCR greater than 1, we use the hospital ancillary CCR associated with its urban/rural designation and its State location.

Once we have a CCR for each CMHC, we calculate the geometric mean of all CMHC CCRs. As described in the OPPS Claims Accounting narrative, we apply the OPPS ±3 standard deviation trim to the CMHC CCRs; this trim excludes any CMHC with a CCR that is ±3 standard deviations from the geometric mean of all CMHC CCRs. At the end of this process, we have identified a CCR for all CMHCs that have not been excluded.

(2) Calculation and Assessment of Hospital-Based PHP CCRs

Unlike CMHCs where there is one CCR calculated for each CMHC, hospital-based PHPs have CCRs for each cost center that is associated with PHP services. For hospital-based PHPs, we use the provider's most recent full year hospital cost report, whether tentatively settled or final settled, to identify CCRs, using the Healthcare Provider Cost Report Information System (HCRIS) file. The CCRs for hospital-based PHPs are calculated by cost center on hospital cost report Worksheet C, Part I, Column 9. The overall hospital CCR is calculated by the MAC, and is posted in the Provider-Specific File. The hospital cost report form CMS–2552–10 and cost reporting instructions are in Chapter 40 of the Provider Reimbursement Manual—Part 2, which is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.html?DLPage=1&DLSort=0&DLSortDir=ascending*.

We assess the hospital-based PHP CCRs as described in section II.A.2.a. of this proposed rule and in the OPPS Claims Accounting narrative, by applying the OPPS ±3 standard deviation trim to hospital-based PHP CCRs within each cost center and to the overall hospital ancillary CCR. To perform this ±3 standard deviation trim, we follow the following process. Each PHP revenue code is associated with particular cost centers on the cost report. The revenue-to-cost-center crosswalk identifies the primary, secondary (if any), and tertiary (if any) cost centers that are associated with each PHP revenue code, and which are the source for the CCRs used in PHP ratesetting. The PHP portion of that OPPS crosswalk is shown in Table 52 below. Based on the revenue code, we first look for a CCR calculated from the primary cost center; if none exists or the CCR fails the ±3 standard deviation trim, we look for a CCR calculated from the secondary cost center. If there is no CCR calculated from the secondary cost center or the CCR fails the ±3 standard deviation trim, we look for a CCR calculated from the tertiary cost center. If there is no CCR calculated from the tertiary cost center or the CCR fails the ±3 standard deviation trim, we look to the hospital's overall ancillary CCR. If the hospital's overall ancillary CCR fails the ±3 standard deviation trim, we exclude the hospital's claims data from ratesetting.

For example, for revenue code 900, the primary cost center is 3550 ''Psychiatric/Psychological Services.'' If the CCR associated with this cost center passes the ±3 standard deviation trim, we retain that CCR for use in ratesetting. If the CCR associated with primary cost center 3550 fails the trim, it is deleted, and we then move to cost center 9000 ''Clinic'' to assess the provider's CCR. If that CCR passes the ±3 standard deviation trim, it is retained for use in ratesetting. If the CCR fails the ±3 standard deviation trim, it is deleted, and we then would consider the CCR calculated from the tertiary cost center. However, for revenue code 900, there is no tertiary cost center. If the primary, secondary (if any), and tertiary (if any) cost centers' CCRs fail the trim, we assess the hospital's overall ancillary CCR. If that overall ancillary CCR passes the ±3 standard deviation trim, we retain it for use in ratesetting. If the overall ancillary CCR fails the ±3 standard deviation trim, we exclude the provider from ratesetting. This process of assessing the CCRs with a ±3 standard deviation trim is repeated for each revenue code's associated cost centers. After applying this ±3 standard deviation trim, we obtain a file with trimmed CCRs for use in ratesetting.

The revenue-to-cost center crosswalk for all services paid under the OPPS is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html*. We are providing an excerpt of the PHP portion of the OPPS crosswalk below.

TABLE 52—REVENUE-TO-COST CENTER CROSSWALK FOR PHP ALLOWABLE REVENUE CODES

Revenue code	Description	Primary cost center source for CCR	Primary cost center name	Secondary cost center source for CCR	Secondary cost center name
0250	Pharmacy	7300	Drugs Charged to Patients.		
0430	Occupational Therapy	6700	Occupational Therapy		
0900, 0914, 0915, 0916, or 0918.	Psychiatric/Psychological Treatment: Individual, Group, and Family Therapy; Psychological testing.	3550	Psychiatric/Psychological Services.	9000	Clinic.
0904 *	Psychiatric/Psychological Treatment: Activity Therapy.	3580	Recreational Therapy	3550	Psychiatric/Psychological Services.
0942	Other Therapeutic Services: Education/Training.	9000	Clinic		

* Although not listed in this table, revenue code 0904 is the only PHP revenue code with a tertiary cost center serving as a source for the CCR, which is cost center 9000, ''Clinic.''

c. Identification of PHP Allowable Charges

We use the PHP claims derived under the methodology discussed in section VIII.B.2.a. of this proposed rule to identify which charges are allowable for PHP ratesetting. Each revenue code line on the PHP claim must report a HCPCS code and a charge (except for revenue code 0250, which only requires that the charge be reported). Allowable charges are those charges for the HCPCS codes which are associated with PHP allowable revenue codes; PHP allowable revenue codes are revenue codes allowable for OPPS PHP ratesetting purposes. As discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68412 to 68418), we updated the PHP allowable revenue codes and PHP allowable HCPCS codes for CY 2013 and subsequent years. They are included in Section 260, Chapter 4, of the Medicare Claims Processing Manual (IOM Pub. 100–04), which is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf*) and are shown in Table 53 below:

TABLE 53—PHP ALLOWABLE REVENUE AND HCPCS CODES

Revenue code	Description	HCPCS code
0250	Drugs and Biologicals	Not required.
043X	Occupational Therapy	G0129.
0900	Behavioral Health Treatment/Services	90791 or 90792.
0904	Activity Therapy (Partial Hospitalization)	G0176.
0914	Individual Psychotherapy	90785, 90832, 90833, 90834, 90836, 90837, 90838, 90845, 90865, or 90880.
0915	Group Therapy	G0410 or G0411.
0916	Family Psychotherapy	90846 or 90847.
0918	Psychiatric Testing	96101, 96102, 96103, 96116, 96118, 96119, or 96120.
0942	Education Training	G0177.

The HCPCS codes shown in Table 53 above are those which are used in the four PHP APCs (existing APCs 0172, 0173, 0175, 0176, which are proposed to be renumbered APCs 5851, 5852, 5861, and 5862, respectively), and are also shown in Appendix C–a and Appendix P of the Integrated Outpatient Code Editor (IOCE) Specifications. As described in section III.D. of this proposed rule, we are proposing to renumber some of the OPPS APCs, and have shown both the proposed renumbered APCs and the existing APCs for partial hospitalization services above. The IOCE is available on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/OutpatientCodeEdit/OCEQtrReleaseSpecs.html*.

d. Determination of PHP APC Per Diem Costs

The PHP CCRs described in section VIII.B.2.b. of this proposed rule are applied to the PHP claim charges described in section VIII.B.2.c. of this proposed rule to determine the PHP APC geometric mean per diem costs. Costs for each service line reported on CMHC claims are calculated by multiplying each service line charge by the CCR associated with the claim's provider. Costs for each service line reported on the hospital-based PHP claims are calculated by multiplying the service line charge by the CCR associated with the provider's service line's revenue code (using the revenue-to-cost center crosswalk hierarchy described in section VIII.B.2.b. of this proposed rule). For both CMHCs and hospital-based PHPs, charges are set to zero for services reporting revenue codes which are not included in the listing of PHP allowable revenue codes shown in Table 53 above.

e. Development of Service Days and Cost Modeling

Only the claims service lines containing PHP allowable HCPCS codes (shown in Table 53 above) from the remaining hospital-based PHP and CMHC claims are retained for PHP cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed to calculate the PHP APC geometric mean per diem cost, per diem payment, and per diem service volume for each PHP service day. Any service days with zero per diem payments are removed.

Because the PHP costs calculated above include the effects of geographic variation in wages, we use the wage index and county data to wage neutralize PHP APC per diem costs prior to the APC geometric mean per diem cost calculation. This removes the effects of geographic variation in costs used in the OPPS APC ratesetting process. Service days with no per diem costs or with no wage index values are removed. PHP service days with fewer than 3 service units are deleted and not considered for PHP cost modeling.

As discussed in section VIII.B.1. of this proposed rule, there were several PHP providers with aberrant data. As such, we are proposing to exclude CMHCs that have a per diem cost that is ±2 standard deviations from the overall CMHC geometric mean per diem cost, beginning in CY 2016. If implemented as proposed, this trim would exclude from the ratesetting process any CMHCs with extreme costs per day. We also are proposing to exclude service days with extreme hospital-based PHP CCR values which were not removed by the ±3 standard deviation trim discussed above, if those service days have a CCR>5, beginning in CY 2016. Therefore, if our proposal is implemented, we would exclude hospital-based PHP service days where the CCR>5.

PHP service days from CMHCs and from hospital-based PHPs with exactly 3 service units, or with 4 or more service units (based on allowable HCPCS codes shown in Table 53) are assigned to Level 1 or Level 2 PHP APCs as follows: (We note that we are proposing to renumber some of the OPPS APCs, and are showing both the proposed renumbered APCs and the existing APCs for partial hospitalization services below.)

- Level 1 Partial Hospitalization, proposed renumbered APC 5851 (existing APC 0172): CMHC service days with exactly 3 service units;
- Level 2 Partial Hospitalization, proposed renumbered APC 5852 (existing APC 0173): CMHC service days with 4 or more service units;
- Level 1 Partial Hospitalization, proposed renumbered APC 5861 (existing APC 0175): Hospital-based PHP service days with exactly 3 service units; and
- Level 2 Partial Hospitalization, proposed renumbered APC 5862 (existing APC 0176): Hospital-based PHP service days with 4 or more service units.

PHP service days with costs ±3 standard deviations from the geometric mean costs within each APC are deleted and removed from modeling. The remaining PHP service days are used to calculate the geometric mean per diem cost for each PHP APC.

These PHP APC geometric mean per diem costs undergo several more steps, as noted below, before becoming budget neutral PHP APC per diem payment rates. The PHP APCs are part of the larger OPPS. As proposed in section II.A. of this proposed rule, OPPS APC geometric mean per diem costs (including PHP APC geometric mean per diem costs) would be divided by the geometric mean per diem costs for proposed renumbered APC 5012 (Level 2 Examinations and Related Services) to calculate each PHP APC's unscaled relative payment weight. An unscaled relative payment weight is one that is not yet adjusted for budget neutrality. Budget neutrality is required under section 1833(t)(9)(B) of the Act, and ensures that the estimated aggregate weight under the OPPS for a calendar year is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To adjust for budget neutrality (that is, to scale the weights), we compare the estimated aggregated weight using the scaled relative payment weights from the previous calendar year at issue. For example, to adjust for budget neutrality (that is, to scale the weights) in this proposed rule, we compared the estimated aggregated weight using the CY 2015 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2016 unscaled relative payment weights. We refer readers to the ratesetting procedures described in Part 2 of the OPPS Claims Accounting narrative and in section II. of this proposed rule for more information on scaling the weights, and for details on the final steps of the process that lead to PHP APC per diem rates.

f. Issues Regarding Correct Coding and Reasonable Charges

PHP claims with revenue codes other than those listed as allowable in Table 53 above, but which are associated with allowable PHP HCPCS codes, may still be paid, as described in the OPPS Claims Accounting narrative. The OPPS does not include charges associated with revenue codes which are not allowable for ratesetting purposes. In reviewing 2013 and 2014 claims, we noticed that CMHCs were using correct revenue coding for nearly all claims, but that hospital-based PHPs were sometimes using other revenue codes, particularly revenue codes 0912 and 0913. Revenue codes 0912 and 0913 are not on the allowable list of PHP revenue codes. As such, the charges associated with those two revenue codes are not included in ratesetting, even when revenue code 0912 or 0913 is associated with a PHP allowable HCPCS code. For the most accurate ratesetting, it is imperative that providers follow coding guidelines for all revenue codes and all CPT and Level II HCPCS codes in a manner consistent with their descriptors, instructions, and correct coding principles. We also refer readers to the coding instructions given in the Claims Processing Manual. Following the correct coding guidelines will help ensure that we include all PHP costs in ratesetting.

Finally, it appears that a few PHPs may not be reporting reasonable charges for their services on their claims. When this occurs with CMHCs or hospital-based PHPs that provide a high number of services during the year, the data used for ratesetting may be inappropriately skewed. Therefore, we remind PHPs of the regulations at 42

CFR 413.53 and existing CMS guidance related to charges, which is found in Chapter 22 of the Provider Reimbursement Manual, Part 1, which is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.html?DLPage=1&DLSort=0&DLSortDir=ascending*.

In section 2202.4, we define ''Charges,'' as the regular rates established by the provider for services rendered to both beneficiaries and to other paying patients. Charges should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient. We also state in section 2204, ''Medicare Charges,'' that the Medicare charge for a specific service must be the same as the charge made to non-Medicare patients (including Medicaid, CHAMPUS, private, etc.) must be recorded in the respective income accounts of the facility, and must be related to the cost of the service. In section 2203, ''Provider Charge Structure as Basis for Apportionment,'' we state that each facility should have an established charge structure which is applied uniformly to each patient as services are furnished to the patient, and which is reasonably and consistently related to the cost of providing the services, so that its charges may be allowable for use in apportioning costs under the program. The Medicare program cannot dictate to a provider what its charges or charge structure may be. However, the program may determine whether or not the charges are allowable for use in apportioning costs under the program.

C. Proposed Separate Threshold for Outlier Payments to CMHCs

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), after examining the costs, charges, and outlier payments for CMHCs, we believed that establishing a separate OPPS outlier policy for CMHCs would be appropriate. A CMHC-specific outlier policy would direct OPPS outlier payments towards genuine cost of outlier cases, and address situations where charges were being artificially increased to enhance outlier payments.

We created a separate outlier policy that would be specific to the estimated costs and OPPS payments provided to CMHCs. We note that, in the CY 2009 OPPS/ASC final rule with comment period, we established an outlier reconciliation policy to comprehensively address charging aberrations related to OPPS outlier payments (73 FR 68594 through 68599). Therefore, beginning in CY 2004, we designated a portion of the estimated OPPS outlier target amount specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs.

The separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004, and $0.5 million in outlier payments to CMHCs in CY 2005. In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments. We believe that this difference in outlier payments indicates that the separate outlier threshold for CMHCs has been successful in keeping outlier payments to CMHCs in line with the percentage of OPPS payments made to CMHCs.

In this CY 2016 proposed rule, we are proposing to continue to designate a portion of the estimated 1.0 percent outlier target amount specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS in CY 2016, excluding outlier payments. CMHCs are projected to receive 0.04 percent of total OPPS payments in CY 2016, excluding outlier payments. Therefore, we are proposing to designate 0.49 percent of the estimated 1.0 percent outlier target amount for CMHCs. Based on our simulations of CMHC payments for CY 2016, in this proposed rule, we are proposing to continue to set the threshold for CY 2016 at 3.40 times the highest CMHC PHP APC payment rate (that is, proposed renumbered APC 5852 (Level 2 Partial Hospitalization) (existing APC 0173). We continue to believe that this approach would neutralize the impact of inflated CMHC charges on outlier payments and better target outlier payments to those truly exceptionally high-cost cases that might otherwise limit beneficiary access.

In addition, we are proposing to continue to apply the same outlier payment percentage that applies to hospitals. Therefore, for CY 2016, we are proposing to continue to pay 50 percent of CMHC APC geometric mean per diem costs over the threshold. In section II.G. of this proposed rule, for the hospital outpatient outlier payment policy, we are proposing to set a dollar threshold in addition to an APC multiplier threshold. Because the PHP APCs are the only APCs for which CMHCs may receive payment under the OPPS, we would not expect to redirect outlier payments by imposing a dollar threshold. Therefore, we are not proposing to set a dollar threshold for CMHC outlier payments.

In summary, in this CY 2016 proposed rule, we are proposing to establish that if a CMHC's cost for partial hospitalization services, paid under either proposed renumbered APC 5851 (existing APC 0172) or proposed renumbered APC 5852 (existing APC 0173), exceeds 3.40 times the payment rate for proposed renumbered APC 5852, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the renumbered APC 5852 payment rate. We are inviting public comments on these proposals.

IX. Proposed Procedures That Would Be Paid Only as Inpatient Procedures

A. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full historical discussion of our longstanding policies on how we identify procedures that are typically provided only in an inpatient setting (referred to as the inpatient only list) and, therefore, will not be paid by Medicare under the OPPS; and on the criteria that we use to review the inpatient only list each year to determine whether or not any procedures should be removed from the list.

B. Proposed Changes to the Inpatient Only List

For the CY 2016 OPPS, we are proposing to use the same methodology (described in the November 15, 2004 final rule with comment period (69 FR 65835)) of reviewing the current list of procedures on the inpatient only list to identify any procedures that may be removed from the list. The established criteria upon which we make such a determination are as follows:

1. Most outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be performed in most outpatient departments.
3. The procedure is related to codes that we have already removed from the inpatient only list.
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

Using this methodology, we identified seven procedures that could potentially be removed from the inpatient only list for CY 2016. We have reviewed the clinical characteristics and related evidence for these procedures for removal from the inpatient only list and found them to be appropriate candidates.

For CY 2016, we are proposing to remove the following procedures from the inpatient only list:

- CPT code 0312T (Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming);
- CPT code 20936 (Autograft for spine surgery only (includes harvesting the graft); local (*e.g.,* ribs, spinous process, or laminar fragments) obtained from the same incision);
- CPT code 20937 (Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision));
- CPT code 20938 (Autograft for spine surgery only (includes harvesting the graft); structural, bicortical or tricotical (through separate skin or fascial incision));
- CPT code 22552 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace);
- CPT code 54411 (Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including the irrigation and debridement of infected tissue); and
- CPT code 54417 (Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative sessions, including irrigation and debridement of infected tissue).

The seven procedures we are proposing to remove from the inpatient only list for CY 2016 and their CPT codes, long descriptors, proposed APC assignments, and proposed status indictors are displayed in Table 54 below.

The complete list of codes that we are proposing to be paid by Medicare in CY 2016 only as inpatient procedures is included as Addendum E to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 54—PROCEDURES PROPOSED TO BE REMOVED FROM THE INPATIENT ONLY LIST FOR CY 2016

CPT/HCPCS code	Long descriptor	Proposed CY 2016 APC assignment *	Proposed CY 2016 status indicator
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming.	5463	J1
20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from same incision.	N/A	N
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision).	N/A	N
20938	Autograft for spine surgery only (includes harvesting the graft); structural bicortical or tricortical (through separate skin or fascial incision).	N/A	N
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace.	N/A	N
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue.	5377	J1
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue.	5377	J1

* We refer readers to Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) for a crosswalk from the existing APC numbers to the proposed new APC numbers for CY 2016.

X. Proposed Nonrecurring Policy Changes

A. Changes for Payment for Computed Tomography (CT)

Section 218(a)(1) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) amended section 1834 of the Act by establishing a new subsection 1834(p). Effective for services furnished on or after January 1, 2016, new section 1834(p) of the Act reduces payment for the technical component (TC) of applicable computed tomography (CT) services paid under the MPFS and applicable CT services paid under the OPPS (a 5-percent reduction in 2016 and a 15-percent reduction in 2017 and subsequent years). The applicable CT services are identified by HCPCS codes 70450 through 70498; 71250 through 71275; 72125 through 72133; 72191 through 72194; 73200 through 73206; 73700 through 73706; 74150 through 74178; 74261 through 74263; and 75571 through 75574 (and any succeeding codes) for services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013, entitled ''Standard Attributes on CT Equipment Related to Dose Optimization and Management.'' New section 1834(p)(4) of the Act specifies that the Secretary may apply successor standards through rulemaking.

Section 1834(p)(6)(A) of the Act requires that information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable CT service was furnished that was not consistent with the standard set forth in section 1834(p)(6) of the Act (currently the NEMA CT equipment standard) and that such information may be included on a claim and may be a modifier. Section 1834(p)(6)(A) of the Act also provides that such information must be verified, as appropriate, as part of the periodic accreditation of suppliers under section 1834(e) of the Act and

hospitals under section 1865(a) of the Act. Section 218(a)(2) of the PAMA makes a conforming amendment to section 1833(t) of the Act by adding a new paragraph (20), which provides that the Secretary shall not take into account reduced expenditures that result from the application of section 1834(p) of the Act in making any budget neutral adjustments under the OPPS.

To implement this provision, we are proposing to establish a new modifier to be used on claims that describes CT services furnished using equipment that does not meet each of the attributes of the NEMA Standard XR–29–2013. Beginning January 1, 2016, hospitals and suppliers would be required to use this modifier on claims for CT scans described by any of the CPT codes identified above (and any successor codes) that are furnished on non-NEMA Standard XR–29–2013-compliant CT scans. The use of this proposed modifier would result in the applicable payment reduction for the CT service, as specified under section 1834(p) of the Act.

B. Lung Cancer Screening With Low Dose Computed Tomography

On February 5, 2015, CMS issued a national coverage determination (NCD) for the coverage of lung cancer screening with low dose computed tomography (LDCT) under Medicare. This coverage includes a lung cancer screening counseling and shared decision-making visit, and, for appropriate beneficiaries, annual screening for lung cancer with LDCT as an additional preventive service under Medicare if certain criteria are met. The decision memorandum announcing the NCD is available on the CMS Web site at: *http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274*.

The HCPCS codes that describe these services are HCPCS code GXXX1 (Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and share decision making)) and HCPCS code GXXX2 (Low dose CT scan (LDCT) for lung cancer screening). For the CY 2016 OPPS, we are proposing to assign HCPCS code GXXX1 to proposed renumbered APC 5822 (Level 2 Health and Behavior Services) (existing APC 0432) and HCPCS code GXXX2 to proposed renumbered APC 5570 (Computed Tomography without Contrast) (existing APC 0332).

C. Payment for Corneal Tissue in the HOPD and the ASC

1. Background

In both the HOPD and the ASC, we have a longstanding policy of making separate payment for corneal tissue. In the HOPD, we make separate payment outside of the OPPS based on hospitals' reasonable costs to procure corneal tissue (65 FR 18448 through 18449). In the ASC, we pay separately for corneal tissue procurement as a covered ancillary service when it is integral to the performance of an ASC covered surgical procedure based on invoiced costs for the acquisition costs of corneal tissue (72 FR 42508 through 42509 and 42 CFR 416.164(b)(3)). HCPCS code V2785 (Processing, preserving and transporting corneal tissue) is used to report corneal tissue in both the HOPD and the ASC.

The original use (and currently the primary use) of corneal tissue is in corneal transplant surgery. Because corneal transplants are the primary procedures in which corneal tissue is used, in prior rulemaking discussions of the corneal tissue payment policy in both the HOPD and the ASC, we focused on the costs associated with corneal tissue when used in corneal transplants (65 FR 18448 through 18449 and 72 FR 42508 through 42509). However, we have not expressly limited the corneal tissue payment policy to only corneal tissue used in corneal transplants. In the HOPD, we have stated that we will make separate payment, based on the hospital's reasonable costs incurred to acquire corneal tissue (65 FR 18450). Moreover, corneal tissue acquisition costs are excluded from the determination of OPPS payment rates under 42 CFR 419.2(c)(8). This regulation was amended in the CY 2002 OPPS final rule (66 FR 59922) and the phrase ''incurred by hospitals that are paid on a reasonable cost basis'' was deleted. In the ASC, as stated above, we include corneal tissue procurement in the scope of ASC services as a covered ancillary service when it is integral to the performance of an ASC covered surgical procedure and pay separately for this service, so payment is not packaged into the ASC payment for the associated covered surgical procedure (72 FR 42509).

In early 2015, a stakeholder asked whether the acquisition of corneal tissue used as grafting material in glaucoma shunt surgery could be reported with HCPCS code V2785 and separately paid under the ASC payment system. In reviewing our longstanding policy on separate payment for corneal tissue acquisition when furnished integral to a covered ASC surgical procedures, we determined that the current language does not limit separate payment for the acquisition of corneal tissue to corneal transplants. Accordingly, we included an instruction in the April 2015 ASC quarterly update (Transmittal 3234, Change Request 9100) that states that ASCs can bill for the acquisition of corneal allograft tissue used for coverage (CPT code 66180) or revision (CPT code 66185) of a glaucoma aqueous shunt with HCPCS code V2785. In Change Request 9100, we also stated that contractors pay for corneal tissue acquisition reported with HCPCS code V2785 based on acquisition/invoice cost. The April 2015 ASC Change Request is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3234CP.pdf*. Since the publication of the April 2015 ASC instruction, stakeholders have complained about the different payment policies for corneal tissue used for patch grafting (which is paid separately) versus noncorneal tissue (sclera and pericardium, among others) used for patch grafting (which is packaged).

2. Proposed CY 2016 Change to Corneal Tissue Payment Policy in the HOPD and the ASC

For CY 2016, we are proposing to limit the separate payment policy for corneal tissue acquisition costs in the HOPD and the ASC to only corneal tissue that is used in a corneal transplant procedure. In the HOPD, corneal tissue acquisition costs would be separately paid only when the corneal tissue is used in a corneal transplant procedure. Otherwise, the corneal tissue would be a packaged surgical supply in the OPPS under the regulation at 42 CFR 419.2(b)(4). In the ASC, we would include corneal tissue procurement as a covered ancillary service only when it is integral to the performance of a corneal transplant procedure that is an ASC covered surgical procedure, and pay separately for this service under the ASC payment system. We would implement this proposal as final by providing a specific list of corneal transplant procedure HCPCS codes with which HCPCS code V2785 may be reported in the January 2016 OPPS and ASC updates via change requests. This proposal would mean that, in the HOPD and the ASC, we would not make separate payment for corneal tissue when used in any nontransplant procedure (payment for the corneal tissue in that instance will be packaged with the surgical procedure). This proposal also would

mean that we would make packaged payment for all tissues used as patch grafts in glaucoma shunt surgery. We are not proposing to change any other aspect of the corneal tissue payment policy in either the HOPD or the ASC.

We believe that limiting separate payment for corneal tissue to corneal transplants only is warranted for the following reasons:

- The public comments summarized in the CY 2000 OPPS final rule with comment period (65 FR 18448 through 18449) and referenced in the CY 2008 ASC final rule (72 FR 42508 through 42509) by the Eye Bank Association of America (EBAA) and the study report submitted the EBAA focused on corneal tissue acquisition for corneal transplants. These comments and the study were significant factors in the finalized corneal tissue separate payment policy that addressed corneal tissue acquisition costs associated with corneal tissue used in corneal transplants.
- Corneal tissue for transplantation requires more specialized and more costly processing than corneal tissue used as glaucoma shunt-tube patch grafts because of the fragility and importance of the corneal endothelium, of which the health and preservation are necessary for successful transplantation.
- Unlike corneas used for corneal transplantation, in which there is currently no substitute, there are multiple different tissue types, each with their own costs and relative benefits and detriments, available for glaucoma shunt surgery patch grafting.
- Given the numerous tissue options for patch grafting, we believe that Medicare beneficiaries will continue to have access to patch grafting in glaucoma shunt surgery in both the hospital setting and the ASC setting.

We also are proposing to revise the related regulations at 42 CFR 416.164(b)(3) and 419.2(c)(8) to specify that payment would be made for corneal tissue acquisition or procurement costs for corneal transplant procedures.

We are inviting public comments on these proposals.

XI. Proposed CY 2016 OPPS Payment Status and Comment Indicators

A. Proposed CY 2016 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code. The complete list of the payment status indicators and their definitions that we are proposing for CY 2016 is displayed in Addendum D1 to this proposed rule, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The proposed CY 2016 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

For CY 2016, we are proposing to create two new status indicators:

- ''J2'' to identify certain combinations of services that we are proposing to pay through new proposed C–APC 8011 (Comprehensive Observation Services). We refer readers to section II.A.2.e. of this proposed rule for a detailed discussion of this proposed change.
- ''Q4'' to identify conditionally packaged laboratory tests. We refer readers to section II.A.3. of this proposed rule for a detailed discussion of this proposed new status indicator.

B. Proposed CY 2016 Comment Indicator Definitions

For the CY 2016 OPPS, we are proposing to use three comment indicators. Two comment indicators, ''CH'' and ''NI,'' which were in effect in CY 2015 would continue in CY 2016. In this proposed rule, we are proposing to create new comment indicator ''NP'' that would be used in the proposed rule to identify a new code for the next calendar year or an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, proposed APC assignment; and that would indicate that comments will be accepted on the proposed APC assignment for the new code.

- ''CH''—Active HCPCS code in current and next calendar year; status indicator and/or APC assignment have changed or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- ''NP''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

We are proposing to use the ''CH'' comment indicator in this CY 2016 OPPS/ASC proposed rule to indicate HCPCS codes for which the status indicator or APC assignment, or both, are proposed for change in CY 2016 compared to their assignment as of June 30, 2015. We believe that using the ''CH'' indicator in this proposed rule will facilitate the public's review of the changes that we are proposing for CY 2016. We are proposing to use the ''CH'' comment indicator in the CY 2016 OPPS/ASC final rule with comment period to indicate HCPCS codes for which the status indicator or APC assignment, or both, will change in CY 2016 compared to their assignment as of December 31, 2015. Use of the comment indicator ''CH'' in association with a composite APC indicates that the configuration of the composite APC would be changed in the CY 2016 OPPS/ASC final rule with comment period.

For CY 2016, we are proposing that any existing HCPCS codes with substantial revisions to the code descriptors for CY 2016 compared to the CY 2015 descriptors would be labeled with comment indicator ''NI'' in Addendum B to the CY 2016 OPPS/ASC final rule with comment period. However, in order to receive the comment indicator ''NI,'' the CY 2016 revision to the code descriptor (compared to the CY 2015 descriptor) must be significant such that the new code descriptor describes a new service or procedure for which the OPPS treatment may change. We are proposing to use comment indicator ''NI'' to indicate that these HCPCS codes will be open for comment as part of the CY 2016 OPPS/ASC final rule with comment period. Like all codes labeled with comment indicator ''NI,'' we will respond to public comments and finalize their OPPS treatment in the CY 2017 OPPS/ASC final rule with comment period.

In accordance with our usual practice, we are proposing that CPT and Level II HCPCS codes that are new for CY 2016 and that are included in Addendum B to the CY 2016 OPPS/ASC final rule with comment period also would be labeled with comment indicator ''NI'' in Addendum B to the CY 2016 OPPS/ASC final rule with comment period.

We are proposing that CPT codes that are new for CY 2016 and any existing HCPCS codes with substantial revisions

to the code descriptors for CY 2016 compared to the CY 2015 descriptors that are included in Addendum B to this CY 2016 OPPS/ASC proposed rule would be labeled with new comment indicator ''NP'' in Addendum B to indicate that these CPT codes will be open for comment as part of this CY 2016 OPPS/ASC proposed rule. We will respond to public comments and finalize their OPPS assignment in the CY 2016 OPPS/ASC final rule with comment period.

For further discussion on the treatment of new CY 2016 CPT codes that will be effective January 1, 2016, for which we are soliciting public comments in this CY 2016 OPPS/ASC proposed rule, we refer readers to section III. of this proposed rule.

The proposed definitions of the OPPS comment indicators for CY 2016 are listed in Addendum D2 to this proposed rule, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

XII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74378 through 74379), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68434 through 68467), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75064 through 75090), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66915 through 66940).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under 42 CFR 416.2 and 416.166 of the Medicare regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure (''overnight stay''). We adopted this standard for defining which surgical procedures are covered under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs. We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate to be furnished to Medicare beneficiaries in ASCs. We define surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999, as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to ASC covered surgical procedures (72 FR 42478).

In the August 2, 2007 final rule (72 FR 42495), we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) Brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66932 through 66934), we expanded the scope of ASC covered ancillary services to include certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS when they are integral to an ASC covered surgical procedure. Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (§ 416.173; 72 FR 42535). In addition, as discussed in detail in section XII.C. of this proposed rule, because we base ASC payment policies for covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, and we use quarterly change requests to update services covered under the OPPS, we also provide quarterly update change requests (CRs) for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). CMS releases new and revised Level II HCPCS codes to the public or recognizes the release of new and revised CPT codes by the AMA and makes these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. CMS releases new and revised Category III CPT codes in the July and January CRs. Thus, these updates are to implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payment and to update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year and, therefore, are implemented only through the January quarterly update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process was used to update HCPCS and CPT codes (76 FR 42291).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures (including all procedures newly proposed for removal from the OPPS inpatient list), new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

B. Proposed Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised Category I and Category III CPT Codes and Level II HCPCS Codes

Category I CPT, Category III CPT, and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims: (1) Category I CPT codes, which describe surgical procedures and vaccine codes; (2) Category III CPT codes, which describe new and emerging technologies, services, and procedures; and (3) Level II HCPCS codes, which are used primarily to identify items, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes; however, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this proposed rule.

We have separated our discussion below based on when the codes are released and whether we are proposing to solicit public comments in this proposed rule (and respond to those comments in the CY 2016 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2016 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2017 OPPS/ASC final rule with comment period).

We note that we sought public comments in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66918) on the new and revised Category I and III CPT and Level II HCPCS codes that were effective January 1, 2015. We also sought public comments in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66918) on the new and revised Level II HCPCS codes effective October 1, 2014. These new and revised codes, with an effective date of October 1, 2014, or January 1, 2015, were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2015 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2015 OPPS/ASC final rule with comment period. We will respond to public comments and finalize the treatment of these codes under the ASC payment system in the CY 2016 OPPS/ASC final rule with comment period.

2. Proposed Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April 2015 and July 2015 for Which We Are Soliciting Public Comments in This Proposed Rule

In the April 2015 and July 2015 Change Requests (CRs), we made effective for April 1, 2015 and July 1, 2015, respectively, a total of 13 new Level II HCPCS codes and two new Category III CPT codes that describe covered ASC services that were not addressed in the CY 2015 OPPS/ASC final rule with comment period.

In the April 2015 ASC quarterly update (Transmittal 3234, CR 9100, dated April 15, 2015), we added one new device Level II HCPCS code and seven new drug and biological Level II HCPCS codes to the list of covered ancillary services. Table 55 below lists the new Level II HCPCS codes that were implemented April 1, 2015, along with their proposed payment indicators for CY 2016.

In the July 2015 ASC quarterly update (Transmittal 3279, CR 9207, dated June 5, 2015), we added one new device Level II HCPCS code and four new drug and biological Level II HCPCS codes to the list of covered ancillary services. Table 56 below lists the new Level II HCPCS codes that were implemented July 1, 2015. The proposed payment rates, where applicable, for these April and July codes can be found in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site).

Through the July 2015 quarterly update CR, we also implemented ASC payment for two new Category III CPT codes as ASC covered surgical procedures, effective July 1, 2015. These codes are listed in Table 57 below, along with their proposed payment indicators. The proposed payment rates for these new Category III CPT codes, can be found in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We are inviting public comments on these proposed payment indicators and the proposed payment rates for the new Category III CPT code and Level II HCPCS codes that were newly recognized as ASC covered surgical procedures or covered ancillary services in April 2015 and July 2015 through the quarterly update CRs, as listed in Tables 55, 56, and 57 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2016 OPPS/ASC final rule with comment period.

TABLE 55—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2015

CY 2015 HCPCS code	CY 2015 long descriptor	Proposed CY 2016 payment indicator
C2623	Catheter, transluminal angioplasty, drug-coated, non-laser	J7
C9445	Injection, c-1 esterase inhibitor (recombinant), Ruconest, 10 units	K2
C9448*	Netupitant 300mg and palonosetron 0.5 mg, oral	D5
C9449	Injection, blinatumomab, 1 mcg	K2
C9450	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	K2
C9451	Injection, peramivir, 1 mg	K2
C9452	Injection, ceftolozane 50 mg and tazobactam 25 mg	K2
Q9975	Injection, Factor VIII, FC Fusion Protein (Recombinant), per iu	K2

*HCPCS code C9448 was deleted June 30, 2015 and replaced with HCPCS code Q9978 effective July 1, 2015.

TABLE 56—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2015

CY 2015 HCPCS code	CY 2015 long descriptor	Proposed CY 2016 payment indicator
C2613	Lung biopsy plug with delivery system	J7
C9453	Injection, nivolumab, 1 mg	K2
C9454	Injection, pasireotide long acting, 1 mg	K2
C9455	Injection, siltuximab, 10 mg	K2
Q9978*	Netupitant 300 mg and Palonosetron 0.5 mg, oral	K2

* HCPCS code Q9978 replaced HCPCS code C9448 effective July 1, 2015.

TABLE 57—NEW CATEGORY III CPT CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2015

CY 2015 CPT code	CY 2015 long descriptor	Proposed CY 2016 payment indicator
0392T	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (*i.e.,* magnetic band).	G2
0393T	Removal of esophageal sphincter augmentation device	G2

3. Proposed Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2016

a. Current Process for Accepting Comments on New and Revised CPT Codes That Are Effective January 1

Historically, we have not received new and revised Category I and Category III CPT codes that take effect at the beginning of a calendar year in time to include them in the proposed rule for that calendar year. Therefore, under the ASC payment system, the current process we have used is to incorporate new and revised Category I and Category III CPT codes that are effective January 1 in the final rule with comment period thereby updating the ASC payment system for the following calendar year. These codes are released to the public by the AMA via the annual CPT code books and electronic CPT code file. In addition, we include these codes in the January ASC quarterly update CR, and we list the codes in ASC Addendum AA and BB of the OPPS/ASC final rule with comment period. All of the new codes are flagged with comment indicator ''NI'' in Addendum AA and Addendum BB to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. In addition, existing CPT codes that have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator are assigned to comment indicator ''NI.'' The payment indicator and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the OPPS/ASC final rule with comment period, and we respond to these comments in the final rule with comment period for the next calendar year's OPPS/ASC update. For example, the new CPT codes that were effective January 1, 2014 were assigned to comment indicator ''NI'' in Addendum AA and Addendum BB to the CY 2014 OPPS/ASC final rule with comment period. We responded to public comments received on the CY 2014 OPPS/ASC final rule with comment period and finalized the payment indicator assignments for these codes in the CY 2015 OPPS/ASC final rule with comment period; and we included the final ASC payment indicator assignments in Addendum AA and Addendum BB to that final rule with comment period.

Several stakeholders, including consultants, device manufacturers, drug manufacturers, as well as specialty societies and hospitals, have expressed concern with the process we use to recognize new and revised CPT codes. They believe that we should publish proposed ASC payment indicators for the new and revised CPT codes that will be effective January 1 in the OPPS/ASC proposed rule for the prior year, and request public comments prior to finalizing them for the January 1 implementation date. Further, the stakeholders believe that seeking public input on the ASC payment indicator assignments for these new and revised codes would assist CMS in assigning the CPT codes to appropriate payments under the ASC payment system. We were informed of similar concerns regarding our process for assigning interim payment values for revalued, and new and revised codes, under the MPFS and the OPPS. Consequently, we included proposed policies to address those concerns in the CY 2015 MPFS proposed rule (79 FR 40359 through 40364), and in the CY 2015 OPPS/ASC proposed rule (79 FR 40977 through 40979). Based on the comments that we received to the proposed rules, we finalized the policies in the CY 2015 MPFS final rule (79 FR 67602 through 67609) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844).

