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Centers for Medicare & Medicaid Services

42 CFR Parts 411, 412, 416, et al.
Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: CMS-Identified Overpayments Associated with Submitted Payment Data; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 412, 416, 419, 422, 423, and 424

[CMS–1613–FC]

RIN 0938–AS15

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: CMS-Identified Overpayments Associated with Submitted Payment Data

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2015 to implement applicable statutory requirements and changes arising from our continuing experience with these systems. In this final rule with comment period, we describe the 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 final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

In this document, we also are making changes to the data sources permitted for expansion requests for physician-owned hospitals under the physician self-referral regulations; changes to the underlying authority for the requirement of an admission order for all hospital inpatient admissions and changes to require physician certification for hospital inpatient admissions only for long-stay cases and outlier cases; and changes to establish a formal process, including a three-level appeals process, to recoup overpayments that result from the submission of erroneous payment data by Medicare Advantage (MA) organizations and Part D sponsors in the limited circumstances in which the organization or sponsor fails to correct these data.

DATES: *Effective Date:* This final rule with comment period is effective on January 1, 2015.

Comment Period: To be assured consideration, comments on the payment classifications assigned to HCPCS codes identified in Addenda B, AA, and BB to this final rule with comment period with the ''NI'' comment indicator, and on other areas specified throughout this final rule with comment period must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on December 30, 2014.

Application Deadline—New Class of New Technology Intraocular Lenses: Requests for review of applications for a new class of new technology intraocular lenses must be received by 5 p.m. EST on March 2, 2015, at the following address: ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

ADDRESSES: In commenting, please refer to file code CMS–1613–FC. 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–1613–FC, 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–1613–FC, 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:

Marjorie Baldo, (410) 786–4617, for issues related to new CPT and Level II HCPCS codes, revised process for soliciting comments related to new Category I and III CPT codes, and exceptions to the 2 times rule.

Elizabeth Bainger, (410) 786–0529, for issues related to the Hospital Outpatient Quality Reporting—Program Administration, Validation, and Reconsideration Issues.

Anita Bhatia, (410) 786–7236, for issues related to the Ambulatory Surgical Center Quality Reporting (ASCQR) Program—Program Administration and Reconsideration Issues.

Chuck Braver, (410) 786–9379, for issues related to the CMS Web posting of the OPPS and ASC payment files.

Anne Calinger, (410) 786–3396, for issues related to Medicare Advantage (MA) organizations and Medicare Part D sponsor overpayments.

Elisabeth Daniel, (410) 786–0237, for issues related to OPPS drugs, radiopharmaceuticals, biologicals, blood clotting factors, packaged items/services, and brachytherapy sources payment.

Dexter Dickey, (410) 786–6856, or Dorothy Myrick, (410) 786–9671, for issues related to partial hospitalization and community mental health center (CMHC) issues.

Eva Fung, (410) 786–7539, or Vinitha Meyyur, (410) 786–8819, for issues

related to Hospital OQR Program and ASCQR measures issues and publication of Hospital OQR Program data issues.

Twi Jackson, (410) 786–1159, for issues related to device-dependent APCs, composite APCs (extended assessment and management, low dose brachytherapy, multiple imaging), hospital outpatient visits, inpatient procedures list, and no cost/full credit and partial credit devices.

Marina Kushnirova, (410) 786–2682, for issues related to OPPS status indicators and comment indicators.

John McInnes, (410) 786–0791, for issues related to new technology intraocular lenses (NTIOLs).

Esther Markowitz, (410) 786–4595, for issues related to comprehensive APCs and ambulatory surgical center (ASC) payments.

David Rice, (410) 786–6004, for issues related to APC weights, blood and blood products, cancer hospital payments, conversion factor, copayments, cost-to-charge ratios (CCRs), data claims, geometric mean calculation, off-campus provider-based issues, rural hospital payments, outlier payments, and wage index.

Daniel Schroder, (410) 786–4487, for issues related to physician certification of hospital inpatient services.

Carol Schwartz, (410) 786–0576, for issues related to the Advisory Panel on Hospital Outpatient Payment (HOP Panel) and OPPS pass-through devices.

Teresa Walden, (410) 786–3755, or Patricia Taft, (410) 786–4561, for issues related to the physician self-referral law/physician-owned hospital expansion exception process.

Marjorie Baldo, (410) 786–4617, for all other issues related to hospital outpatient and ambulatory surgical center payments not previously identified.

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.

Electronic Access

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

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
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
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
ECG Electrocardiogram
ED Emergency department
E/M Evaluation and management
EHR Electronic health record
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
HH QRP Home Health Quality Reporting Program
HHS Department of Health and Human Services

HIE Health information exchange
HEU Highly enriched uranium
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
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
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
MAP Measure Application Partnership
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
NHSN National Healthcare Safety Network
NOS Not otherwise specified
NPWT Negative Pressure Wound Therapy
NPI National provider identification
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
PBD Provider-Based Department
PCHQR PPS-Exempt Cancer Hospital Quality Reporting
PCR Payment-to-cost ratio
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
RAC Recovery Audit Contractor
RADV Risk Adjustment Data Validation
RFA Regulatory Flexibility Act
RHQDAPU Reporting Hospital Quality Data for Annual Payment Update
RTI Research Triangle Institute, International
RVU Relative value unit
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
TMS Transcranial Magnetic Stimulation [Therapy]
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 final rule with comment period, we are updating the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments and

Ambulatory Surgical Centers (ASCs) beginning January 1, 2015. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the relative payment weights and the conversion factor for services payable under the Outpatient Prospective Payment System (OPPS). 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 final rule with comment period. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

In this document, we also are making changes to the data sources permitted for expansion requests for physician-owned hospitals under the physician self-referral regulations; changes to the underlying authority for the requirement of an admission order for all hospital inpatient admissions and changes to require physician certification for hospital inpatient admissions only for long-stay cases and outlier cases; and changes to establish a formal process, including a three-level appeals process, to recoup overpayments that result from the submission of erroneous payment data by Medicare Advantage (MA) organizations and Part D sponsors in the limited circumstances in which the organization or sponsor fails to correct these data.

2. Summary of the Major Provisions

• *OPPS Update:* For CY 2015, we are increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.2 percent. This increase is based on the final hospital inpatient market basket percentage increase of 2.9 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the multifactor productivity (MFP) adjustment of 0.5 percentage point, and minus a 0.2 percentage point adjustment required by the Affordable Care Act. Under this final rule with comment period, we estimate that total payments for CY 2015, including beneficiary cost-sharing, to the approximate 4,000 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers (CMHCs)), will be approximately $56.1 billion, an increase of approximately $5.1 billion compared to CY 2014 payments, or $900 million excluding our estimated changes in enrollment, utilization, and case-mix.

We are continuing 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 reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.

• *Rural Adjustment:* We are continuing the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This adjustment will 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 2015, we are continuing 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 target PCR of 0.89 will be used to determine the CY 2015 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in a PCR equal to 0.89 for each cancer hospital.

• *Payment of Drugs, Biologicals, and Radiopharmaceuticals:* For CY 2015, 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.

• *Packaging Policies:* We are conditionally packaging certain ancillary services when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service. The initial set of services packaged under this ancillary service policy are the services assigned to APCs having an APC geometric mean cost (prior to application of status indicator Q1) of less than or equal to $100. This $100 geometric mean cost limit for the APC is part of the methodology of establishing an initial set of conditionally packaged ancillary service APCs, and is not meant to represent a threshold above which a given ancillary service will not be packaged, but as a basis for selecting an initial set of APCs that will likely be updated and expanded in future years.

• *Implementation of Comprehensive APCs:* For CY 2015, we are implementing, with several modifications, the policy for comprehensive APCs (C–APCs) that was finalized in the CY 2014 OPPS/ASC final rule with comment period effective January 1, 2015. We are continuing 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 continue to consider the entire hospital stay, defined as all services reported on the hospital claim reporting the primary service, to be one comprehensive service for the provision of a primary service into which all other services appearing on the claim would be packaged. This results in a single Medicare payment and a single beneficiary copayment under the OPPS for the comprehensive service based on all included charges on the claim.

We are establishing a total of 25 C–APCs for CY 2015, including all of the formerly device-dependent APCs remaining after some restructuring and consolidation of these APCs (except for APCs 0427, 0622, and 0652) and two C–APCs for other procedures that are either largely device-dependent or represent single session services with multiple components (single-session cranial stereotactic radiosurgery and intraocular telescope implantation). We are modifying the complexity adjustment criteria finalized last year by lowering volume and cost threshold criteria for complexity adjustments. Finally, we are packaging all add-on codes furnished as part of a comprehensive service, which is consistent with our general add-on code packaging policy. However, the add-on codes assigned to the CY 2014 device-dependent APCs will be being evaluated with a primary service for a potential complexity adjustment.

• *Ambulatory Surgical Center Payment Update:* For CY 2015, we are increasing payment rates under the ASC payment system by 1.4 percent. This increase is based on a projected CPI–U update of 1.9 percent minus a multifactor productivity adjustment required by the Affordable Care Act that is projected to be 0.5 percentage point. Based on this update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2015 will be approximately $4.147 billion, an increase of approximately $236 million compared to estimated CY 2014 Medicare payments.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are adding one claims-based quality measure for the CY 2018 payment determination and subsequent years instead of the CY 2017 payment determination and subsequent years as proposed. However, prior to publicly reporting this measure, we plan to conduct a dry run (a preliminary analysis) for hospitals to review their performance and provide feedback using the most recently available data. There will be no payment impact during this dry-run period, and the results of the dry run will not be publicly reported. We are refining the criteria for determining ''topped-out'' measures, and we are removing the OP–6 and OP–7 measures due to ''topped-out'' status. In addition, we are updating several previously adopted measures. We are clarifying data submission requirements for OP–27 and are noting a delayed data collection for OP–29 and OP–30. We are excluding one previously adopted measure (OP–31) from the measure set for the CY 2016 payment determination and changing this measure from required to voluntary for the CY 2017 payment determination and subsequent years. We will not subject hospitals to payment reductions with respect to the OP–31 measure for the CY 2016 payment determination or during the period of voluntary reporting. In addition, we are formalizing a review and corrections period for chart-abstracted measures. We also are updating validation procedures and changes to regulation text to correct typographical errors. We are changing the eligibility criteria for validation; a hospital will only be eligible for random selection for validation if it submits at least 12 cases to the Hospital OQR Program Clinical Data Warehouse during the quarter with the most recently available data. Hospitals also will have the option to submit validation data using electronic methods and must identify the medical record staff responsible for submission of records to the designated CMS contractor. Finally, we are clarifying how we refer to the extraordinary circumstances extensions or exemptions process.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are adopting one new quality measure (ASC–12) for the CY 2018 payment determination and subsequent years. This measure will be computed using paid Medicare fee-for-service (FFS) claims data and will not impose any additional burden on ASCs. We also are excluding one measure (ASC–11) previously adopted for the CY 2016 payment determination and providing that this measure may be voluntarily rather than mandatorily reported for the CY 2017 payment determination and subsequent years. We will not subject ASCs to payment reductions with respect to this measure for the CY 2016 payment determination or during the period of voluntary reporting. In addition, we are establishing a measure removal process and criteria, defining data collection timeframes and submission deadlines, and clarifying how we refer to the extraordinary circumstances extensions or exemptions process.