Like the MPFS and the OPPS, the ASC payment system relies principally upon the Current Procedural Terminology (CPT®) coding system maintained by the AMA for billing. CPT® is the standard code set adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) for outpatient services. The AMA CPT Editorial Panel's coding cycle occurs concurrently with our calendar year rulemaking cycle for the OPPS and the ASC payment system. The OPPS/ASC proposed rules have historically been published prior to the publication of the CPT codes that are generally made public in the fall, with a January 1 effective date, and therefore, we have not historically been able to include these codes in the OPPS/ASC proposed rules.

b. Proposed Modification of the Current Process for Accepting Comments on New and Revised Category I and III CPT Codes That Are Effective January 1

In this CY 2016 OPPS/ASC proposed rule, we are proposing to make changes in the process we use to establish ASC payment indicators for new and revised Category I and Category III CPT codes. As discussed above, we finalized similar

revisions under the MPFS and the OPPS for establishing payment indicators for new and revised CPT codes that take effect each January 1. Because new and revised codes that are received in time for the proposed rule are assigned proposed payment indicators and proposed APC assignments in the OPPS, we also need to propose corresponding payment rates and payment indicators in the ASC for those codes that are ASC covered surgical procedures and covered ancillary services. The proposed revised process would eliminate our current practice of assigning interim payment indicators for the vast majority of new and revised CPT codes that take effect on January 1 each year.

Consequently, we are proposing that, for new and revised Category I and III CPT codes that we receive from the AMA CPT Editorial Panel too late for inclusion in the proposed rule for a year, we would delay adoption of the new and revised codes for that year and, instead, adopt coding policies and payment rates that conform, to the extent possible, to the policies and payment rates in place for the previous year. We are proposing to adopt these conforming coding and payment policies on an interim basis pending the result of our specific proposals for these new and revised codes through notice-and-comment rulemaking in the OPPS/ASC proposed rule for the following year. Because the changes in CPT codes are effective on January 1 of each year, and we would not have established payment indicators for these new or revised codes, it would not be practicable for Medicare to use those CPT codes. In this circumstance, we are proposing to create HCPCS G-codes to describe the predecessor codes for any codes that were revised or deleted as part of the annual CPT coding changes. However, if certain CPT codes are revised in a manner that would not affect the cost of inputs (for example, a grammatical change to CPT code descriptors), we would use these revised codes and continue to assign those codes to their current ASC payment indicator. For example, under this proposed process, if a single CPT code was separated into two codes and we did not receive those codes until May 2016, we would assign each of those codes to proposed payment indicator ''B5'' (Alternative code may be available; no payment made) in the final rule with comment period, to indicate that an alternate code is recognized under the ASC payment system. ASCs could not use those two new CPT codes to bill Medicare for ASC services the first year after the effective date of the codes. Instead, we would create a HCPCS G-code with the same description as the single predecessor CPT code, and continue to use the same ASC payment indicator for that code during the year. We would propose payment indicators for the two new CPT codes during rulemaking in CY 2017 for payment beginning in CY 2018.

For new codes that describe wholly new services, as opposed to new or revised codes that describe services for which ASC payment indicator assignments are already established, we would make every effort to work with the AMA CPT Editorial Panel to ensure that we received the codes in time to propose payment rates in the proposed rule. However, if we do not receive the code for a wholly new service in time to include proposed ASC payment indicator assignments in the proposed rule for a year, we would need to establish interim ASC payment indicator assignments for the initial year. We are proposing to establish the initial ASC payment indicator assignments for wholly new services as interim final assignments, and to follow our current process to solicit and respond to public comments and finalize the ASC payment indicator assignments in the subsequent year.

We recognize that the use of HCPCS G-codes may place an administrative burden on those ASCs that bill for services under the ASC payment system. We are hopeful that the AMA CPT Editorial Panel ultimately will be able to adjust its timelines and processes so that most, if not all, of the annual coding changes can be addressed in the proposed rule. We are proposing to finalize and implement the revised CMS process for establishing ASC payment indicator assignments for new and revised codes for CY 2016.

In summary, we are proposing to include in the OPPS/ASC proposed rule the proposed ASC payment indicators for the vast majority of new and revised CPT codes before they are used for payment purposes under the ASC payment system. We would address new and revised CPT codes for the upcoming year that are available in time for the proposed rule by proposing ASC payment indicators for the codes. Otherwise, we would delay adoption of the new and revised codes for a year while using methods (including creating G-codes that describe the predecessor codes) to maintain the existing ASC payment indicators until the following year when we would include proposed assignments for the new and revised codes in the proposed rule. We are proposing to follow this revised process except in the case of a new CPT code that describes a wholly new service (such as a new technology or new surgical procedure) that has not previously been addressed under the ASC payment system. For codes that describe wholly new services for which we do not receive timely information from the AMA, we are proposing to establish interim ASC payment indicators in the OPPS/ASC final rules with comment period, as is our current process. The proposed revised process would eliminate our current practice of assigning interim ASC payment indicators for the vast majority of new and revised CPT codes that take effect on January 1 each year. We are inviting public comment on these proposals.

For the CY 2016 ASC update, we received the CY 2016 Category I and Category III CPT codes from AMA in time for inclusion in this CY 2016 OPPS/ASC proposed rule. The new and revised CY 2016 Category I and III CPT codes can be found in ASC Addendum AA and Addendum BB (which are available via the Internet on the CMS Web site) and are assigned to proposed new comment indicator ''NP'' to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year with a proposed ASC payment indicator and that comments will be accepted on the proposed payment indicator. We refer readers to section XII.F. of this proposed rule for further discussion on the new proposed comment indicator ''NP.'' Therefore, in this CY 2016 OPPS/ASC proposed rule, we are soliciting public comments on the proposed CY 2016 ASC payment indicators for the new and revised Category I and III CPT codes that would be effective January 1, 2016.

Further, we remind readers that the CPT code descriptors that appear in ASC Addendum AA and BB are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the long descriptors for the new and revised CY 2016 CPT codes in Addendum O to this proposed rule (which is available via the Internet on the CMS Web site) so that the public can adequately comment on our proposed ASC payment indicators. Because CPT procedure codes are 5 alpha-numeric characters and CMS systems only utilize 5 characters HCPCS codes, we have developed alternative 5-character placeholder codes for this proposed rule. The placeholder codes can be found in Addendum O to this proposed

rule, specifically under the column labeled ''CY 2016 OPPS/ASC Proposed Rule 5-Digit CMS Placeholder Code.'' The final CPT code numbers would be included in the CY 2016 OPPS/ASC final rule with comment period.

4. Proposed Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2015 and January 1, 2016 for Which We Will Be Soliciting Public Comments in the CY 2016 OPPS/ASC Final Rule With Comment Period

Although we are proposing to revise our process for requesting public comments on the new and revised Category I and III CPT codes, we are not proposing any change to the process for requesting public comments on the new and revised Level II HCPCS codes that would be effective October 1 and January 1.

As has been our practice in the past, we incorporate those new and revised Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS Web site, and also through the January ASC quarterly update CRs. In the past, we also released new and revised Level II HCPCS codes that are effective October 1 through the October ASC quarterly update CRs and incorporated these new and revised codes in the final rule with comment period, thereby updating the ASC for the following calendar year. All of these codes are flagged with comment indicator ''NI'' in Addenda AA and BB to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. The payment indicator and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the OPPS/ASC final rule with comment period, and we respond to these comments in the final rule with comment period for the next calendar year's OPPS/ASC update.

We are proposing to continue this process for CY 2016. Specifically, the Level II HCPCS codes that will be effective October 1, 2015 and January 1, 2016 would be flagged with comment indicator ''NI'' in Addendum AA and BB to the CY 2016 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim ASC payment status for CY 2016. We will be inviting public comments on the proposed payment indicators and payment rates for these codes, if applicable, that would be finalized in the CY 2017 OPPS/ASC final rule with comment period.

In Table 58 below, we summarize the CY 2016 process described in this section XII.B. of this proposed rule for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new and revised codes under the ASC payment system.

TABLE 58—PROPOSED COMMENT TIMEFRAME FOR CY 2016 FOR NEW OR REVISED CATEGORY I AND III CPT CODES AND LEVEL II HCPCS CODES

ASC quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April I, 2015	Level II HCPCS Codes	April 1, 2015	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.
July 1, 2015	Level II HCPCS Codes	July 1, 2015	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2015	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.
October 1, 2015	Level II HCPCS Codes	October 1, 2015	CY 2016 OPPS/ASC final rule with comment period.	CY 2017 OPPS/ASC final rule with comment period.
January 1, 2016	Level II HCPCS Codes	January 1, 2016	CY 2016 OPPS/ASC final rule with comment period.	CY 2017 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes.	January 1, 2016	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.

We are inviting public comment on this proposed process.

C. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Proposed Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years that we determine are performed predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC list of covered surgical procedures beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the standard ASC payment methodology based on its

OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the list of covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2016 to Covered Surgical Procedures Designated as Office-Based

In developing this proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. We reviewed CY 2014 volume and utilization data and the clinical characteristics for all covered surgical procedures that are assigned payment indicator ''G2'' (Nonoffice-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in CY 2015, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2,'' ''P3,'' or ''R2'' in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66921 through 66923).

Our review of the CY 2014 volume and utilization data resulted in our identification of two covered surgical procedures, CPT codes 43197 (Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)) and 43198 (Esophagoscopy, flexible, transnasal; with biopsy, single or multiple) that we believe meet the criteria for designation as office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians' offices and we believe the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The two CPT codes we are proposing to permanently designate as office-based are listed in Table 59 below.

We are inviting public comment on this proposal.

TABLE 59—ASC COVERED SURGICAL PROCEDURES NEWLY PROPOSED AS PERMANENTLY OFFICE-BASED FOR CY 2016

Proposed CY 2016 CPT code	Proposed CY 2016 long descriptor	CY 2015 ASC payment indicator	Proposed CY 2016 ASC payment indicator *
43197	Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure).	G2	P3
43198	Esophagoscopy, flexible, transnasal; with biopsy, single or multiple	G2	P3

* Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2016. For a discussion of the MPFS rates, we refer readers to the CY 2016 MPFS proposed rule.

We also reviewed CY 2014 volume and utilization data and other information for six procedures finalized for temporary office-based status in Table 47 in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66922 through 66923). Among these six procedures, there were very few claims in our data or no claims data for five procedures: CPT code 0099T (Implantation of intrastromal corneal ring segments); CPT code 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound); CPT code C9800 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies); CPT code 10030 (Image-guided fluid collection drainage by catheter (*e.g.,* abscess, hematoma, seroma, lymphocele, cyst), soft tissue (*e.g.,* extremity, abdominal wall, neck), percutaneous); and CPT code 67229 (Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (*e.g.,* retinopathy of prematurity), photocoagulation or cryotherapy). Consequently, we are proposing to maintain the temporary office-based designations for these five codes for CY 2016. We list all of these codes in Table 60, except for HCPCS code 0099T. HCPCS code 0099T was assigned payment indicator * R2 in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66922), but this code is being replaced with a new CPT code currently identified with a CMS 5-digit placeholder code of 657XG. Table 61 reflects the new CY 2016 codes for ASC covered surgical procedures with proposed temporary office-based designations.

For CPT code 64617 (Chemodenervation of muscle(s); larynx, unilateral, percutaneous (*e.g.,* for spasmodic dysphonia), includes guidance by needle electromyography, when performed), claims data indicate these procedures are performed more than 50 percent of the time in physicians' offices and we believe the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. Therefore, we are proposing to make the office-based designation for CPT code 64617 permanent.

The proposed CY 2016 payment indicator designations for the procedures that were temporarily designated as office-based in CY 2015 are displayed in Table 60. The procedures for which the proposed office-based designations for CY 2016 are temporary also are indicated by asterisks in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 60—PROPOSED CY 2016 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2015 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2015 CPT code	CY 2015 long descriptor	CY 2015 ASC payment indicator	Proposed CY 2016 ASC payment indicator**
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound.	*R2	*R2
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies.	*R2	*R2
10030	Image-guided fluid collection drainage by catheter (*e.g.,* abscess, hematoma, seroma, lymphocele, cyst), soft tissue (*e.g.,* extremity abdominal wall, neck), percutaneous.	*P2	*P2
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (*e.g.,* for spasmodic dysphonia), includes guidance by needle electromyography, when performed.	*P3	*P3
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (*e.g.,* retinopathy of prematurity), photocoagulation or cryotherapy.	*R2	*R2

*If designation is temporary.
**Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2016. For a discussion of the MPFS rates, we refer readers to the CY 2016 MPFS proposed rule.

For CY 2016, we also are proposing to designate certain new CY 2016 codes for ASC covered surgical procedures as temporary office-based, displayed in Table 61. After reviewing the clinical characteristics, utilization, and volume of related codes, we determined that the procedures described by these new CPT codes would be predominantly performed in physicians' offices. However, because we had no utilization data for the procedures specifically described by these new CPT codes, we made the office-based designations temporary rather than permanent and we will reevaluate the procedures when data become available. The procedures for which the proposed office-based designations for CY 2016 are temporary also are indicated by asterisks in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We are inviting public comment on these proposals.

TABLE 61—PROPOSED CY 2016 PAYMENT INDICATORS FOR NEW CY 2016 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE–BASED

Proposed CY 2016 OPPS/ASC proposed rule 5-digit CMS placeholder code***	Proposed CY 2016 long descriptor	Proposed CY 2016 ASC payment indicator**
6446A	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed).	*R2
6446C	Paravertebral block (PVB) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed).	*R2
03XXB	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed).	*R2
657XG	Implantation of intrastromal corneal ring segments	P2*

*If designation is temporary.
**Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2016. For a discussion of the MPFS rates, we refer readers to the CY 2016 MPFS proposed rule.
***New CPT codes (with CMS 5-digit placeholder codes) that will be effective January 1, 2016. The proposed ASC payment rate for this code can be found in ASC Addendum AA, which is available via the Internet on the CMS Web site.

b. ASC Covered Surgical Procedures Designated as Device-Intensive—Finalized Policy for CY 2015 and Proposed Policy for CY 2016

(1) Background

As discussed in the August 2, 2007 final rule (72 FR 42503 through 42508), we adopted a modified payment methodology for calculating the ASC payment rates for covered surgical procedures that are assigned to the subset of OPPS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS, in order to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures. According to that modified ASC payment methodology, we apply the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment to determine the device cost included in the OPPS payment rate for a device-intensive ASC covered surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We then calculate the service portion of the ASC payment for device-intensive procedures by applying the uniform ASC conversion factor to the service (nondevice) portion of the OPPS relative payment weight for the device-intensive procedure. Finally, we sum the ASC device portion and ASC service portion to establish the full payment for the device-intensive procedure under the revised ASC payment system. For CY 2015, we implemented a

comprehensive APC policy under the OPPS under which we created comprehensive APCs to replace most of the then-current device-dependent APCs and a few nondevice-dependent APCs under the OPPS, which discontinued the device-dependent APC policy (79 FR 66798 through 66810). We did not implement comprehensive APCs in the ASC payment system.

Therefore, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66925), we provided that all separately paid covered ancillary services that are provided integral to covered surgical procedures that mapped to comprehensive APCs continue to be separately paid under the ASC payment system instead of being packaged into the payment for the comprehensive APC as under the OPPS. To avoid duplicating payment we provided that the CY 2015 ASC payment rates for these comprehensive APCs are based on the CY 2015 OPPS relative payments weights that had been calculated using the standard APC ratesetting methodology for the primary service instead of the relative payment weights that are based on the comprehensive bundled service. For the same reason, under the ASC payment system, we also used the standard OPPS APC ratesetting methodology instead of the comprehensive methodology to calculate the device offset percentage for comprehensive APCs for purposes of identifying device-intensive procedures and to calculate payment rates for device-intensive procedures assigned to comprehensive APCs. Because we implemented the comprehensive APC policy and, therefore, eliminated device-dependent APCs under the OPPS in CY 2015, we revised our definition of ASC device-intensive procedures to be those procedures that are assigned to any APC (not only an APC formerly designated as device-dependent) with a device offset percentage greater than 40 percent based on the standard OPPS APC ratesetting methodology.

We also provided that we would update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with our modified definition of device-intensive procedures, reflecting the APC assignments of procedures and APC device offset percentages based on the CY 2013 OPPS claims and cost report data available for the CY 2015 OPPS/ASC proposed rule and final rule with comment period.

(2) Proposed Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2016

For CY 2016, we are proposing to continue our CY 2015 policies. Specifically, for CY 2016, we are proposing to update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with our proposed modified definition of device-intensive procedures, reflecting the proposed APC assignments of procedures and APC device offset percentages based on the CY 2014 OPPS claims and cost report data available for the proposed rule.

The ASC covered surgical procedures that we are proposing to designate as device-intensive and that would be subject to the device-intensive procedure payment methodology for CY 2016 are listed in Table 62 below. The CPT code, the CPT code short descriptor, the proposed CY 2016 ASC payment indicator, the proposed CY 2016 OPPS APC assignment, the proposed CY 2016 OPPS APC device offset percentage, and an indication if the full credit/partial credit (FB/FC) device adjustment policy would apply are also listed in Table 62 below. All of these procedures are included in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We are inviting public comment on these proposals.

(3) Solicitation of Comments on Device-Intensive Policy for ASCs

As discussed previously, prior to CY 2015, ASC device-intensive procedures were defined as those procedures that are assigned to device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS. Because we implemented the comprehensive APC policy and, therefore, eliminated device-dependent APCs under the OPPS in CY 2015, we redefined ASC device-intensive procedures for CY 2015 as those procedures that are assigned to any APC with a device offset percentage greater than 40 percent based on the standard OPPS APC ratesetting methodology (79 FR 66923 through 66925).

Payment rates for ASC device-intensive procedures are based on a modified payment methodology. As described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829), under that modified payment methodology, we apply the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment to determine the device cost included in the non-comprehensive OPPS unadjusted payment rate for a device-intensive ASC covered surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We then calculate the service portion of the ASC payment for device-intensive procedures by applying the uniform ASC conversion factor to the service (nondevice) portion of the OPPS relative payment weight for the device-intensive procedure, which is then scaled for ASC budget neutrality. Finally, we sum the ASC device portion and the ASC service portion to establish the full payment for the device-intensive procedure under the revised ASC payment system.

We recognize that, in some instances, there may be a procedure that contains high-cost devices but is not assigned to a device-intensive APC. Where an ASC covered surgical procedure is not designated as device-intensive, the procedure would be paid under the ASC methodology established for that covered surgical procedure, through either an MPFS nonfacility PE RVU-based amount or an OPPS relative payment weight based methodology, depending on the ASC status indicator assignment.

In response to stakeholder concerns regarding the situation where procedures with high-cost devices are not classified as device-intensive under the ASC payment system, we are soliciting public comments for alternative methodologies for establishing device-intensive status for ASC covered surgical procedures.

c. Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC policy with regard to payment for costly devices implanted in ASCs at no cost/full credit or partial credit as set forth in § 416.179 is consistent with the OPPS policy that was in effect until CY 2014. The established ASC policy reduces payment to ASCs when a specified device is furnished without cost or with full credit or partial credit for the cost of the device for those ASC covered surgical procedures that are assigned to APCs under the OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/ASC final rule with comment period for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices (73 FR 68742 through 68744).

As discussed in section IV.B. of the CY 2014 OPPS/ASC final rule with

comment period (78 FR 75005 through 75006), we finalized our proposal to modify our former policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Formerly, under the OPPS, our policy was to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more (but less than 100 percent) of the cost for the specified device. For CY 2014, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a replaced device, capped at the device offset amount.

Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in that final rule with comment period (78 FR 75076 through 75080), we finalized our proposal for CY 2014 to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the actual amount received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

We are proposing to update the list of ASC covered device-intensive procedures, based on the revised device-intensive definition finalized last year, which would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2016. Table 62 below displays the ASC covered device-intensive procedures that we are proposing would be subject to the no cost/full credit or partial credit device adjustment policy for CY 2016. Specifically, when a procedure that is listed in Table 62 is subject to the no cost/full credit or partial credit device adjustment policy and is performed to implant a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS ''FB'' modifier on the line with the procedure to implant the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost to the ASC or with full credit. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure being furnished by the ASC.

For partial credit, we are proposing to reduce the payment for implantation procedures listed in Table 62 of this proposed rule that are subject to the no cost/full credit or partial credit device adjustment policy by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC would append the HCPCS ''FC'' modifier to the HCPCS code for a surgical procedure listed in Table 62 that is subject to the no cost/full credit or partial credit device adjustment policy, when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. In order to report that they received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs would have the option of either: (1) Submitting the claim for the device replacement procedure to their Medicare contractor after the procedure's performance but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment once the credit determination is made; or (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device. Beneficiary coinsurance would continue to be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period, in order to ensure that our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost/full credit or partial credit, we apply our FB/FC policy to all device-intensive procedures (79 FR 66926).

We are inviting public comment on these proposals.

TABLE 62—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DESIGNATION AS DEVICE-INTENSIVE FOR CY 2016, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH THE PROPOSED NO COST/FILL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY

HCPCS code	Short descriptor	Proposed CY 2016 ASC PI	Proposed CY 2016 OPPS APC**	Proposed CY 2016 device offset percentage	Proposed FB/FC policy would apply
0100T	Prosth retina receive&gen	J8	1593	99.99%	Y
0171T	Lumbar spine proces distract	J8	5124	49.60%	Y
0238T	Trluml perip athrc iliac art	J8	5193	60.43%	Y
0282T	Periph field stimul trial	J8	5462	56.27%	Y
0283T	Periph field stimul perm	J8	5464	86.77%	Y
0302T	Icar ischm mntrng sys compl	J8	5223	68.50%	Y
0303T	Icar ischm mntrng sys eltrd	J8	5222	72.88%	Y
0304T	Icar ischm mntrng sys device	J8	5222	72.88%	Y
0307T	Rmvl icar ischm mntrng dvce	J8	5221	45.44%	Y
0308T	Insj ocular telescope prosth	J8	5494	81.62%	Y
0316T	Replc vagus nerve pls gen	J8	5463	85.69%	Y
0387T	Leadless c pm ins/rpl ventr	J8	5193	60.43%	Y
04XX1*	Insj/rplc cardiac modulj sys	J8	5223	68.50%	Y
04XX2*	Insj/rplc cardiac modulj pls gn	J8	5223	68.50%	Y
04XX3*	Insj/rplc car modulj atr elt	J8	5222	72.88%	Y
04XX4*	Insj/rplc car modulj vnt elt	J8	5222	72.88%	Y

TABLE 62—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DESIGNATION AS DEVICE-INTENSIVE FOR CY 2016, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH THE PROPOSED NO COST/FILL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY—Continued

HCPCS code	Short descriptor	Proposed CY 2016 ASC PI	Proposed CY 2016 OPPS APC**	Proposed CY 2016 device offset percentage	Proposed FB/FC policy would apply
04XX5*	Rmvl cardiac modulj pls gen	J8	5222	72.88%	Y
04XX7*	Rmvl & rpl car modulj pls gn	J8	5224	72.68%	Y
19298	Place breast rad tube/caths	J8	5093	41.08%	Y
19325	Enlarge breast with implant	J8	5093	41.08%	Y
19342	Delayed breast prosthesis	J8	5093	41.08%	Y
19357	Breast reconstruction	J8	5093	41.08%	Y
22551	Neck spine fuse&remov bel c2	J8	5124	49.60%	Y
22554	Neck spine fusion	J8	5124	49.60%	Y
22612	Lumbar spine fusion	J8	5124	49.60%	Y
23465	Repair shoulder capsule	J8	5124	49.60%	Y
23485	Revision of collar bone	J8	5124	49.60%	Y
23491	Reinforce shoulder bones	J8	5124	49.60%	Y
23552	Treat clavicle dislocation	J8	5124	49.60%	Y
23615	Treat humerus fracture	J8	5124	49.60%	Y
23616	Treat humerus fracture	J8	5124	49.60%	Y
23680	Treat dislocation/fracture	J8	5124	49.60%	Y
23800	Fusion of shoulder joint	J8	5124	49.60%	Y
23802	Fusion of shoulder joint	J8	5124	49.60%	Y
24346	Reconstruct elbow med ligmnt	J8	5124	49.60%	Y
24361	Reconstruct elbow joint	J8	5124	49.60%	Y
24363	Replace elbow joint	J8	5124	49.60%	Y
24365	Reconstruct head of radius	J8	5124	49.60%	Y
24366	Reconstruct head of radius	J8	5124	49.60%	Y
24370	Revise reconst elbow joint	J8	5124	49.60%	Y
24371	Revise reconst elbow joint	J8	5124	49.60%	Y
24410	Revision of humerus	J8	5124	49.60%	Y
24430	Repair of humerus	J8	5124	49.60%	Y
24435	Repair humerus with graft	J8	5124	49.60%	Y
24498	Reinforce humerus	J8	5124	49.60%	Y
24515	Treat humerus fracture	J8	5124	49.60%	Y
24516	Treat humerus fracture	J8	5124	49.60%	Y
24545	Treat humerus fracture	J8	5124	49.60%	Y
24546	Treat humerus fracture	J8	5124	49.60%	Y
24575	Treat humerus fracture	J8	5124	49.60%	Y
24579	Treat humerus fracture	J8	5124	49.60%	Y
24586	Treat elbow fracture	J8	5124	49.60%	Y
24587	Treat elbow fracture	J8	5124	49.60%	Y
24666	Treat radius fracture	J8	5124	49.60%	Y
24802	Fusion/graft of elbow joint	J8	5124	49.60%	Y
25391	Lengthen radius or ulna	J8	5124	49.60%	Y
25420	Repair/graft radius & ulna	J8	5124	49.60%	Y
25441	Reconstruct wrist joint	J8	5124	49.60%	Y
25442	Reconstruct wrist joint	J8	5124	49.60%	Y
25444	Reconstruct wrist joint	J8	5124	49.60%	Y
25446	Wrist replacement	J8	5124	49.60%	Y
25575	Treat fracture radius/ulna	J8	5124	49.60%	Y
25800	Fusion of wrist joint	J8	5124	49.60%	Y
25810	Fusion/graft of wrist joint	J8	5124	49.60%	Y
27279	Arthrodesis sacroiliac joint	J8	5124	49.60%	Y
27415	Osteochondral knee allograft	J8	5124	49.60%	Y
27428	Reconstruction knee	J8	5124	49.60%	Y
27429	Reconstruction knee	J8	5124	49.60%	Y
27438	Revise kneecap with implant	J8	5124	49.60%	Y
27440	Revision of knee joint	J8	5124	49.60%	Y
27442	Revision of knee joint	J8	5124	49.60%	Y
27443	Revision of knee joint	J8	5124	49.60%	Y
27446	Revision of knee joint	J8	5124	49.60%	Y
27745	Reinforce tibia	J8	5124	49.60%	Y
27758	Treatment of tibia fracture	J8	5124	49.60%	Y
27759	Treatment of tibia fracture	J8	5124	49.60%	Y
27823	Treatment of ankle fracture	J8	5124	49.60%	Y
27827	Treat lower leg fracture	J8	5124	49.60%	Y
27828	Treat lower leg fracture	J8	5124	49.60%	Y
27870	Fusion of ankle joint open	J8	5124	49.60%	Y
27871	Fusion of tibiofibular joint	J8	5124	49.60%	Y
28320	Repair of foot bones	J8	5124	49.60%	Y
28420	Treat/graft heel fracture	J8	5124	49.60%	Y

TABLE 62—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DESIGNATION AS DEVICE-INTENSIVE FOR CY 2016, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH THE PROPOSED NO COST/FILL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY—Continued

HCPCS code	Short descriptor	Proposed CY 2016 ASC PI	Proposed CY 2016 OPPS APC**	Proposed CY 2016 device offset percentage	Proposed FB/FC policy would apply
28705	Fusion of foot bones	J8	5124	49.60%	Y
28715	Fusion of foot bones	J8	5124	49.60%	Y
28725	Fusion of foot bones	J8	5124	49.60%	Y
28730	Fusion of foot bones	J8	5124	49.60%	Y
28735	Fusion of foot bones	J8	5124	49.60%	Y
28737	Revision of foot bones	J8	5124	49.60%	Y
28740	Fusion of foot bones	J8	5124	49.60%	Y
29889	Knee arthroscopy/surgery	J8	5124	49.60%	Y
29899	Ankle arthroscopy/surgery	J8	5124	49.60%	Y
29907	Subtalar arthro w/fusion	J8	5124	49.60%	Y
33206	Insert heart pm atrial	J8	5223	68.50%	Y
33207	Insert heart pm ventricular	J8	5223	68.50%	Y
33208	Insrt heart pm atrial & vent	J8	5223	68.50%	Y
33210	Insert electrd/pm cath sngl	J8	5222	72.88%	Y
33211	Insert card electrodes dual	J8	5222	72.88%	Y
33212	Insert pulse gen sngl lead	J8	5222	72.88%	Y
33213	Insert pulse gen dual leads	J8	5223	68.50%	Y
33214	Upgrade of pacemaker system	J8	5223	68.50%	Y
33216	Insert 1 electrode pm-defib	J8	5222	72.88%	Y
33217	Insert 2 electrode pm-defib	J8	5222	72.88%	Y
33218	Repair lead pace-defib one	J8	5221	45.44%	Y
33220	Repair lead pace-defib dual	J8	5221	45.44%	Y
33221	Insert pulse gen mult leads	J8	5224	72.68%	Y
33224	Insert pacing lead & connect	J8	5223	68.50%	Y
33227	Remove&replace pm gen singl	J8	5222	72.88%	Y
33228	Remv&replc pm gen dual lead	J8	5223	68.50%	Y
33229	Remv&replc pm gen mult leads	J8	5224	72.68%	Y
33230	Insrt pulse gen w/dual leads	J8	5231	77.49%	Y
33231	Insrt pulse gen w/mult leads	J8	5232	80.65%	Y
33233	Removal of pm generator	J8	5221	45.44%	Y
33234	Removal of pacemaker system	J8	5221	45.44%	Y
33235	Removal pacemaker electrode	J8	5221	45.44%	Y
33240	Insrt pulse gen w/singl lead	J8	5231	77.49%	Y
33241	Remove pulse generator	J8	5221	45.44%	Y
33249	Insj/rplcmt defib w/lead(s)	J8	5232	80.65%	Y
33262	Rmvl& replc pulse gen 1 lead	J8	5231	77.49%	Y
33263	Rmvl & rplcmt dfb gen 2 lead	J8	5231	77.49%	Y
33264	Rmvl & rplcmt dfb gen mlt ld	J8	5232	80.65%	Y
33270	Ins/rep subq defibrillator	J8	5232	80.65%	Y
33271	Insj subq impltbl dfb elctrd	J8	5222	72.88%	Y
33273	Repos prev impltbl subq dfb	J8	5221	45.44%	Y
33282	Implant pat-active ht record	J8	5222	72.88%	Y
36261	Revision of infusion pump	J8	5221	45.44%	Y
36262	Removal of infusion pump	J8	5221	45.44%	Y
37221	Iliac revasc w/stent	J8	5192	50.56%	Y
37225	Fem/popl revas w/ather	J8	5192	50.56%	Y
37226	Fem/popl revasc w/stent	J8	5192	50.56%	Y
37227	Fem/popl revasc stnt & ather	J8	5193	60.43%	Y
37228	Tib/per revasc w/tla	J8	5192	50.56%	Y
37229	Tib/per revasc w/ather	J8	5193	60.43%	Y
37230	Tib/per revasc w/stent	J8	5193	60.43%	Y
37231	Tib/per revasc stent & ather	J8	5193	60.43%	Y
37236	Open/perq place stent 1st	J8	5192	50.56%	Y
37238	Open/perq place stent same	J8	5192	50.56%	Y
50080	Removal of kidney stone	J8	5376	53.72%	Y
50081	Removal of kidney stone	J8	5376	53.72%	Y
53440	Male sling procedure	J8	5376	53.72%	Y
53444	Insert tandem cuff	J8	5376	53.72%	Y
53445	Insert uro/ves nck sphincter	J8	5377	70.25%	Y
53447	Remove/replace ur sphincter	J8	5377	70.25%	Y
54112	Treat penis lesion graft	J8	5376	53.72%	Y
54400	Insert semi-rigid prosthesis	J8	5376	53.72%	Y
54401	Insert self-contd prosthesis	J8	5377	70.25%	Y
54405	Insert multi-comp penis pros	J8	5377	70.25%	Y
54410	Remove/replace penis prosth	J8	5377	70.25%	Y
54416	Remv/repl penis contain pros	J8	5377	70.25%	Y
55873	Cryoablate prostate	J8	5376	53.72%	Y

TABLE 62—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DESIGNATION AS DEVICE-INTENSIVE FOR CY 2016, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH THE PROPOSED NO COST/FILL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY—Continued

HCPCS code	Short descriptor	Proposed CY 2016 ASC PI	Proposed CY 2016 OPPS APC**	Proposed CY 2016 device offset percentage	Proposed FB/FC policy would apply
57120	Closure of vagina	J8	5415	19.94%	Y
57310	Repair urethrovaginal lesion	J8	5416	18.21%	Y
58260	Vaginal hysterectomy	J8	5415	19.94%	Y
58262	Vag hyst including t/o	J8	5415	19.94%	Y
58543	Lsh uterus above 250 g	J8	5362	16.68%	Y
58544	Lsh w/t/o uterus above 250 g	J8	5362	16.68%	Y
58553	Laparo-vag hyst complex	J8	5362	16.68%	Y
58554	Laparo-vag hyst w/t/o compl	J8	5362	16.68%	Y
58573	Tlh w/t/o uterus over 250 g	J8	5362	16.68%	Y
61885	Insrt/redo neurostim 1 array	J8	5463	85.69%	Y
61886	Implant neurostim arrays	J8	5464	86.77%	Y
61888	Revise/remove neuroreceiver	J8	5462	56.27%	Y
62360	Insert spine infusion device	J8	5471	79.84%	Y
62361	Implant spine infusion pump	J8	5471	79.84%	Y
62362	Implant spine infusion pump	J8	5471	79.84%	Y
63650	Implant neuroelectrodes	J8	5462	56.27%	Y
63655	Implant neuroelectrodes	J8	5463	85.69%	Y
63663	Revise spine eltrd perq aray	J8	5462	56.27%	Y
63664	Revise spine eltrd plate	J8	5462	56.27%	Y
63685	Insrt/redo spine n generator	J8	5464	86.77%	Y
64553	Implant neuroelectrodes	J8	5462	56.27%	Y
64555	Implant neuroelectrodes	J8	5462	56.27%	Y
64561	Implant neuroelectrodes	J8	5462	56.27%	Y
64565	Implant neuroelectrodes	J8	5462	56.27%	Y
64568	Inc for vagus n elect impl	J8	5464	86.77%	Y
64569	Revise/repl vagus n eltrd	J8	5462	56.27%	Y
64575	Implant neuroelectrodes	J8	5462	56.27%	Y
64580	Implant neuroelectrodes	J8	5463	85.69%	Y
64581	Implant neuroelectrodes	J8	5462	56.27%	Y
64590	Insrt/redo pn/gastr stimul	J8	5463	85.69%	Y
65770	Revise cornea with implant	J8	5493	62.97%	Y
69714	Implant temple bone w/stimul	J8	5124	49.60%	Y
69715	Temple bne implnt w/stimulat	J8	5124	49.60%	Y
69718	Revise temple bone implant	J8	5124	49.60%	Y
69930	Implant cochlear device	J8	5166	83.03%	Y
C9740	Cysto impl 4 or more	J8	1564	63.71%	Y

* New CPT codes (with CMS 5-digit placeholder codes) that would be effective January 1, 2016. The long descriptors for these new codes can be found in Addendum O to this proposed rule (which is available via the Internet on the CMS Web site).

** Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the proposed new CY 2016 APC numbers.

d. Proposed Adjustment to ASC Payments for Discontinued Device-Intensive Procedures

As discussed in section IV.B.4. of this proposed rule, we are proposing to modify the calculation of OPPS payment when modifiers indicating that the procedure was discontinued appear on the claim. When a procedure assigned to a device-intensive APC is discontinued either prior to administration of anesthesia or for a procedure that does not require anesthesia, we presume that, in the majority of cases, the device was not used and remains sterile such that it could be used for another case. In these circumstances, under current policy, providers are being paid twice by Medicare for the same device, once for the initial procedure that was discontinued and again when the device is actually used. We believe that in cases where the procedure was not performed, that it would be appropriate to remove the estimated cost of the device, since it would have presumably not been used.

We believe these same issues exist in the ASC setting, and thus are proposing that this alternative payment calculation where the device offset is removed before applying any standard downward payment adjustments because a full procedure was not performed would also apply to device-intensive procedures in the ASC system beginning in CY 2016, with modifiers 52 (reduced services) and 73 (Discontinued outpatient procedure prior to anesthesia administration), which are the same modifiers proposed in the OPPS. Modifier 52 is used to indicate certain circumstances in which a procedure is partially reduced or eliminated. Modifier 73 is used when a service is canceled prior to the surgical preparation due to circumstances that may threaten the well-being of a patient. Under this proposed methodology, any adjustment policies reducing payment would only apply to the procedural portion of the service, based on ASC payment after the device offset is removed. Use of modifiers 52 or 73 would thus result in 50 percent of ASC payment for the service, after the device offset has first been subtracted from the standard ASC payment amount. We are proposing to restrict the policy to ASC device-intensive procedures so that the adjustment would not be triggered by the use of an inexpensive device whose

cost would not constitute a significant portion of the total payment rate.

Similar to the OPPS, we are not proposing to deduct the device offset amount from a procedure that was discontinued after anesthesia was administered (modifier 74) as we believe that it may be more likely that devices involved with such procedures are more likely to no longer be sterile such that they could be restocked and used for another case. However, we are soliciting public comments on how often the device becomes ineligible for use in a subsequent case and whether we should deduct the device offset amount from claims with modifier 74 as well. We are proposing to revise 42 CFR 416.172 to reflect this proposal.

We are inviting public comment on this proposal and this proposed codification.

e. Proposed Additions to the List of ASC Covered Surgical Procedures

We conducted a review of HCPCS codes that currently are paid under the OPPS, but not included on the ASC list of covered surgical procedures, to determine if changes in technology and/or medical practice affected the clinical appropriateness of these procedures for the ASC setting. Based on this review, we are proposing to update the list of ASC covered surgical procedures by adding 11 procedures to the list for CY 2016. We determined that these 11 procedures would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. Therefore, we are proposing to include them on the list of ASC covered surgical procedures for CY 2016.