3. Summary of Costs and Benefits

In sections XXI. and XXII. of this final rule with comment period, we set forth a detailed analysis of the regulatory and federalism impacts that the changes will have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of the OPPS Update

(1) Impacts of All OPPS Changes

Table 49 in section XXI. of this final rule with comment period displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2015 compared to all estimated OPPS payments in CY 2014. We estimate that the policies in this final rule with comment period will result in a 2.3 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2015, including beneficiary cost-sharing, to the approximate 4,000 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) will be approximately $56.1 billion, an increase of approximately $5.1 billion compared to CY 2014 payments, or $900 million, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our 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 1.3 percent increase in CY 2015 payments to CMHCs relative to their CY 2014 payments.

(2) Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes and application of the frontier State wage index, including changes resulting from the adoption of the new OMB labor market area delineations and the transitional 1-year, 50/50 blended wage index, will mitigate any negative changes due to the new CBSA delineations.

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

There are no significant impacts of our CY 2015 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not making 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 OPD Fee Schedule Increase Factor

We estimate that, for most hospitals, the application of the OPD fee schedule increase factor of 2.2 percent to the conversion factor for CY 2015 will mitigate the small negative impacts of the budget neutrality adjustments. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban and rural hospitals will experience increases of approximately 2.3 percent for urban hospitals and 1.9 percent for rural hospitals. Classifying hospitals by teaching status or type of ownership suggests that these hospitals will receive similar increases.

b. Impacts of the 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 percentage change in estimated total payments by specialty groups under the CY 2015 payment rates compared to estimated CY 2014 payment rates ranges between −4.0 percent for ancillary items and services and 14 percent for hematologic and lymphatic system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our CY 2015 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 CY 2015 proposed 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; and the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013.

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 final rule with comment period. 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 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 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) 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, at that time named the APC Panel. This expert panel, which may be composed of up to 19 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 current charter was amended on November 15, 2011, and the Panel was renamed to reflect expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and therefore to add CAHs to its membership.

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/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage*.

3. Panel Meetings and Organizational Structure

The Panel has held multiple meetings, with the last meeting taking place on August 25, 2014. 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 SIs 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 August 2014 meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the August 2014 Panel meeting are included in the sections of this final rule with comment period 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://fido.gov/facadatabase/public.asp*.

F. Public Comments Received on the CY 2015 OPPS/ASC Proposed Rule

We received approximately 719 timely pieces of correspondence on the CY 2015 OPPS/ASC proposed rule that appeared in the **Federal Register** on July 14, 2014 (79 FR 40915). We note that we received some public comments that are outside the scope of the CY 2015 OPPS/ASC proposed rule. Out-of-scope public comments are not addressed in this CY 2015 OPPS/ASC final rule with comment period. Summaries of those public comments that are within the scope of the proposed rule and our responses are set forth in the various sections of this final rule with comment period under the appropriate headings.

G. Public Comments Received on the CY 2014 OPPS/ASC Final Rule With Comment Period

We received approximately 490 timely pieces of correspondence on the CY 2014 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on December 10, 2013 (78 FR 74826), 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 are set forth in this CY 2015 OPPS/ASC final rule with comment period under the appropriate subject-matter headings.

II. Updates Affecting OPPS Payments

A. 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.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40925), for the CY 2015 OPPS, we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2015, and before January 1, 2016 (CY 2015), using the same basic methodology that we described in the CY 2014 OPPS/ASC final rule with comment period. That is, we proposed 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 2015, we used approximately 149 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, 2013, and before January 1, 2014. For this final rule with comment period, for the purpose of recalibrating the final APC relative payment weights for CY 2015, we used approximately 161 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2013, and before January 1, 2014. For exact counts of claims used, we refer readers to the claims accounting narrative under supporting documentation for the CY 2015 OPPS/ASC proposed rule and this final rule with comment period on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Of the approximately 161 million final action claims for services provided in hospital outpatient settings used to calculate the CY 2015 OPPS payment rates for this final rule with comment period, approximately 123 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 123 million claims, approximately 5 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 118 million claims, we created approximately 101 million single records, of which approximately 50 million were ''pseudo'' single or ''single session'' claims (created from approximately 22 million multiple procedure claims using the process we discuss later in this section). Approximately 1 million claims were trimmed out on cost or units in excess of ± 3 standard deviations from the geometric mean, yielding approximately 101 million single bills for ratesetting. As described in section II.A.2. of this final rule with comment period, 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 final rule with comment period. 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 final APC relative weights and payments for CY 2015 in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site) were calculated using claims from CY 2013 that were processed through June 30, 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 2015 OPPS, we proposed and are using 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 2015 payment rates.

b. Use of Single and Multiple Procedure Claims

For CY 2015, in general, and as we proposed, we are continuing 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 continuing 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 2014 OPPS/ASC final rule with comment period (78 FR 74849 through 74851). 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 2014. 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 2014, and as we proposed, we are continuing this policy for CY 2015. We refer readers to section II.A.2.f. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74910 through 74925) for a discussion of the use of claims in modeling the costs for composite APCs and to section II.A.3. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925 through 74948) for a discussion of our packaging policies for CY 2014. In addition, as we proposed, we are establishing additional packaging policies for the CY 2015 OPPS, as discussed in section II.A.3. of this final rule with comment period.

As we proposed, we are continuing to apply these processes to enable us to use as much claims data as possible for ratesetting for the CY 2015 OPPS. This methodology enabled us to create, for this final rule with comment period, approximately 50 million ''pseudo'' single procedure claims, including multiple imaging composite ''single session'' bills (we refer readers to section II.A.2.f.(4) of this final rule with comment period for further discussion), to add to the approximately 51 million ''natural'' single procedure claims.

For CY 2015, we proposed to bypass 227 HCPCS codes that were identified in Addendum N to the CY 2015 OPPS/ASC 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 2015, data available for the March 10, 2014 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) from CY 2013 claims processed through September 30, 2013, and CY 2012 claims data processed through June 30, 2013, used to model the payment rates for CY 2014) to determine whether it would be appropriate to add additional codes to the previous year's bypass list. For CY 2015, we proposed to continue to bypass all of the HCPCS codes on the CY 2014 OPPS bypass list, with the exception of HCPCS codes that we proposed to delete for CY 2015, which were listed in Table 1 of the proposed rule (79 FR 40927 through 40929). We also proposed 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 proposed to remove from the CY 2015 bypass list are affected by the CY 2015 final packaging policy, discussed in section II.A.3. of this final rule with comment period. In addition, we proposed to add to the bypass list for CY 2015 HCPCS codes not on the CY 2014 bypass list that, using either the CY 2014 final rule with comment period data (CY 2012 claims) or the March 10, 2014 Panel data (first 9 months of CY 2013 claims), met the empirical criteria for the bypass list that are summarized below. Finally, to remain consistent with the CY 2015 proposal to continue to develop OPPS relative payment weights based on geometric mean costs, we also proposed that the packaged cost criterion continue to be based on the geometric mean cost. The entire list proposed for CY 2015 (including the codes that remain on the bypass list from prior years) was open to public comment in the CY 2015 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 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 2014, we proposed to continue to establish the CY 2015 OPPS relative payment weights based on geometric mean costs. To remain consistent in the metric used for identifying cost patterns, we proposed 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 2014 OPPS/ASC final rule with comment period (78 FR 74838), we proposed for CY 2015 to continue to update the packaged cost threshold by the market basket increase. By applying the final CY 2014 market basket increase of 1.7 percent to the prior nonrounded dollar threshold of $54.73 (78 FR 74838), we determined that the threshold remains for CY 2015 at $55 ($55.66 rounded to $55, the nearest $5 increment). Therefore, we proposed to set the geometric mean packaged cost threshold on the CY 2013 claims at $55 for a code to be considered for addition to the CY 2015 OPPS bypass list.

- The code is not a code for an unlisted service. Unlisted codes do not describe a specific service, and thus their costs would not be appropriate for bypass list purposes.

In addition, we proposed to continue to include on the bypass list HCPCS codes that CMS medical advisors believe have minimal associated packaging based on their clinical assessment of the complete CY 2015 OPPS proposal. Some of these codes were identified by CMS medical

advisors and some were identified in prior years by commenters with specialized knowledge of the packaging associated with specific services. We also proposed 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 final rule with comment period 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 multiple imaging composite APCs are identified by asterisks (*) in Addendum N to this final rule with comment period (which is available via the Internet on the CMS Web site).

Comment: One commenter supported the CY 2015 proposal to remove certain codes from the bypass list, in particular for the anatomic pathology procedures, and suggested that the bypass list undervalues codes and artificially lowers their estimated costs, as evidenced by the estimated increase in payment for some of those services in the CY 2015 OPPS/ASC proposed rule.

Response: We appreciate the commenter's support. The bypass list process is used to extract more data from claims that would otherwise be unusable. We use a variety of information in identifying codes that could be potentially added to the bypass list each year, including codes selected based on the empirical criteria, CMS medical advisor recommendations, and commenter requests. In doing so, we attempt to ensure that the amount of packaged cost being redistributed as a result of the process is limited.

After consideration of the public comments we received, we are adopting as final the proposed ''pseudo'' single claims process. As discussed earlier in this section, there are interactions between the application of a bypass list and various other OPPS payment policies. As a result of modifications to the packaging policies described in section III. of this final rule with comment period, we are adding codes that we had originally proposed to remove from the CY 2015 bypass list back on the CY 2015 final OPPS bypass list.

Addendum N to this final rule with comment period (which is available via the Internet on the CMS Web site) includes the list of bypass codes for CY 2015. The list of bypass codes contains codes that were reported on claims for services in CY 2013 and, therefore, includes codes that were in effect in CY 2013 and used for billing but were deleted for CY 2014. We retained these deleted bypass codes on the CY 2015 bypass list because these codes existed in CY 2013 and were covered OPD services in that period, and CY 2013 claims data are used to calculate CY 2015 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 were members of the multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this final rule with comment period. HCPCS codes that we are adding for CY 2015 are identified by asterisks (*) in the fourth column of Addendum N.

Table 1 of the proposed rule contained the list of codes that we proposed to remove from the CY 2015 bypass list (79 FR 40927 through 40929). Table 1 below contains the list of codes that we are removing from the final CY 2015 bypass list because these codes were either deleted from the HCPCS before CY 2013 (and therefore were not covered OPD services in CY 2013) or were not separately payable codes under the CY 2015 OPPS because these codes are not used for ratesetting through the bypass process. The list of codes for removal from the bypass list includes those that will be affected by the CY 2015 OPPS packaging policy described in section II.A.3. of this final rule with comment period.

TABLE 1—HCPCS CODES REMOVED FROM THE CY 2015 BYPASS LIST

HCPCS Code	HCPCS Short descriptor
11056	Trim skin lesions 2 to 4.
11300	Shave skin lesion 0.5 cm/<.
11301	Shave skin lesion 0.6–1.0 cm.
11719	Trim nail(s) any number.
11720	Debride nail 1–5.
11721	Debride nail 6 or more.
17000	Destruct premalg lesion.
17110	Destruct b9 lesion 1–14.
29240	Strapping of shoulder.
29260	Strapping of elbow or wrist.
29280	Strapping of hand or finger.
29520	Strapping of hip.
29530	Strapping of knee.
51741	Electro-uroflowmetry first.
51798	Us urine capacity measure.
53601	Dilate urethra stricture.
53661	Dilation of urethra.
54240	Penis study.
67820	Revise eyelashes.
69210	Remove impacted ear wax uni.
69220	Clean out mastoid cavity.
70030	X-ray eye for foreign body.
70100	X-ray exam of jaw <4 views.
70110	X-ray exam of jaw 4/>≤ views.
70120	X-ray exam of mastoids.
70130	X-ray exam of mastoids.
70140	X-ray exam of facial bones.
70150	X-ray exam of facial bones.
70160	X-ray exam of nasal bones.
70200	X-ray exam of eye sockets.
70210	X-ray exam of sinuses.
70220	X-ray exam of sinuses.
70240	X-ray exam pituitary saddle.
70250	X-ray exam of skull.
70260	X-ray exam of skull.
70320	Full mouth x-ray of teeth.
70328	X-ray exam of jaw joint.
70330	X-ray exam of jaw joints.
70355	Panoramic x-ray of jaws.
70360	X-ray exam of neck.
71021	Chest x-ray frnt lat lordotc.
71022	Chest x-ray frnt lat oblique.
71023	Chest x-ray and fluoroscopy.
71030	Chest x-ray 4/> views.
71035	Chest x-ray special views.
71100	X-ray exam ribs uni 2 views.
71101	X-ray exam unilat ribs/chest.
71110	X-ray exam ribs bil 3 views.
71111	X-ray exam ribs/chest4/> vws.
71120	X-ray exam breastbone 2/> vws.
71130	X-ray strenoclavic jt 3/>vws.
72020	X-ray exam of spine 1 view.
72040	X-ray exam neck spine 2–3 vw.
72050	X-ray exam neck spine 4/5vws.
72052	X-ray exam neck spine 6/>vws.
72069	X-ray exam trunk spine stand.
72070	X-ray exam thorac spine 2vws.
72072	X-ray exam thorac spine 3vws.
72074	X-ray exam thorac spine4/>vw.

TABLE 1—HCPCS CODES REMOVED FROM THE CY 2015 BYPASS LIST—Continued

HCPCS Code	HCPCS Short descriptor
72080	X-ray exam trunk spine 2 vws.
72090	X-ray exam scloiosis erect.
72100	X-ray exam l-s spine 2/3 vws.
72110	X-ray exam l-2 spine 4/>vws.
72114	X-ray exam l-s spine bending.
72120	X-ray bend only l-s spine.
72170	X-ray exam of pelvis.
72190	X-ray exam of pelvis.
72202	X-ray exam si joints 3/> vws.
72220	X-ray exam sacrum tailbone.
73000	X-ray exam of collar bone.
73010	X-ray exam of shoulder blade.
73020	X-ray exam of shoulder.
73030	X-ray exam of shoulder.
73050	X-ray exam of shoulders.
73060	X-ray exam of humerus.
73070	X-ray exam of elbow.
73080	X-ray exam of elbow.
73090	X-ray exam of forearm.
73100	X-ray exam of wrist.
73110	X-ray exam of wrist.
73120	X-ray exam of hand.
73130	X-ray exam of hand.
73140	X-ray exam of finger(s).
73510	X-ray exam of hip.
73520	X-ray exam of hips.
73540	X-ray exam of pelvis & hips.
73550	X-ray exam of thigh.
73560	X-ray exam of knee 1 or 2.
73562	X-ray exam of knee 3.
73564	X-ray exam knee 4 or more.
73565	X-ray exam of knees.
73590	X-ray exam of lower leg.
73600	X-ray exam of ankle.
73610	X-ray exam of ankle.
73620	X-ray exam of foot.
73630	X-ray exam of foot.
73650	X-ray exam of heel.
73660	X-ray exam of toe(s).
74000	X-ray exam of abdomen.
74010	X-ray exam of abdomen.
74020	X-ray exam of abdomen.
74022	X-ray exam series abdomen.
76100	X-ray exam of body section.
76510	Ophth us b & quant a.
76514	Echo exam of eye thickness.
76516	Echo exam of eye.
76519	Echo exam of eye.
76645	Us exam breast(s).
76816	Ob us follow-up per fetus.
76882	Us xtr non-vasc lmtd.
76970	Ultrasound exam follow-up.
76977	Us bone density measure.
77072	X-rays for bone age.
77073	X-rays bone length studies.
77074	X-rays bone survey limited.
77076	X-rays bone survey infant.
77077	Joint survey single view.
77078	Ct bone density axial.
77079	Ct bone density peripheral.
77080	Dxa bone density axial.
77081	Dxa bone density/peripheral.
77082	Dxa bone density vert fx.
77083	Radiographic absorptiometry.
80500	Lab pathology consultation.
80502	Lab pathology consultation.
85097	Bone marrow interpretation.
86510	Histoplasmosis skin test.
86850	Rbc antibody screen.

TABLE 1—HCPCS CODES REMOVED FROM THE CY 2015 BYPASS LIST—Continued

HCPCS Code	HCPCS Short descriptor
86870	Rbc antibody identification.
86880	Coombs test direct.
86885	Coombs test indirect qual.
86886	Coombs test indirect titer.
86900	Blood typing abo.
86901	Blood typing rh (d).
86904	Blood typing patient serum.
86905	Blood typing rbc antigens.
86906	Blood typing rh phenotype.
86930	Frozen blood prep.
86970	Rbc pretx incubatj w/chemicl.
86977	Rbc serum pretx incubj/inhib.
88104	Cytopath fl nongyn smears.
88106	Cytopath fl nongyn filter.
88107	Cytopath fl nongyn sm/fltr.
88108	Cytopath concentrate tech.
88112	Cytopath cell enhance tech.
88120	Cytp urne 3–5 probes ea spec.
88160	Cytopath smear other source.
88161	Cytopath smear other source.
88162	Cytopath smear other source.
88172	Cytp dx eval fna 1st ea site.
88173	Cytopath eval fna report.
88182	Cell marker study.
88184	Flowcytometry/tc 1 marker.
88189	Flowcytometry/read 16 & >.
88300	Surgical path gross.
88302	Tissue exam by pathologist.
88304	Tissue exam by pathologist.
88305	Tissue exam by pathologist.
88307	Tissue exam by pathologist.
88312	Special stains group 1.
88313	Special stains group 2.
88321	Microslide consultation.
88323	Microslide consultation.
88325	Comprehensive review of data.
88329	Path consult introp.
88331	Path consult intraop 1 bloc.
88342	Immunohisto antibody slide.
88346	Immunofluorescent study.
88347	Immunofluorescent study.
88348	Electron microscopy.
88358	Analysis tumor.
88360	Tumor immunohistochem/manual.
88361	Tumor immunohistochem/comput.
88365	Insitu hybridization (fish).
88368	Insitu hybridization manual.
88385	Eval molecul probes 51–250.
88386	Eval molecul probes 251–500.
89049	Chct for mal hyperthermia.
89220	Sputum specimen collection.
89230	Collect sweat for test.
89240	Pathology lab procedure.
92020	Special eye evaluation.
92025	Corneal topography.
92060	Special eye evaluation.
92081	Visual field examination(s).
92082	Visual field examination(s).
92083	Visual field examination(s).
92133	Cmptr ophth img optic nerve.
92134	Cptr ophth dx img post segmt.
92136	Ophthalmic biometry.
92225	Special eye exam initial.
92226	Special eye exam subsequent.
92230	Eye exam with photos.
92250	Eye exam with photos.
92285	Eye photography.