The 11 procedures that we are proposing to add to the ASC list of covered surgical procedures, including their HCPCS code long descriptors and proposed CY 2016 payment indicators, are displayed in Table 63 below.

We are inviting public comment on this proposal.

TABLE 63—PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2016

Proposed CY 2016 HCPCS code	Proposed CY 2016 long descriptor	Proposed CY 2016 ASC payment indicator
0171T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level.	J8
0172T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level.	N1
57120	Colpocleisis (Le Fort type)	J8
57310	Closure of urethrovaginal fistula	J8
58260	Vaginal hysterectomy, for uterus 250 g or less	J8
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)	J8
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g	J8
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	J8
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g	J8
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	J8
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	J8

f. ASC Treatment of Surgical Procedures Proposed for Removal From the OPPS Inpatient List for CY 2016

As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68724), we adopted a policy to include, in our annual evaluation of the ASC list of covered surgical procedures, a review of the procedures that are being proposed for removal from the OPPS inpatient list for possible inclusion on the ASC list of covered surgical procedures. We evaluated each of the seven procedures we are proposing to remove from the OPPS inpatient list for CY 2016 according to the criteria for exclusion from the list of covered ASC surgical procedures. We believe that these seven procedures should continue to be excluded from the ASC list of covered surgical procedures for CY 2016 because they would be expected to pose a significant risk to beneficiary safety or to require an overnight stay in ASCs. The CPT codes for these seven procedures and their long descriptors are listed in Table 64 below.

We are inviting public comment on the continued exclusion of these codes from the ASC list of covered surgical procedures.

TABLE 64—PROCEDURES PROPOSED FOR EXCLUSION FROM THE ASC LIST OF COVERED SURGICAL PROCEDURES FOR CY 2016 THAT ARE PROPOSED FOR REMOVAL FROM THE CY 2016 OPPS INPATIENT LIST

CPT Code	Long descriptor
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming
20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from same incision
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision)
20938	Autograft for spine surgery only (includes harvesting the graft); structural bicortical or tricortical (through separate skin or fascial incision)
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace

TABLE 64—PROCEDURES PROPOSED FOR EXCLUSION FROM THE ASC LIST OF COVERED SURGICAL PROCEDURES FOR CY 2016 THAT ARE PROPOSED FOR REMOVAL FROM THE CY 2016 OPPS INPATIENT LIST—Continued

CPT Code	Long descriptor
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue

2. Covered Ancillary Services

a. Proposed List of Covered Ancillary Services

Consistent with the established ASC payment system policy, we are proposing to update the ASC list of covered ancillary services to reflect the proposed payment status for the services under the CY 2016 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary services because of changes that are being proposed under the OPPS for CY 2016. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2015 may be proposed for packaged status under the CY 2016 OPPS and, therefore, also under the ASC payment system for CY 2016.

To maintain consistency with the OPPS, we are proposing that these services also would be packaged under the ASC payment system for CY 2016. We are proposing to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator ''CH,'' discussed in section XII.F. of this proposed rule, is used in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site) to indicate covered ancillary services for which we are proposing a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2016.

All ASC covered ancillary services and their proposed payment indicators for CY 2016 are included in Addendum BB to this proposed rule. We are inviting public comment on this proposal.

b. Proposal To Exclude Corneal Tissue Procurement From the Covered Ancillary Services List When Used for Nontransplant Procedures

We refer readers to section X.C. of this proposed rule for a discussion of our proposal to include corneal tissue procurement as a covered ancillary service only when it is integral to the performance of a corneal transplant procedure that is an ASC covered surgical procedure.

c. Proposal to Remove Certain Services From the Covered Ancillary Services List That Are Not Used as Ancillary and Integral To a Covered Surgical Procedure

It has come to our attention that we include codes for services on our covered ancillary services list that are not used as ancillary and integral to a covered ASC surgical procedure. In some cases, codes on the ASC covered ancillary services list are not provided in the ASC setting due to clinical practice. In examining the current ancillary services list and claims data available to us for CY 2016 proposed ASC rulemaking, we noted several services that are not and have not been historically furnished in the ASC setting. Several radiation therapy treatment services, including gamma knife stereotactic radiosurgery (SRS), are most frequently provided in the hospital outpatient setting and paid through the OPPS and also are infrequently furnished in freestanding radiation therapy centers and paid under the MPFS. Claims data indicate that it is not furnished in the ASC setting. Since ASCs do not appear to be utilizing these services as integral and ancillary to covered ASC surgical procedures, and given the specialized nature of the SRS treatment services, we would not expect them to be integral and ancillary to an ASC covered surgical procedure, we are proposing to remove radiation treatment codes for SRS services from the list of ASC covered ancillary services. Specifically, we are proposing to remove CPT codes 77371 (Radiation treatment delivery, stereotactic radiosurgery (srs), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source cobalt 60 based), 77372 (Radiation treatment delivery, stereotactic radiosurgery (srs), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based), and 77373 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions) from the list of ASC covered ancillary services for CY 2016 and subsequent years. We note that while we are proposing to remove these three codes from the list of ancillary covered services for CY 2016 and subsequent years, we will continue to monitor the claims data to identify services for which clinical practice patterns indicate they are not provided in the ASC setting.

We are inviting public comment on this proposal.

D. Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are fully described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy for the revised ASC payment system, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators ''G2'' and ''A2.'' Payment indicator ''A2'' was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we retained payment indicator ''A2'' because it is used to identify procedures that are exempted from application of the office-based designation.

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so that the packaged device payment amount is the same as under the OPPS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66915 through 66940), we updated the CY 2014 ASC payment rates for ASC

covered surgical procedures with payment indicators of ''A2,'' ''G2,'' and ''J8'' using CY 2013 data, consistent with the CY 2015 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2015 OPPS device offset percentages calculated under the standard APC ratesetting methodology as discussed earlier in this section.

Payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') are the lower of the MPFS nonfacility PE RVU-based amount (we refer readers to the CY 2016 MPFS proposed rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2015 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') using the most recent available MPFS and OPPS data. We compared the estimated CY 2015 rate for each of the office-based procedures, calculated according to the ASC standard ratesetting methodology, to the MPFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2015 payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package device removal codes under the OPPS. Under the OPPS, a conditionally packaged code (status indicators ''Q1'' and ''Q2'') describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator ''N1'') under the ASC payment system. Therefore, no Medicare payment would be made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To address this concern, for the device removal procedures that are conditionally packaged in the OPPS (status indicator ''Q2''), we assigned the current ASC payment indicators associated with these procedures and continued to provide separate payment in CYs 2014 and 2015.

b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2016

We are proposing to update ASC payment rates for CY 2016 and subsequent years using the established rate calculation methodologies under § 416.171 and using our established modified definition of device-intensive procedures, as discussed above. Because the proposed OPPS relative payment weights are based on geometric mean costs for CY 2016 and subsequent years, the ASC system will use geometric means to determine proposed relative payment weights under the ASC standard methodology. We are proposing to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2.''

We are proposing that payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') and device-intensive procedures (payment indicator ''J8'') be calculated according to our established policies and, for device-intensive procedures, using our established modified definition of device-intensive procedures, as discussed above. Therefore, we are proposing to update the payment amount for the service portion of the device-intensive procedures using the ASC standard ratesetting methodology and the payment amount for the device portion based on the proposed CY 2016 OPPS device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Payment for office-based procedures is at the lesser of the proposed CY 2016 MPFS nonfacility PE RVU-based amount or the proposed CY 2016 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 and 2015, for CY 2016 and subsequent years, we are proposing to continue our policy for device removal procedures such that device removal procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2'') would be assigned the current ASC payment indicators associated with these procedures and would continue to be paid separately under the ASC payment system.

We are inviting public comment on these proposals.

c. Waiver of Coinsurance and Deductible for Certain Preventive Services

Section 1833(a)(1) and section 1833(b)(1) of the Act waive the coinsurance and the Part B deductible for those preventive services under section 1861(ddd)(3)(A) of the Act as described in section 1861(ww)(2) of the Act (excluding electrocardiograms) that are recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population and that are appropriate for the individual. Section 1833(b) of the Act also waives the Part B deductible for colorectal cancer screening tests that become diagnostic. In the CY 2011 OPPS/ASC final rule with comment period, we finalized our policies with respect to these provisions and identified categories of services and the ASC covered surgical procedures and covered ancillary services that are preventive services that are recommended by the USPSTF with a grade of A or B for which the coinsurance and the deductible are waived. For a complete discussion of our policies and categories of services, we refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72047 through 72049). We are not proposing any changes to our policies or the categories of services for CY 2016. We identify the specific services with a double asterisk in Addenda AA and BB to this proposed rule (which are available via the Internet on the CMS Web site).

d. Payment for Cardiac Resynchronization Therapy Services

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. CRT utilizes a pacing electrode implanted in combination with either a pacemaker or an implantable cardioverter defibrillator (ICD). CRT performed by the implantation of an ICD along with a pacing electrode is referred to as ''CRT–D.'' In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to establish the CY 2012 ASC payment rate for CRT–D services based on the OPPS payment rate applicable to APC 0108 when procedures described by CPT codes 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (eg, for upgrade to dual chamber system) (list separately in addition to code for primary procedure)) and 33249 (Insertion or replacement of

permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber) are performed on the same date of service in an ASC.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66931), we finalized our proposals under the OPPS that CPT code 33249, the primary code for CRT–D services, continue to be assigned to APC 0108, and that payment for CPT code 33225 be packaged under the OPPS. We also finalized our proposals under the ASC payment system that CPT code 33249, the primary code for CRT–D services, will continue to be assigned to APC 0108, and payment for CPT code 33225 will be packaged into the payment for the primary covered surgical procedure (for example, CPT code 33249). We are not proposing any changes to these policies for CY 2016. We note that, in this proposed rule, we are proposing to renumber APC 0108 as APC 5232.

e. Payment for Low Dose Rate (LDR) Prostate Brachytherapy Composite

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through the needles/catheters. At least two CPT codes are used to report the treatment service because there are separate codes that describe placement of the needles/catheters and the application of the brachytherapy sources: CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy); and CPT code 77778 (Interstitial radiation source application; complex). Generally, the component services represented by both codes are provided in the same operative session on the same date of service to the Medicare beneficiary being treated with LDR brachytherapy for prostate cancer.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to establish the CY 2013 ASC payment rate for LDR prostate brachytherapy services based on the OPPS relative payment weight applicable to APC 8001 when CPT codes 55875 and 77778 are performed on the same date of service in an ASC. ASCs use the corresponding HCPCS Level II G-code (G0458) for proper reporting when the procedures described by CPT codes 55875 and 77778 are performed on the same date of service, and therefore receive the appropriate LDR prostate brachytherapy composite payment. When not performed on the same day as the service described by CPT code 55875, the service described by CPT code 77778 will be assigned to APC 0651 (in this proposed rule, proposed to be renumbered APC 5641). When not performed on the same day as the service described by CPT code 77778, the service described by CPT code 55875 will be assigned to APC 0162 (in this proposed rule, proposed to be renumbered APC 5374). For a complete discussion of our policy regarding payment for LDR prostate brachytherapy services in ASCs, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68457). We are not proposing any changes to our current policy regarding ASC payment for LDR prostate brachytherapy services for CY 2016.

2. Proposed Payment for Covered Ancillary Services

a. Background

Our final payment policies under the revised ASC payment system for covered ancillary services vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N,'' ''Q1,'' and ''Q2'') under the OPPS. In the CY 2013 OPPS/ASC rulemaking (77 FR 45169; 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment of codes that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged code describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indictor ''N1'') under the ASC payment system. Thus, our final policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates. We generally pay for separately payable radiology services at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount, regardless of which is lower.

Similarly, we also finalized our policy to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight and, therefore, will include the cost for the contrast agent (42 CFR 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to the final policies for the revised ASC payment system (72 FR 42502 and 42508 through 42509; 42 CFR 416.164(b)). Under the revised ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (nondevice) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a ''device offset'' to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator ''Z2'' and revised the definition of payment indicator ''Z2'' to include reference to diagnostic services and those for which the payment is based on the MPFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3,'' and revised the definition of payment indicator ''Z3'' to include reference to diagnostic services.

b. Proposed Payment for Covered Ancillary Services for CY 2016

For CY 2016 and subsequent years, we are proposing to update the ASC payment rates and to make changes to ASC payment indicators as necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2016 OPPS and ASC payment rates and subsequent year payment rates. We also are proposing to continue to set the CY 2016 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the proposed OPPS payment rates for CY 2016.

Consistent with established ASC payment policy (72 FR 42497), we are proposing that the CY 2016 payment for separately payable covered radiology services be based on a comparison of the proposed CY 2016 MPFS nonfacility PE RVU-based amounts (we refer readers to the CY 2016 MPFS proposed rule) and the CY 2016 ASC payment rates calculated according to the ASC standard ratesetting methodology and then set at the lower of the two amounts (except as discussed below for nuclear medicine procedures and radiology services that use contrast agents). We would make this same proposal for subsequent years. For CY 2016 and subsequent years, we also are proposing that payment for a radiology service would be packaged into the payment for the ASC covered surgical procedure if the radiology service is packaged or conditionally packaged under the OPPS. The payment indicators in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site) indicate whether the proposed payment rates for radiology services are based on the MPFS nonfacility PE RVU-based amount or the ASC standard ratesetting methodology, or whether payment for a radiology service is packaged into the payment for the covered surgical procedure (payment indicator ''N1''). Radiology services that we are proposing to pay based on the ASC standard ratesetting methodology in CY 2016 and subsequent years are assigned payment indicator ''Z2'' (Radiology or diagnostic service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight), and those for which the proposed payment is based on the MPFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3'' (Radiology or diagnostic service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS nonfacility PE RVUs).

As finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment for these procedures will be based on the OPPS relative payment weight (rather than the MPFS nonfacility PE RVU-based amount, regardless of which is lower) and, therefore, will include the cost for the diagnostic radiopharmaceutical. We are proposing to continue this modification to the payment methodology for CY 2016 and subsequent years and, therefore, are proposing to assign the payment indicator ''Z2'' to nuclear medicine procedures.

As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430), payment indicators for radiology services that use contrast agents are set to ''Z2'' so that payment for these procedures will be based on the OPPS relative payment weight and, therefore, will include the cost for the contrast agent. We are proposing to continue this modification to the payment methodology for CY 2016 and subsequent years and, therefore, are proposing to assign the payment indicator ''Z2'' to radiology services that use contrast agents.

We are proposing to not make separate payment as a covered ancillary service for procurement of corneal tissue when used in any nontransplant procedure under the ASC payment system. For more detail on this CY 2016 proposal, we refer readers to section X.C. of this proposed rule. We are proposing, for CY 2016 ASC payment purposes, to continue to designate hepatitis B vaccines as contractor-priced based on the invoiced costs for the vaccine, and corneal tissue acquisition as contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplant.

Consistent with our established ASC payment policy, we are proposing that the CY 2016 payment for devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and would be contractor-priced. Currently, the three devices that are eligible for pass-through payment in the OPPS are described by HCPCS code C1841 (Retinal prosthesis, includes all internal and external components), HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) and, beginning on July 1, HCPCS code C2613 (Lung biopsy plug with delivery system). As finalized in the CY 2015 OPPS/ASC final rule with comment period, HCPCS code C1841 will no longer be eligible for pass-through

payment in the OPPS for CY 2016 (79 FR 66870 through 66871), and thus the costs for devices described by HCPCS code C1841 would be packaged into the costs of the procedures with which the devices are reported in the hospital claims data used in the development of the OPPS relative payment weights that will be used to establish ASC payment rates for CY 2016. Payment amounts for HCPCS codes C2623 and C2613 under the ASC payment system would be contractor-priced for CY 2016. Consistent with our current policy, we are proposing that payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (nondevice) portion of the procedure's OPPS relative payment weight, if the APC weight for the procedure includes similar packaged device costs.

Consistent with our current policy, we are proposing that certain diagnostic tests within the medicine range of CPT codes (that is, all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT) for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We would pay for these tests at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). As discussed in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66934), for CY 2015, we identified one diagnostic test that is within the medicine range of CPT codes and for which separate payment is allowed under the OPPS: CPT code 91035 (Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation). We added this code to the list of ASC covered ancillary services and finalized separate ASC payment as a covered ancillary service for this code beginning in CY 2015 when the test is integral to an ASC covered surgical procedure. We stated that we would expect the procedure described by CPT code 91035 to be integral to the endoscopic attachment of the electrode to the esophageal mucosa. There are no additional codes that meet this criterion for CY 2016.

In summary, for CY 2016, we are proposing to continue the methodologies for paying for covered ancillary services established for CY 2015. Most covered ancillary services and their proposed payment indicators for CY 2016 are listed in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site).

E. New Technology Intraocular Lenses (NTIOLs)

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

- Applicants submit their NTIOL requests for review to CMS by the annual deadline. For a request to be considered complete, we require submission of the information that is found in the guidance document entitled ''Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an existing NTIOL Class'' posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*.
- We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Pub. L. 103–432 and our regulations at 42 CFR 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.
- In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments;

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2016

We did not receive any requests for review to establish a new NTIOL class for CY 2016 by March 2, 2015, the due date published in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66935).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we are not proposing to revise the payment adjustment amount for CY 2016.

4. Proposed Newness Criterion

Since the inception of the NTIOL policy in 1999, there has not been any specific criterion provided to evaluate the newness of a candidate IOL for new technology payment under the ASC payment system. Absence of any specific criterion means that, regardless of when an IOL was originally FDA approved and available on the U.S. market, the IOL could be established as a new NTIOL class if it satisfies the requirements of 42 CFR 416.195. We believe that because the NTIOL payment adjustment under the statute was specifically created for IOLs that are ''new,'' the regulations at § 416.195 should include a newness criterion. Therefore, we are proposing that, beginning in CY 2016, any application for a new NTIOL class must fulfill an additional criterion. Specifically, we are proposing that, beginning January 1, 2016, an NTIOL application will only be evaluated by CMS for a new IOL class if the IOL has received initial FDA premarket approval within the 3 years prior to the NTIOL application submission date. Without this proposed requirement, there is nothing in the existing regulations that would preclude an applicant from applying for and possibly being granted NTIOL status, despite U.S. market entry many years ago, which would be contrary to the plain meaning of ''new'' technology IOLs. We are proposing to revise § 416.195(a)(1) of the regulations to reflect this proposal. We are inviting public comments on this proposal.

F. Proposed ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we also created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC list of covered services prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators used in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NI'' is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). In the CY 2016 OPPS/ASC final rule with comment period, we will respond to public comments and finalize the ASC treatment of all codes that are labeled with comment indicator ''NI'' in Addenda AA and BB to the CY 2015 OPPS/ASC final rule with comment period.

The ''CH'' comment indicator is used in Addenda AA and BB to this proposed rule (which are available via the Internet on the CMS Web site) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year; an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

2. Proposed ASC Payment and Comment Indicators

For CY 2016 and subsequent years, we are proposing to continue using the current comment indicators of ''NI'' and ''CH.'' For CY 2016, there are new and revised Category I and III CPT codes, as well as new and revised Level II HCPCS codes. Therefore, we are proposing that Category I and III CPT codes that are new and revised for CY 2016 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2016 compared to the CY 2015 descriptors that are included in ASC Addendum AA and BB to this CY 2016 OPPS/ASC proposed rule would be labeled with proposed new comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes are open for comment as part of this CY 2016 OPPS/ASC proposed rule. Proposed new comment indicator ''NP'' means a new code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, proposed ASC payment indicator; comments will be accepted on the proposed ASC payment indicator for the new code.

For the CY 2016 update, we also are proposing to add ASC payment indicator ''B5'' (Alternative code may be available; no payment made) to ASC Addendum DD1 to this proposed rule (which is available via the Internet on the CMS Web site). This code indicates that an alternative code is recognized under the ASC payment system. We are proposing to add this payment indicator for situations where we receive new and revised Category I and Category III CPT codes too late for inclusion in a proposed rule, as discussed in section XII.B.3.b. of this proposed rule regarding our proposed process for accepting comments on new and revised Category I and III CPT codes that are effective January 1. We will respond to public comments and finalize their ASC assignment in the CY 2016 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 to this proposed rule (which are available via the Internet on the CMS Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2016 update.

G. Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007 as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; 42 CFR 416.171(e)).

We note that we consider the term ''expenditures'' in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget

neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.D.2. of the proposed rule), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor cost when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs. Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at: *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13–01.pdf.*) In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), we implemented the use of the CBSA delineations issued by OMB in OMB Bulletin 13–01 for the IPPS hospital wage index beginning in FY 2015. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66937), we finalized a one-year transition policy that we applied in CY 2015 for all ASCs that experienced any decrease in their actual wage index exclusively due to the implementation of the new OMB delineations. This transition does not apply in CY 2016.

For CY 2016, the proposed CY 2016 ASC wage indexes fully reflect the new OMB labor market area delineations.

We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a border). For example, for CY 2014, we applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA) and CBSA 08 (Rural Delaware).

When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, we determine the ASC wage index by calculating the average of all wage indexes for urban areas in the State (75 FR 72058 through 72059).

2. Proposed Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2016 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). Consistent with our established policy, we are proposing to scale the CY 2016 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2014, we are proposing to compare the total payment using the CY 2015 ASC relative payment weights with the total payment using the CY 2016 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2015 and CY 2016. We are proposing to use the ratio of CY 2015 to CY 2016 total payment (the weight scaler) to scale the ASC relative payment weights for CY 2016. The proposed CY 2016 ASC scaler is 0.9180 and scaling would apply to the ASC relative payment weights of the covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model

budget neutrality adjustments. At the time of this proposed rule, we have available 98 percent of CY 2014 ASC claims data.

To create an analytic file to support calculation of the weight scaler and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2014 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2014 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for this proposed rule, is posted on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html*.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2016 ASC payment system and subsequent years, we are proposing to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2016, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2014 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2016 ASC wage indexes. Specifically, holding CY 2014 ASC utilization and service-mix and the proposed CY 2016 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2015 ASC wage indexes (which reflect the new OMB delineations and include any applicable transition period) and the total adjusted payment using the proposed CY 2016 ASC wage indexes (which would fully reflect the new OMB delineations). We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2015 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2016 ASC wage indexes and applied the resulting ratio of 1.0014 (the proposed CY 2016 ASC wage index budget neutrality adjustment) to the CY 2015 ASC conversion factor to calculate the proposed CY 2016 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. Therefore, the statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at 42 CFR 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years. Therefore, the annual update to the ASC payment system is the CPI–U (referred to as the CPI–U update factor).

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new clause (v) which requires that any annual update under the ASC payment system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, effective with the calendar year beginning January 1, 2011. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). Clause (iv) of section 1833(i)(2)(D) of the Act authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) of section 1833(i)(2)(D) of the Act states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized a policy that ASCs begin submitting data on quality measures for services beginning on October 1, 2012 for the CY 2014 payment determination under the ASCQR Program. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), we finalized a methodology to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for the CY 2014 payment determination and subsequent years. The application of the 2.0 percentage point reduction to the annual update factor, which currently is the CPI–U, may result in the update to the ASC payment system being less than zero for a year for ASCs that fail to meet the ASCQR Program requirements. We amended §§ 416.160(a)(1) and 416.171 to reflect these policies.

In accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determines the ''percentage increase'' in the CPI–U, which we interpret cannot be a negative percentage. Thus, in the instance where the percentage change in the CPI–U for a year is negative, we would hold the CPI–U update factor for the ASC payment system to zero. For the CY 2014 payment determination and subsequent years, under section 1833(i)(2)(D)(iv) of the Act, we would reduce the annual update by 2.0 percentage points for an ASC that fails to submit quality information under the rules established by the Secretary in accordance with section 1833(i)(7) of the Act. Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that the Secretary reduce the annual update factor, after application of any quality reporting reduction, by the MFP adjustment, and states that application of the MFP adjustment to the annual update factor after application of any quality reporting reduction may result in the update being less than zero for a year. If the application of the MFP adjustment to the annual update factor after application of any quality reporting reduction would result in an MFP-adjusted update factor that is less than zero, the resulting update to the ASC payment rates would be negative and payments would decrease relative to the prior year. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064) for examples of how the MFP adjustment is applied to the ASC payment system.

For this proposed rule, based on IHS Global Insight's (IGI's) 2015 first quarter forecast with historical data through 2014 fourth quarter, for the 12-month period ending with the midpoint of CY 2016, the CPI–U update is projected to

be 1.7 percent. Also, based on IGI's 2015 first quarter forecast, the MFP adjustment for the period ending with the midpoint of CY 2016 is projected to be 0.6 percent. We finalized the methodology for calculating the MFP adjustment in the CY 2011 MPFS final rule with comment period (75 FR 73394 through 73396) as revised in the CY 2012 MPFS final rule with comment period (76 FR 73300 through 73301).

As we discussed in the CY 2011 MPFS final rule with comment period, section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that any annual update to the ASC payment system after application of the quality adjustment be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). Historical published data on the measure of MFP is available on the Bureau of Labor Statistics' (BLS) Web site at *http://www.bls.gov/mfp*.

MFP is derived by subtracting the contribution of labor and capital inputs growth from output growth. The projection of the components of MFP are currently produced by IHS Global Insight, Inc. (IGI), a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of MFP. To generate a forecast of MFP, IGI replicates the MFP measure calculated by the BLS using a series of proxy variables derived from IGI's U.S. macroeconomic models. In the CY 2011 and CY 2012 MPFS final rules with comment period (75 FR 73394 through 73396, 76 FR 73300 through 73301), we set forth the current methodology to generate a forecast of MFP. We identified each of the major MFP component series employed by the BLS to measure MFP as well as provided the corresponding concepts determined to be the best available proxies for the BLS series.

Beginning with the CY 2016 rulemaking cycle, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs. Specifically, IGI has replaced the Real Effective Capital Stock used for Full Employment GDP with a forecast of BLS aggregate capital inputs recently developed by IGI using a regression model. This series provides a better fit to the BLS capital inputs, as measured by the differences between the actual BLS capital input growth rates and the estimated model growth rates over the historical time period. Therefore, we are using IGI's most recent forecast of the BLS capital inputs series in the MFP calculations beginning with the CY 2016 rulemaking cycle. A complete description of the MFP projection methodology is available on CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*. Although we discuss the IGI changes to the MFP proxy series in this proposed rule, in the future, when IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

For CY 2016, we are proposing to reduce the CPI–U update of 1.7 percent by the MFP adjustment of 0.6 percentage point, resulting in an MFP-adjusted CPI–U update factor of 1.1 percent for ASCs meeting the quality reporting requirements. Therefore, we are proposing to apply a 1.1 percent MFP-adjusted CPI–U update factor to the CY 2015 ASC conversion factor for ASCs meeting the quality reporting requirements. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the CPI–U for ASCs that fail to meet the ASCQR Program requirements. We are proposing to reduce the CPI–U update of 1.7 percent by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then apply the 0.6 percentage point MFP reduction. Therefore, we are proposing to apply a −0.9 percent quality reporting/MFP-adjusted CPI–U update factor to the CY 2015 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also are proposing that if more recent data are subsequently available (for example, a more recent estimate of the CY 2016 CPI–U update and MFP adjustment), we would use such data, if appropriate, to determine the CY 2016 ASC update for the final rule with comment period.

For CY 2016, we also are proposing to adjust the CY 2015 ASC conversion factor ($44.058) by the proposed wage index budget neutrality factor of 1.0014 in addition to the MFP-adjusted CPI–U update factor of 1.1 percent discussed above, which results in a proposed CY 2016 ASC conversion factor of $44.605 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we are proposing to adjust the CY 2015 ASC conversion factor ($44.058) by the proposed wage index budget neutrality factor of 1.0014 in addition to the quality reporting/MFP-adjusted CPI–U update factor of −0.9 percent discussed above, which results in a proposed CY 2016 ASC conversion factor of $43.723.

We are inviting public comment on these proposals.

3. Display of Proposed CY 2016 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available via the Internet on the CMS Web site) display the proposed updated ASC payment rates for CY 2016 for covered surgical procedures and covered ancillary services, respectively. For those covered surgical procedures and covered ancillary services where the payment rate is the lower of the proposed rates under the ASC standard ratesetting methodology and the MPFS proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed MPFS rates that would be effective January 1, 2016. For a discussion of the MPFS rates, we refer readers to the CY 2016 MPFS proposed rule.

The proposed payment rates included in these addenda reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program. These addenda contain several types of information related to the proposed CY 2016 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''Proposed to be Subject to Multiple Procedure Discounting'' indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

Display of the comment indicator ''CH'' in the column titled ''Comment Indicator'' indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2016. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that

comments will be accepted on the interim APC assignment for the new code. Display of the comment indicator ''NP'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the proposed assignments for the new code.

The values displayed in the column titled ''Proposed CY 2016 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2016. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs.

To derive the proposed CY 2016 payment rate displayed in the ''Proposed CY 2016 Payment Rate'' column, each ASC payment weight in the ''Proposed CY 2016 Payment Weight'' column was multiplied by the proposed CY 2016 conversion factor of $44.605. The proposed conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment (as discussed in section XII.G.2.b. of this proposed rule).

In Addendum BB, there are no relative payment weights displayed in the ''Proposed CY 2016 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Proposed CY 2016 Payment'' column displays the proposed CY 2016 national unadjusted ASC payment rates for all items and services. The proposed CY 2016 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in April 2015.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2016.

XIII. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

CMS seeks to promote higher quality and more efficient healthcare for Medicare beneficiaries. In pursuit of these goals, CMS has implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). The Hospital OQR Program has generally been modeled after the quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program (formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program).

In addition to the Hospital IQR and Hospital OQR Programs, CMS has implemented quality reporting programs for other care settings that provide financial incentives for the reporting of quality data to CMS. These additional programs include reporting for 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 (LTCH QRP) 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 Facility Quality Reporting (IPFQR) Program;
- Home health agencies, under the Home Health Quality Reporting Program (HH QRP); and
- Hospices, under the Hospice Quality Reporting Program.

In addition, CMS has implemented several value-based purchasing programs, including the Hospital Value-Based Purchasing (VBP) Program and the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP), that link payment to performance.

In implementing the Hospital OQR Program and other quality reporting programs, we have focused on measures that have high impact and support national priorities for improved quality and efficiency of care for Medicare beneficiaries as reflected in the National Quality Strategy (NQS) and the CMS Quality Strategy, as well as conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. To the extent possible under various authorizing statutes, our ultimate goal is to align the clinical quality measure requirements of the various quality reporting programs. As appropriate, we will consider the adoption of measures with electronic specifications to enable the collection of this information as part of care delivery.

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68467 through 68469) for a discussion on the principles underlying consideration for future measures that we intend to use in implementing this and other quality reporting programs.

2. Statutory History of the Hospital OQR Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program.

B. Hospital OQR Program Quality Measures

1. Considerations in the Selection of Hospital OQR Program Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74458 through 74460) for a detailed discussion of the priorities we consider for the Hospital OQR Program quality measure selection. We are not proposing any changes to our measure selection policy.

2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously adopted a policy to retain measures from the previous year's Hospital OQR Program measure set for subsequent years' measure sets in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471). Quality measures adopted in a previous year's rulemaking are retained in the Hospital OQR Program for use in subsequent years unless otherwise specified. We refer readers to that rule for more information. We are not proposing any

changes to our retention policy for previously adopted measures.

3. Removal of Quality Measures From the Hospital OQR Program Measure Set

a. Considerations in Removing Quality Measures From the Hospital OQR Program

In the FY 2010 IPPS/LTCH PPS final rule for the Hospital IQR Program, we finalized a process for immediate retirement, which we later termed ''removal'' (74 FR 43863), of Hospital IQR Program measures based on evidence that the continued use of the measure as specified raised patient safety concerns. We adopted the same immediate measure retirement policy for the Hospital OQR Program in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634 through 60635). We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our reasons for changing the term ''retirement'' to ''removal'' in the Hospital OQR Program. We are not proposing any changes to our policy to immediately remove measures as a result of patient safety concerns.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized a set of criteria for determining whether to remove measures from the Hospital OQR Program. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our policy on removal of quality measures from the Hospital OQR Program. The benefits of removing a measure from the Hospital OQR Program will be assessed on a case-by-case basis (79 FR 66941 through 66942). We note that, under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific criterion.

The following criteria will be used to determine whether to remove a measure from the Hospital OQR Program: (i) Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures); (ii) performance or improvement on a measure does not result in better patient outcomes; (iii) a measure does not align with current clinical guidelines or practice; (iv) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (v) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (vi) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and (vii) collection or public reporting of a measure leads to negative unintended consequences such as patient harm. We are not proposing any changes to our measure removal policy.

b. Criteria for Removal of ''Topped-Out'' Measures

As provided above, quality measures may be removed from the Hospital OQR Program when they are ''topped-out.'' We refer readers to CY 2015 OPPS/ASC final rule with comment period where we finalized our proposal to refine the criteria for determining when a measure is ''topped-out'' (79 FR 66942). We are not proposing any changes to our ''topped-out'' criteria policy.

4. Hospital OQR Program Quality Measures Adopted in Previous Rulemaking

The previously finalized measure set for the Hospital OQR Program CY 2017 payment determination and subsequent years is listed below.

HOSPITAL OQR PROGRAM MEASURE SET PREVIOUSLY ADOPTED FOR THE CY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure name
N/A	OP–1: Median Time to Fibrinolysis.
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival.
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286	OP–4: Aspirin at Arrival.
0289	OP–5: Median Time to ECG.
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
N/A	OP–9: Mammography Follow-up Rates.
N/A	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
N/A	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery.
N/A	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
N/A	OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.**
N/A	OP–17: Tracking Clinical Results between Visits.
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
N/A	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP–21: Median Time to Pain Management for Long Bone Fracture.
N/A	OP–22: ED—Left Without Being Seen.
0661	OP–23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival.
N/A	OP–25: Safe Surgery Checklist Use.
N/A	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.*
0431	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.
0658	OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients.
0659	OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
1536	OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.***

* OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244*.

** Measure we are proposing for removal.

*** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 6947).

In the CY 2015 OPPS/ASC final rule with comment period, we finalized one new measure beginning with the CY 2018 payment determination: OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (79 FR 66948 through 66955). The previously finalized measure set for the Hospital OQR Program CY 2018 payment determination and subsequent years is listed below. We note that we are proposing one new measure for the CY 2018 payment determination and subsequent years in section XIII.B.6.a. of this proposed rule.

HOSPITAL OQR PROGRAM MEASURE SET PREVIOUSLY ADOPTED FOR THE CY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure name
N/A	OP–1: Median Time to Fibrinolysis.
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival.
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286	OP–4: Aspirin at Arrival.
0289	OP–5: Median Time to ECG.
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
N/A	OP–9: Mammography Follow-up Rates.
N/A	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
N/A	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non- Cardiac Low-Risk Surgery.
N/A	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
N/A	OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.**
N/A	OP–17: Tracking Clinical Results between Visits.
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
N/A	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP–21: Median Time to Pain Management for Long Bone Fracture.
N/A	OP–22: ED—Left Without Being Seen.
0661	OP–23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival.
N/A	OP–25: Safe Surgery Checklist Use.
N/A	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.*
0431	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.
0658	OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients.
0659	OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
1536	OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.***
2539	OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

* OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244*.

** Measure we are proposing for removal.

*** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

5. Proposed Hospital OQR Program Quality Measure for Removal for CY 2017 Payment Determination and Subsequent Years

We are proposing to remove one measure from the Hospital OQR Program quality measure set beginning with the CY 2017 payment determination and subsequent years: OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache. The inclusion of OP–15 in the Hospital OQR Program consistently has generated concerns from stakeholders since its adoption in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72077 through 72082). In the CY 2012 OPPS/ASC final rule with comment period, we deferred the public reporting of OP–15 (76 FR 74456). We extended the postponement of public reporting for this measure in the CY 2013 and CY 2014 OPPS/ASC final rules with comment period (77 FR 68478 and 78 FR 75096). In addition, as we noted in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66963), we did not propose any changes to this policy. Public reporting for OP–15 continues to be deferred, and this deferral has no effect on any payment determinations (79 FR 66963).

Since deferring the measure however, we continued to evaluate OP–15. In CY 2011, we conducted a dry run of the measure and received many suggestions for refinements to the measure. Our technical expert panel examined the suggestions we received regarding the measure during the dry run as well as the comments we received during the maintenance process for this measure. Based on these comments, CMS refined the measure specifications for OP–15 to address most stakeholder concerns. Nevertheless, as discussed below, given the continued inconsistency of current clinical practice guidelines on which the measure is based, we are proposing to remove OP–15 for the CY 2017 payment determination and subsequent years.

Based on our analysis, OP–15 meets the following criterion for removal: (iii) The measure does not align with current clinical guidelines or practice. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472) and the discussion above for a list of criteria we consider when determining whether to remove quality measures from the Hospital OQR Program. In peer-reviewed literature, headache guidelines have either excluded older adults or recommended a lower threshold for the use of CT

scans.[1] Furthermore, stakeholders have expressed concern that this measure is influenced significantly by case mix, patient severity, and clinician behavior, and thus, fails to represent appropriateness or efficiency accurately.[2] Based upon guidelines for use of CT scans published in peer-reviewed literature, we believe that OP–15,[3] as currently adopted in the Hospital OQR Program, does not align with the most updated clinical guidelines or practice, satisfying removal criterion (iii).

For the reason stated above, we are proposing to remove OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache from the Hospital OQR Program beginning with the CY 2017 payment determination. Set out in the table below is the measure we are proposing to remove for the CY 2017 payment determination and subsequent years.

HOSPITAL OQR PROGRAM MEASURE PROPOSED FOR REMOVAL FOR THE CY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure
N/A	OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.

We are inviting public comment on this proposal.