TABLE 1—HCPCS CODES REMOVED FROM THE CY 2015 BYPASS LIST—Continued

HCPCS Code	HCPCS Short descriptor
92286	Internal eye photography.
92520	Laryngeal function studies.
92541	Spontaneous nystagmus test.
92542	Positional nystagmus test.
92550	Tympanometry & reflex thresh.
92552	Pure tone audiometry air.
92553	Audiometry air & bone.
92555	Speech threshold audiometry.
92556	Speech audiometry complete.
92557	Comprehensive hearing test.
92567	Tympanometry.
92570	Acoustic immitance testing.
92582	Conditioning play audiometry.
92603	Cochlear implt f/up exam 7/>.
92604	Reprogram cochlear implt 7/>.
92626	Eval aud rehab status.
93005	Electrocardiogram tracing.
93017	Cardiovascular stress test.
93225	Ecg monit/reprt up to 48 hrs.
93226	Ecg monit/reprt up to 48 hrs.
93270	Remote 30 day ecg rev/report.
93278	Ecg/signal-averaged.
93279	Pm device progr eval sngl.
93280	Pm device progr eval dual.
93281	Pm device progr eval multi.
93282	Icd device progr eval 1 sngl.
93283	Icd device progr eval dual.
93284	Icd device progr eval mult.
93285	Ilr device eval progr.
93288	Pm device eval in person.
93289	Icd device interrogate.
93290	Icm device eval.
93291	Ilr device interrogate.
93292	Wcd device interrogate.
93293	Pm phone r-strip device eval.
93296	Pm/icd remote tech serv.
93299	Icm/ilr remote tech serv.
93701	Bioimpedance cv analysis.
93786	Ambulatory bp recording.
93788	Ambulatory bp analysis.
93875	Extracranial study.
94015	Patient recorded spirometry.
94690	Exhaled air analysis.
95803	Actigraphy testing.
95869	Muscle test thor paraspinal.
95900	Motor nerve conduction test.
95921	Autonomic nrv parasym inervj.
95970	Analyze neurostim no prog.
96900	Ultraviolet light therapy.
96910	Photochemotherapy with uv-b.
96912	Photochemotherapy with uv-a.
96920	Laser tx skin < 250 sq cm.
96921	Laser tx skin 250–500 sq cm.
98925	Osteopath manj 1–2 regions.
98926	Osteopath manj 3–4 regions.
98927	Osteopath manj 5–6 regions.
98928	Osteopath manj 7–8 regions.
98929	Osteopath manj 9–10 regions.
98940	Chiropract manj 1–2 regions.
98941	Chiropract manj 3–4 regions.
98942	Chiropractic manj 5 regions.
G0127	Trim nail(s).
G0130	Single energy x-ray study.
G0166	Extrnl counterpulse, per tx.
G0239	Oth resp proc, group.
G0389	Ultrasound exam aaa screen.
G0404	Ekg tracing for initial prev.
G0424	Pulmonary rehab w exer.
Q0091	Obtaining screen pap smear.

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

In the CY 2015 OPPS/ASC proposed rule (79 FR 40929), we proposed 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 2015 APC payment rates were based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2013 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, were from CY 2012. For the CY 2015 OPPS proposed rates, we used the set of claims processed during CY 2013. 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 2013 (the year of claims data we used to calculate the proposed CY 2015 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2013 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.(2) of this final rule with comment period.

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 2013 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 2012. For the proposed rule, we used the most recently submitted cost reports to calculate the CCRs to be used to calculate costs for the proposed CY 2015 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 proposed to continue this longstanding methodology for the calculation of costs for CY 2015.

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 for the CY 2014 OPPS and, as we proposed, we are continuing this practice for the CY 2015 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 HCRIS update for the CY 2015 final rule cycle, which we used to estimate costs in the CY 2015 OPPS ratesetting process, as discussed in the CY 2015 OPPS/ASC proposed rule (79 FR 40930), we were able to calculate a valid implantable device CCR for 2,895 hospitals, a valid MRI CCR for 1,934 hospitals, a valid CT scan CCR for 2,035 hospitals, and a valid Cardiac Catheterization CCR for 1,397 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 proposed rule (78 FR 43550), we have 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, and proposed to continue for the CY 2015 OPPS, to calculate the OPPS relative payment weights using distinct CCRs for cardiac catheterization, CT scan, MRI, and implantable medical devices. Section XXI. of this final rule with comment period includes the impacts of calculating the CY 2015 OPPS relative payment weights using these new standard cost centers.

Comment: A few commenters encouraged CMS to ensure data quality and continue to test, refine, and improve its CCR analysis for CT scans and MRI.

Response: We will continue to monitor the CCRs for these services.

After consideration of the public comments we received, we are finalizing our proposal to calculate the OPPS relative payment weights using distinct CCRs for cardiac catheterization, CT scan, MRI, and implantable medical devices for CY 2015 without modification.

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	0.0464	0.0608	0.0901	0.1151
Square Feet Only	0.0370	0.0502	0.0787	0.1013
Direct Assign	0.0640	0.0740	0.1063	0.1294
Dollar Value	0.0555	0.0718	0.1046	0.1298
Direct Assign and Dollar Value	0.0554	0.0715	0.1047	0.1297

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 2015.

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

CY 2015 APC	CY 2015 APC Descriptor	Percent change
0283	Computed Tomography with Contrast	9.6
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast	4.0
0331	Combined Abdomen and Pelvis CT without Contrast	12.1
0332	Computed Tomography without Contrast	14.5
0333	Computed Tomography without Contrast followed by Contrast	12.3
0334	Combined Abdomen and Pelvis CT with Contrast	10.1
0336	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast	7.5
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast f	6.4
0383	Cardiac Computed Tomographic Imaging	3.6
0662	CT Angiography	10.3
8005	CT and CTA without Contrast Composite	12.8
8006	CT and CTA with Contrast Composite	9.4
8007	MRI and MRA without Contrast Composite	6.7
8008	MRI and MRA with Contrast Composite	6.9

Comment: A few commenters supported CMS' proposal to continue removing claims from providers that use the ''square feet'' cost allocation method from the cost model. One commenter suggested that CMS continue removing claims from providers that use this method in CY 2018 and beyond.

Response: We thank the commenters for their support and are finalizing this policy as proposed. We will continue to only include cost data from providers that do not use ''square feet'' as the cost allocation statistic in relative payment weights through CY 2017. For CY 2018 and beyond, 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 summary, as we proposed, we are continuing 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 2015 OPPS. For the ''Magnetic Resonance Imaging (MRI)'' and ''Computed Tomography (CT) Scan'' APCs identified in Table 3 of this final rule with comment period, we are continuing our policy of removing claims from cost modeling for those providers using ''square feet'' as the cost allocation statistic for CY 2015.

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

In this section of this final rule with comment period, we discuss the use of claims to calculate the OPPS payment rates for CY 2015. The Hospital OPPS page on the CMS Web site on which this final rule with comment period 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 final 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 2013 claims that were used to calculate the final payment rates for the CY 2015 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 2015, as we proposed, we are continuing to use geometric mean costs to calculate the relative weights on which the CY 2015 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.f. of this final rule with comment period to calculate the costs we used to establish the relative weights used in calculating the OPPS payment rates for CY 2015 shown in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site). We refer readers to section II.A.4. of this final rule with comment period for a discussion of the conversion of APC costs to scaled payment weights.

a. Claims Preparation

For this final rule with comment period, we used the CY 2013 hospital outpatient claims processed through June 30, 2014, to calculate the geometric mean costs of APCs that underpin the relative payment weights for CY 2015. To begin the calculation of the relative payment weights for CY 2015, we pulled all claims for outpatient services furnished in CY 2013 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 123 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 final rule with comment period. 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 claims from all 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. For the CY 2014 OPPS, we continued the CY 2013 payment policy for separately payable drugs and biologicals, and we are continuing this payment policy for CY 2015. We refer readers to section V.B.3. of this final rule with comment period for a complete discussion of our CY 2015 final payment policy for separately paid drugs and biologicals.

We then removed line-items that were not paid during claim 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 2014 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 2015, as we proposed, we are continuing the policy we implemented for CY 2013 and CY 2014 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 2014 OPPS/ASC final rule with comment period (78 FR 74849) of line-items with a status indicator of ''S,'' ''T,'' ''V,'' or ''X,'' we believe that unpaid line-items represent services that are invalidly reported and, therefore, should not be used for ratesetting. 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 2015 OPPS, as part of our continued packaging of clinical diagnostic laboratory tests, we also are applying 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 2015 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 2015 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, under the proposed CY 2015 OPPS packaging policy (79 FR 40933), we proposed to delete status indicator ''X'' and revise the title and description of status indicator ''Q1'' to reflect that deletion, as discussed in sections II.A.3. and XI. of this final rule with comment period. We note that we also proposed to create status indicator ''J1'' to reflect the comprehensive APCs (C–APCs) discussed in section II.A.2.e. of this final rule with comment period. For CY 2015, we proposed to define major procedures as any HCPCS code having a status indicator of ''J1,'' ''S,'' ''T,'' or ''V,'' define minor procedures as any code having a status indicator of ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N,'' and classify ''other'' procedures as any code having a status indicator other than one that we have classified as major or minor. For CY 2015, we proposed 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. As we proposed, we are treating these codes in the same manner for data purposes for CY 2015 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 final rule with comment period.

Specifically, we divided 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,'' which receive special processing for C–APCs, as discussed in section II.A.2.e. of this final rule with comment period; 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 final rule with comment period, depending on the specific composite calculation.

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

To develop ''pseudo'' single procedure claims for this final rule with comment period, 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).

As proposed, we also use the bypass codes listed in Addendum N to this final rule with comment period (which is available via the Internet on our Web site) and discussed in section II.A.1.b. of this final rule with comment period 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 final CY 2015 ''overlap bypass codes'' are listed in Addendum N to this final rule with comment period (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 criteria for the multiple imaging composite APCs, discussed in section II.A.2.f.(5) of this final rule with comment period, 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 CY 2015 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.

As we proposed, we also examined 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 2014 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 2014 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 2014 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 2014 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 2014 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 2014 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 2014 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 2014 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 2014 relative payment weights. If a status indicator ''Q1'' HCPCS code had a higher CY 2014 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 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 final rule with comment period.

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 modifier (Modifier 50 (Bilateral procedure)) 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 proposed to continue to apply the methodology described above for the purpose of creating ''pseudo'' single procedure claims for the CY 2015 OPPS.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to continue to apply the methodology described above for the purpose of creating ''pseudo'' single procedure claims for the CY 2015 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 final rule with comment period (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 final CY 2015 OPPS packaging policy, we refer readers to section II.A.3. of this final rule with comment period.

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, and as we proposed, we are continuing to compare the final list of packaged revenue codes that we adopt for CY 2015 to the revenue codes that the I/OCE will package for CY 2015 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 2015, as we did for CY 2014, we reviewed the changes to revenue codes that were effective during CY 2013 for purposes of determining the charges reported with revenue codes but without HCPCS codes that we proposed to package for CY 2015. We believe that the charges reported under the revenue codes listed in Table 4 of the proposed rule continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes. Therefore, for CY 2015, we proposed to continue to package the costs that we derive from the charges reported without HCPCS codes under the revenue codes displayed in Table 4 of the proposed rule for purposes of calculating the geometric mean costs on which the final CY 2015 OPPS/ASC payment rates are based.

Comment: One commenter recommended that CMS include, in the list of packaged revenue codes, revenue codes 0331 (Radiology—Therapeutic and/or Chemotherapy Administration; Chemotherapy Admin—Injected), 0332 (Radiology—Therapeutic and/or Chemotherapy Administration; Chemotherapy Admin—Oral), 0335 (Radiology—Therapeutic and/or Chemotherapy Administration; Chemotherapy Admin—IV), 0360 (Operating Room Services; General Classification), 0361 (Operating Room Services; Minor Surgery), 0362 (Operating Room Services; Organ Transplant—Other than Kidney), 0369 (Operating Room Services; Other OR Services), 0410 (Respiratory Services; General Classification), 0412 (Respiratory Services; Inhalation Services), 0413 (Respiratory Services; Hyperbaric Oxygen Therapy), 0419 (Respiratory Services; Other Respiratory Services), 0722 (Labor Room/Delivery; Delivery Room), 0724 (Labor Room/Delivery; Birthing Center), 0729 (Labor Room/Delivery; Other Labor Room/Delivery), 0760 (Specialty Services; General Classification), 0761 (Specialty Services; Treatment Room), 0762 (Specialty Services; Observation), 0769 (Specialty Services; Other Specialty Services), 0770 (Preventive Care Services; General Classification). The commenter stated that charge data on claim lines with these revenue codes is currently included in OPPS modeling, and including them when they appear without a HCPCS would more accurately capture the costs from these lines.

Response: On the OPPS revenue code-to-cost center modeling crosswalk that we make available online, we indicate which revenue codes we believe are appropriately used for OPPS ratesetting purposes. As the commenter noted, coded lines billed using these specific revenue codes are already currently included for ratesetting purposes. While we note that including the packaged costs associated with uncoded lines billed with these revenue codes has a minimal impact on the relative payment weights, we believe that including them when establishing the OPPS relative payment weights would better estimate the full range of costs for services to which these lines are packaged. Including the uncoded lines and capturing the costs billed using these revenue codes would generally be appropriate in establishing the OPPS relative payment weights and our ratesetting methodology. Therefore, we have updated Table 4 which appeared in the proposed rule (79 FR 40935

through 40936) (also Table 4 in this final rule with comment period) to reflect the addition of these packaged revenue codes and incorporated these changes into our cost modeling logic. We will also ensure that this list corresponds with that used for I/OCE purposes.

After consideration of the public comments we received, we are finalizing the proposed packaged revenue codes for CY 2015, which are identified in Table 4 below, with modification to include the revenue codes described earlier in this section.

TABLE 4—CY 2015 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.
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.

TABLE 4—CY 2015 PACKAGED REVENUE CODES—Continued

Revenue code	Description
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.
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 proposed 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 proposed to continue these processes for the CY 2015 OPPS.

For the remaining claims, we proposed 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 proposed 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 proposed to use these pre-reclassified wage indices for standardization using the new OMB labor market area delineations described in section II.C. of this final rule with comment period.

In accordance with our longstanding practice, we also proposed 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 118 million claims were left. Using these approximately 118 million claims, we created approximately 100 million single and ''pseudo'' single procedure claims, of which we used approximately 51 million single bills (after trimming out approximately 1 million claims as discussed in section II.A.1.a. of this final rule with comment period) in the CY 2015 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 CY 2013 OPPS and the CY 2014 OPPS, we calculated the APC relative payment weights using geometric mean costs, and we are continuing this practice for CY 2015. 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 2015 OPPS/ASC policy to calculate relative payment weights based on geometric means, we refer readers to section II.A.2.f. of this final rule with comment period.

We proposed to use these claims to calculate the CY 2015 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 2015 OPPS, we are continuing 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 100 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 CY 2015 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 pay separately under this final rule with comment period, and we reassigned HCPCS codes to different APCs where it was necessary to ensure clinical and resource homogeneity within the APCs. The 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.

We did not receive any public comments on our proposed CY 2015 methodology for calculating the geometric mean costs upon which the CY 2015 OPPS payment rates are based, and therefore are finalizing our methodology as proposed.

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

(2) Recommendations of the Panel Regarding Data Development

At the August 2014 meeting of the Panel, we discussed changes in APC geometric mean cost between the CY 2015 Proposed OPPS and the CY 2014 Final OPPS, the CY 2015 proposed comprehensive APC policy, and a study examining the packaged codes most commonly appearing with clinic visit codes.

At the August 2014 Panel meeting, the Panel made a number of 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 Jim Nelson serve as the Chair of the Data Subcommittee.

CMS Response: We are accepting this recommendation.

Recommendation: The Panel recommends that CMS provide the Panel with a list of APCs for which costs fluctuate by more than 20 percent relative to the APCs in the most recent prior rulemaking cycle.

CMS Response: We are accepting this recommendation and will provide this information regarding fluctuating APC costs at the next HOP Panel meeting.

d. Calculation of Single Procedure APC Criteria-Based Costs

(1) Device-Dependent APCs

Historically, device-dependent APCs are populated by HCPCS codes that usually, but not always, require that a device be implanted or used to perform the procedure. The standard methodology for calculating device-dependent APC costs utilizes claims data that generally reflect the full cost of the required device by using only the subset of single procedure claims that pass the procedure-to-device and device-to-procedure edits; do not contain token charges (less than $1.01) for devices; and, until January 1, 2014, did not contain the ''FB'' modifier signifying that the device was furnished without cost to the provider, or where a full credit was received; and do not contain the ''FC'' modifier signifying that the hospital received partial credit for the device. For a full history of how we have calculated payment rates for device-dependent APCs in previous years and a detailed discussion of how we developed the standard device-dependent APC ratesetting methodology, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66739 through 66742). Overviews of the procedure-to-device edits and device-to-procedure edits used in ratesetting for device-dependent APCs are available in the CY 2005 OPPS final rule with comment period (69 FR 65761 through 65763) and the CY 2007 OPPS/ASC final rule with comment period (71 FR 68070 through 68071).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74857 through 74859), we finalized a policy to define 29 device-dependent APCs as single complete services and to assign them to comprehensive APCs (C–APCs) that provide all-inclusive payments for those services, but we delayed implementation of this policy until CY 2015 (78 FR 74862). This policy is a further step toward improving the prospective nature of our payments for these services where the cost of the device is relatively high compared to the other costs that contribute to the cost of the service. Table 5 of the CY 2014 OPPS/ASC final rule with comment period provided a list of the 39 APCs recognized as device-dependent APCs and identified the 29 device-dependent APCs that would have been converted to C–APCs. In addition, in the CY 2014 OPPS/ASC final rule with comment period, we finalized a policy for the treatment of the remaining 10 device-dependent APCs that applied our standard APC ratesetting methodology to calculate the CY 2014 payment rates for these APCs, but implementation of the entire policy was delayed until CY 2015.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43556 through 43557) and in the CY 2015 OPPS/ASC proposed rule (79 FR 40937 through 40938), for CY 2015, we proposed to no longer implement procedure-to-device edits and device-to-procedure edits for any APC. Under this proposed policy, which was discussed but not finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74857 through 74858), hospitals are still expected to adhere to the guidelines of correct coding and append the correct device

code to the claim, when applicable. However, claims would no longer be returned to providers when specific procedure and device code pairings do not appear on a claim. As we stated in both the CY 2014 OPPS/ASC proposed rule (78 FR 43556 through 43557) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 74857 through 74858), we believe that this is appropriate because of hospitals' multiyear experience in coding and reporting charges for medical device implantation procedures. We also believe that the C–APCs will reliably reflect the cost of the devices as the C–APCs will include all costs on the claim (except for the few categories of items and services that are excluded from the comprehensive APC policy). Therefore, we do not believe that the burden imposed upon hospitals to adhere to the procedure-to-device edits and device-to-procedure edits and the burden imposed upon the Medicare program to maintain those edits continue to be necessary. As with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

The CY 2015 comprehensive APC policy that we proposed in the CY 2015 OPPS/ASC proposed rule consolidates and restructures the 39 current device-dependent APCs into 26 (of the total 28) proposed C–APCs, which were listed in Table 5 of the proposed rule. The final CY 2015 comprehensive APC policy is discussed in section II.A.2.e. of this final rule with comment period. As a result of the final CY 2015 comprehensive APC policy, only 3 of the current 39 device-dependent APCs will remain in the CY 2015 OPPS because all other device-dependent APCs are being converted to C–APCs. All of the remaining device-dependent APCs were either deleted due to the consolidation and restructuring of these APCs or they were converted to C–APCs. In conjunction with the conversion of almost all of the 39 device-dependent APCs into C–APCs, and as discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74857 through 74858), in the CY 2015 OPPS/ASC proposed rule, we proposed to no longer use procedure-to-device edits and device-to-procedure edits for any APC because we continue to believe that the elimination of device-to-procedure edits and procedure-to-device edits is appropriate considering the experience that hospitals now have in coding and reporting these claims fully and, for the more costly devices, the C–APCs will reliably reflect the cost of the device if it is included anywhere on the claim.

While we believe that device-to-procedure edits and procedure-to-device edits are no longer necessary, we are sensitive to the concerns raised by stakeholders in the past about the costs of devices being reported and captured. In light of these concerns, in the CY 2015 OPPS/ASC proposed rule (79 FR 40937 through 40938), we proposed to create claims processing edits that require *any* of the device codes used in the previous device-to-procedure edits for device-dependent APCs to be present on the claim whenever a procedure code assigned to any of the former device-dependent APCs (most of which are being converted to C–APCs) is reported on the claim to ensure that device costs are captured by hospitals. We stated that we expect that hospitals would use an appropriate device code consistent with correct coding in order to ensure that device costs are always reported on the claim, so that costs are appropriately captured in claims that CMS uses for ratesetting.

Comment: The majority of commenters requested that CMS maintain device-to-procedure and procedure-to-device edits in order to ensure continued complete and accurate cost reporting by hospitals. One commenter recommended that CMS adopt its proposal to require any appropriate device code used in the previous device-to-procedure edits to be present on the claim, if CMS discontinues the current edits and educates hospitals on the continued need to report the actual device used in the procedure for accurate ratesetting. One commenter was cautiously optimistic that CMS' proposal requiring any appropriate device code used in the previous device-to-procedure edits to be present on the claim for most comprehensive APCs could promote complete reporting in a potentially less prescriptive way for hospitals. Another commenter believed CMS' proposed policy change would result in ''ridiculous'' combinations of device and procedure codes for some services and thus would result in invalid mean costs for the procedures. Other commenters recommended that CMS modify its proposed policy to incorporate edit logic that will allow exceptions for comprehensive APCs that do not require device codes to be reported with every assigned procedural code. One commenter recommended that the claims edits be implemented initially on a 1-year trial/interim basis. Other commenters suggested that CMS eliminate the device claims processing edits altogether.