6. Proposed New Hospital OQR Program Quality Measures for the CY 2018 and CY 2019 Payment Determinations and Subsequent Years

We are proposing to adopt a total of two new measures for the Hospital OQR Program: (1) A Web-based quality measure for the CY 2018 payment determination and subsequent years; and (2) a Web-based quality measure for the CY 2019 payment determination and subsequent years. These measures are discussed in detail below.

a. Proposed New Quality Measure for the CY 2018 Payment Determination and Subsequent Years: OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822)

Bone metastases are a common manifestation of malignancy. Some cancer types have a bone metastasis prevalence as high as 70 to 95 percent.[4] EBRT is a widely used modality[5] to provide pain relief in 50 to 80 percent of patients with painful bone metastases.[6] In October 2009, the American Society for Radiation Oncology (ASTRO) organized a Task Force to perform an assessment of existing recommendations in order to address a lack of palliative radiotherapy guidelines. Based on a review of the literature, the Task Force recommended the following EBRT dosing schedules for patients with previously unirradiated painful bone metastases: 30 Gy over the course of 10 fractions; 24 Gy over the course of 6 fractions; 20 Gy over the course of 5 fractions; and a single 8 Gy fraction.[7] Despite the recommendations, the actual doses applied for EBRT continue to include dosing schedules as high as 25 fractions.[8] An international survey of radiation oncologists, of which ¾ of the respondents were members of ASTRO, found more than 100 different dose schedules in use.[9] Measure testing by ASTRO noted nearly a 20 percent performance gap. Many studies support the conclusion that shorter EBRT schedules produce similar pain relief outcomes when compared to longer EBRT schedules, and that patients prefer shorter EBRT schedules because of their convenience, increased tolerability, and reduced side effects.[10] In addition, the ASTRO Task Force found that the frequency and severity of side effects associated with a single fraction were the same or less than those associated with multiple fraction regimens, indicating that shorter treatment schedules may be preferable.[11]

To address concerns associated with unnecessary exposure to radiation and a desire for shorter and less painful treatment options, we are proposing to adopt one new Web-based quality measure for the CY 2018 payment determination and subsequent years: OP–33: External Beam Radiotherapy for Bone Metastases (NQF #1822). This measure assesses the ''[p]ercentage of patients (all-payer) with painful bone metastases and no history of previous radiation who receive EBRT with an acceptable dosing schedule.'' [12] The measure numerator includes all patients with painful bone metastases and no previous radiation to the same site who receive EBRT with any of the following recommended fractionation schemes: 30Gy/10fxns; 24Gy/6fxns; 20Gy/5fxns; or 8Gy/1fxn. The measure denominator includes all patients with painful bone metastases and no previous radiation to the same site who receive EBRT. The following patients are excluded from the denominator: patients who have had previous radiation to the same site; patients with femoral axis cortical involvement greater than 3 cm in length; patients who have undergone a surgical stabilization procedure; and patients with spinal cord compression, cauda equina compression, or radicular pain. Detailed specifications for this proposed measure may be found at: *https://www.qualityforum.org/QPS/1822*. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278 through 50279), the PCHQR Program adopted the EBRT measure for the FY 2017 program and subsequent years.

We believe that this measure will reduce the rate of EBRT services overuse, support our commitment to promoting patient safety, and support the NQS priority of Making Care Safer. Specifically, the proposed External Beam Radiotherapy for Bone Metastases

[1] *Available at: http://www.acepnow.com/article/proposed-measures-ct-scans-cause-concern/2/.*

[2] Ibid.

[3] Hartsell W, et al. Randomized Trial of Short-Versus Long-Course Radiotherapy for Palliation of Painful Bone Metastases. Journal of the National Cancer Institute, 2005: 97 (11): 798–804.

[4] Coleman RE. Metastatic bone disease: clinical features, pathophysiology and treatment strategies. Cancer Treat Rev. 2001;27:165–176.

[5] Chow E, Zeng L, Salvo N, Dennis K, Tsao M, Lutz S. Update on the Systematic Review of Palliative Radiotherapy Trials for Bone Metastases. Clin Onc. 2012;24:112–124. doi:10.1016/j.clon.2011.11.004

[6] Lutz S, Berk L, Chang E, et al. Palliative radiotherapy for bone metastases: An ASTRO evidence-based guideline. Int J Radiat Oncol Biol Phys. 2011;79(4):965–976.

[7] Ibid.

[8] Available at: *http://www.qualityforum.org/Measure_Evaluation_Form/Cancer_Project/1822.aspx.*

[9] Fairchild A, Barnes E, Ghosh S, et al. International Patterns of Practice in Palliative Radiotherapy for Painful Bone Metastases: Evidence-Based Practice? Int J Radiat Oncol Biol Phys. 2009;75(5):1501–1510.

[10] Available at: *http://www.qualityforum.org/Measure_Evaluation_Form/Cancer_Project/1822.aspx.*

[11] Lutz S, Berk L, Chang E, et al. Palliative radiotherapy for bone metastases: An ASTRO evidence-based guideline. Int J Radiat Oncol Biol Phys. 2011;79(4):965–976.

[12] Available at: *http://www.qualityforum.org/Measure_Evaluation_Form/Cancer_Project/1822.aspx.*

measure seeks to address the performance gap in treatment variation, ensure appropriate use of EBRT, and prevent the overuse of radiation therapy. We believe that this measure is necessary to support patient preferences for shorter EBRT schedules as well as to ensure patient safety, given that shorter treatment courses show similar or fewer side effects while producing similar clinical outcomes. The measure also takes into account the effective schedule for relieving pain from bone metastases, patient preferences and time and cost effectiveness.[13]

In compliance with section 1890A(a)(2) of the Act, this measure was included in the publicly available document: ''List of Measures under Consideration for December 1, 2014.'' [14] The MAP, a multi-stakeholder group convened by the NQF, reviews the measures under consideration for the Hospital OQR Program, among other Federal programs, and provides input on those measures to the Secretary. The MAP's 2015 recommendations for quality measures under consideration are captured in the ''Spreadsheet of MAP 2015 Final Recommendations.'' [15]

As required under section 1890A(a)(4) of the Act, we considered the input and recommendations provided by the MAP in selecting measures to propose for the Hospital OQR Program. The MAP supported this proposed measure, stating that ''External beam radiation can help provide patients with pain relief . . . this measure has a demonstrated performance gap and would begin to expand cancer care measurement to settings beyond the PPS-exempt cancer hospitals.'' [16]

Furthermore, we believe that this measure meets the requirement under section 1833(t)(17)(C)(i) of the Act, which states that ''The Secretary shall develop measures . . . that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.'' We believe that this proposed measure reflects consensus among the affected parties, because it is NQF-endorsed and recommended by the MAP.

We are inviting public comment on the proposal to include the following measure in the Hospital OQR Program for the CY 2018 payment determination and subsequent years.

NQF #	Proposed measure for the CY 2018 payment determination and subsequent years
1822	OP–33: External Beam Radiotherapy for Bone Metastases

The proposed and previously finalized measures for CY 2018 payment determination and subsequent years are listed below.

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF #	Measure name
N/A	OP–1: Median Time to Fibrinolysis.
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival.
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0289	OP–5: Median Time to ECG.
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
N/A	OP–9: Mammography Follow-up Rates.
N/A	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
N/A	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery.
N/A	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
N/A	OP–17: Tracking Clinical Results between Visits.
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
N/A	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP–21: Median Time to Pain Management for Long Bone Fracture.
N/A	OP–22: ED—Left Without Being Seen.
0661	OP–23: ED—Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival.
N/A	OP–25: Safe Surgery Checklist Use.
N/A	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.*
0431	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.
0658	OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients
0659	OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
1536	OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.**
2539	OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
1822	OP–33: External Beam Radiotherapy for Bone Metastases.***

*OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244*.

[13] Measure Submission and Evaluation Worksheet. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70374*.

[14] ''List of Measures under Consideration for December 1, 2014.'' Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78318*.

[15] ''Spreadsheet of MAP 2015 Final Recommendations.'' Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711*.

[16] Ibid.

**Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

***New measure proposed for the CY 2018 payment determination and subsequent years.

b. Proposed New Hospital OQR Program Quality Measure for the CY 2019 Payment Determination and Subsequent Years: OP–34: Emergency Department Transfer Communication (EDTC) (NQF #0291)

Communication problems significantly contribute to adverse events in hospitals, accounting for 65 percent of sentinel events (patient safety events not primarily related to the natural course of the patient's illness or underlying condition that result in death, permanent harm, or severe temporary harm where intervention is required to sustain life) tracked by The Joint Commission.[17] Additionally, information deficits frequently result when patients transfer between hospitals and primary care physicians in the community [18] and between hospitals and long-term care facilities.[19] According to patient safety studies,[20] the highest percentage of preventable and negligent adverse events within a hospital occur in the Emergency Department.[21] The prevention of medical errors in the Emergency Department setting is gaining attention throughout the nation,[22] but performance measures for Emergency Department care are lacking.[23]

Effective and timely communication of a patient's clinical status and other relevant information at the time of transfer from the hospital is essential for supporting appropriate continuity of care. Establishment of an effective transition from one treatment setting to another is enhanced by providing the receiving providers and facilities with sufficient information regarding treatment during hospitalization. Studies have shown that readmissions can be prevented by providing detailed, personalized information about patients at the time they are transferred to home or any other site.[24]

To address concerns associated with care when patients are transferred from Emergency Departments to other facilities, we are proposing to adopt one new Web-based quality measure for the Hospital OQR Program effective with the CY 2019 payment determination and subsequent years: OP–34: Emergency Department Transfer Communication (EDTC) (NQF #0291).

We are proposing to implement this measure beginning with the CY 2019 payment determination and subsequent years instead of the CY 2018 payment determination and subsequent years in order to give hospitals adequate time to implement the proposed measure. We believe hospitals will require approximately three to six months in order to familiarize themselves with the implementation protocol and tools related to the EDTC measure and to make associated improvements prior to the first reporting deadline. If we were to propose and finalize this measure beginning with the CY 2018 payment determination, we believe that hospitals may not have adequate time to put the processes and procedures in place necessary to collect this measure.

The EDTC measure captures the ''[p]ercentage of patients transferred to another healthcare facility whose medical record documentation indicated that administrative and clinical information was communicated to the receiving facility in an appropriate time frame.'' [25] This measure is designed to prevent gaps in care transitions caused by inadequate or insufficient information that lead to avoidable adverse events. Such events cost CMS approximately $15 billion due in part to avoidable patient readmissions.[26] The measure has been rigorously peer reviewed and extensively tested with field tests from 2004 to 2014 across 16 States in 249 hospitals.[27]

The measure consists of seven subcomponents: (a) Administrative data; (b) patient information; (c) vital signs; (d) medication; (e) physician information; (f) nursing information; and (g) procedure and test results. The subcomponents are further comprised of a total of twenty-seven elements, illustrated in the table below. We note that the EDTC measure does not require hospitals to submit patient data on each of these elements; but rather, hospitals would be required to answer yes or no as to whether these clinical indicators were recorded and communicated to the receiving facility prior to departure (Subsection 1) or within 60 minutes of transfer (Subsections 2 through 7).

NUMERATOR ELEMENTS FOR OP–34: EMERGENCY DEPARTMENT TRANSFER COMMUNICATION (EDTC) Measure (NQF #0291)

Administrative communication (EDTC-Subsection 1)	
	Nurse to nurse communication. Physician to physician communication.
Patient information (EDTC-Subsection 2)	
	Name.

[17] Available at: *http://www.jointcommission.org/Improving_Americas_Hospitals_The_Joint_Commissions_Annual_Report_on_Quality_and_Safety_-_2007/*..

[18] Kripalani, S., LeFevre, F., Phillips, C. et al. Deficits in Communication and Information Transfer between Hospital-Based and Primary Care Physicians: Implications for Patient Safety and Continuity of Care. JAMA 297(8):831–841, 2007.

[19] Cortes T., Wexler S. and Fitzpatrick J. The transition of elderly patients between hospitals and nursing homes. Improving nurse-to-nurse communication. Journal of Gerontological Nursing. 30(6):10–5, 2004.

[20] Leape, L., Brennan, T., Laird, N. et al. The Nature of Adverse Events in Hospitalized Patients. Results of the Harvard Medical Practice Study II. New England Journal of Medicine 324:377–384, 1991.

[21] Thomas, E., Studdert, D., Burstin, H. et al. Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado. Medical Care 38:261–271, 2000.

[22] Schenkel, S. Promoting Patient Safety and Preventing Medical Error in Emergency Departments. Academic Emergency Medicine 7:1204–1222, 2000.

[23] Welch, S., Augustine, J., Camago, C. and Reese, C. Emergency Department Performance Measures and Benchmarking Summit. Academic Emergency Medicine, 13(10):1074–1080, 2006.

[24] Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization. *Ann Intern Med* 2009; 150:178–187.

[25] Available at: *http://www.qualityforum.org/QPS/0291*.

[26] Medicare Payment Advisory Commission. Promoting Greater Efficiency in Medicare. June 2007. Available at: *http://www.medpac.gov/documents/reports/Jun07_EntireReport.pdf*.

[27] Refining and Field Testing a Relevant Set of Quality Measures for Rural Hospitals Final Report June 30, 2005. Available at: *http://rhrc.umn.edu/wp-content/files_mf/rh_ruralmeasuresfinalreport_063005.pdf*.

NUMERATOR ELEMENTS FOR OP–34: EMERGENCY DEPARTMENT TRANSFER COMMUNICATION—Continued
(EDTC) Measure (NQF #0291)

	Address. Age. Gender. Significant others contact information. Insurance.
Vital signs (EDTC-Subsection 3)	
	Pulse. Respiratory rate. Blood pressure. Oxygen saturation. Temperature. Glasgow score or other neuro assessment for trauma, cognitively altered or neuro patients only.
Medication information (EDTC-Subsection 4)	
	Medications administered in ED. Allergies. Home medications.
Physician or practitioner generated information (EDTC-Subsection 5)	
	History and physical. Reason for transfer and/or plan of care.
Nurse generated information (EDTC-Subsection 6)	
	Assessments/interventions/response. Sensory Status (formerly Impairments). Catheters. Immobilizations. Respiratory support. Oral limitations.
Procedures and tests (EDTC-Subsection 7)	
	Tests and procedures done. Tests and procedure results sent.

We are proposing to use a scoring methodology by which the facility score is reported as the percentage (0–100 percent) of all cases with a perfect score of ''7.'' To calculate this score, hospitals assign a value of ''0'' or ''1'' to each of the seven subcomponents for each case. In order to achieve a value of ''1'' for each subcomponent, the hospital must have recorded and transferred patient data pertaining to all of the elements that comprise that particular subcomponent; if data for any element fails to be recorded or transferred, then the value assigned to that subcomponent would be ''0.'' Next, subcomponent scores are added together, for a total ranging from ''0'' to ''7'' per case. Finally, the facility score is calculated by adding all of the cases that achieved a perfect score of ''7'' and dividing that number by the total number of cases to reflect the percentage of all cases that received a perfect score.

Example 1 below illustrates a case in which all patient data elements were recorded and transferred to the receiving facility.

EXAMPLE 1 OF CALCULATION FOR OP–34: EMERGENCY DEPARTMENT TRANSFER COMMUNICATION
(EDTC) Measure (NQF #0291) by Case

Administrative communication (EDTC-Subsection 1)	
Y	Nurse to nurse communication.
Y	Physician to physician communication.
Sub-1 Score = 1	
Patient information (EDTC-Subsection 2)	
Y	Name.
Y	Address.
Y	Age.
Y	Gender.
Y	Significant others contact information.
Y	Insurance.

EXAMPLE 1 OF CALCULATION FOR OP–34: EMERGENCY DEPARTMENT TRANSFER COMMUNICATION—Continued

(EDTC) Measure (NQF #0291) by Case

Sub-2 Score = 1	
Vital signs (EDTC-Subsection 3)	
Y	Pulse.
Y	Respiratory rate.
Y	Blood pressure.
Y	Oxygen saturation.
Y	Temperature.
Y	Glasgow score or other neuro assessment for trauma, cognitively altered or neuro patients only.
Sub-3 Score = 1	
Medication information (EDTC-Subsection 4)	
Y	Medications administered in ED.
Y	Allergies.
Y	Home medications.
Sub-4 Score = 1	
Physician or practitioner generated information (EDTC-Subsection 5)	
Y	History and physical.
Y	Reason for transfer and/or plan of care.
Sub-5 Score = 1	
Nurse generated information (EDTC-Subsection 6)	
Y	Assessments/interventions/response.
Y	Sensory Status (formerly Impairments).
Y	Catheters.
Y	Immobilizations.
Y	Respiratory support.
Y	Oral limitations.
Sub-6 Score = 1	
Procedures and tests (EDTC-Subsection 7)	
Y	Tests and procedures done.
Y	Tests and procedure results sent.
Sub-7 Score = 1	
(Sub-1 (1) + Sub-2 (1) + Sub-3 (1) + Sub-4 (1) + Sub-5 (1) + Sub-6 (1) + Sub-7 (1) = 7	
''7'' equals a perfect score; therefore, TOTAL SCORE FOR THIS CASE = 7	

Example 2 below illustrates a case in which some patient data elements failed to be recorded and/or transferred to the receiving facility.

EXAMPLE 2 OF CALCULATION FOR OP–34: EMERGENCY DEPARTMENT TRANSFER COMMUNICATION

(EDTC) Measure (NQF #0291) by Case

Administrative communication (EDTC-Subsection 1)	
Y	Nurse to nurse communication.
Y	Physician to physician communication.
Sub-1 Score = 1	
Patient information (EDTC-Subsection 2)	
Y	Name.
Y	Address.
Y	Age.
Y	Gender.
Y	Significant others contact information.

EXAMPLE 2 OF CALCULATION FOR OP–34: EMERGENCY DEPARTMENT TRANSFER COMMUNICATION—Continued

(EDTC) Measure (NQF #0291) by Case

Y	Insurance.
Sub-2 Score = 1	
Vital signs (EDTC-Subsection 3)	
Y	Pulse.
Y	Respiratory rate.
Y	Blood pressure.
Y	Oxygen saturation.
Y	Temperature.
N	Glasgow score or other neuro assessment for trauma, cognitively altered or neuro patients only.
Sub-3 Score = 0	
Medication information (EDTC-Subsection 4)	
Y	Medications administered in ED.
Y	Allergies.
N	Home medications.
Sub-4 Score = 0	
Physician or practitioner generated information (EDTC-Subsection 5)	
Y	History and physical.
Y	Reason for transfer and/or plan of care.
Sub-5 Score = 1	
Nurse generated information (EDTC-Subsection 6)	
Y	Assessments/interventions/response.
Y	Sensory Status (formerly Impairments).
Y	Catheters.
Y	Immobilizations.
Y	Respiratory support.
Y	Oral limitations.
Sub-6 Score = 1	
Procedures and tests (EDTC-Subsection 7)	
Y	Tests and procedures done.
Y	Tests and procedure results sent.
Sub-7 Score = 1	
(Sub-1 (1) + Sub-2 (1) + Sub-3 (0) + Sub-4 (0) + Sub-5 (1) + Sub-6 (1) + Sub-7 (1) = 5	
''5'' does not equal a perfect score of ''7''; therefore, TOTAL SCORE FOR THIS CASE = 0	

For more information on this measure, including its specifications, we refer readers to the Current Emergency Department Transfer Communication Measurement Specifications, Data Definitions, and Data Collection Tool at: *http://rhrc.umn.edu/2012/02/ed-transfer-submission-manual*.

Additional information on this measure is also available at: *http://www.qualityforum.org/QPS/0291*.

As discussed above, the proposed EDTC measure seeks to address gaps in care coordination, by ensuring that vital patient information is both recorded and shared with the subsequent provider. We believe that the EDTC measure would increase the quality of care provided to patients, reduce avoidable readmissions, and increase patient safety. More timely communication of vital information results in better care, reduction of systemic medical errors, and improved patient outcomes. In addition, we believe that this measure will promote the NQS priority of Effective Communication and Coordination of Care. As articulated by HHS, ''Care coordination is a conscious effort to ensure that all key information needed to make clinical decisions is available to patients and providers. It is defined as the deliberate organization of patient care activities between two or more participants involved in a patient's care to facilitate appropriate delivery of health care services.'' [28] Critically, the availability of the transfer record to the next level provider within 60 minutes after departure supports more effective care coordination and patient safety, since a delay in communication can result in medication or treatment errors.

In compliance with section 1890A(a)(2) of the Act, this measure was included in the publicly available document: ''List of Measures under

[28] US DHHS. ''National Healthcare Disparities Report 2013.'' Available at: *http://www.ahrq.gov/research/findings/nhqrdr/nhdr13/chap7.html*.

Consideration for December 1, 2014.'' [29] As stated above, the MAP reviews the measures under consideration for the Hospital OQR Program, among other federal programs, and provides input on those measures to the Secretary. The MAP's 2015 recommendations for quality measures under consideration are captured in the ''Spreadsheet of MAP 2015 Final Recommendations.'' [30]

As required under section 1890A(a)(4) of the Act, we considered the input and recommendations provided by the MAP in selecting measures to propose for the Hospital OQR Program. The MAP supported this measure, stating that ''This measure would help to address a previously identified gap around improving care coordination and would help ensure vital information is transferred between sites of care. The EDTC measure set consists of seven components that focus on communication between facilities around the transfer of patients. The measure set assists in filling the workgroup identified priority gap of enhancing care coordination efforts.'' [31] In addition, as stated above, the proposed measure addresses the NQS priority of Communication and Care Coordination.

We believe this measure meets the requirement under section 1833(t)(17)(C)(i) of the Act, which states that ''The Secretary shall develop measures . . . that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.'' We believe this proposed measure reflects consensus among the affected parties, because it is NQF-endorsed and supported by the MAP.

We are inviting public comment on the proposal to include the following measure in the Hospital OQR Program for the CY 2019 payment determination and subsequent years.

NQF #	Proposed Measure for the CY 2019 Payment Determination and Subsequent Years
0291	OP–34: Emergency Department Transfer Communication Measure.

The proposed and previously finalized measures for the CY 2019 payment determination and subsequent years are listed below.

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF #	Measure name
N/A	OP–1: Median Time to Fibrinolysis.
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival.
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0289	OP–5: Median Time to ECG.
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
N/A	OP–9: Mammography Follow-up Rates.
N/A	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
N/A	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery.
N/A	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
N/A	OP–17: Tracking Clinical Results between Visits.
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
N/A	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP–21: Median Time to Pain Management for Long Bone Fracture.
N/A	OP–22: ED—Left Without Being Seen.
0661	OP–23: ED—Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival.
N/A	OP–25: Safe Surgery Checklist Use.
N/A	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.*
0431	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.
0658	OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients.
0659	OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
1536	OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.**
2539	OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
1822	OP–33: External Beam Radiotherapy for Bone Metastases.****
0291	OP–34: Emergency Department Transfer Communication Measure.****

*OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244*.

**Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

***New measure proposed for the CY 2018 payment determination and subsequent years.

****New measure proposed for the CY 2019 payment determination and subsequent years.

[29] ''List of Measures under Consideration for December 1, 2014.'' Available at: *www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78318*.

[30] MAP. February 2015. ''Spreadsheet of MAP 2015 Final Recommendations''. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711*.

[31] Ibid.

7. Hospital OQR Program Measures and Topics for Future Consideration

The current measure set for the Hospital OQR Program includes measures that assess process of care, imaging efficiency patterns, care transitions, ED throughput efficiency, the use of health information technology (health IT), care coordination, patient safety, and volume. For future payment determinations, we are considering expanding these measure areas and creating measures in new areas. Specifically, we are exploring electronic clinical quality measures (eCQMs) and whether, in future rulemaking, we would propose that hospitals have the option to voluntarily submit data for OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients electronically beginning with the CY 2019 payment determination. Hospitals would otherwise still be required to submit data for this measure through chart abstraction.

We believe all patients, their families, and their healthcare providers should have consistent and timely access to their health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care.[32] To that end, we are committed to accelerating health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health IT across the broader care continuum through a number of initiatives including: (1) Alignment of incentives and payment adjustments to encourage provider adoption and optimization of health IT and HIE services through Medicare and Medicaid payment policies; (2) adoption of common standards and certification requirements for interoperable health IT; (3) support for privacy and security of patient information across all HIE-focused initiatives; and (4) governance of health information networks. More information on the governance of health information networks and its role in facilitating interoperability of health information systems can be found at: *http://www.healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf*.

We believe that HIE and the use of certified EHR technology can effectively and efficiently help providers improve internal care delivery practices, support management of patient care across the continuum, and support the reporting of electronically specified clinical quality measures. On March 30, 2015, ONC published in the **Federal Register** a proposed rule (80 FR 16804) that proposes a new 2015 Edition Base EHR definition, as well as modifications to the ONC Health IT Certification Program to make it open and accessible to more types of health IT and health IT that supports various care and practice settings. It also proposes to establish the capabilities and specifications that certified EHR technology (CEHRT) would need to include to, at a minimum, support the achievement of meaningful use by eligible professionals and hospitals under the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs) when such edition is required for use under these programs. More information on the 2015 Edition EHR Certification Criteria proposed rule can be found at: *http://healthit.gov/policy-researchers-implementers/standards-and-certification-regulations*.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810), the Hospital IQR Program finalized a policy to allow hospitals to voluntarily electronically report at least one quarter of CY 2014 quality measure data for each measure in one or more of four measure sets (STK, VTE, ED, and PC). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50246 and 50249 through 50253), the Hospital IQR Program finalized a policy that hospitals may voluntarily report any 16 of 28 Hospital IQR Program electronic clinical quality measures that align with the Medicare EHR Incentive Program as long as those measures span three different NQS priority areas. Most recently in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24581 through 24582), the Hospital IQR Program proposed to make reporting of electronic clinical quality measures required rather than voluntary. Under the proposal, hospitals would be required to submit both Q3 and Q4 of 2016 data for 16 electronic clinical quality measures (80 FR 24581 through 24582).

We anticipate that as EHR technology evolves and more health IT infrastructure is operational, we will begin to accept electronic reporting of many measures from EHR technology certified under the ONC Health IT Certification Program. We are working diligently toward this goal. We believe that this progress would significantly reduce the administrative burden on hospitals under the Hospital OQR Program to report chart-abstracted measures.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72074) we finalized OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF # 0496), the only measure in our current measure set which is specified as an eCQM, or e-specified. The e-specification for this measure is available at: *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2014_eCQM_Specs_for_EH.zip* in the folder entitled: EH_CMS32v2_NQF0496_ED3_MedianTime.

Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496) was adopted by the Medicare and Medicaid EHR Incentive Program for Eligible Hospitals and Critical Access Hospitals (CAHs) as one of 29 clinical quality measures available for reporting under the program beginning with Federal fiscal year 2014 (77 FR 54086 through 54087).

For the reasons stated above, we believe it is important to encourage providers to submit this measure electronically. In addition, allowing submission of OP–18 as an eCQM will begin to align the Hospital OQR Program with the Medicare EHR Incentive Program for Eligible Hospitals and CAHs in a manner similar to our proposals for the Hospital IQR Program (80 FR 24581 through 24582; 24587). Therefore, we are considering proposing a policy in future rulemaking that would give hospitals an option to voluntarily submit data for this measure electronically beginning with the CY 2019 payment determination. Hospitals that chose not to submit electronically would still be required to submit data though chart abstraction.

We are inviting public comment on our intention to make this proposal in the future.

8. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for previously adopted Hospital OQR Program measures. These specifications are updated as we continue to develop the Hospital OQR Program. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet Web site at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244*.

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68469 through 68470), for a discussion of our policy for updating Hospital OQR Program measures, the same policy we adopted for updating Hospital IQR Program measures, which

[32] HHS August 2013 Statement, ''Principles and Strategies for Accelerating Health Information Exchange.'' Available at: *http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf*.

includes the subregulatory process for making updates to the adopted measures (77 FR 53504 through 53505). This policy expanded upon the subregulatory process for updating measures that we finalized in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767). We are not proposing any changes to these policies.

9. Public Display of Quality Measures

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75092) for our finalized public display policy. A more robust discussion of our policy for the publication of Hospital OQR Program data on the *Hospital Compare* Web site and noninteractive CMS Web sites can be found in the CY 2014 OPPS/ASC proposed rule (78 FR 43645). We are not proposing any changes to our public display policy.

C. Administrative Requirements

1. QualityNet Account and Security Administrator

The QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines, are unchanged from those adopted in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109). In that final rule with comment period, we codified these procedural requirements at 42 CFR 419.46(a).

We are not proposing any changes to these requirements.

2. Proposed Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109) for requirements for participation and withdrawal from the Hospital OQR Program. In that final rule with comment period, we codified these procedural requirements at 42 CFR 419.46(b).

In this proposed rule, we are proposing to make one change to the requirements regarding participation in the Hospital OQR Program beginning with the CY 2017 payment determination. Currently, a participating hospital may withdraw from the Hospital OQR Program any time from January 1 to November 1 (42 CFR 419.46(b)) of the year prior to the affected annual payment update by submitting a withdrawal form to CMS via the secure portion of the QualityNet Web site at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1192804525137*.

We are proposing that beginning with the CY 2017 payment determination, hospitals must submit a withdrawal form to CMS via the QualityNet Web site up to and including August 31 of the year prior to the affected annual payment update. For example, for the CY 2017 payment determination, the withdrawal deadline would change from November 1, 2016 to any time up to and including August 31, 2016 under this proposal.

The proposed change to the withdrawal deadline is consistent with the ASCQR Program withdrawal deadline described in section XIV.C.2. of this proposed rule and in proposed 42 CFR 416.305(b). We believe aligning deadlines across programs will reduce provider burden by streamlining processes and procedures.

In addition, as we discuss below in section XIII.D.1. of this proposed rule, we are proposing to move the timeline for when we make annual percentage update (APU) determinations to allow both CMS and stakeholders more time to review the APU determinations before the beginning of the calendar year. To ensure the correct hospitals are included in the APU determinations, we also need to know at an earlier date which hospitals have withdrawn from the Hospital OQR Program.

We also are proposing to make a conforming revision to 42 CFR 419.46(b) which currently states that the hospital may withdraw any time from January 1 to November 1 of the year prior to the affected annual payment updates to state that the hospital may withdraw any time up to and including August 31 of the year prior to the affected annual payment updates.

We are inviting public comment on our proposals to change the withdrawal deadline and to revise 42 CFR 419.46(b) to reflect this change.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Proposed Change Regarding Hospital OQR Program Annual Percentage Update (APU) Determinations

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75110 through 75111), we specify that our data submission deadlines will be posted on QualityNet at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1205442058760*.

The data submission requirements document, Hospital OQR Quality Measures and Timelines for CY 2016 and Subsequent Payment Determinations,[33] explains that the chart-abstracted data on which we base APU determinations on is quarter 3 of the 2 years prior to the payment determination through quarter 2 of the year prior to the payment determination. For example, we base our APU determinations for the CY 2016 Hospital OQR Program on chart-abstracted data from quarter 3, 2014, through quarter 2, 2015. Chart-abstracted data from quarter 2, 2015 must be submitted by November 1, 2015. APU determinations are applied to payments beginning in January of the following year, providing less than 2 months between the time the data on which we base APU determinations is submitted for validation and the beginning of the payments that are affected by this data. This timeline creates compressed processing issues for CMS, and compressed timelines for hospitals to review their APU determination decisions.

To ease this burden for both CMS and hospitals, we are proposing to change the timeframe on which we base APU determinations for the Hospital OQR Program. We currently base APU determinations on chart-abstracted data from patient encounter quarter 3 of 2 years prior to the payment determination through patient encounter quarter 2 of the year prior to the payment determination. We are proposing to change that timeframe to patient encounter quarter 2 of the 2 years prior to the payment determination through patient encounter quarter 1 of the year prior to the payment determination beginning with the CY 2018 payment determination and for subsequent years. Because the deadline for hospitals to submit chart-abstracted data for quarter 1 is August 1, this will afford both CMS and hospitals additional time to review the APU determinations before they are implemented in January. Current and detailed information about data validation requirements and deadlines is posted on QualityNet at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228758729356*.

To facilitate this process, we are proposing to transition to the newly proposed timeframe for the CY 2018 payment determination and subsequent

[33] The Hospital OQR Quality Measures and Timelines for CY 2016 and Subsequent Payment Determinations. Available at: *https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890446207&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3DHOQR_CY2016_MsrTmlns_0315.pdf&blobcol=urldata&blobtable=MungoBlobs*.

years and use only three quarters of data for determining the CY 2017 payment determination as illustrated in the tables below. However, we note that data submission deadlines will not be changing.

APU DETERMINATION TRANSITION

[CY 2016 Payment Determination (Current State)]

Patient encounter quarter	Clinical data submission deadline
Q3 2014 (July 1–Sept. 30) ...	2/1/2015
Q4 2014 (Oct. 1–Dec. 31)	5/1/2015
Q1 2015 (Jan. 1–March 31)	8/1/2015
Q2 2015 (April 1–June 30) ...	11/1/2015

[Proposed CY 2017 Payment Determination (Future State—Transition Period)]

Patient encounter quarter	Clinical data submission deadline
Q3 2015 (July 1–Sept. 30).	2/1/2016
Q4 2015 (Oct. 1–Dec. 31).	5/1/2016
Q1 2016 (Jan. 1–March 31).	8/1/2016

[Proposed CY 2018 Payment Determination and Subsequent Years (Future State)]

Patient encounter quarter	Clinical data submission deadline
Q2 2016 (April 1–June 30).	11/1/2016
Q3 2016 (July 1–Sept. 30).	2/1/2017
Q4 2016 (Oct. 1–Dec. 31).	5/1/2017
Q1 2017 (Jan. 1–March 31).	8/1/2017

We refer readers to section XIII.D.8. of this proposed rule, where we are proposing to update our validation processes to reflect these changes.

We are inviting public comment on our proposals.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS

The following previously finalized Hospital OQR Program chart-abstracted measures require patient-level data to be submitted for the CY 2018 payment determination and subsequent years:

- OP–1: Median Time to Fibrinolysis;
- OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (NQF #0288);
- OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention (NQF #0290);
- OP–4: Aspirin at Arrival (NQF #0286)
- OP–5: Median Time to ECG (NQF #0289);
- OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496);
- OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional;
- OP–21: ED—Median Time to Pain Management for Long Bone Fracture (NQF #0662);
- OP–23: ED—Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 Minutes of Arrival (NQF #0661);

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form, manner, and timing for data submission requirements of these measures for the CY 2014 payment determination and subsequent years.

We are not proposing any changes to these policies.

3. Claims-Based Measure Data Requirements

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75111 through 75112) for a discussion of the general claims-based measure data submission requirements for the CY 2015 payment determination and subsequent years. We note that, in section XIII.B.5. of this proposed rule, we are proposing to remove OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache beginning with the CY 2017 payment determination and subsequent years. If this proposal is adopted, for the CY 2018 payment determination and subsequent years, there will be a total of seven claims-based measures:

- OP–8: MRI Lumbar Spine for Low Back Pain (NQF #0514);
- OP–9: Mammography Follow-Up Rates;
- OP–10: Abdomen CT—Use of Contrast Material;
- OP–11: Thorax CT—Use of Contrast Material (NQF #0513);
- OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery (NQF #0669);
- OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT); and
- OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

We are not proposing any changes to our claims-based measure data submission requirements.

4. Proposed Data Submission Requirements for Measure Data Submitted via a Web-Based Tool

a. Previously Finalized Measures

The following Web-based quality measures previously finalized and retained in the Hospital OQR Program require data to be submitted via a Web-based tool (CMS' QualityNet Web site or CDC's NHSN Web site) for the CY 2017 payment determination and subsequent years:

- OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data (via CMS' QualityNet Web site);
- OP–17: Tracking Clinical Results between Visits (via CMS' QualityNet Web site);
- OP–22: ED—Left Without Being Seen (via CMS' QualityNet Web site);
- OP–25: Safe Surgery Checklist Use (via CMS' QualityNet Web site);
- OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (via CMS' QualityNet Web site); and,
- OP–27: Influenza Vaccination Coverage among Healthcare Personnel (via the CDC NHSN Web site).

In addition to these measures, the following chart-abstracted measures previously finalized and retained in the Hospital OQR Program require data to be submitted via the Web-based tool for the CY 2017 payment determination and subsequent years:

- OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); and
- OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #1536).

We note that, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66962 through 66963), we categorized OP–29 and OP–30 as chart-abstracted measures. However, unlike other chart-abstracted measures, OP–29 and OP–30 are submitted through a Web-based tool (CMS' QualityNet Web site).

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75115) for a discussion of the requirements for measure data submitted via the CMS QualityNet Web site (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1205442125082*) for the CY 2016 payment determination and subsequent years. In addition, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the requirements for measure data submitted via the CDC NHSN Web site.

We are proposing to make one change to the data submission requirements for measures submitted via the CMS Web-based tool (QualityNet Web site) beginning with the CY 2017 payment determination. This proposal does not affect OP–27, which is submitted via the CDC NHSN Web site. Previously, we finalized that for measures reported via the CMS Web-based tool, hospitals must report data between July 1 and November 1 of the year prior to the payment determination with respect to the encounter period of January 1 to December 31 of 2 years prior to the payment determination year (78 FR 75112).

Beginning with the CY 2017 payment determination, however, we are proposing that hospitals must report data between January 1 and May 15 of the year prior to the payment determination with respect to the encounter period of January 1 to December 31 of 2 years prior to the payment determination year. For example, for the CY 2017 payment determination, the data submission window would be January 1, 2016 through May 15, 2016 for the January 1, 2015 to December 31, 2015 encounter period.

We are proposing this new data submission period to be consistent with the data submission deadlines proposed by the ASCQR Program in section XIV.D.3. of this proposed rule and to align with the submission deadline for OP–27: Influenza Vaccination Coverage among Healthcare Personnel, reported via the CDC NHSN Web site. We have determined that aligning all Web-based tool data submission deadlines with this May 15 deadline would allow for streamlined hospital submissions, earlier public reporting of that measure data—possibly as soon as October of the data submission year—and reduced administrative burden associated with tracking multiple submission deadlines for these measures.

We are inviting public comment on our proposal to change the data submission period for measures submitted via the CMS Web-based tool.

b. Proposed Data Submission Requirements for Web-Based Measure OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822) for the CY 2018 Payment Determination and Subsequent Years

As discussed in section XIII.B.6.a. of this proposed rule, we are proposing one new Web-based measure for the CY 2018 payment determination and subsequent years, OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822). For data submission for the CY 2018 payment determination and subsequent years, we are proposing that hospitals can either: (1) Report OP–33 beginning with services furnished on January 1, 2016 in accordance with the data submission requirements for measure data submitted via the CMS Web-based tool (QualityNet Web site) as proposed above in section XIII.D.4.a. of this proposed rule; or (2) submit an aggregate data file (for example, a file in comma separated value (csv) format or other format as will be specified in the data submission requirements on QualityNet [34]) for this measure through a vendor (via QualityNet infrastructure) containing aggregated data at the hospital level. The aggregate data file shall combine all patient information, rather than reporting individual patient level data. The data submission deadline for either method would be May 15. We believe that also giving hospitals the option to submit data via vendors will help to streamline processes and procedures. Detailed information about format and submission requirements will be posted on QualityNet at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1191255879384*.

We are inviting public comment on our proposal.

c. Proposed Data Submission Requirements for Web-Based Measure OP–34: Emergency Department Transfer Communication (EDTC) Measure for the CY 2019 Payment Determination and Subsequent Years

As discussed in section XIII.B.6.b. of this proposed rule, we are proposing one new Web-based measure for the CY 2019 payment determination and subsequent years, OP–34: Emergency Department Transfer Communication (EDTC) Measure (NQF #0291). For data submission for the CY 2019 payment determination and subsequent years, we are proposing that hospitals can either: (1) Report OP–34 beginning with January 1, 2017 outpatient encounter dates in accordance with the data submission requirements for measure data submitted via the CMS Web-Based Tool (QualityNet Web site) as proposed above in section XIII.D.4.a. of this proposed rule; or (2) submit an aggregate data file (for example, a file in comma separated value (csv) format or other format as will be specified in the data submission requirements on QualityNet [35]) for this measure through a vendor (via QualityNet infrastructure) containing aggregated data at the hospital level. The aggregate data file shall combine all patient information, rather than reporting individual patient level data. The data submission deadline for either method would be May 15. We believe that also giving hospitals the option to submit data via vendors will help to streamline processes and procedures. Detailed information about format and submission requirements will be posted on QualityNet at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1191255879384*.