Response: We continue to believe that the elimination of device-to-procedure edits and procedure-to-device edits is appropriate due to the experience hospitals now have in coding and reporting these claims fully. More specifically, for the more costly devices, we believe the C–APCs will reliably reflect the cost of the device if charges for the device are included anywhere on the claim. We remind commenters that, under our proposed policy, hospitals would still be expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable. We also remind commenters that, as with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place. We do not believe that our proposed policy will result in ridiculous combinations of device and procedure codes for some services, as this would require deliberate miscoding by hospitals, which we do not believe would result from this change to the device code reporting requirements. We continue to expect that hospitals would use an appropriate device code consistent with correct coding in order to ensure that device costs are always reported on the claim, so that costs are appropriately captured in claims that CMS uses for ratesetting. While we believe that device-to-procedure edits and procedure-to-device edits are no longer necessary at this time, we are sensitive to commenters' concerns that all relevant costs for the APCs currently recognized as device-dependent APCs are appropriately included in the claims that CMS will use for ratesetting. In light of those concerns, we believe creating a claims processing edit requiring a device code to be present on the claim whenever a procedure code from the APCs currently recognized as a device-dependent APCs will help to ensure continued complete and accurate cost reporting by hospitals. Device edits will not apply to procedures assigned to C–APCs that either do not use implantable medical devices or procedures that do not have device-to-procedure or procedure-to-device edits assigned to them currently for CY 2014. This will ensure that the proposed device edit policy (requiring only that any device code be reported on a claim containing a procedure assigned to one of the formerly device-dependent APCs) will only apply to those procedures that currently have device-to-procedure or

procedure-to-device edits currently assigned to them.

After consideration of the public comments we received, we are finalizing our proposal to no longer implement specific procedure-to-device and device-to-procedure edits for any APC. We also are finalizing our proposal to create 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 current device-dependent APCs (that remain after the consolidation and restructuring of these APCs) listed in Table 5 below is reported on the claim to ensure that device costs are captured by hospitals. CMS will monitor the claims data to ensure that hospitals continue reporting appropriate device codes on the claims for the formerly device-dependent APCs. We note that while we proposed to make all 26 of the APCs listed in Table 5 C–APCs for CY 2015, in section II.A.2.e. of this final rule with comment period, we are not finalizing our proposal to recognize APCs 0427, 0622, and 0652 as C–APCs. While APCs 0427, 0622, and 0652 will not be recognized as comprehensive APCs for CY 2015, our finalized device edit policy will apply to these 3 APCs, as these 3 APCs are formerly device-dependent APCs. The term ''device-dependent APC'' will no longer be employed beginning in CY 2015. We will refer to APCs with a device offset of more than 40 percent as ''device-intensive'' APCs. Device-intensive APCs will be subject to the no cost/full credit and partial credit device policy. For a discussion of device-intensive APCs and the no cost/full credit and partial credit device policy, we refer readers to section IV.B. of this final rule with comment period. For a discussion of ASC procedures designated as device intensive, we refer readers to section XII.C.1.c. of this final rule with comment period.

TABLE 5—APCS THAT WILL REQUIRE A DEVICE CODE TO BE REPORTED ON A CLAIM WHEN A PROCEDURE ASSIGNED TO ONE OF THESE APCS IS REPORTED

APC	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.

TABLE 5—APCS THAT WILL REQUIRE A DEVICE CODE TO BE REPORTED ON A CLAIM WHEN A PROCEDURE ASSIGNED TO ONE OF THESE APCS IS REPORTED—Continued

APC	APC Title
0108	Level II ICD.
0202	Level V Female Reproductive.
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.

(2) 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.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40938), for CY 2015, we proposed 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 proposed 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 proposed 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 proposed to calculate the costs upon which the proposed CY 2015 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.

Comment: Commenters supported the proposal to continue to separately pay for blood and blood products using a blood-specific CCR methodology.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal 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.

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 2015 will 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 and this final rule with comment period, we established comprehensive APCs that will provide all-inclusive payments for certain device-dependent procedures. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these comprehensive APCs. We proposed 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 comprehensive APCs (79 FR 40939). Because the costs of blood and blood products will be reflected in the overall costs of the comprehensive APCs (and, as a result, in the final payment rates of the comprehensive APCs), we proposed to not make separate payments for blood and blood products when they appear on the same claims as services assigned to the comprehensive APCs (79 FR 40939).

We did not receive any public comments on this proposal and are finalizing the policy as proposed. We refer readers to Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site) for the final CY 2015 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).

(3) 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 2008 OPPS/ASC final rule with comment period (72 FR 66779 through 66787), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68668 through 68670, the CY 2010 OPPS/ASC final rule with comment period (74 FR 60533 through 60537), the CY 2011 OPPS/ASC final rule with comment period (75 FR 71978 through 71981), the CY 2012 OPPS/ASC final rule with comment period (76 FR 74160 through 74163), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68240 through 68242), and the CY 2014 OPPS/ASC final rule with comment period (78 FR 74860) for further discussion of the history of OPPS payment for brachytherapy sources.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40939 through 40940), for CY 2015, we proposed to use the costs derived from CY 2013 claims data to set the proposed CY 2015 payment rates for brachytherapy sources, as we proposed to use to set the proposed payment rates for most other items and services that would be paid under the CY 2015 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 the proposed rule. We also proposed 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 proposed to pay for the stranded and non-stranded not otherwise specified (NOS) codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or non-stranded 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). We also proposed 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 2015 payment rates for brachytherapy sources were included in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site) and were identified with status indicator ''U.''

We invited public comment on this proposed policy and also requested recommendations for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources. In the CY 2015 OPPS/ASC proposed rule, we provided an appropriate address for receipt of these recommendations; the address is repeated at the end of this section. We indicated that we will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

Comment: Commenters expressed a number of concerns regarding CMS' outpatient hospital claims data used to set prospective payment rates for brachytherapy sources. Commenters stated that high dose rate (HDR) brachytherapy devices decay over a 90-day period and are used to treat multiple patients during this time period. According to the commenters, the true cost of brachytherapy sources depends on the number of patients treated by a hospital within a 90-day period, as well as the number of treatments required and the intensity of the treatments. For this reason, the commenters believed that it is difficult to establish fair and adequate prospective payment rates for brachytherapy sources. Commenters also noted that the brachytherapy source payment data continue to show huge variation in per unit cost across hospitals. In addition, the commenters believed that CMS' claims data contain rank order anomalies, causing the usual cost relationship between the high activity palladium-103 source (HCPCS code C2635, Brachytherapy source, non-stranded, high activity, palladium-103, greater than 2.2 mci (NIST) per source) and the low activity palladium-103 sources (HCPCS codes C2640, Brachytherapy source, stranded, palladium-103, per source and C2641, Brachytherapy source, non-stranded,

palladium-103, per source) to be reversed. The commenters noted that the proposed geometric mean costs of the brachytherapy source HCPCS codes are approximately $26, $69, and $72, respectively. The commenters stated that stranded palladium-103 sources (HCPCS code C2640) always cost more than non-stranded palladium-103 sources (HCPCS code C2641), which is not reflected in the proposed rule claims data.

Response: As stated above, we believe that geometric mean costs based on hospital claims data for brachytherapy sources have produced reasonably consistent per-source cost estimates over the past several years, comparable to the patterns we have observed for many other OPPS services whose payments are set based upon relative payment weights from claims data. We believe that our per-source payment methodology specific to each source's radioisotope, radioactive intensity, and stranded or non-stranded configuration, supplemented by payment based on the number of sources used in a specific clinical case, adequately accounts for the major expected sources of variability across treatments. (We refer readers to the CY 208 OPPS final rule with comment period (72 FR 66782); the CY 2010 OPPS/ASC final rule with comment period (74 FR 60534); the CY 2011 OPPS/ASC final rule with comment period (75 FR 71979); the CY 2012 OPPS/ASC final rule with comment period (76 FR 74161); the CY 2013 OPPS/ASC final rule with comment period (77 FR 68241); and the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861)). We believe that the CY 2013 brachytherapy source claims data used for CY 2015 ratesetting produce adequate payment for these services. Also, as we have explained previously, a prospective payment system relies upon the concept of averaging, where the payment may be more or less than the estimated cost of providing a service for a particular patient. With the exception of outlier cases, the payment for services is adequate to ensure access to appropriate care. In the case of brachytherapy sources for which the law requires separate payment groups, without packaging, the costs of these individual items could be expected to show greater variation than some other APCs under the OPPS because higher variability in costs for some component items and services is not balanced with lower variability in costs for others, and because relative payment weights are typically estimated using a smaller set of claims. Nevertheless, we believe that prospective payment for brachytherapy sources based on geometric mean costs of the services reported on claims calculated according to the standard OPPS methodology is appropriate and provides hospitals with the greatest incentives for efficiency in furnishing brachytherapy treatment.

Under the budget neutral provision for the OPPS, it is the relativity of costs, not the absolute costs, that is important, and we believe that brachytherapy sources are appropriately paid according to the standard OPPS payment approach. Furthermore, some sources may have geometric mean costs and payment rates based on 50 or fewer providers because it is not uncommon for OPPS prospective payment rates to be based on claims from a relatively small number of hospitals that furnished the service in the year of claims data available for the OPPS update year. Fifty hospitals may report hundreds of brachytherapy source services on claims for many cases and comprise the universe of providers using particular low volume sources, for which we are required to pay separately by statute. Further, our methodology for estimating geometric mean costs for brachytherapy sources utilizes all line-item charges for those sources, which allows us to use all hospital reported charge and estimated cost information to set payment rates for these items. Therefore, no brachytherapy source claims are excluded from the estimate of geometric means costs. We have no reason to believe that prospective payment rates based on claims data from those providers furnishing a particular source do not appropriately reflect the cost of that source to hospitals. As for most other OPPS services, we note that the geometric mean costs for brachytherapy sources are based upon the costs of those providers sources in CY 2013. Hospitals individually determine their charge for an item or service, and one of Medicare's primary requirements for setting a charge is that it be reasonably and consistently related to the cost of the item or service for that facility. (We refer readers to the Medicare Provider Reimbursement Manual, Part I, Section 2203, 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.*) We then estimate a cost from that charge using the hospital's most recent Medicare hospital cost report data in our standard OPPS ratesetting process.