We are inviting public comment on our proposal.

5. Population and Sampling Data Requirements for the CY 2018 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of our policy that hospitals may voluntarily submit aggregate population and sample size counts for Medicare and non-Medicare encounters for the measure populations for which chart-abstracted data must be submitted.

We are not proposing any changes to our population and sampling requirements.

6. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2018 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment

[34] Data Submission Requirements will be available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228775181731*.

[35] Data Submission Requirements will be available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228775181731*.

period (77 FR 68484 through 68487) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965) for a discussion of finalized policies regarding our validation requirements. We codified these policies at 42 CFR 419.46(e). Currently, validation is based on four quarters of data (validation quarter 2, validation quarter 3, validation quarter 4, and validation quarter 1) (75 FR 72104 and 79 FR 66965).

As discussed above in section XIII.D.1. of this proposed rule, we are proposing to make conforming changes to our validation scoring process to reflect proposed changes in the APU determination timeframes. For the CY 2017 payment determination, we are proposing that validation be based on three quarters of data (quarter 2, quarter 3 and quarter 4 of 2015). In addition, for the CY 2018 payment determination and subsequent years, we are proposing that validation again be based on four quarters of data; however those quarters are validation quarter 1, validation quarter 2, validation quarter 3 and validation quarter 4. We note that the data submission deadlines will remain unchanged. Detailed information about data validation requirements and deadlines will be posted on QualityNet at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228758729356*.

Finally, we are proposing to make one editorial correction to 42 CFR 419.46(e)(2) to replace the term ''fiscal year'' with the term ''calendar year.''

We are inviting public comment on our proposals.

7. Extension or Exemption Process for the CY 2018 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75119 through 75120), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966), and 42 CFR 419.46(d) for a complete discussion of our extraordinary circumstances extension or exception process under the Hospital OQR Program.

We are proposing to change the name of this process from extension and exception to extension and exemption. We also are proposing to make corresponding changes to the regulation text at 42 CFR 419.46(d). These proposed changes would align the Hospital OQR Program policies with those of the Hospital IQR Program (79 FR 50101) and ASCQR Program (79 FR 66987).

We are inviting public comment on our proposals.

8. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2018 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487 through 68489) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118 through 75119) for a discussion of our reconsideration and appeals procedures. We codified this process by which participating hospitals may submit requests for reconsideration at 42 CFR 419.46(f). We also codified language at § 419.46(f)(3) stating that a hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board.

Currently, a hospital must submit a reconsideration request to CMS via the QualityNet Web site no later than the first business day of the month of February of the affected payment year (78 FR 75118 through 75119). We are proposing that beginning with the CY 2018 payment determination, hospitals must submit a reconsideration request to CMS via the QualityNet Web site by no later than the first business day on or after March 17 of the affected payment year.

We are proposing this new reconsideration submission deadline to be consistent with the proposed ASCQR Program reconsideration submission deadline in section XIV.D.8. of this proposed rule. As stated above, we believe that aligning deadlines across programs leads to decreased provider burden by streamlining processes and procedures.

We also are proposing to make a conforming change to 42 CFR 419.46(f)(1) from the first business day of the month of February of the affected payment year to the first business day on or after March 17 of the affected payment year.

In addition, we are proposing to make an editorial correction to 42 CFR 419.46(f)(1) to replace the term ''fiscal year'' with the term ''calendar year.''

We are inviting public comment on these proposals.

E. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital Outpatient Quality Reporting (OQR) Program Requirements for the CY 2016 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on the measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent payment year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site): ''J1,'' ''J2,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' or ''U.'' We note that we are proposing to adopt status indicator ''J2'' for certain comprehensive services furnished to beneficiaries who receive at least 8 hours of observation services in the hospital outpatient department; more information about this status indicator may be found in section XI.A. of this proposed rule. Payment for all services assigned to these status indicators will be subject to the reduction of the

national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or ''T.'' We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; the rural sole community hospital adjustment; and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this proposed rule.

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2016

We are proposing to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2016 annual payment update factor. For the CY 2016 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of $72.478 by the proposed full conversion factor of $73.929. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2016 OPPS, we are proposing to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of ''J1,'' ''J2,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' and ''U'' (other than new technology APCs to which we have proposed status indicator assignment of ''S'' and ''T''). We note that, discussed in sections II.A.2.e. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66962), we finalized our proposal to develop status indicator ''J1'' as part of our CY 2015 comprehensive APC policy, and to apply the reporting ratio to the comprehensive APCs. We are proposing to continue to exclude services paid under New Technology APCs. We are proposing to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also are proposing to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we are proposing to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements.

We are inviting public comments on these proposals.

XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIII.A.1. of this proposed rule for a general overview of our quality reporting programs.

2. Statutory History of the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

We refer readers to section XIV.K.1. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We refer readers to section XV.A.3. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75122) for an overview of the regulatory history of the ASCQR Program, and to section XIV.4. of the CY 2015 OPPS/ASC final rule with comment period for subsequently enacted policies (79 FR 66966 through 66987).

In this proposed rule, we are proposing to establish a new Subpart H under 42 CFR part 416 to codify many of the administrative policies regarding

the ASCQR Program. We are proposing to codify our statutory authority for the ASCQR Program in new proposed 42 CFR 416.300(a). In that proposed section, we state that section 1833(i)(2)(D)(iv) and (i)(7) of the Act authorizes the Secretary to implement a revised ASC payment system in a manner so as to provide for a 2.0 percentage point reduction in any annual update for an ASC's failure to report on quality measures in accordance with the Secretary's requirements. In new proposed 42 CFR 416.300(b), we state that this subpart contains the specific requirements and standards for the ASCQR Program. We note that we have previously referenced the statutory basis for the ASCQR Program in 42 CFR part 416, subpart F (42 CFR 416.160(a)) and the 2 percentage point reduction for ASCs that do not meet ASCQR Program requirements at 42 CFR 416.171(a)(2)(iii).

We are inviting public comment on our proposals to codify the scope and basis for the ASCQR Program.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of the priorities we consider for ASCQR Program quality measure selection. We are not proposing any changes to this policy.

2. Policies for Retention and Removal of Quality Measures From the ASCQR Program

We previously adopted a policy that quality measures adopted for an ASCQR Program measure set for a previous payment determination year be retained in the ASCQR Program for measure sets for subsequent payment determination years, except when they are removed, suspended, or replaced as indicated (76 FR 74494 and 74504; 77 FR 68494 through 68495; 78 FR 75122; 79 FR 66967 through 66969). We are not proposing any changes to this policy; however, we are proposing to codify this policy at proposed new 42 CFR 416.320(a).

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967 through 66969), we finalized a process for removing adopted measures. Specifically, in cases where we believe that the continued use of a measure as specified raises patient safety concerns, we will immediately remove a quality measure from the ASCQR Program. In these situations, we will promptly notify ASCs and the public of the removal of the measure and the reasons for its removal through the ASCQR Program ListServ and the ASCQR Program QualityNet Web site. We will confirm the removal of the measure due to patient safety concerns in the next ASCQR Program rulemaking. We are not proposing any changes to this process. However, we are proposing to codify this process at proposed new 42 CFR 416.320(b).

As stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66968), unless a measure raises specific safety concerns, we will use the regular rulemaking process to remove, suspend, or replace quality measures in the ASCQR Program to allow for public comment. In these situations, we will use the following criteria to determine whether to remove a measure from the ASCQR Program: (1) Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures); (2) availability of alternative measures with a stronger relationship to patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (5) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. The benefits of removing a measure from the ASCQR Program will be assessed on a case-by-case basis. We intend for all the criteria to apply to all measures to the extent possible. A measure will not be removed solely on the basis of meeting any specific criterion. In any given situation, we will focus only on the criteria that are relevant to a particular set of circumstances.

As provided above, one of the criteria to determine whether to remove a measure from the ASCQR Program is when it is ''topped-out'' (that is, when measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made). For purposes of the ASCQR Program, a measure is considered to be topped-out when it meets both of the following criteria: (1) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for an ASC's measure is within two times the standard error of the full data set); and (2) a truncated coefficient of variation less than or equal to 0.10. We are not proposing any changes to this process for measure removal, suspension, or replacement. However, we are proposing to codify this measure removal process at proposed new 42 CFR 416.320(c).

We are inviting public comment on our proposals to codify these existing policies.

3. ASCQR Program Quality Measures Adopted in Previous Rulemaking

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we implemented the ASCQR Program effective with the CY 2014 payment determination. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74496 through 74511), we adopted five claims-based measures for the CY 2014 payment determination and subsequent years, two measures with data submission directly to CMS via an online Web-based tool for the CY 2015 payment determination and subsequent years, and one process of care, preventive service measure submitted via an online, Web-based tool to CDC's National Health Safety Network (NHSN) for the CY 2016 payment determination and subsequent years. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124 through 75130), we adopted three chart-abstracted measures with data submission to CMS via an online Web-based tool for the CY 2016 payment determination and subsequent years. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985), we excluded one of these measures, ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536), from the CY 2016 payment determination measure set and allowed for voluntary data collection and reporting for the CY 2017 payment determination and subsequent years. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66970 through 66979), we adopted one additional claims-based measure for the CY 2018 payment determination and subsequent years.

Most of the quality measures adopted for use by the ASCQR Program are NQF-endorsed, although such endorsement is not an ASCQR Program requirement for adopting a measure. Two measures previously adopted for the ASCQR Program are not currently NQF-endorsed, and were not endorsed when

adopted for the program (ASC–6: Safe Surgery Checklist Use and ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures). Further, ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539) was not NQF-endorsed at the time it was adopted for the ASCQR Program, but now is NQF-endorsed. Recently, NQF removed endorsement from ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing (formerly NQF #0264).[36] We continue to believe that ASC–5 is appropriate for measurement of the quality of care furnished by ASCs and should be retained by the ASCQR Program; the measure is supported by clinical evidence[37] and the measure steward will be continuing to support the measure.[38] We will continue to evaluate the appropriateness of this measure for the ASCQR Program as we do other measures.

The previously finalized measure set for the ASCQR Program CY 2017 payment determination and subsequent years is listed below.

ASCQR PROGRAM MEASURE SET PREVIOUSLY FINALIZED FOR THE CY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC No.	NQF No.	Measure name
ASC–1	0263	Patient Burn.
ASC–2	0266	Patient Fall.
ASC–3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC–4	0265	All-Cause Hospital Transfer/Admission.*
ASC–5	N/A	Prophylactic Intravenous (IV) Antibiotic Timing.
ASC–6	N/A	Safe Surgery Checklist Use.
ASC–7	N/A	ASC Facility Volume Data on Selected ASC Surgical Procedures. Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754*.
ASC–8	0431	Influenza Vaccination Coverage among Healthcare Personnel.
ASC–9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
ASC–10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
ASC–11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.**

* This measure was previously titled ''Hospital Transfer/Admission.'' According to the NQF Web site, the title was changed to better reflect what is being measured. We have updated the title of this measure to align it with the NQF update to the title.

** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

The previously finalized measure set for the ASCQR Program CY 2018 payment determination and subsequent years is listed below.

ASCQR PROGRAM MEASURE SET PREVIOUSLY FINALIZED FOR THE CY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC No.	NQF No.	Measure name
ASC–1	0263	Patient Burn.
ASC–2	0266	Patient Fall.
ASC–3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC–4	0265	All-Cause Hospital Transfer/Admission.*
ASC–5	N/A	Prophylactic Intravenous (IV) Antibiotic Timing.
ASC–6	N/A	Safe Surgery Checklist Use.
ASC–7	N/A	ASC Facility Volume Data on Selected ASC Surgical Procedures. Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754*.
ASC–8	0431	Influenza Vaccination Coverage among Healthcare Personnel.
ASC–9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
ASC–10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
ASC–11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.**
ASC–12	2539	Facility Seven-Day Risk—Standardized Hospital Visit Rate after Outpatient Colonoscopy.***

* This measure was previously titled ''Hospital Transfer/Admission.'' According to the NQF Web site, the title was changed to better reflect what is being measured. We have updated the title of this measure to align it with the NQF update to the title.

** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

*** New measure finalized for the CY 2018 payment determination and subsequent years in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66970 through 66979).

[36] *http://www.qualityforum.org/Publications/2015/02/NQF-Endorsed_Measures_for_Surgical_Procedures.aspx*.

[37] Burke J. Maximizing appropriate antibiotic prophylaxis for surgical patients: An update from LDS Hospital, Salt Lake City. Clin Infect Dis. 2001; 33 (Suppl 2): S78–83.

[38] *http://ascquality.org/documents/ASC_QC_ImplementationGuide_3.0_January_2015.pdf*.

4. ASCQR Program Quality Measures for the CY 2018 Payment Determination and Subsequent Years

We are not proposing to adopt any additional measures for the ASCQR Program for the CY 2018 payment determination and subsequent years in this proposed rule.

5. ASCQR Program Measures for Future Consideration

In the CY 2013 OPPS/ASC final rule with comment period, we set forth our approach to future measure selection and development (77 FR 68493 through 68494). We seek to develop a comprehensive set of quality measures to be available for widespread use for making informed decisions and quality improvement in the ASC setting (77 FR 68496). We also seek to align these quality measures with the National Quality Strategy (NQS), the CMS Strategic Plan (which includes the CMS Quality Strategy), and our other quality reporting and value-based purchasing programs, as appropriate. Accordingly, as we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66979), in considering future ASCQR Program measures, we are focusing on the following NQS and CMS Quality Strategy measure domains: Make care safer; strengthen person and family engagement; promote effective communication and coordination of care; promote effective prevention and treatment; work with communities to promote best practices of healthy living; and make care affordable.

In this proposed rule, we also are inviting public comment on two measures developed by the ASC Quality Collaboration for inclusion in the ASCQR Program in the future.

a. Normothermia Outcome

The first measure under consideration is the Normothermia Outcome measure which assesses the percentage of patients having surgical procedures under general or neuraxial anesthesia of 60 minutes or more in duration who are normothermic within 15 minutes of arrival in the post-anesthesia care unit. This issue is of interest to the ASCQR Program because impairment of thermoregulatory control due to anesthesia may result in perioperative hypothermia. Perioperative hypothermia is associated with numerous adverse outcomes, including: Cardiac complications;[39] surgical site infections;[40] impaired coagulation;[41] and colligation of drug effects.[42] When intraoperative normothermia is maintained, patients experience fewer adverse outcomes and their overall care costs are lower.[43] This measure is of interest to the ASCQR Program because many surgical procedures performed at ASCs involve anesthesia; therefore, it is an outcome measure of significance for ASCs.[44] It also addresses the MAP-identified priority measure area for the ASCQR Program of anesthesia-related complications.[45]

The specifications for this measure for the ASC setting can be found at: *http://ascquality.org/documents/ASC_QC_ImplementationGuide_3.0_January_2015.pdf*.

b. Unplanned Anterior Vitrectomy

The second measure under consideration for future payment determination years is the Unplanned Anterior Vitrectomy measure. This measure assesses the percentage of cataract surgery patients who have an unplanned anterior vitrectomy (removal of the vitreous present in the anterior chamber of the eye). Cataracts are a leading cause of blindness in the United States, with 24.4 million cases in 2010.[46] Each year, approximately 1.5 million patients undergo cataract surgery to improve their vision.[47] An unplanned anterior vitrectomy is performed when vitreous inadvertently prolapses into the anterior segment of the eye during cataract surgery. While unplanned anterior vitrectomy rates are relatively low, this procedure complication may result in poor visual outcomes and other complications, including retinal detachment.[48] This measure is of interest to the ASCQR Program because cataract surgery is a procedure commonly performed at ASCs; therefore, it is an outcome measure of significance for ASCs.[49] It also addresses the MAP-identified priority measure area of procedure complications for the ASCQR Program.[50]

The specifications for this measure for the ASC setting can be found at: *http://ascquality.org/documents/ASC_QC_ImplementationGuide_3.0_January_2015.pdf*.

Both measures have received conditional support from the MAP, pending the completion of reliability testing and NQF endorsement. A summary of the MAP recommendations can be found at: *http://www.qualityforum.org/setting_priorities/partnership/measure_applications_partnership.aspx* under the title ''Spreadsheet of MAP 2015 Final Recommendations.''

We are inviting public comment on the possible inclusion of these measures in the ASCQR Program measure set in the future. As stated previously, we are not proposing to adopt any new measures for the CY 2018 payment determination or subsequent years in this proposed rule.

6. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74513 through 74514), where we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures, including the subregulatory process for making updates to the adopted measures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68496 through 68497), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131), and the CY 2015 OPPS/ASC final rule with

[39] Frank S.M., Fleisher L.A., Breslow M.J., et al. Perioperative maintenance of normothermia reduces the incidence of morbid cardiac events: A randomized clinical trial. *JAMA.* 1997; 277(14): 1127–1134.

[40] Kurz A., Sessler D.I., Lenhardt R. Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization: Study of wound infection and temperature group. *N Engl J Med.* 1996; 334(19): 1209–1215.

[41] Rajagopalan S., Mascha E., Na J., Sessler D.I. The effects of mild hypothermia on blood loss and transfusion requirements during total hip arthroplasty. *Lancet.* 1996; 347(8997): 289–292.

[42] Kurz A. Physiology of thermoregulation. *Best Pract Res Clin Anaesthesiol.* 2008; 22(4): 627–644.

[43] Mahoney C.B., Odom J. Maintaining intraoperative normothermia: A meta-analysis of outcomes with costs. *AANA Journal.* 1999; 67(2): 155–164.

[44] MAP Hospital Workgroup Transcript.

[45] National Quality Forum. *MAP 2015 Considerations for Selection of Measures for Federal Programs: Hospitals.* Rep. National Quality Forum, Feb. 2015. Available at: *http://www.qualityforum.org/Publications/2015/02/MAP_Hospital_Programmatic_Deliverable_-_Final_Report.aspx*.

[46] National Eye Institute. ''*Cataracts.*'' Cataracts. National Institutes of Health, n.d. Available at: *https://www.nei.nih.gov/eyedata/cataract#1*.

[47] ''Measure Application Partnership Hospital Workgroup'', National Quality Forum. Dec. 2014, Transcript. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369*.

[48] Chen M., Lamattina K.C., Patrianakos T, Dwarakanathan S. Complication rate of posterior capsule rupture with vitreous loss during phacoemulsification at a Hawaiian cataract surgical center: A clinical audit. *Clin Ophthamlol.* 2014 Feb 5; 8: 375–378.

[49] ''Measure Application Partnership Hospital Workgroup'', National Quality Forum. Dec. 2014, Transcript. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369*.

[50] National Quality Forum. *MAP 2015 Considerations for Selection of Measures for Federal Programs: Hospitals.* Rep. National Quality Forum, Feb. 2015. Available at: *http://www.qualityforum.org/Publications/2015/02/MAP_Hospital_Programmatic_Deliverable_-_Final_Report.aspx*.

comment period (79 FR 66981), we provided additional clarification regarding the ASCQR Program policy in the context of the previously finalized Hospital OQR Program policy, including the processes for addressing nonsubstantive and substantive changes to adopted measures.

We maintain technical specifications for previously adopted ASCQR Program measures in the ASCQR Program Measures Specifications Manual. These specifications are updated as we continue to develop the ASCQR Program. We maintain the technical specifications for the measures adopted for the ASCQR Program by updating this Specifications Manual. The versions of the Specifications Manual that contain specifications for the previously adopted measures can be found on the QualityNet Web site at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754.*

As stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131), we will determine what constitutes a substantive versus a nonsubstantive change to a measure's specifications on a case-by-case basis. If we determine that a change to a measure previously adopted in the ASCQR Program is nonsubstantive, we will use a subregulatory process to revise the ASCQR Program Specifications Manual so that it clearly identifies the updates to that measure and provide links to where additional information on the changes can be found. We will provide notification of the measure specification update on the QualityNet Web site and in the ASCQR Program Specifications Manual, and will provide sufficient lead time for ASCs to implement the revisions where changes to the data collection systems would be necessary. We will continue to use rulemaking to adopt substantive updates to measures in the ASCQR Program. We are not proposing any changes to these policies. However, we are proposing to codify these policies at proposed new 42 CFR 416.325.

We previously finalized a policy to post technical specifications on a CMS Web site in addition to posting this information on QualityNet because we believed doing so would increase ASC awareness of our technical specifications in our outreach and education (76 FR 74514). However, we now believe that posting technical specifications on QualityNet alone is preferable to prevent possible inconsistencies associated with accessing multiple sites for information and to reduce burden. We believe that posting this information on a single site is a more efficient process that still provides ASCs with complete access to the technical specifications for ASCQR Program purposes. Therefore, we are not posting the technical specifications on a CMS Web site in addition to posting this information on QualityNet for the ASCQR Program.

We are inviting public comment on our proposal to codify our existing policies.

7. Public Reporting of ASCQR Program Data

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we finalized a policy to make data that an ASC submitted for the ASCQR Program publicly available on a CMS Web site after providing an ASC an opportunity to review the data to be made public. We are proposing to codify this existing policy at proposed new 42 CFR 416.315.

We also finalized a policy to display these data at the CMS Certification Number (CCN) level in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515). However, we are now proposing to change this policy. ASCs typically report quality measure data to CMS using their National Provider Identifier (NPI), which is their billing identifier on the CMS–1500 form as non-institutional billers. Further, payment determinations also are made by NPI. Because an ASC CCN can have multiple NPIs, publication of data by CCN can aggregate data for multiple facilities, thereby reducing identification of individual facility information. To allow for identification of individual facility information, beginning with any public reporting that occurs on or after January 1, 2016, we are proposing to display the data by the NPI when data are submitted by the NPI. We believe identifying data by the NPI would enable consumers to make more informed decisions about their care because the public would be able to distinguish between ASCs. Further, it would also help ASCs to better understand their performance on measures collected under the ASCQR Program. We also are proposing, beginning with any public reporting that occurs on or after January 1, 2016, to display data by the CCN when data are submitted by the CCN. When data are submitted by the CCN, all NPIs associated with the CCN would be assigned the CCN's value because we would not be able to parse the data by the NPI. For example, in the case of ASC–8: Influenza Vaccination Coverage among Healthcare Personnel measure (NQF #0431), the one ASCQR Program measure where data are submitted by the CCN as this is the identifier used by the CDC's NHSN, we would not be able to parse the data by the NPI. Thus, the data displayed for ASC–8 would be the same for all of the NPIs under the same CCN. We are proposing to codify this proposal at proposed new 42 CFR 416.315.

We are inviting public comment on our proposal to display data by the NPI if the data are submitted by the NPI and to display data by the CCN if the data are submitted by the CCN beginning with any public reporting that occurs on or after January 1, 2016, and to codify this policy and our existing policies.

C. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Administrator

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75132 through 75133), we finalized our requirements regarding QualityNet accounts and QualityNet security administrators under the ASCQR Program for the CY 2016 payment determination and subsequent years. Under these requirements, ASCs must maintain a QualityNet account in order to submit quality measure data to the QualityNet Web site for all Web-based measures submitted via a CMS online data submission tool. Further, a QualityNet security administrator is necessary to set up a QualityNet user account to be able to enter data via an online tool located on the QualityNet Web site. The registration process for the QualityNet security administrator is described on the QualityNet Web site. We recommend that ASCs submit documentation required for the creation of a QualityNet Account at least 4 to 6 weeks prior to any quality measure data submission deadline for the ASCQR Program. The QualityNet security administrator typically fulfills a variety of tasks related to quality reporting for ASCs, such as creating, approving, editing, and terminating QualityNet user accounts, and monitoring QualityNet usage to maintain proper security and confidentiality. We are not proposing any changes to these policies. We are proposing to codify these existing requirements at proposed new 42 CFR 416.310(c)(1)(i).

We are inviting public comment on our proposal to codify our existing requirements.

2. Requirements Regarding Participation Status

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53639 through 53640), we

finalized our participation policy. Under this policy, an ASC is considered as participating in the ASCQR Program once the ASC submits any quality measure data to the ASCQR Program. Further, once an ASC submits any quality measure data and is considered participating in the ASCQR Program, an ASC would still be considered participating in the ASCQR Program, regardless of whether the ASC continues to submit quality measure data, unless the ASC withdraws from the ASCQR Program.

An ASC may withdraw from the ASCQR Program by submitting to CMS a withdrawal of participation form that can be found in the secure portion of the QualityNet Web site, indicating that it is withdrawing and the initial payment determination year to which the withdrawal applies. Once the ASC has withdrawn, an ASC will incur a 2.0 percentage point reduction in its ASC annual payment update for that payment determination year and any subsequent payment determinations in which it is withdrawn.

An ASC will be considered as rejoining the ASCQR Program if it begins to submit any quality measure data again to the ASCQR Program. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75133 through 75135), for the CY 2016 payment determination and subsequent years, we finalized our policies that all program requirements would apply to all ASCs designated as open in the Certification and Survey Provider Enhanced Reporting (CASPER) system for at least four months prior to the beginning of data collection for a payment determination and that an ASC may withdraw from the ASCQR Program any time up to and including August 31 of the year preceding a payment determination. For example, an ASC can withdraw from the ASCQR Program at any time up to and including August 31, 2016 for the CY 2017 payment determination. We are not proposing any changes to these policies. However, we are proposing to codify these existing requirements at proposed new 42 CFR 416.305(a) and (b).

As finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135 through 75137), for the CY 2016 payment determination and subsequent years, ASCs with fewer than 240 Medicare claims (Medicare primary and secondary payer) per year during an annual reporting period for a payment determination year are not required to participate in the ASCQR Program for the subsequent annual reporting period for that subsequent payment determination year. For example, an ASC with fewer than 240 Medicare claims in CY 2016 (payment determination year 2018) would not be required to participate in the ASCQR Program in CY 2017 (payment determination year 2019). We are not proposing any changes to these existing requirements. However, we are proposing to codify these existing requirements at proposed new 42 CFR 416.305(c).

We are inviting public comment on our proposal to codify our existing policies.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68497 through 68498), we finalized our data processing and collection policies for the claims-based measures using QDCs for the CY 2015 payment determination and subsequent years. Specifically, ASCs must submit complete data on individual claims-based quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims. The data collection period for claims-based quality measures reported using QDCs is the calendar year 2 years prior to the payment determination year. Only claims for services furnished in each calendar year paid by the Medicare administrative contractor (MAC) by April 30 of the following year of the ending data collection time period will be included in the data used for the payment determination. In this proposed rule, we are not proposing any changes to these existing requirements. However, we are proposing to codify these existing requirement at proposed new 42 CFR 416.310(a)(1) and (2).

We are inviting public comment on our proposal to codify our existing policies.

2. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

The requirements for minimum threshold, minimum case volume, and data completeness for participation in the ASCQR program for the CY 2015 payment determination and subsequent years are set forth in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68498 through 68499) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135 through 75137). As stated in the CY 2013 rule, for ASCQR Program purposes, data completeness for claims-based measures using QDCs is determined by comparing the number of Medicare claims (where Medicare is the primary or secondary payer) meeting measure specifications that contain the appropriate QDCs with the number of Medicare claims that meet measure specifications, but do not have the appropriate QDCs on the submitted Medicare claims. For the CY 2016 payment determination and subsequent years, the minimum threshold for successful reporting is that at least 50 percent of Medicare claims meeting measures specifications contain the appropriate QDC. ASCs that meet this minimum threshold are regarded as having provided complete data for the claims-based measures using QDCs for the ASCQR Program. In this proposed rule, we are not proposing any changes to these existing requirements. However, we are proposing to codify these existing requirements at proposed new 42 CFR 416.310(a)(3).

We are inviting public comment on our proposal to codify our existing policies.

3. Requirements for Data Submitted Via an Online Data Submission Tool

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75137 through 75139), we finalized the data collection time period for quality measures for which data are submitted via a CMS online data submission tool as services furnished during the calendar year 2 years prior to the payment determination year. We also finalized our policy that these data will be submitted during the time period of January 1 to August 15 in the year prior to the affected payment determination year.

We established a different time period for data collection and submission for ASC–8: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), which is submitted via the CDC's NHSN rather than a CMS online data submission tool. For ASC–8, the data collection for the CY 2016 payment determination is from October 1, 2014 through March 31, 2015 (the 2014–2015 influenza season data) (76 FR 74510) and for the CY 2017 payment determination and subsequent years is from October 1 of the year 2 years prior to the payment determination year to March 31 of the year prior to the payment determination year (79 FR 66986), and the submission deadline is May 15 of the year when the influenza season ends (79 FR 66985 through 66986).

We are proposing to implement a May 15 submission deadline for all data

submitted via a CMS Web-based tool in the ASCQR Program for the CY 2017 payment determination and subsequent years. This proposal currently would include the following measures: ASC–6: Safe Surgery Checklist Use; ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures; ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659); and ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).[51] Therefore, we are proposing that data collected for a quality measure for which data are submitted via a CMS online data submission tool must be submitted during the time period of January 1 to May 15 in the year prior to the payment determination year for the CY 2017 payment determination and subsequent years. We are proposing this change because we believe that aligning all Web-based tool data submission deadlines with the end date of May 15 would allow for earlier public reporting of measure data and reduce the administrative burden for ASCs associated with tracking multiple submission deadlines for these measures.

We also are proposing to codify these proposed and existing requirements at proposed new 42 CFR 416.310(c)(1)(ii) and (2).

We are inviting public comment on our proposal to change the data submission time period beginning with the CY 2017 payment determination for measures for which data are submitted via a CMS online data submission tool, and our proposal to codify this proposed policy and our existing policy.

4. Claims-Based Measure Data Requirements for the ASC–12: Facility Seven-Day Risk—Standardized Hospital Visit Rate After Outpatient Colonoscopy Measure for the CY 2018 Payment Determination and Subsequent Years

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66970 through 66979), we adopted ASC–12: Facility 7-Day Risk—Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539) in the ASCQR Program for the CY 2018 payment determination and subsequent years. At the time we adopted this measure, it was not NQF-endorsed; it has subsequently been endorsed by the NQF. Unlike the other claims-based measures adopted for the ASCQR Program, this claims-based measure does not require any additional data submission, such as QDCs. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985), we finalized the policy to use paid Medicare FFS claims from the calendar year 2 years before the payment determination year. We are now proposing to align our policy regarding the paid claims to be included in the calculation for claims-based measures not using QDCs with our policy regarding the paid claims to be included for the claims-based measures using QDCs.

Therefore, beginning with the CY 2018 payment determination, we are proposing to use claims for services furnished in each calendar year that have been paid by the MAC by April 30 of the following year of the ending data collection time period to be included in the data used for the payment determination. We believe that this claim paid date would allow ASCs sufficient time to submit claims and at the same time allow CMS sufficient time to complete required data analysis and processing to make payment determinations and to supply this information to the MACs. For example, for the CY 2018 payment determination, for calculating ASC–12, we would use claims for services furnished in CY 2016 (January 1, 2016 through December 21, 2016) that were paid by the MAC by April 30, 2017.

We are proposing to codify this policy at proposed new 42 CFR 416.310(b).

We are inviting public comment on our proposal regarding the paid claims to be included in the data used for the payment determination year beginning with the CY 2018 payment determination, and our proposal to codify this proposal and our existing policies.

5. Proposal for Indian Health Service (IHS) Hospital Outpatient Departments To Not Be Considered ASCs for the Purposes of the ASCQR Program

Indian Health Service (IHS) hospital outpatient departments are able to bill Medicare for ASC services and be paid based on the ASC rates for services under the ASC payment system as described in Section 40.2.1, Chapter 19 of the Medicare Claims Processing Manual and Section 260.1, Chapter 15 of the Medicare Benefit Policy Manual (*http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c19.pdf, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf*). We have considered these entities to be ASCs for purposes of the ASCQR Program due to their payment under the ASC payment system. These entities are included under Section 260.1 (Definition of Ambulatory Surgical Centers), Chapter 15 of the Medicare Benefit Policy Manual.

We now are proposing that these facilities not be considered ASCs for purposes of the ASCQR Program, beginning with the CY 2017 payment determination. As stated in the manuals, in order to bill for ASC services, these IHS hospital outpatient departments must meet the conditions of participation for hospitals defined in 42 CFR part 482 and are not certified as separate ASC entities. Because these IHS hospital outpatient departments are required to meet the conditions of participation for hospitals, which state that the hospital's governing body must ensure that its quality assessment and performance improvement program involves all hospital departments and services, they should be included in the hospitals' ongoing, hospital-wide, data-driven quality assessment and performance improvement programs (42 CFR 482.21), which we believe ensures that these IHS hospital outpatient departments engage in continuous quality improvement efforts outside of participation in CMS' quality reporting programs. For these reasons, we are proposing that IHS hospital outpatient departments that bill Medicare for ASC services under the ASC payment system are not to be considered as ASCs for the purposes of the ASCQR Program. These facilities would not be required to meet ASCQR Program requirements and would not receive any payment reduction under the ASCQR Program. We are proposing to codify this proposal at proposed new 42 CFR 416.305(d).

We are inviting public comment on this proposal and our proposal to codify it.

6. ASCQR Program Validation of Claims-Based and CMS Web-Based Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53641 through 53642) for a complete discussion of our policy not to require validation of claims-based measures (beyond the usual claims validation activities conducted by our MACs) or Web-based measures for the ASCQR

[51] We note that this is a voluntary measure for the CY 2017 payment determination and subsequent years. This proposal would mean that ASCs that choose to submit data for this measure also would need to submit such data between January 1 and May 15 for the CY 2018 payment determination and subsequent years.

Program. In this proposed rule, we are not proposing any changes to this policy.

7. Extraordinary Circumstances Extensions or Exemptions for the CY 2018 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53642 through 53643) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75140 through 75141), we adopted procedures for extraordinary circumstance extensions or exemption requests for the submission of information required under the ASCQR Program.[52] Specifically, CMS may grant an extension or exemption for the submission of information in the event of extraordinary circumstances beyond the control of an ASC, such as when an act of nature affects an entire region or locale, or a systematic problem with one of our data collection systems directly or indirectly affects data submission. We may grant an extension or exemption as follows:

(1) Upon request by the ASC. Specific requirements for submission of a request for an extension or exemption are available on the QualityNet Web site; or

(2) At the discretion of CMS. CMS may grant extensions or exemptions to ASCs that have not requested them when CMS determines that an extraordinary circumstance has occurred.

In this proposed rule, we are not proposing any changes to these requirements. However, we are proposing to codify these existing procedures at proposed new 42 CFR 416.310(d).

We are inviting public comment on our proposal to codify our existing policies.

8. ASCQR Program Reconsideration Procedures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 through 53644) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75141), we set forth our requirements for an informal reconsideration process. Specifically, an ASC may request reconsideration of a decision by CMS that it has not met the requirements of the ASCQR Program for a particular payment determination year by submitting a reconsideration request (signed by a person who has authority to sign on behalf of the ASC) to CMS by March 17 of the affected payment determination year. A reconsideration request must contain the following information:

- ASC CCN and related NPI(s);
- The name of the ASC;
- The CMS-identified reason for not meeting the requirements of the ASCQR Program for the affected payment determination year as provided in any CMS notification to the ASC;
- The ASC's basis for requesting reconsideration. The ASC must identify its specific reason(s) for believing it met the ASCQR Program requirements for the affected payment determination year and should not be subject to the reduced ASC annual payment update;
- The ASC-designated personnel contact information, including name, email address, telephone number, and mailing address (must include physical mailing address, not just a post office box); and
- A copy of all materials that the ASC submitted to comply with the requirements of the affected ASCQR Program payment determination year. With regard to information on claims, ASCs are not required to submit copies of all submitted claims, but instead may focus on the specific claims at issue. For these claims, ASCs should submit relevant information, which could include copies of the actual claims at issue.

Upon receipt of a request for reconsideration, CMS will do the following:

- Provide an email acknowledgement, using the contact information provided in the reconsideration request, notifying the ASC that the request has been received; and
- Provide a formal response to the ASC contact, using the information provided in the reconsideration request notifying the ASC of the outcome of the reconsideration process.

For those ASCs that submit a reconsideration request, the reconsideration determination is the final ASCQR Program payment determination. For ASCs that do not submit a timely reconsideration request, the CMS determination is the final payment determination. There is no appeal of any final ASCQR Program payment determination.

In this proposed rule, we are proposing one change to these requirements. Under our current reconsideration procedures, ASCs are required to submit reconsideration requests by March 17 of the affected payment determination year (77 FR 53643 through 53644). However, we recognize that, in some payment years, March 17 may fall outside of the business week. Therefore, we are proposing that, beginning with the CY 2017 payment determination, ASCs must submit a reconsideration request to CMS by no later than the first business day on or after March 17 of the affected payment year . We are proposing to codify these existing procedures at proposed new 42 CFR 416.330.

We are inviting public comment on our proposal to change the reconsideration request submission deadline and our proposal to codify these policies.

E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to section XV.C.1. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131 through 75132) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Reduction to the ASC Payment Rates for ASCs That Fail to Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system equal the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. Currently, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the MFP-adjusted CPI–U update factor, which is the adjustment set forth in section 1833(i)(2)(D)(v) of the Act. The MFP-adjusted CPI–U update factor is the Consumer Price Index for all urban consumers (CPI–U), which currently is the annual update for the ASC payment system, minus the MFP adjustment. As discussed in the CY 2011 MPFS final rule with comment period (75 FR 73397), if the CPI–U is a negative number, the CPI–U would be held to zero. Under the ASCQR Program, any annual update will be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates. For a complete discussion of the calculation of the ASC conversion factor, we refer readers to section XII.G. of this proposed rule.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the

[52] In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66987), we stated that we will refer to the process as the ''Extraneous Circumstances Extensions or Exemptions'' process rather than the ''Extraordinary Circumstances Extensions or Waivers'' process.

ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: a full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the MFP adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to this proposed rule, which are available via the Internet on the CMS Web site): ''A2,'' ''G2,'' ''P2,'' ''R2,'' ''Z2,'' as well as the service portion of device-intensive procedures identified by ''J8.'' We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor.

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2,'' ''G2,'' ''J8,'' ''P2,'' ''R2,'' and ''Z2.'' These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, certain radiology services and diagnostic tests where payment is based on the MPFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment. As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update.

Office-based surgical procedures (performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the MPFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in section XII.D.2.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for the new category of covered ancillary services (that is, certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS and when they are integral to an ASC covered surgical procedure) will be at the lesser of the MPFS nonfacility PE RVU-based amounts or the rate calculated according to the standard ASC ratesetting methodology. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we believe that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced copayment liability for beneficiaries. Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In that final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: the wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, and the adjustment for devices furnished with full or partial credit or without cost. We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements.

In the CY 2014 and CY 2015 OPPS/ASC final rules with comment periods (78 FR 75132 and 79 FR 66981 through 66982), we did not make any changes to these policies.

In this CY 2016 OPPS/ASC proposed rule, we are not proposing any changes to these policies.

XV. Short Inpatient Hospital Stays

A. Background on the 2-Midnight Rule

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954), we discussed CMS' longstanding policy on how Medicare contractors review inpatient hospital and CAH admissions for payment purposes. In that final rule, we discussed previously existing Medicare policy contained in the Section 10, Chapter 1 of the Medicare Benefit Policy Manual (MBPM) that stated that when a beneficiary receives a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for only a few hours (less than 24 hours), the services generally should be billed as outpatient hospital services, regardless of the hour the beneficiary comes to the hospital, whether he or she uses a bed, and whether he or she remains in the hospital past midnight. We noted that we have been clear that this billing instruction does not override the clinical judgment of the physician to keep the beneficiary at the hospital, to order specific services, or to determine appropriate levels of nursing care or physical locations within the hospital. Rather, this instruction provided a benchmark to ensure that all beneficiaries received consistent application of their Medicare Part A benefit to whatever clinical services were medically necessary.

However, due to persistently 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, we modified and clarified our general rule in the regulations with respect to Medicare payment for inpatient hospital admissions. Specifically, in the FY 2014 IPPS/LTCH PPS final rule, we provided guidance for payment purposes that specified that, generally, a hospital inpatient admission is considered reasonable and necessary if a physician or other qualified practitioner (collectively, ''physician'') orders such admission based on the expectation that the

beneficiary's length of stay will exceed 2 midnights or if the beneficiary requires a procedure specified as inpatient only under § 419.22 of the regulations. We finalized at § 412.3(d)(1) of the regulations that services designated under the OPPS as inpatient only procedures would continue to be appropriate for inpatient hospital admission and payment under Medicare Part A. In addition, we finalized a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation. Conversely, when a beneficiary enters a hospital for a surgical procedure not specified as inpatient only under § 419.22(n), a diagnostic test, or any other treatment, and the physician expects to keep the beneficiary in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A, regardless of the hour that the beneficiary came to the hospital or whether the beneficiary used a bed.

We finalized a policy at § 412.3(d)(2) (originally designated as § 412.3(e)(2) and later redesignated as § 412.3(d)(2)) of the regulations that if an unforeseen circumstance, such as beneficiary death or transfer, results in a shorter beneficiary stay than the physician's reasonable expectation of at least 2 midnights, the patient may still be considered to be appropriately treated on an inpatient basis for payment purposes, and the hospital inpatient payment may be made under Medicare Part A.

In addition to the new hospital admission guidance, we also finalized two distinct, although related, medical review policies, a 2-midnight ''benchmark'' and a 2-midnight ''presumption,'' effective for admissions on or after October 1, 2013. The 2-midnight benchmark, which is described in more detail below, represents guidance to reviewers to identify when an inpatient admission is generally appropriate for Medicare coverage and payment, while the 2-midnight presumption relates to instructions to medical reviewers regarding the selection of claims for medical review. Specifically, under the 2-midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order are presumed to be appropriate for Medicare Part A payment and will not be the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-midnight presumption.

With respect to the 2-midnight benchmark, the starting point is when the beneficiary begins receiving hospital care as either a registered outpatient or after inpatient admission. That is, for purposes of determining whether the 2-midnight benchmark is met and, therefore, whether an inpatient admission is appropriate for Medicare Part A payment, we consider the physician's expectation including the total time spent receiving hospital care—not only the expected duration of care after inpatient admission, but also any time the beneficiary has spent (before inpatient admission) receiving outpatient services such as observation services, treatments in the emergency department, and procedures provided in the operating room or other treatment area. From the medical review perspective, while the time the beneficiary spent as an outpatient before the admission order is written is not considered inpatient time, it is considered during the medical review process for purposes of determining whether the 2-midnight benchmark was met and, therefore, whether payment is appropriate under Medicare Part A. For beneficiaries who do not arrive through the emergency department or are directly receiving inpatient services (for example, inpatient admission order written prior to admission for an elective admission), the starting point for medical review purposes is when the beneficiary starts receiving services following arrival at the hospital. For Medicare payment purposes, both the decision to keep the patient at the hospital and the expectation of needed duration of the stay must be supported by documentation in the medical record based on such factors as beneficiary medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event during hospitalization.

With respect to inpatient stays spanning less than 2 midnights after admission, we instructed contractors that, although such claims would not be subject to the presumption, the admission may still be appropriate for Medicare Part A payment because time spent as an outpatient should be considered in determining whether there was a reasonable expectation that the hospital care would span 2 or more midnights. In other words, even if an inpatient admission was for only 1 Medicare utilization day, medical reviewers are instructed to consider the total duration of hospital care, both pre- and post-inpatient admission, when making the determination of whether the inpatient stay was reasonable and necessary for purposes of Medicare Part A payment. For those admissions in which the basis for the physician expectation of care surpassing 2 midnights is reasonable and well-documented, reviewers may apply the 2-midnight benchmark to incorporate all of the time a beneficiary received care in the hospital.

We continue to believe that use of the 2-midnight benchmark gives appropriate consideration to the medical judgment of physicians and also furthers the goal of clearly identifying when an inpatient admission is appropriate for payment under Medicare Part A. More specifically, as we described in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954), factors such as the procedures being performed and the beneficiary's condition and comorbidities apply when the physician formulates his or her expectation regarding the need for hospital care, while the determination of whether an admission is appropriately billed and paid under Medicare Part A or Part B is based upon the physician's medical judgment regarding the beneficiary's expected length of stay. We have not identified any circumstances where the 2-midnight benchmark restricts the physician to a specific pattern of care, as the 2-midnight benchmark, like the previous 24-hour benchmark, does not prevent the physician from ordering or providing any service at any hospital, regardless of the expected duration of the service. Rather, this policy provides guidance on when the hospitalized beneficiary's care is appropriate for coverage and payment under Medicare Part A benefits as an inpatient, and when the beneficiary's care is appropriate for coverage and payment under Medicare Part B benefits as an outpatient.

On the other hand, we also acknowledge that certain procedures may have intrinsic risks, recovery impacts, or complexities that would cause them to be appropriate for inpatient coverage under Medicare Part A regardless of the length of hospital time the admitting physician expects a particular patient to require. We believe that the OPPS inpatient only list of procedures identifies those procedures and, therefore, procedures on that list are not subject to the 2-midnight benchmark for purposes of inpatient hospital payment. We explained in the

FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954) that we might specify additional exceptions to the generally applicable benchmark through subregulatory guidance, including revised manual instructions. Accordingly, since publication of the final rule, we have accepted and considered suggestions from stakeholders regarding potential ''rare and unusual'' circumstances under which an inpatient admission that is expected to span less than 2 midnights would nonetheless be appropriate for Medicare Part A payment.

In January 2014, we identified medically necessary, newly initiated mechanical ventilation (excluding anticipated intubations related to minor surgical procedures or other treatment) as the first such rare and unusual exception to the 2-midnight benchmark. We announced this exception by posting it on the CMS Web site. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50147), we invited further feedback on suggested exceptions to the 2-midnight benchmark, in recognition that there could be additional rare and unusual circumstances that we have not identified that justify payment as an inpatient admission under Medicare Part A, absent an expectation of care spanning at least 2 midnights.

With respect to the 2-midnight benchmark, we have been clear that this instruction does not override the clinical judgment of the physician regarding the need to keep the beneficiary at the hospital, to order specific services, or to determine appropriate levels of nursing care or physical locations within the hospital. Rather, as with the previous 24-hour benchmark in the MBPM, this instruction provides a benchmark to ensure that all beneficiaries receive consistent application of their Medicare Part A benefit to medically necessary clinical services.

As part of our efforts to provide education to stakeholders on the 2-midnight rule, CMS has hosted numerous ''Open Door Forums,'' conducted national provider calls, and shared information and answers to frequently asked questions on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/InpatientHospitalReviews.html.*

In addition, we instructed MACs to conduct ''probe and educate'' reviews 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 policy. We also imposed a moratorium on recovery auditor 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 Pub. L. 113–93 permitted CMS to continue medical review activities under the MAC probe and educate process through March 31, 2015. The same law also extended the CMS moratorium on recovery auditor reviews of inpatient hospital patient status for claims with dates of admission through March 31, 2015. On April 16, 2015, the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) was enacted. Section 521 of Pub. L. 114–10 permitted CMS to further extend the medical review activities under the inpatient hospital probe and educate process and extended the moratorium that precludes recovery auditor reviews of inpatient hospital patient status for claims with dates of admission through September 30, 2015. MACs have completed the first and second rounds of probe reviews and provider education and are starting on a third round of probe reviews, to be completed on or before September 30, 2015. Throughout the probe and educate process to date, we have seen positive effects and improved provider understanding of the 2-midnight rule. For example, the second round of probe and educate denial rates were lower than those in the first round, which may reflect improved provider understanding of the 2 midnight rule after the implementation of the first round of provider education. In addition, anecdotal reports indicate that providers found that the education provided for post-probe reviews was effective in promoting better understanding of the policy.

In response to industry feedback, including suggestions to limit the Recovery Audit Program, on December 30, 2014, we announced a number of changes to the Recovery Audit Program. To address hospitals' concerns that they do not have the opportunity to rebill for medically necessary Medicare Part B inpatient services by the time a medical review contractor has denied a Medicare Part A inpatient claim, we are changing the recovery auditor ''look-back period'' for patient status reviews to 6 months from the date of service in cases where a hospital submits the claim within 3 months of the date that it provides the service. We have established limits on additional documentation requests (ADRs) that are based on a hospital's compliance with Medicare rules, incrementally applied ADR limits for providers that are new to recovery auditor reviews, and diversified ADR limits across all types of claims for a certain provider. We also have established a requirement that recovery auditors must complete complex reviews within 30 days, and failure to do so will result in the loss of the recovery auditor's contingency fee, even if an error is found. Finally, we will require recovery auditors to wait 30 days before sending a claim to the MAC for adjustment. This 30-day period will allow the provider to submit a discussion period request to the recovery auditor before the MAC makes any payment adjustments. These changes will be effective with the next recovery audit program contract awards.

B. Proposed Policy Change for Medical Review of Inpatient Hospital Admissions Under Medicare Part A

While we have been clear that the 2-midnight benchmark does not override the clinical judgment of the physician regarding the need to keep the beneficiary at the hospital, to order specific services, or to determine appropriate levels of nursing care or physical locations within the hospital, some stakeholders have argued that the 2-midnight benchmark removes physician judgment from the decision to admit a patient for inpatient hospital services. We disagree. We continue to believe that the 2-midnight benchmark provides, for payment purposes, clear guidance on when a hospital inpatient admission is appropriate for Medicare Part A payment, while respecting the role of physician judgment, although we acknowledge that our current payment policy and medical review policy focus on physician judgment regarding the expected duration of medically necessary hospital care. However, we believe the concerns raised by stakeholders merit continued consideration.

In light of the aforementioned stakeholder concern 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, we are proposing to modify our existing ''rare and unusual'' exceptions 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. For payment

purposes, the following factors, among others, would be relevant to determining whether an inpatient admission where the patient stay is expected to be less than 2 midnights is nonetheless appropriate for Part A payment:

- The severity of the signs and symptoms exhibited by the patient;
- The medical predictability of something adverse happening to the patient; and
- The need for diagnostic studies that appropriately are outpatient services (that is, their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more).

We note that, under the existing rare and unusual policy, only one exception—prolonged mechanical ventilation—has been identified to date. Upon further consideration and based on feedback from stakeholders, we believe there may be other patient-specific circumstances where certain cases may nonetheless be appropriate for Part A payment, absent an expected stay of at least 2 midnights. Such circumstances would be determined on a case-by-case basis. Under the proposed revised policy, for purposes of Medicare payment, an inpatient admission will be payable under Part A if the documentation in the medical record supports either the admitting physician's reasonable expectation that the patient will require hospital care spanning at least 2 midnights, or the physician's determination based on factors such as those identified above, that the patient requires formal admission to the hospital on an inpatient basis.

Accordingly, we are proposing to revise § 412.3(d)(1) of the regulations to reflect this modification. Existing § 412.3(d)(1) specifies, in relevant part, that if the physician expects to keep the patient in the hospital for only a limited period of time that does not cross 2 midnights, the services are generally inappropriate for inpatient admission and inpatient payment under Medicare Part A, regardless of the hour that the patient came to the hospital or whether the patient used a bed. We are proposing to revise § 412.3(d) to state that when the admitting physician expects a hospital patient to require hospital care for only a limited period of time that does not cross 2 midnights, the services may be appropriate for payment under Medicare Part A if the physician determines and documents in the patient's medical record that the patient requires a reasonable and necessary admission to the hospital as an inpatient. In general, we would expect that with most inpatient admissions where the stay is expected to last less than the 2-midnight benchmark, the patient will remain in the hospital at least overnight but acknowledge that the patient can be unexpectedly discharged or transferred to another hospital and not actually use a hospital bed overnight. Cases for which the physician determines that an inpatient admission is necessary, but that do not span at least 1 midnight, will be prioritized for medical review. In addition to the proposed substantive changes discussed earlier in this section, we also proposing to revise existing paragraphs (d)(1) and (d)(2) for clarity.

Under the proposed policy change, for stays for which the physician expects the patient to need less than 2 midnights of hospital care and the procedure is not on the inpatient only list or on the national exception list, an inpatient admission would be payable on a case-by-case basis under Medicare Part A in those circumstances under which the physician determines that an inpatient stay is warranted and the documentation in the medical record supports that an inpatient admission is necessary.

We are not proposing any changes for hospital stays that are expected to be greater than 2 midnights; that is, if the physician expects the patient to require hospital care that spans at least 2 midnights and admits the patient based on that expectation, the services are generally appropriate for Medicare Part A payment. (We note that this policy applies to hospital admissions where the patient is reasonably expected to stay at least 2 midnights, and payment will still be appropriate where the medical record supports the admitting physician's reasonable expectation that the patient would stay at least 2 midnights but the actual stay was less due to unforeseen circumstances, such as unexpected patient death, transfer, clinical improvement, or departure against medical advice.) We also are not proposing to change the 2-midnight presumption.

Our existing policy provides for payment under Part A based upon the admitting physician's clinical judgment that a patient will require hospital care that is expected to span at least 2 midnights. This proposed change also would allow for payment under Part A on a case-by-case basis for stays expected to last less than the 2-midnight benchmark, based upon the admitting physician's clinical judgment that inpatient hospital admission is appropriate. Consistent with longstanding Medicare policy, the decision to formally admit a patient to the hospital is subject to medical review.

Under our proposed revision to the policy for cases not meeting the 2-midnight rule, where the medical record does not support a reasonable expectation of the need for care crossing at least 2 midnights, and for inpatient admissions not related to a surgical procedure specified by Medicare as inpatient only under § 419.22(n) or for which there was not a national exception (currently, there is an exception for new onset mechanical ventilation), payment of the claim under Medicare Part A will be subject to the clinical judgment of the medical reviewer. As under our current policy, under our proposed revised policy, the medical reviewer's clinical judgment would involve the synthesis of all submitted medical record information (for example, progress notes, diagnostic findings, medications, nursing notes, and other supporting documentation) to make a medical review determination on whether the clinical requirements in the relevant policy have been met. In addition, Medicare review contractors must abide by CMS policies in conducting payment determinations, but are permitted to take into account evidence-based guidelines or commercial utilization tools that may aid such a decision. While Medicare review contractors may continue to use commercial screening tools to help evaluate the inpatient admission decision for purposes of payment under Medicare Part A, such tools are not binding on the hospital, CMS, or its review contractors. This type of information also may be appropriately considered by the physician as part of the complex medical judgment that guides his or her decision to keep a beneficiary in the hospital and formulation of the expected length of stay. Some members of the hospital industry have argued that Medicare should adopt specific criteria for medical review entities to use when reviewing short-stay hospital claims. We are inviting public comments on whether specific medical review criteria should be adopted for inpatient hospital admissions that are not expected to span at least 2 midnights and, if so, what those criteria should be.

Although CMS reviewers will take into consideration the physician's decision to admit a beneficiary, the admission must be reasonable and necessary and supported by clear documentation in the patient's medical record in order to be covered under Medicare Part A. Likewise, in order to be covered under Medicare Part A, the care furnished must also be reasonable

and necessary. Section 1862(a)(1) of the Act prohibits payment under the Medicare program for services that are not reasonable and necessary for the diagnosis or treatment of illness or injury. In cases where CMS reviewers find that an inpatient admission is not medically reasonable and necessary and thus not appropriate for payment under Medicare Part A, we note that the beneficiary's patient status remains ''inpatient'' as of the time of the inpatient admission, and 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, as stated in CMS Ruling 1455–R (78 FR 16617). In these cases, the hospital will not receive payments for the beneficiary under Medicare Part A but may be able to submit a Medicare Part B inpatient claim for the Part B services that would have been payable to the hospital had the beneficiary originally been treated as an outpatient.

We note that our proposed change in policy for payment of hospital care expected to last less than 2 midnights does not negate our longstanding policy, which recognizes that there are certain situations in which a hospital inpatient admission is rarely appropriate for Medicare Part A payment. We continue to believe, as stated above and as stated in the MBPM, that when a beneficiary receives a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for only a few hours (less than 24 hours), the services should generally be billed as outpatient hospital services, regardless of the hour the beneficiary comes to the hospital, whether he or she uses a bed, and whether he or she remains in the hospital past midnight (Section 10, Chapter 1 of the MBPM). Accordingly, we would expect it to be rare and unusual for a beneficiary to require inpatient hospital admission after having a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for only a few hours and not at least overnight. We will monitor the number of these types of admissions and plan to prioritize these types of cases for medical review.

Currently, the MACs perform ''probe and educate'' audits under the 2-midnight rule. Regardless of whether we finalize the policy proposals outlined above, we are announcing that, no later than October 1, 2015, we are changing the medical review strategy and plan to have Quality Improvement Organization (QIO) contractors conduct these reviews of short inpatient stays rather than the MACs. Among the QIO's statutory duties is the review of some or all of the professional activities of providers and practitioners in the QIO's service area, subject to the terms of the QIO contracts, in the provision of health care items or services to Medicare beneficiaries. Such QIO reviews are for the purposes of determining whether providers and practitioners are delivering services that are reasonable and medically necessary, whether the quality of services meets professionally recognized standards of care, and, for inpatient services, whether the services could be effectively furnished on an outpatient basis or in a different type of inpatient facility. Section 1154(a)(1) of the Act authorizes QIOs to review whether services and items billed under Medicare are reasonable and medically necessary and whether services that are provided on an inpatient basis could be appropriately and effectively provided on an outpatient basis, while section 1154(a)(2) of the Act provides for payment determinations to be made based on these QIO reviews. Section 1154(a)(18) of the Act includes provisions that involve broad authority for the Secretary to direct additional activities by QIOs to improve the effectiveness, efficiency, economy, and quality of services under the Medicare program. These reviews are integral to the determination of whether items and services should be payable under the Medicare program.

In addition to the reviews to ensure coverage in accordance with Medicare standards under sections 1154(a)(1) and (a)(2) of the Act, QIO case review work is an effort to measurably improve the quality of health care for Medicare beneficiaries as well as all individuals protected under the Emergency Medical Treatment and Labor Act (EMTALA) and to provide peer review. QIOs have longstanding program experience in addressing beneficiary complaints, provider-based notice appeals, violations of EMTALA, Higher Weighted Diagnosis Related-Group (HWDRG) coding reviews, and other related responsibilities as articulated in the Act. Further, in the performance of their current quality improvement activities and medical reviews, QIOs routinely collaborate and interact with State survey agencies, MACs, recovery auditors, and qualified independent contractors (QICs).

In addition to their expedited appeal and quality of care review expertise, QIOs currently perform both coding and medical necessity reviews. For example, when conducting HWDRG coding reviews, QIOs already analyze claims submitted by hospitals with proposed changes to billing codes that would allow the hospital to receive a higher weighted DRG payment for the care delivered. In these HWDRG reviews, QIOs ensure that the clinical circumstances in which the care was provided accurately matches the provider's claim for payment. QIOs also currently perform reviews to confirm that all services and items provided were reasonable and medically necessary, consistent with section 1862(a)(1) or 1862(a)(9) of the Act. Further in those instances when the HWDRG review involves a service provided during a short inpatient stay, QIOs also perform a corresponding medical review to validate adherence to the current 2-midnight policy.

As previously mentioned in this section, we are changing our medical review strategy for short hospital stays and will have QIO contractors conduct reviews of short inpatient stays. QIO contractors are well-suited to conduct these short-stay inpatient reviews because these reviews fit within the scope of the QIO statutory functions and because their quality improvement programs are aligned with the HHS' National Quality Strategy objective to provide ''better care and better health at lower cost.'' QIOs, by their design, are groups of regional and national health quality experts, clinicians, and consumers organized to improve the care delivered to people with Medicare. As indicated previously, QIOs manage a variety of beneficiary complaints and quality of care case reviews to ensure consistency in health care delivery and practice in the inpatient and outpatient setting while taking into consideration clinical practice guidelines and other local factors important to beneficiaries, providers, and practitioners, and the Department. These capabilities will be useful in making case-by-case review determinations.

To mitigate the perception of a potential conflict of interest between medical review and quality improvement functions of the QIOs, on August 1, 2014, the QIO program separated medical case review from its quality improvement activities in each State under two types of regional contracts. These include Beneficiary and Family Centered Care QIOs (BFCC–QIOs) contractors who perform medical case review, and Quality Innovation Network QIOs (QIN–QIOs) contractors who perform quality improvement activities and provide technical assistance to providers and practitioners. In addition, the restructured QIO program uses a non-QIO a contractor to assist CMS in the

monitoring and oversight of the BFCC–QIO case review activities.

Under the new medical review short-stay inpatient review process that we will adopt by October 1, 2015, QIOs will review a sample of post-payment claims and make a determination of the medical appropriateness of the admission as an inpatient. As mentioned earlier in this section, we continue to believe that when a beneficiary receives a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for only a few hours (less than 24 hours), the services should generally be billed as outpatient hospital services, regardless of the hour the beneficiary comes to the hospital, whether he or she uses a bed, and whether he or she remains in the hospital past midnight (Section 10, Chapter 1 of the MBPM). Accordingly, we would expect it to be rare and unusual for a beneficiary to require inpatient hospital admission after having a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for a period of time that is only for a few hours and does not span at least overnight. We will monitor the number of these types of admissions and plan to prioritize these types of cases for medical review.

QIOs will refer claim denials to the MACs for payment adjustments. Providers' appeals of denied claims will be addressed under the provisions of section 1869 of the Act. QIOs will educate hospitals about claims denied under the 2-midnight policy and collaborate with these hospitals in their development of a quality improvement framework to improve organizational processes and/or systems. Under the QIO short-stay inpatient review process, those hospitals that are found to exhibit a pattern of practices, including, but not limited to: Having high denial rates and consistently failing to adhere to the 2-midnight rule (including having frequent inpatient hospital admissions for stays that do not span one midnight), or failing to improve their performance after QIO educational intervention, will be referred to the recovery auditors for further payment audit.

In addition to the formal medical review process, we intend to continuously monitor and evaluate the proposed changes to the 2-midnight payment policy and medical review strategy. We will specifically examine and evaluate applicable claims data and any other data available in order to determine whether any patterns of case-by-case exceptions exist that might be appropriately announced as uniform, national exceptions, to examine the effect on short-stay inpatient claims and long outpatient observation stays, and to observe any other trends which might affect beneficiary access, outcomes, and quality of care. We also will monitor applicable data for signs of systematic gaming of this policy. We will continue to assess the 2-midnight payment policy in future years, and, as with all Medicare payment policies, may make future payment modifications based on the trends observed.

As mentioned earlier in this section, section 521 of Pub. L. 114–10 prohibits recovery auditors from performing patient status reviews for claims with dates of admission October 1, 2013 through September 30, 2015. Under current law, recovery auditors may resume such reviews for dates of admission of October 1, 2015 and later. After that date, the recovery auditors will conduct patient status reviews focused on those providers that are referred from the QIOs and have high denial rates. The number of claims that a recovery auditor will be allowed to review for patient status will be based on the claim volume of the hospital and the denial rate identified by the QIO. We will adopt this new medical review strategy regardless of whether the 2-midnight rule remains unchanged or is modified.

As stated earlier, one of the reasons we adopted the 2-midnight rule was because of concerns about the growing trend of long outpatient hospital stays. We note that preliminary data suggest that the 2-midnight rule as it relates to hospital stays spanning at least 2 midnights has been effective in reducing long outpatient hospital stays. Specifically, our data show that the proportion of outpatient long-stay encounters (more than 2 days) involving observation services decreased by 11 percent in FY 2014 compared to FY 2013. The trend in these data is consistent with our adoption of the 2-midnight rule on October 1, 2013.

As noted previously, we are not proposing to change the 2-midnight presumption for purposes of medical review. That is, inpatient stays for which the patient remained in the hospital at least 2 midnights following formal admission to the hospital will continue to be presumed appropriate for inpatient hospital payment under Medicare Part A and will generally not be selected for medical review of patient status.

We welcome stakeholder comment and feedback on this proposed change and on future changes to the 2-midnight rule. We note that several stakeholder groups have examined short-stay payment policies, but that there is no consensus on what a short-stay payment policy should be. We also note that MedPAC has recently recommended repealing the 2-midnight rule in its entirety, in Chapter 7 of its June Report to Congress. MedPAC has not recommended a short-stay payment policy. We have requested public comment on three different occasions on issues related to when a patient is appropriately admitted as an inpatient or when the patient is appropriately treated as an outpatient, including potential payment policy options to address this issue. The public comment process has not produced any consensus on a recommended payment policy proposal to address this issue. In a letter earlier this year, the American Hospital Association provided us with its analysis for several payment policy alternatives and their potential impact. The association did not recommend adoption of a particular payment policy in this area. We continue to be open to considering potential payment policy options that have the potential to address this issue.

XVI. Proposed Transition for Medicare-Dependent, Small Rural Hospitals (MDHs) in All-Urban States Under the Hospital Inpatient Prospective Payment System

A. Background on the Medicare-Dependent, Small Rural Hospital (MDH) Program

Section 1885(d)(5)(G) of the Act provides special payment protections under the hospital inpatient prospective payment system (IPPS) to Medicare-dependent, small rural hospitals (MDHs). 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 a sole community hospital (SCH), and has a high percentage of Medicare discharges (that is, not less than 60 percent of its inpatient days or discharges either in its 1987 cost reporting year or in 2 of its most recent 3 settled Medicare cost reporting years). MDHs are paid for their hospital inpatient services based on the higher of the Federal rate or a blended rate based, in part, on the Federal rate and, in part, on the MDH's hospital-specific rate. Specifically, the blended rate is calculated using the Federal rate payment plus 75 percent of the amount by which the Federal rate payment is exceeded by the MDH's hospital-specific rate payments. 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 discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50022), 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. The program has since been extended several times. Most recently, section 205 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015, provides for an extension of the MDH program through FY 2017. Specifically, section 205 of the MACRA amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act by striking the ''April 1, 2015'' end date for the MDH program and inserting ''October 1, 2017''.

B. Implementation of New OMB Delineations and Urban to Rural Reclassification

On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas (MSAs), Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. These delineations are based on 2010 decennial Census data. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49950 through 49991), we adopted the new OMB labor market area delineations beginning in FY 2015. Consequently, there were 105 counties that were previously located in rural areas that became urban under the new OMB delineations (79 Fr 49953). As noted above, under section 1886(d)(5)(G)(iv) of the Act, an MDH must be located in a rural area.

The transition of certain counties from rural to urban under the new OMB delineations required MDHs in those counties to apply for rural status in order to retain their MDH classifications and avoid losing the special payment protections provided to MDHs. In order to be approved for a rural reclassification, a hospital that is located in an urban area must meet one of the following four criteria under section 1886(d)(8)(E)(ii) of the Act (codified at 42 CFR 412.103):

(1) The hospital is located in a rural census tract of an MSA, as determined under the most recent version of the Goldsmith Modification, the Rural-Urban Commuting Area (RUCA) codes;

(2) The hospital is located in an area designated by any law or regulation of such State as a rural area or is designated by such State as a rural hospital;

(3) The hospital would qualify as a rural referral center (RRC) or a sole community hospital (SCH) if the hospital were located in a rural area; and

(4) The hospital meets such other criteria as the Secretary may specify.

In addition, under section 1886(d)(8)(E) of the Act, in order for a hospital to reclassify from an urban area to a rural area, the State in which the hospital is located must have a rural area. In other words, a hospital may not reclassify from urban to rural under section 1886(d)(8)(E) of the Act in an all-urban State, which, as of October 1, 2014, included New Jersey, Delaware, and Rhode Island.

MDHs that shifted from rural to urban under the new OMB delineations may apply for rural reclassification under § 412.103. In a situation where a hospital could not reclassify to a rural area under § 412.103 because it is now located in an all-urban State, the hospital would have lost its MDH status and would be paid for hospital inpatient services at the Federal rate, which may be substantially lower than the MDH's hospital-specific rate. Given that the MDH program was scheduled to expire April 1, 2015, but was recently extended to expire effective October 1, 2017, by section 205 of the MACRA, we believe it would be appropriate to provide a prospective payment rate transition period for MDHs that cannot retain such status due to their location in a newly redesignated urban area located in an all-urban State and, therefore, the lack of a rural area within their State into which they could reclassify.

We are proposing that, effective January 1, 2016, payments to hospitals that lost their MDH status because they are no longer in a rural area due to the adoption of the new OMB delineations and are now located in all-urban States would transition from payments based, in part, on the hospital-specific rate to payments based entirely on the Federal rate. As stated earlier, currently, an MDH receives the higher of the Federal rate or the Federal rate payment plus 75 percent of the amount by which the Federal rate payment is exceeded by its hospital-specific rate payment. We are proposing that, for discharges occurring on or after January 1, 2016, and before October 1, 2016, a former MDH in an all-urban State would receive the Federal rate plus two-thirds of 75 percent of the amount by which the Federal rate payment is exceeded by its hospital-specific rate payment. For FY 2017, that is, for discharges occurring on or after October 1, 2016, and before October 1, 2017, we are proposing that such a former MDH would receive the Federal rate plus one-third of 75 percent of the amount by which the Federal rate payment is exceeded by the hospital's hospital-specific rate. For FY 2018, that is, for discharges occurring on or after October 1, 2018, we are proposing that these former MDHs would be solely paid based on the Federal rate.

We believe it is appropriate to apply these proposed transitional payments for hospitals formerly located in rural areas and formerly classified as MDHs that are now located in all-urban States, given the potentially significant payment impacts for these hospitals and the fact that a hospital may not reclassify from urban to rural under section 1886(d)(8)(E) of the Act in an all-urban State. Allowing a gradual transition for such hospitals from payments based, in part, on the hospital-specific rate to payments based solely on the Federal rate would minimize the negative impact of our adoption of the new OMB delineations which caused certain rural hospitals to lose their MDH status.

We are inviting public comments on our proposal.

XVII. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and the final rules with comment period are published and available only via the Internet on the CMS Web site. To view the Addenda to this proposed rule pertaining to proposed CY 2016 payments under the OPPS, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html;* select ''1633–P'' from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder entitled ''Proposed 2016 OPPS 1633–P Addenda'' at the bottom of the page. To view the Addenda to this proposed rule pertaining to the proposed CY 2016 payments under the ASC payment system, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html;* select ''1633–P'' from the list of regulations. All ASC Addenda to this proposed rule are contained in the zipped folders entitled ''Addendum AA, BB, DD1 and DD2'' and ''Addendum EE''.

For CY 2016, we are proposing to add two new Addenda: Proposed Addendum O, which lists the proposed new and revised CPT codes for CY 2016; and proposed Addendum Q, which includes a crosswalk from CY 2015 APC numbers to proposed new CY 2016 APC numbers.

XVIII. Collection of Information Requirements

A. Legislative Requirements for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and to solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comments on each of the issues outlined above for the information collection requirements discussed below.

B. Associated Information Collections Not Specified in Regulatory Text

In this CY 2016 OPPS/ASC proposed rule, we make reference to proposed associated information collection requirements that were not discussed in the regulation text contained in the proposed rule. The following is a discussion of those proposed requirements.

1. Hospital OQR Program

As we stated in section XIV. of the CY 2012 OPPS/ASC final rule with comment period, the Hospital OQR Program has been generally modeled after the quality data reporting program for the Hospital IQR Program (76 FR 74451). We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72111 through 72114), the CY 2012 OPPS/ASC final rule with comment period (76 FR 74549 through 74554), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68527 through 68532), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75170 through 75172), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 67012 through 67015) for detailed discussions of Hospital OQR Program information collection requirements we have previously finalized. The information collection requirements associated with the Hospital OQR Program are currently approved under OMB control number 0938–1009.

Below we discuss only the changes in burden resulting from the provisions in this proposed rule.

a. Estimated Burden of Hospital OQR Program Proposals for the CY 2017 Payment Determination and Subsequent Years

In section XIII. of this proposed rule, we are proposing to make several changes to the Hospital OQR Program for the CY 2017 payment determination and subsequent years. Specifically, we are proposing to: (1) Remove the OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache measure, effective January 1, 2016 (no data for this measure will be used for any payment determination); (2) change the deadline for withdrawing from the Hospital OQR Program from November 1 to August 31; (3) shift the quarters on which we base payment determinations; (4) change the data submission timeframe for measures submitted via the CMS Web-based tool (QualityNet Web site) from July 1 through November 1 to January 1 through May 15; (5) rename our extension and exception policy to extension and exemption policy; (6) change the deadline for submitting a reconsideration request from the first business day of the month of February of the affected payment year to the first business day on or after March 17 of the affected payment year; and (7) amend 42 CFR 419.46(f)(1) and 42 CFR 419.46(e)(2) to replace the term ''fiscal year'' with the term ''calendar year.'' While there is burden associated with filing a reconsideration request, section 3518(c)(1)(B) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3518(c)(1)(B)) excludes collection activities during the conduct of administrative actions such as reconsiderations. We do not believe that any of these changes would increase burden, as further discussed below.

We are proposing to make conforming changes to our validation scoring process to reflect proposed changes in the APU determination timeframes. For the CY 2017 payment determination, we are proposing that validation be based on three quarters of data (quarter 2, quarter 3 and quarter 4 of 2015.) For this transition year, we estimate that the burden associated with validation reporting would be reduced by 25 percent because hospitals would submit validation data for three quarters instead of four.

(1) Measure Proposed for Removal for the CY 2017 Payment Determination and Subsequent Years

As discussed in section XIII.B.5. of this proposed rule, we are proposing to remove OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache beginning with the CY 2017 payment determination. OP–15 is a claims-based measure. As we noted in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68530), we calculate claims-based measures using Medicare FFS claims data that do not require additional hospital data submissions. In addition, public reporting of OP–15 has been deferred since the CY 2013 OPPS/ASC final rule with comment period (76 FR 74456 and *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228774991461* under 1.6—Imaging Efficiency, ''OP–15 Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache''). We estimate that there would be no change in burden based on our proposal to remove this measure.

(2) Changes to Reporting Requirements for the CY 2017 Payment Determination and Subsequent Years

In section XIII.E. of this proposed rule, we are proposing to make several changes to the reporting requirements for the Hospital OQR Program. Specifically, we are proposing to: (1) Change the deadline for withdrawing from the program from November 1 to up to and including August 31; (2) shift the quarters on which we base payment determinations; (3) change the data submission timeframe for measures submitted via the CMS Web-based tool (QualityNet Web site) from July 1 through November 1 to January 1 through May 15; (4) rename our extension and exception policy to extension and exemption policy; (5) change the deadline for submitting a reconsideration request from the first business day of the month of February of the affected payment year to the first business day on or after March 17 of the affected payment year. Although we are proposing to change deadlines, these date changes do not change the amount of time required to enter data. Therefore, the hourly burden and resultant financial impact would remain the same.

In addition, we are proposing to make conforming changes to our validation scoring process to reflect proposed changes in the APU determination

timeframes. For the CY 2017 payment determination, we are proposing that validation be based on three quarters of data (quarter 2, quarter 3 and quarter 4 of 2015.) For prior payment determinations, we sampled 500 hospitals for validation and estimated that it would take each hospital 12 hours to comply with the data submission requirements for four quarters. We estimate that data submission for three quarters would reduce the number of hours required by 25 percent (from 12 hours to 9 hours per hospital). Therefore, we estimate a total burden of approximately 4,500 hours (500 hospitals × 9 hours/hospital) and a total financial impact of $135,000 ($30/hour × 4,500 hours) for the CY 2017 payment determination. In summary, for the CY 2017 payment determination, we estimate a total burden of 3.5 million hours across all hospitals for a total of $105 million. This is a reduction of 1,500 hours and $45,000 across all hospitals from last year's estimate.

b. Estimated Burden of Hospital OQR Program Proposals for the CY 2018 Payment Determination and Subsequent Years

For the CY 2018 payment determination and subsequent years, we are making two new proposals. First, in section XIII.B.6.a. of this proposed rule, we are proposing one new measure for the CY 2018 payment determination and subsequent years: OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822). In section XIII.E.5. of this proposed rule, we are proposing that hospitals can either: (1) Report aggregate level data for OP–33 submitted via the CMS Web-based tool (QualityNet Web site); or (2) submit an aggregate data file for this measure through a vendor (via the QualityNet infrastructure).

For hospitals choosing the first data submission method, and consistent with prior years, we believe that submitting a measure through the Web-based tool has two burden components: first, the time required to abstract the data for the measure; and second, the time required to enter these data into the Web-based tool. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 67013), we estimated that it would take hospitals approximately a total of 35 minutes to collect chart-abstracted data for 12 Web-based measures. To calculate the burden associated with a collecting chart-abstracted data for a single Web-based measure, we divided the total number of minutes (35) previously estimated by the number of measures (12). Therefore, we estimate the burden to collect chart-abstracted data for a single Web-based measure to be 2.92 minutes (or 0.049 hours.). Based on our most recent data (Quarter 4 2013—Quarter 3 2014) for Hospital OQR Program measures, we estimate that the average hospital would submit 48 cases per year for OP–33. Therefore, we believe that the average hospital would spend 2.352 hours (0.049 hours/measure/case × 48 cases) chart-abstracting data for this measure.

In addition, consistent with prior years (78 FR 75171 through 75172), we estimate that each participating hospital would spend 10 minutes (0.167 hours) per measure per year to collect and submit the data via the Web-based tool. Therefore, we estimate that, in total, the proposed measure would increase burden by 2.519 hours (2.352 hours + 0.167 hours) per year. Consistent with prior years (79 FR 67013), we believe that approximately 3,300 hospitals participate in the Hospital OQR Program for the CY 2017 payment determination. Therefore, we estimate a total increase in burden across all participating hospitals of approximately 8,313 hours (2.519 hours/hospital × 3,300 hospitals) (rounded) per year. Finally, consistent with prior years (79 FR 67013), we estimate that a hospital pays an individual approximately $30 per hour to abstract and submit these data.