We acknowledge that HDR brachytherapy sources such as HDR iridium-192 have a fixed active life and must be replaced every 90 days. As a result, a hospital's per treatment cost for the source would be dependent on the number of treatments furnished per source. The source's cost must be amortized over the life of the source. Therefore, when establishing charges for HDR iridium-192, we expect hospitals to project the number of treatments that would be provided over the life of the source and establish charges for the source accordingly (72 FR 66783; 74 FR 60535; 75 FR 71980; 76 FR 74162; 77 FR 68242; and 78 FR 74861). For most payable services under the OPPS, our practice is to establish prospective payment rates based on the geometric mean costs determined from hospitals' claims data to provide incentives for efficient and cost effective delivery of these services.

In the case of high-activity and low-activity iodine-125 sources, our CY 2013 claims data show that the hospitals' relative costs for the high-activity source are greater than the costs of the low-activity sources. As we have stated in the past, we do not have any information about the expected cost differential between high-activity and low-activity sources of various isotopes other than what is available in our claims and hospital cost report data (75 FR 71979; 76 FR 74162; 77 FR 68242; and 78 FR 74861). In the case of the relationship between high-activity and low-activity palladium-103, our claims data consistently have shown higher average costs for low-activity palladium-103. For the high-activity palladium-103 sources (HCPCS code C2635), 8 hospitals reported this service in CY 2013, compared to 104 and 159 hospitals that reported services for the low-activity palladium-103 sources described by HCPCS codes C2640 and C2641, respectively. It is clear that fewer hospitals furnished the high-activity palladium-103 source than the low-activity palladium-103 sources, and we expect that the hospital cost distribution for those hospitals could be different than the cost distribution of the large numbers of hospitals reporting the low-activity palladium-103 sources, as previously stated (74 FR 60535; 75 FR 71979; 76 FR 74162; 77 FR 68242; and 78 FR 74861). These varied cost distributions clearly contribute to the observed relationship in geometric mean cost between the different types of sources. However, we see no reason why our standard ratesetting methodology for brachytherapy sources that relies on all claims data from all hospitals furnishing brachytherapy sources would not yield valid geometric

mean costs for those hospitals furnishing the different brachytherapy sources upon which CY 2015 prospective payments are based.

Comment: One commenter, a developer of a linear non-stranded palladium-103 source described by HCPCS code C2636 (Brachytherapy linear source, nonstranded, palladium-103, per 1 mm), believed that CY 2013 claims data for services furnished prior to November 2013 used to determine the CY 2015 payment rates are invalid because the claims data do not reflect the costs of its linear non-stranded palladium-103 source, which became commercially available in November 2013. Further, the commenter stated that there were no other linear non-stranded palladium-103 sources commercially available prior to November 2013. Therefore, the commenter requested that payment for HCPCS code C2636 remain at the current CY 2014 payment rate until claims data for HCPCS code C2636 become available in CY 2016.

Response: We understand the commenter's claim that its linear non-stranded palladium-103 source described by HCPCS code C2636 became commercially available in November 2013. However, we disagree with the commenter's assertion that there were no other commercially available linear non-stranded palladium-103 sources described by HCPCS code C2636 prior to November 2013. We also disagree with the commenter that the CY 2013 claims data used to determine the CY 2015 payment rate for HCPCS code C2636 are invalid. As discussed in the CY 2005 OPPS final rule (69 FR 65840), we established HCPCS code C2636 to uniquely identify linear non-stranded Palladium-103 brachytherapy sources. Since the HCPCS code became effective January 1, 2005, we have used historical claims data to set the prospective payment rates. To determine the CY 2015 OPPS payment rate for HCPCS code C2636, we used CY 2013 claims data, which include brachytherapy sources costs for linear non-stranded palladium-103 sources. Despite the date of commercial availability for the commenter's linear non-stranded palladium-103 brachytherapy source, we do have CY 2013 claims data for HCPCS code C2636. Therefore, in accordance with our above-mentioned methodology and consistent with our policy used to set the prospective payment rates for brachytherapy sources, we are finalizing our proposed payment rate for HCPCS code C2636 based on CY 2013 claims data.

Comment: One commenter expressed concern regarding CMS' CY 2014 payment rate for a new brachytherapy source described by HCPCS code C2644 (Brachytherapy source, cesium-131 chloride solution, per millicurrie), which became effective July 1, 2014. In the July 2014 OPPS Change Request (CR) 8776, dated May 23, 2014, CMS established a payment rate for HCPCS code C2644 of $18.97. The commenter, who also petitioned for the initial establishment of HCPCS code C2644 to describe the new brachytherapy source, requested clarification on how the payment rate was established by CMS, given that the cost of the new brachytherapy source is $25 per millicurie and claims data are not yet available.

Response: As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786), we assign new HCPCS codes that describe new brachytherapy sources to their own APCs, with prospective payment rates set based on consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The commenter provided CMS with clinical information on the brachytherapy source cesium-131 chloride solution within its petition for the establishment of the new HCPCS code, and noted the source's clinical similarities with the liquid iodine-125 solution source, which is described by HCPCS code A9527 (Iodine I–125 sodium iodide). The commenter stated that both iodine I–125 sodium iodide and cesium-131 chloride solution ''have similar energies, are capable of delivering the same radiation dose to the planned treatment volume, are supplied in liquid form, and are compatible with the GliaSite RTS Catheter''. Based on clinical information provided by the commenter and a clinical review by CMS' medical advisors, we believe that the brachytherapy sources described by HCPCS code C2644 and HCPCS code A9527 are clinical substitutes. Therefore, we set a payment rate for HCPCS code C2644 that is equal to the payment rate for HCPCS code A9527 when it became effective in CY 2014, and proposed to apply the same methodology for CY 2015. We are finalizing our proposal for CY 2015 to set the payment rate for HCPCS code C2644 as the equivalent of the payment rate for HCPCS code A9527. (We refer readers to Addendum B of this final rule with comment period for the CY 2015 OPPS payment rate. Addendum B is available via the Internet on the CMS Web site.)

After consideration of the public comments we received, we are finalizing our proposal to continue to set the payment rates for brachytherapy sources using our established prospective payment methodology, which is based on geometric mean costs. The CY 2015 final payment rates for brachytherapy sources are found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

As stated in the CY 2015 OPPS/ASC proposed rule (79 FR 40940), we continue to invite hospitals and other parties to submit recommendations to CMS for new HCPCS codes that 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.

e. Comprehensive APCs

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 (primarily medical device implantation procedures) under the OPPS at the claim level, effective January 1, 2015. 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. We established comprehensive APCs as a category broadly for OPPS payment and established 29 C–APCs to prospectively pay for 167 of the most costly device-dependent services assigned to these 29 APCs beginning in CY 2015 (78 FR 74910). Under this policy, we designated each service described by a HCPCS code assigned to a C–APC as the primary service and, with few exceptions described below, consider all other services reported on a hospital outpatient claim in combination with the primary service to be related to the delivery of the primary service (78 FR 74869). In addition, under this policy, we calculate a single payment for the entire hospital stay, defined by a single claim, regardless of the date of service span over which the primary service and all related services are delivered. This comprehensive APC packaging policy packages payment for all items and services typically packaged under the OPPS, but also packages payment

for other items and services that are not typically packaged under the OPPS (78 FR 74909).

Because of the overall complexity of this new policy and our introduction of complexity adjustments in the CY 2014 OPPS/ASC final rule with comment period, we modeled the policy as if we were implementing it for CY 2014, but delayed the effective date until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. In the CY 2015 OPPS/ASC proposed rule (79 FR 40941 through 40953), we discussed our review of the policies finalized in the CY 2014 OPPS/ASC final rule with comment period for C–APCs, and summarized and responded to public comments received in response to the CY 2014 OPPS/ASC final rule with comment period relating to the comprehensive APC payment policy. We then outlined our proposed policy for CY 2015, which included several clarifications and proposed modifications in response to public comments received. In this section, we use the terms ''service'' and ''procedure'' interchangeably.

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a policy, with a delayed implementation date of CY 2015, that designated certain covered OPD services as primary services (identified by a new OPPS status indicator of ''J1'') assigned to C–APCs. When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we treat all other items and services reported on the claim as integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as ''adjunctive services'') and representing components of a comprehensive service (78 FR 74865). This results in a single prospective payment for the primary, comprehensive service based on the cost of all reported services at the claim level. We only exclude charges for services that are statutorily excluded from the OPPS, such as certain mammography and ambulance services that are never covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; charges for brachytherapy seeds, which must receive separate payment under section 1833(t)(2)(H) of the Act; charges for pass-through drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; and charges for 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 (78 FR 74865).

The ratesetting process set forth in the CY 2014 OPPS/ASC final rule with comment period for the comprehensive APC payment policy is summarized as follows (78 FR 74887):

APC assignment of primary (''J1'') services. HCPCS codes assigned to status indicator ''J1'' are assigned to C–APCs based on our usual APC assignment methodology of evaluating the geometric mean cost of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC. Claims reporting multiple procedures described by HCPCS codes assigned to status indicator ''J1'' are identified and the procedures are then assigned to a C–APC based on the primary HCPCS code that has the highest APC geometric mean cost. This ensures that multiple procedures described by HCPCS codes assigned to status indicator ''J1'' reported on claims are always paid through and assigned to the C–APC that would generate the highest APC payment. If multiple procedures described by HCPCS codes assigned to status indicator ''J1'' that are reported on the same claim have the same APC geometric mean estimated cost, as would be the case when two different procedures described by HCPCS codes assigned to status indicator ''J1'' are assigned to the same APC, identification of the primary service is then based on the procedure described by the HCPCS code assigned to status indicator ''J1'' with the highest HCPCS-level geometric mean cost. When there is no claims data available upon which to establish a HCPCS-level comprehensive geometric mean cost, we use the geometric mean cost for the APC to which the HCPCS code is assigned.

Complexity adjustments and determination of final C–APC groupings. We then considered reassigning complex subsets of claims for each primary service described by a HCPCS code assigned to status indicator ''J1.'' All claims reporting more than one procedure described by HCPCS codes assigned to status indicator ''J1'' are evaluated for the existence of commonly occurring pairs of procedure codes reported on claims that exhibit a materially greater comprehensive geometric mean cost relative to the geometric mean cost of the claims reporting that primary service. This indicates that the subset of procedures identified by the secondary HCPCS code has increased resource requirements relative to less complex subsets of that primary procedure (78 FR 74887). The CY 2014 complexity adjustment criteria are as follows:

- The comprehensive geometric mean cost of the claims reporting the combination of procedures is more than two times the comprehensive geometric mean cost of the single major claims reporting only the primary service;
- There are more than 100 claims in the data year reporting the specific code combination;
- The number of claims reporting the specific code combination exceed 5 percent of the volume of all claims reporting the designated primary service; and
- There would be no violation of the ''2 times'' rule within the receiving C–APC (78 FR 74886).