For hospitals choosing the second data submission method, we do not have any baseline data on which to estimate how many hospitals might elect to submit data through a vendor. However, we generally estimate that burden will be less than the first data submission method. In future years, we will adjust the burden estimate to account for hospitals that elect to submit data through a vendor.

The second proposal we are proposing for the CY 2018 payment determination and subsequent years, is that validation again be based on four quarters of data; however those quarters are validation quarter 1, validation quarter 2, validation quarter 3 and validation quarter 4. For payment determinations prior to CY 2017, we sampled 500 hospitals for validation and estimated that it would take each hospital 12 hours to comply with the data submission requirements for four quarters. Therefore, we estimate a total burden of approximately 6,000 hours (500 hospitals × 12 hours/hospital) and a total financial impact of $180,000 ($30/hour × 6,000 hours) in burden associated with validation for the CY 2018 payment determination and subsequent years. This is an increase of 1,500 hours and $45,000 across all hospitals from the CY 2017 estimate.

Therefore, we estimate a total financial increase in burden would be $89.21 per hospital (2.97 hours × $30/hour) or $294,000 (9,813 hours × $30/hour) (rounded) across all participating hospitals as a result of our proposals for the CY 2018 payment determination and subsequent years.

c. Estimated Burden of Hospital OQR Program Proposals for the CY 2019 Payment Determination and Subsequent Years

For the CY 2019 payment determination and subsequent years, we are making one new proposal. In section XIII.B.6.b. of this proposed rule, we are proposing one new measure for the CY 2019 payment determination and subsequent years: OP–34: Emergency Department Transfer Communication (EDTC) (NQF #0291). In section XIII.E.6. of this proposed rule, we are proposing that hospitals can either: (1) Report aggregate level data for OP–34 submitted via the CMS Web-based tool (QualityNet Web site); or (2) submit an aggregate data file for this measure through a vendor (via QualityNet infrastructure). For hospitals choosing the first data submission method, and consistent with prior years, we believe that submitting a measure through the Web-based tool has two burden components: first, the time required to abstract the data for the measure; and second, the time required to enter this data into the Web-based tool. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 67013), we estimated that it would take hospitals approximately a total of 35 minutes to collect chart-abstracted data for 12 Web-based measures.

To calculate the burden associated with a collecting chart-abstracted data for a single Web-based measure, we divided the total number of number of minutes (35) previously estimated by the number of measures (12). Therefore, we estimate the burden to collect chart-abstracted data for a single Web-based measure to be 2.92 minutes (or 0.049 hours). Based on our most recent data (Quarter 4 2013–Quarter 3 2014) for Hospital OQR Program, ED-Throughput measures OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF# 0496) (75 FR 72086) and OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional (75 FR 72087 through 72088), we estimate that the average hospital would submit 495 cases per year for OP–34. Therefore, we believe that the average hospital would spend 24.255 hours (0.049 hours/case × 495 cases) chart-abstracting data for this measure.

In addition, consistent with prior years (78 FR 75171), we estimate that each participating hospital would spend 10 minutes (0.167 hours) per measure per year to collect and submit the data via the Web-based tool. Therefore, we estimate that, in total, the proposed measure would increase burden by 24.422 hours (24.255 hours + 0.167 hours) per hospital per year. Consistent with prior years (79 FR 67013), we believe that approximately 3,300 hospitals participate in the Hospital OQR Program for the CY 2017 payment determination. Therefore, we estimate a total increase in burden across all participating hospitals of 80,592.6 hours (24.422 hours/hospital × 3,300 hospitals) per year. Finally, consistent with prior years (79 FR 67013), we estimate that a hospital pays an individual approximately $30 per hour to abstract and submit this data.

For hospitals choosing the second data submission method, we do not have any baseline data on which to estimate how many hospitals might elect to submit data through a vendor. However, we generally estimate that burden will be less than the first data submission method. In future years, we will adjust the burden estimate to account for hospitals that elect to submit data through a vendor.

Therefore, we estimate a total financial increase in burden would be $732.66 per hospital (24.422 hours × $30/hour) or $2.4 million (80,592.6 hours × $30/hour) (rounded) across all participating hospitals as a result of our proposals for the CY 2019 payment determination and subsequent years.

We are inviting public comment on the burden associated with these proposed information collection requirements.

2. ASCQR Program Requirements

a. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532 through 68533), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75172 through 75174), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 67015 through 67016) for detailed discussions of the ASCQR Program information collection requirements we have previously finalized.

b. Policy Proposals Effective Beginning With the CY 2017 Payment Determination

We are proposing to codify a number of existing policies related to program participation and withdrawal, data collection and submission, public reporting, retention and removal of quality measures, measures maintenance, extraordinary circumstances extensions or waivers, and the reconsideration process. We are codifying only existing policies with the exception of the policy proposals discussed below. For existing policies with proposed codification, we do not anticipate any additional burden to ASCs affecting the CY 2017 payment determination or subsequent years because there are no changes to these policies.

In terms of our proposals for the ASCQR Program in this proposed rule, we are proposing to implement a submission deadline with an end date of May 15 for all data submitted via a Web-based tool beginning with the CY 2017 payment determination. We do not anticipate additional burden as the data collection and submission requirements have not changed, only the deadline has moved to a slightly earlier date that we anticipate would alleviate burden by aligning data submission deadlines. We also are proposing, beginning with the CY 2017 payment determination, to not consider IHS hospital outpatient departments that bill as ASCs to be ASCs for purposes of the ASCQR Program. This proposal would eliminate the burden associated with participation in the ASCQR Program for six IHS hospital outpatient departments that currently are required to participate in the ASCQR Program or be subject to a possible reduction in payment.

We are further proposing a minor change to the reconsideration request deadline to ensure our deadline for these requests will always fall on a business day effective beginning with the CY 2017 payment determination. We do not anticipate that there would be any additional burden as the materials to be submitted are unchanged and the deadline does not result in reduced time to submit a reconsideration request. In addition, we are proposing to display data by the NPI if data are submitted by the NPI or by the CCN if data are submitted by the CCN for any public reporting that occurs on or after January 1, 2016. Again, we do not anticipate any additional burden because it does not alter the administrative or reporting requirements governing ASC's participation in the ASCQR Program.

Finally, we are proposing, for claims-based measures not using QDCs, to use claims for services furnished in each calendar year that have been paid by the MAC by April 30 of the following year of the ending data collection time period in the measure calculation for the payment determination year beginning with the CY 2018 payment determination. We do not anticipate any additional burden to ASCs based on this proposal affecting the CY 2017 payment determination or subsequent years because it does not alter the administrative or reporting requirements governing ASC's participation in the ASCQR Program.

c. Claims-Based Measures for the CY 2018 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75172 through 75174), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 67015 through 67016) for detailed discussions of the information collection requirements for the six previously adopted claims-based ASCQR Program measures (five outcome measures and one process measure). The six previously adopted measures are: ASC–1: Patient Burn (NQF #0263); ASC–2: Patient Fall (NQF #0266); ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267); ASC–4: Hospital Transfer/Admission (NQF #0265); ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing; and ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. The first five of these measures require the reporting of Quality Data Codes (QDCs), but the sixth measure, ASC–12, while utilizing data from paid Medicare FFS claims, it does not require ASCs to submit QDCs. For the reasons we discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75172 through 75173) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 67016), we estimate that the reporting burden to report QDCs for the five claims-based outcome measures that utilize QDCs would be nominal. We do not anticipate that ASC–12 would create any additional burden to ASCs for the CY 2018 payment determination and for subsequent years because no additional data are required from ASCs; only information necessary for Medicare payment is utilized for calculating this measure.

d. Web-Based Measures for the CY 2018 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532) and the CY 2014 OPPS/ASC final rule with comment

period (78 FR 75172 through 75174) for detailed discussions of the information collection requirements for the five previously-adopted Web-based measures, excluding ASC–11, which we proposed for voluntary inclusion in the ASCQR Program for the CY 2017 payment determination and subsequent years. The five previously adopted measures are: ASC–6: Safe Surgery Checklist Use; ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures; ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); and ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (NQF #0659).

For the reasons we discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75173 through 75174), we estimate that the reporting burden for the ASC–6: Safe Surgery Checklist Use and the ASC–7: ASC Facility Volume measures would be 1,757 hours (5,260 ASCsx × x2 measures × 0.167 hours per ASC) and $52,710 (1,757 hours × $30.00 per hour) annually for the CY 2018 payment determination and for subsequent years.

For the reasons discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75173 through 75174), we estimate that the reporting burden for the ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure would be 18,005 hours (5,260 ASCs × 0.083 hours per facility = 437 hours for NHSN registration, and 5,260 ASCs × 0.167 hours per response for 20 workers per facility = 17,568 hours for data submission) and $540,150 (18,005 hours × $30.00 per hour) annually for the CY 2018 payment determination and for subsequent years.

For the reasons discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75173 through 75174), we estimate that the reporting burden for ASCs with a single case per ASC for the chart-abstracted ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) and ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (NQF #0659) measures would be 3,067 hours (5,260 ASCs × 0.583 hours per case per ASC) and $92,010 (3,067 hours × $30.00 per hour) annually for the CY 2018 payment determination and for subsequent years.

In the CY 2015 OPPS/ASC final rule with comment period, we finalized our proposal that data collection and submission be voluntary for the CY 2017 payment determination and subsequent years for ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536); that is, we will not subject ASCs to a payment reduction with respect to this measure during the period of voluntary reporting (79 FR 66984 through 66985). For the reasons discussed in the CY 2015 OPPS/ASC final rule with comment period (79 FR 67016), we estimate the total burden for this measure for ASCs with a single case per ASC to be 613 hours (1,052 ASCs × 0.583 hours per case per ASC) and $18,390 (613 hours × $30.00 per hour) annually for the CY 2018 payment determination and subsequent years.

e. Extraordinary Circumstances Extension or Exemptions Process

For a complete discussion of our ''Extraordinary Circumstances Extension or Waiver'' process under the ASCQR Program, which we retitled as the ''Extraordinary Circumstances Extensions or Exemptions'' process in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66987), we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53642 through 53643) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75140). We are not proposing to make any changes to this process.

e. Reconsideration

In this proposed rule, we are proposing a minor change to the reconsideration request deadline to ensure our deadline for these requests would always fall on a business day. We do not anticipate that there would be any additional burden as the materials to be submitted are unchanged and the deadline does not result in reduced time to submit a reconsideration request. We also are proposing to codify our reconsideration request process at 42 CFR 416.330.

While there is burden associated with filing a reconsideration request, section 3518(c)(1)(B) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3518(c)(1)(B)) excludes collection activities during the conduct of administrative actions such as reconsiderations.

We are inviting public comment on the burden associated with these information collection requirements.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–1633–P; Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*.

XIX. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XX. Economic Analyses

A. Regulatory Impact Analysis

1. 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 (January 18, 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 (UMRA) (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Contract with America Advancement Act of 1996 (Pub. L. 104–121) (5 U.S.C. 804(2)). This section of the proposed rule contains the impact and other economic analyses for the provisions that we are proposing for CY 2016.

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. This proposed rule has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866

and a major rule under the Contract with America Advancement Act of 1996 (Pub. L. 104–121). Accordingly, this proposed rule has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this proposed rule. We are soliciting comments on the regulatory impact analysis in this proposed rule, and we will address the public comments we receive in the final rule with comment period as appropriate.

2. Statement of Need

This proposed rule is necessary to propose updates to the Medicare hospital OPPS rates. It is necessary to make proposed changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2016. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are proposing to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2014, through and including December 31, 2014 and processed through December 31, 2014, and updated cost report information.

This proposed rule also is necessary to propose updates to the ASC payment rates for CY 2016, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC in CY 2016. Because ASC payment rates are based on the OPPS relative payment weights for the majority of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC not less frequently than every 2 years.

3. Overall Impacts for the Proposed OPPS and ASC Payment Provisions

We estimate that the total decrease in Federal government expenditures under the OPPS for CY 2016 compared to CY 2015 due to the proposed changes in this proposed rule, would be approximately $43 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate that the proposed OPPS expenditures for CY 2016 would be approximately $3.2 billion higher relative to expenditures in CY 2015. We note that this estimate of $3.2 billion does not include the proposed 2.0 percent reduction to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests that are excepted from our final CY 2014 laboratory packaging policy, as discussed in section II.B. of this proposed rule. Because this proposed rule is economically significant as measured by the threshold of an additional $100 million in expenditures in 1 year, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 65 displays the distributional impact of the proposed CY 2016 changes in OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the proposed update to the conversion factor and other proposed adjustments (not including the effects of proposed outlier payments, the proposed pass-through estimates, and the proposed application of the frontier State wage adjustment for CY 2016) would decrease total OPPS payments by 0.1 percent in CY 2016. The proposed changes to the APC weights, the proposed changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, and the proposed payment adjustment for cancer hospitals would not increase OPPS payments because these proposed changes to the OPPS are budget neutral. However, these proposed updates would change the distribution of payments within the budget neutral system. We estimate that the proposed total change in payments between CY 2015 and CY 2016, considering all payments, including the proposed adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests, proposed changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment outside of budget neutrality, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, would decrease total estimated OPPS payments by 0.2 percent.

We estimate the proposed total increase (from proposed changes to the ASC provisions in this proposed rule as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures under the ASC payment system for CY 2016 compared to CY 2015 to be approximately $169 million. Because the proposed provisions for the ASC payment system are part of a proposed rule that is economically significant as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the proposed changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of the proposed rule. Table 66 and Table 67 of this proposed rule display the redistributive impact of the proposed CY 2016 changes on ASC payment, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Detailed Economic Analyses

a. Estimated Effects of Proposed OPPS Changes in This Proposed Rule

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2016 policy changes on various hospital groups. We post on the CMS Web site our proposed hospital-specific estimated payments for CY 2016 with the other supporting documentation for this proposed rule. To view the proposed hospital-specific estimates, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At the Web site, select ''regulations and notices'' from the left side of the page and then select ''CMS–1633–P'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 65 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the proposed individual policy changes by estimating payments per service, while holding all other proposed payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we have not made

adjustments for future changes in variables such as service volume, service-mix, or number of encounters. We are soliciting public comment and information about the anticipated effects of our proposed changes on providers and our methodology for estimating them. Any public comments that we receive will be addressed in the applicable sections of the final rule with comment period that discuss the specific policies.

(2) Estimated Effects of Proposed OPPS Changes on Hospitals

Table 65 below shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the proposed change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 65, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2016, we are proposing to continue to pay CMHCs under proposed renumbered APC 5851 (existing APC 0172) (Level 1 Partial Hospitalization (3 services) for CMHCs) and proposed renumbered APC 5852 (existing APC 0173) (Level 2 Partial Hospitalization (4 or more services) for CMHCs), and we are proposing to pay hospitals for partial hospitalization services under proposed renumbered APC 5861 (existing APC 0175) (Level 1 Partial Hospitalization (3 services) for hospital-based PHPs) and APC 5862 (existing APC 0176) (Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs).

The estimated decrease in the proposed total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology and the proposed adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor as discussed in detail in section II.B. of this proposed rule. Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The proposed IPPS market basket percentage increase for FY 2016 is 2.7 percent (80 FR 24477). Section 1833(t)(3)(F)(i) of the Act reduces that 2.7 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is proposed to be 0.6 percentage point for FY 2016 (which is also the proposed MFP adjustment for FY 2016 in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24478)); and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(iv) of the Act further reduce the market basket percentage increase by 0.2 percentage point, resulting in the proposed OPD fee schedule increase factor of 1.9 percent. We are using the proposed OPD fee schedule increase factor of 1.9 percent in the calculation of the CY 2016 OPPS conversion factor. We are also applying a proposed reduction of 2.0 percent to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.00. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2016 estimates in Table 65.

To illustrate the impact of the proposed CY 2016 changes, our analysis begins with a baseline simulation model that uses the CY 2015 relative payment weights, the FY 2015 final IPPS wage indexes that include reclassifications, and the final CY 2015 conversion factor. Table 65 shows the estimated redistribution of the proposed increase or decrease in payments for CY 2016 over CY 2015 payments to hospitals and CMHCs as a result of the following factors: The impact of the proposed APC reconfiguration and recalibration changes between CY 2015 and CY 2016 (Column 2); the proposed wage indexes and the proposed provider adjustments (Column 3); the combined impact of all of the proposed changes described in the preceding columns plus the proposed 1.9 percent OPD fee schedule increase factor update to the conversion factor and the proposed −2.0 percent adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests (Column 4); and the estimated impact taking into account all proposed payments for CY 2016 relative to all payments for CY 2015, including the impact of proposed changes in estimated outlier payments, the frontier State wage adjustment, and proposed changes to the pass-through payment estimate (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are proposing to maintain the current adjustment percentage for CY 2016. Because the proposed updates to the conversion factor (including the proposed update of the OPD fee schedule increase factor), the estimated cost of the proposed rural adjustment, and the estimated cost of proposed projected pass-through payment for CY 2016 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the proposed wage index changes on the hospital. However, proposed total payments made under this system and the extent to which this proposed rule would redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2015 and CY 2016 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed rates for CY 2016 would decrease Medicare OPPS payments by an estimated 0.2 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in a proposed estimated 0.2 percent decrease in Medicare payments to all other hospitals. These proposed estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 65 shows the total number of facilities (3,912), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2014 hospital outpatient and CMHC claims data to model CY 2015 and proposed CY 2016 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2015 or proposed CY 2016 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive

hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this proposed rule. At this time, we are unable to calculate a disproportionate share hospital (DSH) variable for hospitals that are not also paid under the IPPS, since DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,791), excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their ''pre-BBA amount'' as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 58 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration—All Proposed Changes

Column 2 shows the estimated effect of proposed APC recalibration. Column 2 also reflects any proposed changes in multiple procedure discount patterns or conditional packaging that occur as a result of the proposed changes in the relative magnitude of payment weights. As a result of proposed APC recalibration, we estimate that urban hospitals would experience no change, with the impact ranging from an increase of 0.1 percent to a decrease of 0.2 percent, depending on the number of beds. Rural hospitals would experience a 0.2 percent increase, with the impact ranging from an increase of 0.7 percent to a decrease of 0.1 percent, depending on the number of beds. Major teaching hospitals would experience a decrease of 0.1 percent overall.

Column 3: Proposed Wage Indexes and the Effect of the Proposed Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the proposed APC recalibration; the proposed updates for the wage indexes with the proposed fiscal year (FY) 2016 IPPS post-reclassification wage indexes; and the proposed rural adjustment. We modeled the independent effect of the proposed budget neutrality adjustments and the proposed OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2015 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the proposed updated wage indexes, including the application of proposed budget neutrality for the proposed rural floor policy on a nationwide basis. This column excludes the effects of the proposed frontier State wage index adjustment, which is not budget neutral and is included in Column 5. We did not model a proposed budget neutrality adjustment for the proposed rural adjustment for SCHs because we are proposing to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2016, as described in section II.E. of this proposed rule.

We modeled the independent effect of proposing to update the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the proposed CY 2016 scaled weights and a CY 2015 conversion factor that included a budget neutrality adjustment for the effect of the proposed changes to the wage indexes between CY 2015 and CY 2016. The proposed FY 2016 wage policy results in modest redistributions.

There is no difference in impact between the CY 2015 cancer hospital payment adjustment and the proposed CY 2016 cancer hospital payment adjustment because we are proposing to use the same payment-to-cost ratio target in CY 2016 as in the CY 2015 OPPS/ASC final rule with comment period correction notice (80 FR 9629 through 9636).

Column 4: All Proposed Budget Neutrality Changes Combined With the Proposed Market Basket Update and the Proposed Adjustment To Address Excess Packaged Payment for Laboratory Tests

Column 4 demonstrates the combined impact of all of the proposed changes previously described, the proposed update to the conversion factor of 1.9 percent, and the proposed 2.0 percent reduction due to the proposed adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests. Overall, these proposed changes would decrease payments to urban hospitals by 0.1 percent and to rural hospitals by 0.3 percent. Most classes of hospitals would receive a decrease in line with the proposed 0.1 percent overall decrease after the proposed update and the proposed adjustment to the conversion factor to address excess packaged payment for laboratory tests are applied to the proposed budget neutrality adjustments.

Column 5: All Proposed Changes for CY 2016

Column 5 depicts the full impact of the proposed CY 2016 policies on each hospital group by including the effect of all of the proposed changes for CY 2016 and comparing them to all estimated payments in CY 2015. Column 5 shows the combined budget neutral effects of Column 2 and 3; the proposed OPD fee schedule increase; the impact of the proposed frontier State wage index adjustment; the impact of estimated proposed OPPS outlier payments as discussed in section II.G. of this proposed rule; the proposed change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIII. of this proposed rule); and the difference in proposed total OPPS payments dedicated to transitional pass-through payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2015 update (and assumed, for modeling purposes, to be the same number for CY 2016), we included 60 hospitals in our model because they had both CY 2014 claims data and recent cost report data. We estimate that the cumulative effect of all of the proposed changes for CY 2016 would decrease payments to all facilities by 0.2 percent for CY 2016. We modeled the independent effect of all of the proposed changes in Column 5 using the final relative payment weights for CY 2015 and the proposed relative payment weights for CY 2016. We used the final conversion factor for CY 2015 of $74.173 and the proposed CY 2016 conversion factor of $73.929 discussed in section II.B. of this proposed rule.

Column 5 contains simulated outlier payments for each year. We used the proposed 1-year charge inflation factor used in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24632) of 4.8 percent (1.048116) to increase individual costs on the CY 2014 claims, and we used the most recent overall CCR in the April 2015 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2015. Using the CY 2014 claims and a proposed 4.8 percent charge inflation factor, we currently estimate that outlier payments for CY 2015, using a multiple

threshold of 1.75 and a fixed-dollar threshold of $2,775 would be approximately 0.95 percent of total payments. The estimated current outlier payments of 0.95 percent are incorporated in the comparison in Column 5. We used the same set of claims and a proposed charge inflation factor of 9.8 percent (1.098547) and the CCRs in the April 2015 OPSF, with an adjustment of 0.9795, to reflect relative changes in cost and charge inflation between CY 2014 and CY 2016, to model the proposed CY 2016 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a proposed fixed-dollar threshold of $3,650. The charge inflation and CCR inflation factors are discussed in detail in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24632 through 24633).

We estimate that the anticipated change in payment between CY 2015 and CY 2016 for the hospitals failing to meet the Hospital OQR Program requirements would be negligible. Overall, we estimate that facilities would experience a decrease of 0.2 percent under this proposed rule in CY 2016 relative to total spending in CY 2015. This projected decrease (shown in Column 5) of Table 65 reflects the proposed 1.9 percent OPD fee schedule increase factor, less 2.0 percent for the proposed adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests, less 0.12 percent for the proposed change in the pass-through estimate between CY 2015 and CY 2016, plus 0.05 percent for the difference in estimated outlier payments between CY 2015 (0.95 percent) and CY 2016 (proposed 1.0 percent). We estimate that the combined effect of all of the proposed changes for CY 2016 would decrease payments to urban hospitals by 0.2 percent. Overall, we estimate that rural hospitals would experience a 0.3 percent decrease as a result of the combined effects of all of the proposed changes for CY 2016.

Among hospitals by teaching status, we estimate that the impacts resulting from the combined effects of all proposed changes would include a decrease of 0.3 percent for major teaching hospitals and a decrease of 0.2 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated decrease of 0.1 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience a decrease of 0.2 percent, proprietary hospitals would experience a decrease of 0.2 percent, and governmental hospitals would experience a decrease of 0.4 percent.

TABLE 65—ESTIMATED IMPACT OF THE PROPOSED CY 2016 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals	APC Recalibration (all proposed changes)	New wage index and provider adjustments	All proposed budget neutral changes (combined cols 2,3) with proposed market basket update and proposed adjustment to address excess packaged payment for laboratory tests	All proposed changes
	(1)	(2)	(3)	(4)	(5)
ALL FACILITIES*	3,912	0.0	0.0	−0.1	−0.2
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs):	3,791	0.0	0.0	−0.1	−0.2
URBAN HOSPITALS	2,942	0.0	0.1	−0.1	−0.2
LARGE URBAN (GT 1 MILL.)	1,613	0.0	0.1	0.0	−0.1
OTHER URBAN (LE 1 MILL.)	1,329	−0.1	0.0	−0.1	−0.2
RURAL HOSPITALS:	849	0.2	−0.4	−0.3	−0.3
SOLE COMMUNITY	379	0.1	−0.3	−0.3	−0.3
OTHER RURAL	470	0.3	−0.5	−0.3	−0.3
BEDS (URBAN):					
0–99 BEDS	1,015	0.0	−0.2	−0.4	−0.5
100–199 BEDS	844	0.1	0.1	0.0	−0.1
200–299 BEDS	463	0.1	0.1	0.1	0.0
300–499 BEDS	406	0.0	0.1	0.0	−0.1
500+ BEDS	214	−0.2	0.0	−0.3	−0.4
BEDS (RURAL):					
0–49 BEDS	337	0.7	−0.3	0.3	0.2
50–100 BEDS	311	0.3	−0.2	−0.1	−0.1
101–149 BEDS	114	0.1	−0.5	−0.5	−0.5
150–199 BEDS	46	0.3	−0.2	−0.1	−0.3
200+ BEDS	41	−0.1	−0.7	−1.0	−1.1
REGION (URBAN):					
NEW ENGLAND	150	0.7	−0.5	0.0	0.0
MIDDLE ATLANTIC	352	−0.1	0.2	0.0	−0.1
SOUTH ATLANTIC	469	−0.1	0.2	−0.1	−0.3
EAST NORTH CENT.	475	−0.1	0.0	−0.2	−0.3
EAST SOUTH CENT.	181	−0.3	−0.3	−0.8	−0.9
WEST NORTH CENT.	183	0.0	−0.3	−0.4	−0.5

TABLE 65—ESTIMATED IMPACT OF THE PROPOSED CY 2016 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals	APC Recalibration (all proposed changes)	New wage index and provider adjustments	All proposed budget neutral changes (combined cols 2,3) with proposed market basket update and proposed adjustment to address excess packaged payment for laboratory tests	All proposed changes
	(1)	(2)	(3)	(4)	(5)
WEST SOUTH CENT.	509	0.2	−0.2	−0.1	−0.2
MOUNTAIN	193	0.0	0.3	0.2	−0.1
PACIFIC	381	−0.1	0.7	0.5	0.4
PUERTO RICO	49	−1.6	−1.7	−3.3	−3.4
REGION (RURAL):					
NEW ENGLAND	22	0.5	−0.6	−0.2	−0.2
MIDDLE ATLANTIC	58	0.4	−0.9	−0.6	−0.3
SOUTH ATLANTIC	126	−0.1	0.2	0.0	−0.1
EAST NORTH CENT.	120	0.1	−0.1	−0.1	−0.2
EAST SOUTH CENT.	162	0.3	−0.7	−0.5	−0.6
WEST NORTH CENT.	102	0.2	−0.5	−0.4	−0.3
WEST SOUTH CENT.	174	0.8	−1.1	−0.5	−0.6
MOUNTAIN	61	0.0	0.1	−0.1	−0.4
PACIFIC	24	0.0	0.3	0.1	0.1
TEACHING STATUS:					
NON-TEACHING	2758	0.0	0.0	−0.1	−0.2
MINOR	709	0.1	0.0	0.0	−0.1
MAJOR	324	−0.1	0.1	−0.2	−0.3
DSH PATIENT PERCENT:					
0	24	−1.2	−0.4	−1.7	−1.4
GT 0–0.10	324	−0.3	0.0	−0.4	−0.5
0.10–0.16	331	0.1	0.0	0.0	0.0
0.16–0.23	650	0.0	0.0	−0.2	−0.2
0.23–0.35	1086	0.0	−0.1	−0.2	−0.3
GE 0.35	817	0.0	0.1	0.0	−0.1
DSH NOT AVAILABLE **	559	3.1	−0.1	2.8	2.4
URBAN TEACHING/DSH:					
TEACHING & DSH	941	0.0	0.1	−0.1	−0.2
NO TEACHING/DSH	1456	0.0	0.0	−0.1	−0.2
NO TEACHING/NO DSH	23	−1.2	−0.3	−1.6	−1.5
DSH NOT AVAILABLE **	522	3.2	0.1	3.0	2.6
TYPE OF OWNERSHIP:					
VOLUNTARY	2000	0.0	0.1	−0.1	−0.2
PROPRIETARY	1271	0.4	−0.2	0.0	−0.2
GOVERNMENT	520	−0.1	0.0	−0.2	−0.4
CMHCs	58	22.2	−0.4	21.1	14.8

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed CY 2016 OPPS policies and compares those to the CY 2015 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2016 hospital inpatient wage index, including all hold harmless policies and transitional wages. The final rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.000 because the payment-to-cost ratio target remains the same as in the CY 2015 OPPS/ASC final rule with comment period correction notice (80 FR 9629 through 9636).

Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 1.9 percent OPD fee schedule update factor (2.7 percent reduced by 0.6 percentage points for the proposed productivity adjustment and further reduced by 0.2 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act). Column 4 also includes the proposed −2.0 percent adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests.

Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, adding estimated outlier payments, and applying the frontier State wage adjustment.

* These 3,912 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

(3) Estimated Effects of Proposed OPPS Changes on CMHCs

The last line of Table 65 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2015, CMHCs are paid under two APCs for these services: Existing APC 0172 (Level 1 Partial Hospitalization (3 services) for CMHCs) (proposed renumbered APC 5851 for CY 2016) and existing APC 0173 (Level 2 Partial Hospitalization (4

or more services) for CMHCs) (proposed renumbered APC 5852 for CY 2016). Hospitals are paid for partial hospitalization services under existing APC 0175 (Level 1 Partial Hospitalization (3 services) for hospital-based PHPs) (proposed renumbered APC 5861 for CY 2016) and existing APC 0176 (Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs) (proposed renumbered APC 5862 for CY 2016). We use our standard ratesetting methodology to derive the proposed payment rates for each APC based on the cost data derived from claims and cost data for the provider-type-specific APC. For CY 2016, we are proposing to continue the provider-type-specific APC structure that we adopted in CY 2011. We modeled the impact of this APC policy assuming that CMHCs would continue to provide the same number of days of PHP care, with each day having either 3 services or 4 or more services, as seen in the CY 2014 claims data used for this proposed rule. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. We estimate that CMHCs would experience an overall 14.8 percent increase in payments from CY 2015 (shown in Column 5). We note that this would include the proposed trimming methodology described in section VIII.B. of this proposed rule.

Column 3 shows that the estimated impact of adopting the proposed FY 2016 wage index values would result in a small decrease of 0.4 percent to CMHCs. Column 4 shows that combining this proposed OPD fee schedule increase factor, proposed adjustment to the conversion to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests, along with proposed changes in APC policy for CY 2016 and the proposed FY 2016 wage index updates, would result in an estimated increase of 21.1 percent. Column 5 shows that adding the proposed changes in outlier and pass-though payments would result in a total 14.8 percent increase in payment for CMHCs. This reflects all proposed changes to CMHCs for CY 2016.

(4) Estimated Effect of Proposed OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary share of payment would increase for services for which the OPPS payments would rise and would decrease for services for which the OPPS payments would fall. For further discussion on the calculation of the proposed national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this proposed rule. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be 19.3 percent for all services paid under the OPPS in CY 2016. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the proposed recalibration of the APC relative payment weights, proposed APC reorganization, proposed change in the portion of OPPS payments dedicated to pass-through payments, and the proposed CY 2016 comprehensive APC payment policy discussed in section II.A.2.e. of this proposed rule.

(5) Estimated Effects of Proposed OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs as discussed in section XII. of this proposed rule. No types of providers or suppliers other than hospitals, CMHCs, and ASCs would be affected by the proposed changes in this proposed rule.

(6) Estimated Effects of Proposed OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be a decrease of $43 million in program payments for OPPS services furnished in CY 2016. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We refer readers to our discussion of the impact on beneficiaries in section XX.A. of this proposed rule.

(7) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are proposing and the reasons for our selected alternatives are discussed throughout this proposed rule. In this section, we discuss some of the significant issues and the alternatives considered.

- Alternatives Considered for the Methodology for Assigning Skin Substitutes to High or Low Cost Groups

We refer readers to section V.B.2.c. of this proposed rule for a discussion of our proposal to determine the high/low cost status for each skin substitute product based on either a product's mean unit cost (MUC) exceeding the MUC threshold or the product's per day cost (PDC) exceeding the PDC threshold. As discussed in that section, we also considered, but did not propose, to determine high/low cost status for each skin substitute using just MUC or just PDC instead of both.

- Alternatives Considered for Application of the Device Offset for Discontinued Procedures for Device Intensive Procedures

We refer readers to section IV.B.4. of this proposed rule for a discussion of our proposal to deduct the device offset amount for procedures in device-intensive APCs that are discontinued. As discussed in that section, we considered, but did not propose, to apply the device offset to procedures for which anesthesia has already been administered (that is, those identified by Modifier 74).

b. Estimated Effects of Proposed CY 2016 ASC Payment System Policies

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XII. of this proposed rule, we are proposing to set the CY 2016 ASC relative payment weights by scaling the proposed CY 2016 OPPS relative payment weights by the ASC scalar of 0.9180. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 66 and 67 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which currently is the CPI–U) after application of any quality reporting reduction be reduced by a productivity adjustment. The Affordable Care Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, the CY 2016 payment determinations will be based on the application of a 2.0 percentage points reduction to the annual update factor, which currently is the CPI–U. We calculated the proposed CY 2016 ASC conversion factor by adjusting the CY 2015 ASC conversion factor by 1.0014 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2015 and CY 2016 and by applying the

proposed CY 2016 MFP-adjusted CPI–U update factor of 1.1 percent (projected CPI–U update of 1.7 percent minus a proposed projected productivity adjustment of 0.6 percentage point). The proposed CY 2016 ASC conversion factor is $44.605.

(1) Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2016 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2014 and CY 2016 with precision. We believe that the net effect on Medicare expenditures resulting from the proposed CY 2016 changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

(2) Estimated Effects of Proposed ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform the gamut of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the proposed update to the CY 2016 payments would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the proposed CY 2016 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2014 claims data. Table 66 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2015 payments to estimated proposed CY 2016 payments, and Table 67 shows a comparison of estimated CY 2015 payments to estimated proposed CY 2016 payments for procedures that we estimate would receive the most Medicare payment in CY 2015.

Table 66 shows the estimated effects on aggregate Medicare payments under the ASC payment system by surgical specialty or ancillary items and services group. We have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 66.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—Estimated CY 2015 ASC Payments were calculated using CY 2014 ASC utilization (the most recent full year of ASC utilization) and CY 2015 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2015 ASC payments.
- Column 3—Estimated Proposed CY 2016 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that are attributable to proposed updates to ASC payment rates for CY 2016 compared to CY 2015.

As seen in Table 66, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC rates for CY 2016 would result in a 1-percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 3-percent increase in aggregate payment amounts for digestive system procedures, a 1-percent increase in aggregate payment amounts for nervous system procedures, a 2-percent decrease in aggregate payment amounts for musculoskeletal system procedures, a 2-percent increase in aggregate payment amounts for genitourinary system procedures, and no change in aggregate payment amounts for integumentary system procedures.

Also displayed in Table 66 is a separate estimate of Medicare ASC payments for the group of separately payable covered ancillary items and services. The payment estimates for the covered surgical procedures include the costs of packaged ancillary items and services. We estimate that aggregate payments for these items and services would remain at $21 million for CY 2016.

TABLE 66—ESTIMATED IMPACT OF THE PROPOSED CY 2016 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PROPOSED CY 2016 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical specialty group (1)	Estimated CY 2015 ASC payments (in millions) (2)	Estimated proposed CY 2016 percent change (3)
Total	$3,899	1
Eye and ocular adnexa	1,537	1
Digestive system	809	3
Nervous system	618	1
Musculoskeletal system	486	−2
Genitourinary system	176	2
Integumentary system	135	0
Respiratory system	55	4

TABLE 66—ESTIMATED IMPACT OF THE PROPOSED CY 2016 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PROPOSED CY 2016 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP—Continued

Surgical specialty group (1)	Estimated CY 2015 ASC payments (in millions) (2)	Estimated proposed CY 2016 percent change (3)
Cardiovascular system	42	1
Ancillary items and services	21	0
Auditory system	14	5
Hematologic & lymphatic systems	6	−5

Table 67 below shows the estimated impact of the proposed updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2016. The table displays 30 of the procedures receiving the greatest estimated CY 2015 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2015 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2015 ASC Payments were calculated using CY 2014 ASC utilization (the most recent full year of ASC utilization) and the CY 2015 ASC payment rates. The estimated CY 2015 payments are expressed in millions of dollars.
- Column 4—Estimated Proposed CY 2016 Percent Change reflects the percent differences between the estimated ASC payment for CY 2015 and the estimated proposed payment for CY 2016 based on the proposed update.

TABLE 67—ESTIMATED IMPACT OF THE PROPOSED CY 2016 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS code (1)	Short descriptor (2)	Estimated CY 2015 ASC payment (in millions) (3)	Estimated CY 2016 percent change (4)
66984	Cataract surg w/iol 1 stage	$1,094	1
43239	Egd biopsy single/multiple	177	2
45380	Colonoscopy and biopsy	181	−2
45385	Colonoscopy w/lesion removal	117	−2
66982	Cataract surgery complex	95	1
64483	Inj foramen epidural l/s	94	−10
62311	Inject spine lumbar/sacral	75	−10
45378	Diagnostic colonoscopy	69	−3
66821	After cataract laser surgery	65	3
64493	Inj paravert f jnt l/s 1 lev	53	32
G0105	Colorectal scrn; hi risk ind	46	18
64635	Destroy lumb/sac facet jnt	50	−2
63650	Implant neuroelectrodes	52	5
G0121	Colon ca scrn not hi rsk ind	43	18
64590	Insrt/redo pn/gastr stimul	44	−6
15823	Revision of upper eyelid	33	1
63685	Insrt/redo spine n generator	54	2
29827	Arthroscop rotator cuff repr	50	11
64721	Carpal tunnel surgery	30	4
29881	Knee arthroscopy/surgery	28	15
29824	Shoulder arthroscopy/surgery	21	−43
29880	Knee arthroscopy/surgery	24	15
43235	Egd diagnostic brush wash	24	2
62310	Inject spine cerv/thoracic	23	−10
29823	Shoulder arthroscopy/surgery	13	−43
52000	Cystoscopy	22	−4
G0260	Inj for sacroiliac jt anesth	22	−10
45384	Colonoscopy w/lesion removal	20	−2
67042	Vit for macular hole	22	0
26055	Incise finger tendon sheath	21	23

(3) Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2016 update to the ASC payment system would be generally positive for beneficiaries with respect to the new procedures that we are proposing to add to the ASC list of covered surgical procedures and for those that we are proposing to designate as office-based for CY 2016. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with section 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services). Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions would be if the ASC coinsurance amount exceeds the inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the inpatient deductible.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the revised ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. However, for those additional procedures that we are proposing to designate as office-based in CY 2016, the beneficiary coinsurance amount under the ASC payment system generally would be no greater than the beneficiary coinsurance under the MPFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

(4) Alternative ASC Payment Policies Considered

- Alternatives Considered for Application of the Device Offset for Discontinued Procedures for Device Intensive Procedures

We refer readers to section XII.C.1.d. of this proposed rule for a discussion of our proposal to deduct the device offset amount for device intensive procedures that are discontinued before applying any standard downward payment adjustment. As discussed in that section, we considered, but did not propose, to apply the device offset to procedures for which anesthesia has already been administered (that is, those identified by Modifier 74).

c. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget Web site at: *https://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf,* we have prepared two accounting statements to illustrate the impacts of this proposed rule. The first accounting statement, Table 68 below, illustrates the classification of expenditures for the proposed CY 2016 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2016 OPD fee schedule increase, based on the 2015 Trustee's Report, and the proposed adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests. The second accounting statement, Table 69 below, illustrates the classification of expenditures associated with the proposed 1.1 percent CY 2016 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs in the 2015 Trustee's Report. Lastly, the tables classify most estimated impacts as transfers.

TABLE 68—ACCOUNTING STATEMENT: PROPOSED CY 2016 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2015 TO CY 2016 ASSOCIATED WITH THE PROPOSED CY 2016 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE AND THE PROPOSED ADJUSTMENT TO ADDRESS EXCESS PACKAGED PAYMENT FOR LABORATORY TESTS

Category	Transfers
Annualized Monetized Transfers.	−$43 million
From Whom to Whom.	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS
Total	−$43 million

TABLE 69—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2015 TO CY 2016 AS A RESULT OF THE PROPOSED CY 2016 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers.	$35 million
From Whom to Whom.	Federal Government to Medicare Providers and Suppliers
Total	$35 million

d. Effects of Proposed Requirements for the Hospital OQR Program

We refer readers to CY 2015 OPPS/ASC final rule with comment period (79 FR 67018) for the estimated effects of OPPS changes on hospitals for the CY 2017 payment determination. In section XIII. of this proposed rule, we are proposing changes to policies affecting the Hospital OQR Program. Of the 3,292 hospitals that met eligibility requirements for the CY 2015 payment determination, we determined that 113 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. Most of these hospitals (71 of the 113) chose not to participate in the Hospital OQR Program for the CY 2015 payment determination. We estimate that approximately 115 hospitals would not receive the full OPD fee schedule increase factor for the CY 2018 payment determination and subsequent years.

In section XIII. of this proposed rule, we are proposing to make several changes to the Hospital OQR Program for the CY 2017 payment determination and subsequent years, the CY 2018 payment determination and subsequent years, and the CY 2019 payment determination and subsequent years. For the CY 2017 payment determination and subsequent years, we are proposing to: (1) Remove OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache measure, effective January 1, 2016 (no data for this measure will be used for any payment determination); (2) change the deadline for withdrawing from the program from November 1 to August 31; (3) shift the quarters on which we base payment determinations; (4) change the data submission timeframe for measures submitted via the CMS Web-based tool (QualityNet Web site) from July 1 through November 1 to January 1 through May 15; (5) rename our extension and exception

policy to extension and exemption policy; (6) change the deadline for submitting a reconsideration request from the first business day of the month of February of the affected payment year to the first business day on or after March 17 of the affected payment year; and (7) amend 42 CFR 419.46(f)(1) and 42 CFR 419.46(e)(2) to replace the term ''fiscal year'' with the term ''calendar year.'' While there is burden associated with filing a reconsideration request, section 3518(c)(1)(B) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3518(c)(1)(B)) excludes collection activities during the conduct of administrative actions such as reconsiderations. We do not believe that any of the other changes we are proposing would increase burden, as further discussed below.

In addition, we are proposing to make conforming changes to our validation scoring process to reflect proposed changes in the APU determination timeframes. For the CY 2017 payment determination, we are proposing that validation be based on three quarters of data (quarter 2, quarter 3, and quarter 4 of 2015). For the CY 2017 transition year, we estimate that the burden associated with validation reporting would be reduced by 25 percent because hospitals would submit validation data for three quarters instead of four. For prior payment determinations, we sampled 500 hospitals for validation and estimated that it would take each hospital 12 hours to comply with the data submission requirements for four quarters. We estimate that data submission for three quarters would reduce the number of hours required by 25 percent (from 12 hours to 9 hours per hospital). Therefore, we estimate a total burden of approximately 4,500 hours (500 hospitals x 9 hours/hospital) and a total financial impact of $135,000 ($30/hour x 4,500 hours) for the CY 2017 payment determination. In summary, for the CY 2017 payment determination, we estimate a total burden of 3.5 million hours across all hospitals for a total of $105 million. This is a reduction of 1,500 hours and $45,000 across all hospitals from last year's estimate.

For the CY 2018 payment determination and subsequent years, we are proposing two changes to the program. First, we are proposing a new measure OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822). As discussed in section XVIII.B.1.b. of this proposed rule, we believe that this measure would result in a total increase in burden across all participating hospitals of 8,313 hours or $249,000 per year (rounded). Second, we are proposing for the CY 2018 payment determination and subsequent years, that validation again be based on four quarters of data; however those quarters are validation quarter 1, validation quarter 2, validation quarter 3 and validation quarter 4. For payment determinations prior to CY 2017, we sampled 500 hospitals for validation and estimated that it would take each hospital 12 hours to comply with the data submission requirements for four quarters. Therefore, we estimate a total burden of approximately 6,000 hours (500 hospitals x 12 hours/hospital) and a total financial impact of $180,000 ($30/hour x 6,000 hours) in burden associated with validation for the CY 2018 payment determination and subsequent years. This is an increase of 1,500 hours and $45,000 across all hospitals from the CY 2017 estimate.

For the CY 2019 payment determination and subsequent years, we are proposing one change to the program; we are proposing a new measure OP–34: Emergency Department Transfer Communication (EDTC) (NQF #0291). As discussed in section XVIII.B.1.c. of this proposed rule, we believe that this measure would result in a total increase in burden across all participating hospitals of 80,593 hours or $2.41 million per year (rounded). In summary, we estimate that all of the proposals made in this proposed rule for the Hospital OQR Program would result in a total increase in burden across all participating hospitals of 88,905 hours or $2.67 million (rounded).

We refer readers to the information collection requirements section XVIII.B.1. of this proposed rule for a detailed discussion of the financial and hourly burden of the proposed additional requirements for submitting data to the Hospital OQR Program.

e. Effects of Proposed Requirements for the ASCQR Program

As discussed in section XIV. of this proposed rule, we are proposing to adopt policies affecting the ASCQR Program. For the CY 2015 payment determination, of the 5,260 ASCs that met eligibility requirements for the ASCQR Program, 116 ASCs did not meet the requirements to receive the full annual payment update.

We are not proposing to add any quality measures to the ASCQR measure set for the CY 2018 payment determination. We do not believe that the other measures we previously adopted would cause any additional ASCs to fail to meet the ASCQR Program requirements. (We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66978 through 66979) for a list of these measures.) In addition, we do not believe that any of the other proposals we are proposing in this proposed rule would increase the number of ASCs that do not receive a full annual payment update for the CY 2018 payment determination. We expect a reduction due to our proposal that IHS hospital outpatient departments billing as ASCs would no longer be considered ASCs for the purposes of the ASCQR Program. Thus, as CY 2016 and CY 2017 payment determination information is not yet available, using the CY 2015 payment determination numbers as a baseline, we estimate that approximately 115 ASCs would not receive the full annual payment update in CY 2018 due to failure to meet the ASCQR Program requirements.

Based on the previously finalized policies for the ASCQR program and the proposals made in this proposed rule, we estimate a total burden of approximately 4.34 hours per ASC for facilities not submitting data for ASC–11 ([1,757 hours for ASC–6 and ASC–7 + 18,005 hours for ASC–8 + 3,067 hours for ASC–9 and ASC–10]/5,260 ASCs = 4.34 hours per ASC for all required measures) and approximately 4.92 hours for facilities voluntarily reporting data for ASC–11 [53] (4.34 hours for reporting all required measures + [613 hours for ASC–11/1,052 ASCs] = 4.92 hours), or approximately 23,442 hours (1,757 hours for ASC–6 and ASC–7 + 18,005 hours for ASC–8 + 3,067 hours for ASC–9 and ASC–10 + 613 hours for ASC–11 = 23,442 hours) across all ASCs associated with participating in the ASCQR Program for the CY 2018 payment determination. We further estimate a resulting total financial burden of $130 per ASC for facilities not submitting data for ASC–11 ([$52,710 for ASC–6 and ASC–7 + $540,150 for ASC–8 + $92,010 for ASC–9 and ASC–10]/5,260 ASCs = $130 per ASC for all required measures) and approximately $148 per ASC for facilities voluntarily reporting data under ASC–11 ($130 for all required measures + [$18,390/1,052 ASCs] = $148), or $703,260 ($52,710 for ASC–6 and ASC–7 + $540,150 for ASC–8 + $92,010 for ASC–9 and ASC–10 + $18,390 for ASC–11 = $703,260) across all ASCs.

We refer readers to the information collection requirements in section XVIII.B.2 of this proposed rule for a detailed discussion of the financial and

[53] As noted in the CY 2015 OPPS/ASC final rule with comment period, we anticipate that approximately 20 percent of ASCs, or 1,052 facilities, would elect to report ASC–11 on a voluntary basis (79 FR 67016).

hourly burden of the ASCQR Program's current and proposed requirements.

We are inviting public comment on the burden associated with these proposals.

f. Impact of the Proposed Policy Change for Medical Review of Inpatient Hospital Admissions Under Medicare Part A

As discussed in section XV. of this proposed rule, we are proposing a policy change for medical review of inpatient hospital admissions under Medicare Part A. In this section, we discuss the estimate by our actuaries of the overall impact of the proposed policy change described in section XV of this proposed rule. We also discuss the estimate by our actuaries of the overall impact of the 2-midnight rule adopted in the FY 2014 IPPS/LTCH PPS rulemaking, including a review by our actuaries of the claims data since the implementation of the 2-midnight rule.

In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27649 through 27650), we discussed our actuaries' estimate that our current 2-midnight policy would increase IPPS expenditures by approximately $220 million in FY 2014. These additional expenditures were expected to result from a net increase in hospital inpatient encounters due to some outpatient encounters spanning more than 2 midnights moving to the IPPS from the OPPS, and some inpatient encounters of less than 2 midnights moving from the IPPS to the OPPS. We also proposed to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to offset this estimated $220 million in additional expenditures with a −0.2 percent adjustment to the IPPS rates. As discussed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50952 through 50954), after considering the public comments received, our actuaries continued to estimate that there would be approximately $220 million in additional expenditures resulting from the 2-midnight rule and we adopted the −0.2 percent adjustment beginning in FY 2014.

There were several components of the −0.2 percent adjustment estimate. First, in estimating the number of inpatient stays that would shift to the outpatient setting, inpatient claims containing a surgical MS–DRG were analyzed. These claims were from FY 2011, although FY 2009 and FY 2010 claims data were also examined and the results were consistent with the FY 2011 results. Claims containing medical MS–DRGs and those that resulted in death or a transfer were excluded because it was assumed that these cases would be unaffected by the policy change. In making this assumption, the actuaries believed that behavioral changes by hospitals and admitting practitioners would mitigate some of the impact of cases shifting between the inpatient hospital setting and the outpatient hospital setting. Specifically, the actuaries assumed that most inpatient medical encounters spanning less than 2 midnights before the current 2-midnight rule was implemented might extend past 2 midnights after its implementation and still be considered inpatient. They believed that the clinical assessments and protocols used by physicians to develop an expected length of stay for medical cases were, in general, more variable and less defined than those used to develop an expected length of stay for surgical cases. Under our proposed policy, our actuaries assume that some of these medical encounters might revert back to no longer extending past 2-midnights. However, they would not generally cause a significant increase or decrease in expenditures because they are inpatient under the current policy and could remain inpatient under the proposed policy. With respect to surgical encounters, under the current policy our actuaries assumed that cases spanning less than two midnights containing a surgical MS–DRG would shift from the inpatient setting to the outpatient setting. Under the proposed policy, our actuaries assume that as a result of the experience that hospitals have gained under the current 2-midnight rule and the continued potential for medical review of these cases, these cases generally would not shift back to the inpatient setting in significant numbers.

A second component of the −0.2 percent adjustment estimate was the number of outpatient encounters assumed to shift to the inpatient setting. Outpatient claims that included spending for observation care or a major procedure were analyzed. Outpatient stays that were shorter than 2 midnights and those that were not for observation care or for a major procedure were excluded because it was assumed that these cases would be unaffected by the policy change. Under the current policy, our actuaries assumed that the cases for observation care or a major procedure that spanned more than 2 midnights would shift from the outpatient setting to the inpatient setting. Because the proposed policy only impacts cases spanning less than 2 midnights after admission, our actuaries do not assume any significant additional shifts in outpatient encounters spanning more than 2 midnights to the inpatient setting if our proposal is adopted. With respect to outpatient encounters that span less than 2 midnights, as a result of the experience that hospitals have gained under the current 2-midnight rule, the continued potential for medical review of these cases, and the fact that our experience indicates that the majority of these cases were generally not inpatient prior to the current 2-midnight policy, our actuaries assume that these cases would generally remain in the outpatient setting under our proposed policy.

Another component of the −0.2 percent adjustment estimate was the assumption that payment under the OPPS would be roughly 30 percent of the payment under the IPPS for encounters shifting between the two systems, and the beneficiary would be responsible for 20 percent of the payment under the OPPS. Our actuaries continue to assume this payment differential under our proposed policy.

Because our actuaries do not assume any significant additional shifts between the inpatient setting and the outpatient setting as a result of our proposed policy, and because there is also no change in the assumption regarding the 30-percent outpatient/inpatient payment differential, our actuaries do not estimate that overall IPPS expenditures would be significantly different under the proposed policy change for the medical review of inpatient hospital admissions under Medicare Part A described in section XV. of this proposed rule.

As we indicated for the original −0.2 percent adjustment estimate, there is a certain degree of uncertainty surrounding any cost estimate. Our actuaries have determined that the methodology, data, and assumptions used here are reasonable for the purpose of estimating the overall impact of the proposed policy. It is important to note that the assumptions used for purposes of reasonably estimating overall impacts should not be construed as absolute statements about every individual encounter. For example, under our current policy, our actuaries did not expect that every single surgical MS–DRG encounter spanning less than 2 midnights would shift to the outpatient setting, that every single medical MS–DRG encounter would remain in the inpatient setting, and that every single outpatient observation stay or major surgical encounter spanning more than 2 midnights would shift to the inpatient setting. However, for purposes of developing the −0.2 percent adjustment estimate under the current policy, a *model* where cases involving a surgical

MS–DRG spanning less than 2 midnights in the historical data shifted to the outpatient setting, cases involving a medical MS–DRG spanning less than 2 midnights in the historical data remained in the inpatient setting, and outpatient observation stays and major surgical encounters spanning more than 2 midnights in the historical data shifted to the inpatient setting yielded a reasonable estimate of the net effect of the 2-midnight policy. To the extent the actual experience might vary for each of the individual assumptions, our actuaries estimated that the total net effect of that variation would not significantly impact the estimate. Similarly, under our proposed policy, our actuaries do not expect that every single inpatient case would remain an inpatient case and every single outpatient case would remain an outpatient case. Rather, they estimate that total net effect of variation between their assumptions and actual experience would not significantly impact the estimate.

Our actuaries also provided some important caveats with the original estimate that continue to hold true for the estimate of the proposed policy. They noted that the actual costs or savings would depend substantially on possible changes in behavior by hospitals and the medical review entities, and that such changes could not be anticipated with certainty. They also noted that the estimates did depend critically on the assumed utilization changes in the inpatient and outpatient hospital settings. While they believed that the assumptions were reasonable, they indicated that relatively small changes would have a disproportionate effect on the estimate. For this reason, the estimate was subject to a much greater degree of uncertainty than usual, and the actual results could have differed significantly from the estimate. All of these caveats also apply to the estimate that the proposed policy would not have a significant impact on expenditures.

Our actuaries have been periodically reviewing the claims experience to date under the 2-midnight rule and comparing it to the experience of the previous time period. Below are a few observations from this review. Our actuaries have attempted to complete the claims data (that is, to adjust for lags between the time when claims were incurred but not yet received) in performing the review. Full incurred experience for the more recent time periods, when available, could result in a different outcome.

Our actuaries found that the proportion of outpatient long-stay observation encounters (more than 2 days) as compared to all outpatient encounters decreased by 11 percent in FY 2014 compared to FY 2013 (6 percent in the fourth quarter of CY 2013; 11 percent in the first quarter of CY 2014; 13 percent in the second quarter of CY 2014; and 14 percent in the third quarter of CY 2014) and also by 11 percent in CY 2014 compared to CY 2013 (6 percent in the fourth quarter of CY 2014).

They found the proportion of 2–4 day inpatient stays as compared to all inpatient stays increased by 3.0 percent in FY 2014 compared to FY 2013 (3.4 percent in the fourth quarter of CY 2013; 3.5 percent in the first quarter of CY 2014; 2.8 percent in the second quarter of CY 2014; and 2.4 percent in the third quarter of CY 2014) and increased by 2.7 percent in CY 2014 compared to CY 2013 (2 percent in the fourth quarter of CY 2014).

They found the proportion of very short stay inpatient admissions (0 and 1 days) decreased by 9.0 percent in FY 2014 compared to FY 2013 (10.5 percent in the fourth quarter of CY 2013; 8.2 percent in the first quarter of CY 2014; 8.2 percent in the second quarter of CY 2014; and 7.7 percent in the third quarter of CY 2014) and decreased by 7.3 percent in CY 2014 compared to CY 2013 (3.4 percent in the fourth quarter of CY 2014).

Overall, the cumulative effect of these inpatient shifts show no change in the proportion of inpatient stays of 4 days or more.

The data thus far is consistent with the assumptions used by our actuaries to develop the original −0.2 percent adjustment estimate: Outpatient long stay observations (more than 2 days) have declined; 2–4 day inpatient stays have increased; and very short inpatient stays (1 day or less) have decreased. The fact that there has been no change in the proportion of inpatient stays of 4 days or more is consistent with the assumption that the decrease in very short stay inpatient cases under the current policy would be offset by the shift of longer outpatient encounters to inpatient. Our actuaries will continue to review the claims experience under the 2-midnight rule, and we will take those reviews into account when considering future rulemaking.

As was the case when our actuaries developed the original −0.2 percent adjustment estimate and continues to be the case now, the outpatient and inpatient data files are publicly available. The CMS Web site at *http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/HospitalOutpatientPPS/index.html* provides information about ordering the ''OPPS Limited Data Set'' containing the outpatient hospital data. The CMS Web site at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/* provides information about ordering the ''MedPAR Limited Data Set (LDS)-Hospital (National)'' containing the inpatient hospital data.

g. Impact of Proposed Transition for MDHs in All-Urban States Under the IPPS

In section XVI. of this proposed rule, we discuss our proposal to provide a transition period under the IPPS for hospitals that lost their MDH status because they are no longer in a rural area due to the implementation of the new OMB labor market area delineations and are now located in an all-urban State. A facility is eligible for designation as an MDH only if it is either physically located in a rural area or has been reclassified under 42 CFR 412.103. However, a hospital that is located in an all-urban State cannot apply for reclassification as rural under 42 CFR 412.103 because its State does not have a rural area into which it can reclassify. We are proposing that, for discharges occurring on or after January 1, 2016, and before October 1, 2016, under the IPPS, a former MDH in an all-urban State would receive the Federal rate plus two-thirds of 75 percent of the amount by which the Federal rate payment is exceeded by its hospital-specific rate payment. For FY 2017, that is, for discharges occurring on or after October 1, 2016, and before October 1, 2017, we are proposing that such former MDH would receive the Federal rate plus one-third of 75 percent of the amount by which the Federal rate payment is exceeded by the hospital's hospital-specific rate. For FY 2018, that is, for discharges occurring on or after October 1, 2018, we are proposing that these former MDHs would be solely paid based on the Federal rate. We estimate that there is one provider that was classified an MDH prior to the effective date of the new OMB delineations on October 1, 2014, and is located in a newly all-urban State. We estimate the costs associated with the transition period for this hospital to be approximately $9 million.

B. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals, ASCs and

CMHCs are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of $38.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of $15 million or less in any single year. For details, see the Small Business Administration's ''Table of Small Business Size Standards'' at *http://www.sba.gov/content/table-small-business-size-standards*.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule 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. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule may have a significant impact on approximately 648 small rural hospitals.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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. That threshold level is currently approximately $144 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

D. Conclusion

The changes we are proposing to make in this proposed rule would affect all classes of hospitals paid under the OPPS and would affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2015. Table 65 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 0.2 percent decrease in payments for all services paid under the OPPS in CY 2016, after considering all of the proposed changes to APC reconfiguration and recalibration, as well as the proposed OPD fee schedule increase factor, proposed adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests, proposed wage index changes, including the proposed frontier State wage index adjustment, proposed estimated payment for outliers, and proposed changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience more significant gains or losses in OPPS payments in CY 2016.

The proposed updates to the ASC payment system for CY 2016 would affect each of the approximately 5,300 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC will depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 66 demonstrates the estimated distributional impact among ASC surgical specialties of the proposed MFP-adjusted CPI–U update factor of 1.1 percent for CY 2016.

XXI. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 65 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would decrease payment by 0.2 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR Chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for Part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd).

■ 2. Section 410.29 is amended by revising paragraph (a) to read as follows:

§ 410.29 Limitations on drugs and biologicals.

* * * * *

(a) Except as provided in § 410.28(a) for outpatient diagnostic services and § 410.63(b) for blood clotting factors, and except for EPO, any drug or biological which is usually self-administered by the patient.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 3. The authority citation for Part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), 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 412.3 is amended by revising paragraph (d) to read as follows:

§ 412.3 Admissions.

* * * * *

(d)(1) Except as specified in paragraphs (d)(2) and (3) of this section, an inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights.

(i) The expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.

(ii) If an unforeseen circumstance, such as a beneficiary's death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least 2 midnights, the patient may be considered to be appropriately treated on an inpatient basis, and payment for an inpatient hospital stay may be made under Medicare Part A.

(2) An inpatient admission for a surgical procedure specified by Medicare as inpatient only under § 419.22(n) of this chapter is generally appropriate for payment under Medicare Part A, regardless of the expected duration of care.

(3) Where the admitting physician expects a patient to require hospital care for only a limited period of time that does not cross 2 midnights, an inpatient admission may be appropriate for payment under Medicare Part A based on the clinical judgment of the admitting physician and medical record support for that determination. The physician's decision should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. In these cases, the factors that lead to the decision to admit the patient as an inpatient must be supported by the medical record in order to be granted consideration.

PART 416—AMBULATORY SURGICAL SERVICES

■ 5. The authority citation for Part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 6. Section 416.164 is amended by revising paragraph (b)(3) to read as follows:

§ 416.164 Scope of ASC services.

* * * * *

(b) * * *

(3) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the acquisition or procurement of corneal tissue for corneal transplant procedures;

* * * * *

■ 7. Section 416.172 is amended by revising paragraph (f) to read as follows:

§ 416.172 Adjustments to national payment rates.

* * * * *

(f) Interrupted procedures. (1) Subject to the provisions of paragraph (f)(2) of this section, when a covered surgical procedure or covered ancillary service is terminated prior to completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicare program payment amount and the beneficiary coinsurance amount are based on one of the following:

(i) The full program and beneficiary coinsurance amounts if the procedure for which anesthesia is planned is discontinued after the induction of anesthesia or after the procedure is started;

(ii) One-half of the full program and beneficiary coinsurance amounts if the procedure for which anesthesia is planned is discontinued after the patient is prepared for surgery and taken to the room where the procedure is to be performed but before the anesthesia is induced; or

(iii) One-half of the full program and beneficiary coinsurance amounts if a covered surgical procedure or covered ancillary service for which anesthesia is not planned is discontinued after the patient is prepared and taken to the room where the service is to be provided.

(2) Beginning CY 2016, if the covered surgical procedure is a device-intensive procedure, the full device portion of ASC device-intensive procedure is removed prior to determining the Medicare program payment amount and beneficiary copayment amount identified in paragraphs (f)(1)(ii) and (f)(1)(iii) of this section.

* * * * *

■ 8. Section 416.195 is amended by revising paragraph (a)(1) to read as follows:

§ 416.195 Determination of membership in new classes of new technology IOLs.

(a) * * *

(1) The IOL is considered new. Under this provision, CMS will evaluate an application for a new technology IOL only if the IOL type has received initial FDA premarket approval within the 3 years prior to the new technology IOL application submission date.

* * * * *

■ 9. Subpart H is added to read as follows:

Subpart H—Requirements Under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

Sec.
416.300 Basis and scope of subpart.
416.305 Participation and withdrawal requirements under the ASCQR Program.
416.310 Data collection and submission requirements under the ASCQR Program.
416.315 Public reporting of data under the ASCQR Program.
416.320 Retention and removal of quality measures under the ASCQR Program.
416.325 Measure maintenance under the ASCQR Program.
416.330 Reconsiderations under the ASCQR Program.

Subpart H—Requirements Under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

§ 416.300 Basis and scope of subpart.

(a) *Statutory basis.* Section 1833(i)(2)(D)(iv) and (i)(7) of the Act authorizes the Secretary to implement a revised ASC payment system in a manner so as to provide for a 2.0 percentage point reduction in any annual update for an ASC's failure to report on quality measures in accordance with the Secretary's requirements.

(b) *Scope.* This subpart contains specific requirements and standards for the ASCQR Program.

§ 416.305 Participation and withdrawal requirements under the ASCQR Program.

(a) *Participation in the ASCQR Program.* Except as provided in paragraph (c) of this section, an ambulatory surgical center (ASC) is considered as participating in the ASCQR Program once the ASC submits any quality measure data to the ASCQR Program and has been designated as open in the Certification and Survey Provider Enhanced Reporting system for at least four months prior to the beginning of data collection for a payment determination.

(b) *Withdrawal from the ASCQR Program.* (1) An ASC may withdraw from the ASCQR Program by submitting to CMS a withdrawal of participation form that can be found in the secure portion of the QualityNet Web site.

(2) An ASC may withdraw from the ASCQR Program any time up to and

including August 31 of the year preceding a payment determination.

(3) Except as provided in paragraph (c) of this section, an ASC will incur a 2.0 percentage point reduction in its ASC annual payment update for that payment determination year and any subsequent payment determinations in which it is withdrawn.

(4) An ASC will be considered as rejoining the ASCQR Program if it begins to submit any quality measure data again to the ASCQR Program.

(c) *Minimum case volume for program participation.* ASCs with fewer than 240 Medicare claims (Medicare primary and secondary payer) per year during an annual reporting period for a payment determination year are not required to participate in the ASCQR Program for the subsequent annual reporting period for that subsequent payment determination year.

(d) *Indian Health Service hospital outpatient department participation.* Beginning with the CY 2017 payment determination, Indian Health Service hospital outpatient departments that bill Medicare under the Ambulatory Surgical Center payment system are not considered ASCs for the purposes of the ASCQR Program. These facilities are not required to meet ASCQR Program requirements and will not receive payment reductions under the ASCQR Program.

§ 416.310 Data collection and submission requirements under the ASCQR Program.

(a) *Requirements for claims-based measures using quality data codes (QDCs).*

(1) ASCs must submit complete data on individual claims-based quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims.

(2) The data collection period for claims-based quality measures reported using QDCs is the calendar year 2 years prior to the payment determination year. Only claims for services furnished in each calendar year paid by the Medicare Administrative Contractor (MAC) by April 30 of the following year of the ending data collection time period will be included in the data used for the payment determination year.

(3) For ASCQR Program purposes, data completeness for claims-based measures using QDCs is determined by comparing the number of Medicare claims (where Medicare is the primary or secondary payer) meeting measure specifications that contain the appropriate QDCs with the number of Medicare claims that meet measure specifications, but do not have the appropriate QDCs on the submitted Medicare claim. The minimum threshold for successful reporting is that at least 50 percent of Medicare claims meeting measure specifications contain the appropriate QDCs. ASCs that meet this minimum threshold are regarded as having provided complete data for the claims-based measures using QDCs for the ASCQR Program.

(b) *Requirements for claims-based measures not using QDCs.* The data collection period for claims-based quality measures not using QDCs is Medicare fee-for-service claims from the calendar year 2 years prior to the payment determination year. Only claims for services furnished in each calendar year paid by the MAC by April 30 of the following year of the ending data collection time period will be included in the data used for the payment determination.

(c) *Requirements for data submitted via an online data submission tool—(1) Requirements for data submitted via a CMS online data submission tool—(i) QualityNet account for Web-based measures.* ASCs must maintain a QualityNet account in order to submit quality measure data to the QualityNet Web site for all Web-based measures submitted via a CMS online data submission tool. A QualityNet security administrator is necessary to set-up such an account for the purpose of submitting this information.

(ii) *Data collection requirements.* The data collection time period for quality measures for which data is submitted via a CMS online data submission tool is for services furnished during the calendar year 2 years prior to the payment determination year. Beginning with the CY 2017 payment determination year, data collected must be submitted during the time period of January 1 to May 15 in the year prior to the payment determination year.

(2) *Requirements for data submitted via a non-CMS online data submission tool.* The data collection time period for ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel is from October 1 of the year 2 years prior to the payment determination year to March 31 during the calendar year prior to the payment determination year. Data collected must be submitted by May 15 in the year prior to the payment determination year.

(d) *Extension or exemption.* CMS may grant an extension or exemption for the submission of information in the event of extraordinary circumstances beyond the control of an ASC, or a systematic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an extension or exemption as follows:

(1) Upon request of the ASC. Specific requirements for submission of a request for an extension or exemption are available on the QualityNet Web site; or

(2) At the discretion of CMS. CMS may grant extensions or exemptions to ASCs that have not requested them when CMS determines that an extraordinary circumstance has occurred.

§ 416.315 Public reporting of data under the ASCQR Program.

Data that an ASC submitted for the ASCQR Program will be made publicly available on a CMS Web site after providing the ASC an opportunity to review the data to be made public. CMS will display ASC data by the National Provider Identifier (NPI) when data are submitted by the NPI. CMS will display ASC data by the CMS Certification Number (CCN) when data are submitted by the CCNs, such that all NPIs associated with that CCN will be assigned the CCN's value.

§ 416.320 Retention and removal of quality measures under the ASCQR Program.

(a) General rule for the retention of quality measures. Quality measures adopted for an ASCQR Program measure set for a previous payment determination year are retained in the ASCQR Program for measure sets for subsequent payment determination years, except when they are removed, suspended, or replaced as set forth in paragraphs (b) and (c) of this section.

(b) *Immediate measure removal.* In cases where CMS believes that the continued use of a measure as specified raises patient safety concerns, CMS will immediately remove a quality measure from the ASCQR Program and will promptly notify ASCs and the public of the removal of the measure and the reasons for its removal through the ASCQR Program ListServ and the ASCQR Program QualityNet Web site. CMS will confirm the removal of the measure for patient safety concerns in the next ASCQR Program rulemaking.

(c) *Measure removal, suspension, or replacement through the rulemaking process.* Unless a measure raises specific safety concerns as set forth in paragraph (b) of this section, CMS will use the regular rulemaking process to remove, suspend, or replace quality measures in the ASCQR Program to allow for public comment.

(1) *Criteria for removal of quality measures.* (i) CMS will use the following criteria to determine whether to remove a measure from the ASCQR Program:

(A) Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (topped-out measures);

(B) Availability of alternative measures with a stronger relationship to patient outcomes;

(C) A measure does not align with current clinical guidelines or practice;

(D) The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(E) The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(F) The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and

(G) Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(ii) The benefits of removing a measure from the ASCQR Program will be assessed on a case-by-case basis. A measure will not be removed solely on the basis of meeting any specific criterion.

(2) *Criteria to determine topped-out measures.* For the purposes of the ASCQR Program, a measure is considered to be topped-out under paragraph (c)(1)(i)(A) of this section when it meets both of the following criteria:

(i) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for an ASC's measure is within two times the standard error of the full data set); and

(ii) A truncated coefficient of variation less than or equal to 0.10.

§ 416.325 Measure maintenance under the ASCQR Program.

(a) *Measure maintenance under the ASCQR Program.* CMS follows different procedures to update the measure specifications under the ASCQR Program based on whether the change is substantive or nonsubstantive. CMS will determine what constitutes a substantive versus a nonsubstantive change to a measure's specifications on a case-by-case basis.

(b) *Substantive changes.* CMS will continue to use rulemaking to adopt substantive updates to measures in the ASCQR Program.

(c) *Nonsubstantive changes.* If CMS determines that a change to a measure previously adopted in the ASCQR Program is nonsubstantive, CMS will use a subregulatory process to revise the ASCQR Program Specifications Manual so that it clearly identifies the changes to that measure and provide links to where additional information on the changes can be found. When a measure undergoes subregulatory maintenance, CMS will provide notification of the measure specification update on the QualityNet Web site and in the ASCQR Program Specifications Manual, and will provide sufficient lead time for ASCs to implement the revisions where changes to the data collection systems would be necessary.

§ 416.330 Reconsiderations under the ASCQR Program.

(a) *Reconsiderations of ASCQR Program decisions.* An ASC may request reconsideration of a decision by CMS that it has not met the requirements of the ASCQR Program for a particular payment determination year. An ASC must submit a reconsideration request to CMS by no later than the first business day on or after March 17 of the affected payment year.

(b) *Requirements for reconsideration requests.* A reconsideration request must contain the following information:

(1) The ASC CCN and related NPI(s);

(2) The name of the ASC;

(3) The CMS-identified reason for not meeting the requirements of the ASCQR Program for the affected payment determination year as provided in any CMS notification to the ASC;

(4) The ASC's basis for requesting reconsideration. The ASC must identify its specific reason(s) for believing it met the ASCQR Program requirements for the affected payment determination year and should not be subject to the reduced ASC annual payment update;

(5) The ASC-designated personnel contact information, including name, email address, telephone number, and mailing address (must include physical mailing address, not just a post office box); and

(6) A copy of all materials that the ASC submitted to comply with the requirements of the affected ASCQR Program payment determination year. With regard to information on claims, ASCs are not required to submit copies of all submitted claims, but instead may focus on the specific claims at issue. For these claims, ASCs should submit relevant information, which could include copies of the actual claims at issue.

(c) *Reconsideration process.* Upon receipt of a request for reconsideration, CMS will do the following:

(1) Provide an email acknowledgement, using the contact information provided in the reconsideration request, notifying the ASC that the request has been received; and

(2) Provide a formal response to the ASC contact using the information provided in the reconsideration request notifying the ASC of the outcome of the reconsideration process.

(d) *Final ASCQR Program payment determination.* For an ASC that submits a reconsideration request, the reconsideration determination is the final ASCQR Program payment determination. For an ASC that does not submit a timely reconsideration request, the CMS determination is the final payment determination. There is no appeal of any final ASCQR Program payment determination.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 10. The authority citation for Part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

■ 11. Section 419.2 is amended by revising paragraph (c)(8) to read as follows:

§ 419.2 Basis of payment.

* * * * *

(c) * * *

(8) Corneal tissue acquisition or procurement costs for corneal transplant procedures.

■ 12. Section 419.32 is amended by adding new paragraph (b)(1)(iv)(B)(7) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*7*) For calendar year 2016, a multifactor productivity adjustment (as determined by CMS), and 0.2 percentage point.

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■ 13. Section 419.44 is amended by revising paragraph (b) to read as follows:

§ 419.44 Payment reductions for procedures.

* * * * *

(b) *Interrupted procedures.* (1) Subject to the provisions of paragraph (b)(2) of this section, when a procedure is terminated prior to completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicare program payment amount and the

beneficiary copayment amount are based on—

(i) The full program and beneficiary copayment amounts if the procedure for which anesthesia is planned is discontinued after the induction of anesthesia or after the procedure is started;

(ii) One-half the full program and the beneficiary copayment amounts if the procedure for which anesthesia is planned is discontinued after the patient is prepared and taken to the room where the procedure is to be performed but before anesthesia is induced; or

(iii) One-half of the full program and beneficiary copayment amounts if a procedure for which anesthesia is not planned is discontinued after the patient is prepared and taken to the room where the procedure is to be performed.

(2) Beginning CY 2016, if a procedure involves an implantable device assigned to a device-intensive APC, the full device portion of the device-intensive APC procedure payment is removed prior to determining the program and beneficiary copayment amounts identified in paragraphs (b)(1)(ii) and (b)(1)(iii) of this section.

■ 14. Section 419.46 is amended by revising paragraphs (b), (d), (e), and (f)(1) to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(b) *Withdrawal from the Hospital OQR Program.* A participating hospital may withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet Web site. The hospital may withdraw any time up to and including August 31 of the year prior to the affected annual payment updates. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under § 419.43(h), and is required to submit a new participation form in order to participate in any future year of the Hospital OQR Program.

* * * * *

(d) *Exemption.* CMS may grant an extension or exemption of one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an extension or exemption as follows:

(1) Upon request by the hospital. Specific requirements for submission of a request for an extension or exemption are available on the QualityNet Web site.

(2) At the discretion of CMS. CMS may grant extensions or exemptions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

(e) *Validation of Hospital OQR Program data.* CMS may validate one or more measures selected under section 1833(t)(17)(C) of the Act by reviewing documentation of patient encounters submitted by selected participating hospitals.

(1) Upon written request by CMS or its contractor, a hospital must submit to CMS supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 45 days of the date identified on the written request, in the form and manner specified in the written request.

(2) A hospital meets the validation requirement with respect to a calendar year if it achieves at least a 75-percent reliability score, as determined by CMS.

(f) * * *

(1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program for a particular calendar year. Except as provided in paragraph (d) of this section, a hospital must submit a reconsideration request to CMS via the QualityNet Web site, no later than the first business day on or after March 17 of the affected payment year as determined using the date the request was mailed or submitted to CMS.

* * * * *

■ 15. Section 419.66 is amended by revising paragraph (b)(1) to read as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(b) * * *

(1) If required by the FDA, the device must have received FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215 of this chapter), or meet another appropriate FDA exemption from premarket approval or clearance. Under this provision, CMS will consider only applications for a medical device submitted within 3 years from the date of the initial FDA approval or clearance, if required.

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Dated: June 26, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: June 26, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–16577 Filed 7–1–15; 4:15 pm]

BILLING CODE 4120–01–P