If a pair of procedure codes reported on claims is identified that meets these requirements, that is, commonly occurring and exhibiting materially greater resource requirements, the pair of procedure codes is further evaluated to confirm clinical validity as a complex subset of the primary procedure and the pair of procedure codes is then identified as complex, and primary service claims with that combination of procedure codes are subsequently reassigned as appropriate. If a pair of procedure codes does not meet the requirement for a materially greater resource requirement or does not occur commonly, the pair of procedure codes is not considered to be complex, and primary service claims with that combination of procedure codes are not reassigned. All pairs of procedures described by HCPCS codes assigned to status indicator ''J1'' for each primary service are similarly evaluated. Once all pairs of procedures described by HCPCS codes assigned to status indicator ''J1'' have been evaluated, all claims identified for reassignment for each primary service are combined and the group is assigned to a higher level C–APC within a clinical family of C–APCs, that is, an APC with greater estimated resource requirements than the initially assigned C–APC and with appropriate clinical homogeneity. We assessed resource variation for reassigned claims within the receiving APC using the geometric mean cost for all reassigned claims for the primary service relative to other services assigned to that APC using the 2 times rule criteria (78 FR 74887).

For new HCPCS codes and codes without data, we use the best information available to us to identify combinations of procedure codes that represent a more complex form of the primary service and warrant

reassignment to a higher level APC. In the proposed rule, we stated that we would reevaluate our APC assignments and identification and APC placement of complex claims once claims data become available.

(2) CY 2015 Policy for C–APCs

(a) Methodology

Basic C–APC Methodology. After consideration of the public comments we received on the CY 2014 OPPS/ASC final rule with comment period, in the CY 2015 OPPS/ASC proposed rule (79 FR 40941 through 40953), we described our proposed payment methodology for C–APCs for CY 2015. For CY 2015, we proposed to establish a policy that services assigned to C–APCs would be designated as the primary services for C–APCs, using new status indicator ''J1'' as listed in Addendum J and Addendum B to the CY 2015 OPPS/ASC proposed rule (which are available via the Internet on the CMS Web site). We stated that the basic steps for calculating the C–APC payments remain the same as those finalized in the CY 2014 OPPS/ASC final rule with comment period, except for the complexity adjustment criteria described briefly above (78 FR 74885 through 74888). For CY 2015, we proposed to restructure and consolidate some of the current device-dependent APCs to improve both the resource and clinical homogeneity of these APCs. In addition, instead of assigning any add-on codes to status indicator ''J1'' as finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74873 through 74883), we proposed to package all add-on codes, consistent with our CY 2014 OPPS policy to package add-on codes (78 FR 74942), but to allow certain add-on codes to qualify a primary J1 procedure code-add-on code combination for a complexity adjustment. For CY 2015, similar to other procedures described by add-on codes under the OPPS and according to 42 CFR 419.2(b)(18), procedures described by add-on codes furnished in conjunction with primary comprehensive services would be packaged instead of being assigned to an APC with a separately payable status indicator in accordance with the CY 2014 OPPS policy for add-on codes assigned to device-dependent APCs. However, the add-on codes currently assigned to device-dependent APCs (that are converted to C–APCs) may qualify as a secondary code in a complexity adjustment code pair.

Further, we proposed to convert all current device-dependent APCs remaining after the proposed restructuring and consolidation of some of these APCs to C–APCs. We also proposed to create two new C–APCs: C–APC 0067 for single-session cranial stereotactic radiosurgery services (SRS) and C–APC 0351 for intraocular telescope implantation. In addition, we proposed to reassign CPT codes 77424 and 77425 that describe intraoperative radiation therapy (IORT) to C–APC 0648 (Level IV Breast and Skin Surgery). We discuss in detail below our proposed new complexity adjustment criteria and our proposal to package all add-on codes, but to allow complexity adjustments for qualifying code combinations of primary codes and add-on codes currently assigned to device-intensive C–APCs.

As stated in the CY 2014 OPPS/ASC final rule with comment period, we define the comprehensive 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 cannot be covered OPD services or that cannot by statute be paid under the OPPS. Services packaged for payment under the comprehensive APC payment packaging policy, that is, services that are typically integral, ancillary, supportive, dependent, or 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 are provided during the comprehensive service, except excluded services that are described below (78 FR 74865). In addition, payment for outpatient department services that are similar to therapy services and delivered either by therapists or nontherapists is packaged as part of the 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 under section 1834(k) of the Act subject to annual therapy caps, as applicable (78 FR 74867). However, certain other services similar to therapy services are considered and paid as outpatient services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is packaged with the 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 packaged for 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). We refer readers to the Medicare Benefit Policy Manual, Chapter 15, Covered Medical and Other Health Services, Section 50.2.M, for a description of our policy on self-administered drugs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.

Services excluded from the comprehensive APC payment policy are as follows: 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 exclude preventive services defined in 42 CFR 410.2, ''(1) [t]he specific services listed in section 1861(ww)(2) of the Act, with the explicit exclusion of electrocardiograms; (2) [t]he Initial Preventive Physical Examination (IPPE) (as specified by section 1861(ww)(1) of the Act); and (3) Annual Wellness Visit (AWV), providing Personalized Prevention Plan Services (PPPS) (as specified by section 1861(hhh)(1) of the Act).'' These preventive services are listed by their

HCPCS codes in Addendum J to this final rule with comment period and include: 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; 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; and additional preventive services as defined in section 1861(ddd)(1) of the Act. We defined and discussed these services in detail for hospital billing purposes in the CY 2011 OPPS/ASC final rule with comment period pursuant to coverage and payment provisions in the Affordable Care Act (75 FR 72013 through 72020).

This policy is consistent with our policy to exclude preventive services from the ancillary services packaging policy, will encourage the provision of preventive services, and provide maximum flexibility to beneficiaries across different sites of service in receiving preventive services. In addition, the statute does not permit assessment of beneficiary cost-sharing for most preventive services, and some receive cost-based payment (75 FR 72013 through 72020 and 78 FR 74962). While any beneficiary cost-sharing attributable to preventive services, if they were packaged, would be very small in relation to the comprehensive service overall, we believe that we should exclude these services from the OPPS beneficiary copayment calculations, as discussed in section II.I. of this final rule with comment period. We note that payment for one preventive service (HCPCS code G0102 (Prostate cancer screening; digital rectal examination)) will continue to be packaged under the OPPS in CY 2015, both broadly and in the context of comprehensive services. Currently, payment for the procedure described by this HCPCS code is packaged because it is included in evaluation and management services. We note that beneficiary cost-sharing is not waived for the service described by HCPCS code G0102.

Consistent with the policy finalized in the CY 2014 OPPS/ASC final rule with comment period, we exclude brachytherapy services and pass-through drugs, biologicals and devices that are separately payable by statute (78 FR 74868 and 74909). In addition, we exclude services assigned to OPPS status indicator ''F'' that are not paid under the OPPS and are instead paid on a reasonable cost basis (certain CRNA services, Hepatitis B vaccines, and corneal tissue acquisition, which is not part of a comprehensive service for CY 2015). In Table 6 below, we list the services that are excluded from the comprehensive APC payment policy.

TABLE 6—COMPREHENSIVE APC PAYMENT POLICY EXCLUSIONS FOR CY 2015

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 CFR 410.2: • 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 • 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—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)
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 Part B inpatient service (for example, exhausted Medicare Part A benefits, beneficiaries with Part B only)

We proposed to continue to 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). We proposed to sum all line item charges for services included in the C–APC payment, 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 in the C–APC payment bundle). Charges for services that would otherwise have been 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 proposed to 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 proposed to establish a ranking of each primary service (single unit only) 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 2013 claims), we proposed to continue to 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 proposed to use complexity adjustments to provide increased payment for certain comprehensive services. We proposed to 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 proposed to 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).

In the CY 2015 OPPS/ASC proposed rule (79 FR 40947 through 40948, we explained in detail in response to a comment to the CY 2014 OPPS/ASC final rule with comment period the differences between the finalized CY 2014 complexity adjustment criteria and the CY 2015 proposed complexity adjustment criteria and our rationale for the proposed changes.

After designating a single primary service for a claim, we proposed to 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 proposed to determine initial C–APC assignments and complexity adjustments using the best data available, cross-walking 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 proposed to 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 (79 FR 40944). We did not propose to create new APCs with a geometric mean cost that is higher than the highest 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.

As discussed below, we proposed that add-on codes reported in conjunction with a ''J1'' service would receive complexity adjustments when a qualifying add-on code is reported in conjunction with the primary service assigned to status indicator ''J1'' and satisfies the criteria described above for a complexity adjustment. Any combinations of HCPCS codes that fail to meet the proposed complexity adjustment criteria (frequency and cost thresholds) would not be identified as complex subsets of the primary procedure and would not be reassigned to a higher paying C–APC within the same clinical family of C–APCs. We provided a proposed list of qualifying code combinations (including add-on codes) in Addendum J to the proposed rule (which is available via the Internet on the CMS Web site).

We proposed to package payment for all add-on codes into the payment for the C–APC. However, we indicated that add-on codes that are assigned to the current device-dependent APCs listed in Table 5 of the proposed rule (79 FR 40938) would be evaluated for a possible complexity adjustment when they are reported in conjunction with a designated primary service assigned to status indicator ''J1.'' We proposed to only evaluate the add-on codes that are assigned to the current device-dependent APCs listed in Table 5 of the proposed rule for potential complexity adjustments because we believe that, in certain cases, these procedure codes may represent services with additional medical device costs that result in significantly more complex and costly procedures. To determine which combinations of primary service codes reported in conjunction with the add-on code may qualify for a complexity adjustment for CY 2015, we proposed to apply the proposed frequency and cost criteria 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 for a complexity adjustment were met, and reassignment to the next higher cost APC in the clinical family is appropriate, we proposed to make a complexity adjustment for the code combination; that is, we proposed to reassign the primary service code reported in conjunction with the 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 did not qualify for a complexity adjustment, payment for these services would be packaged. We listed the complexity adjustments proposed for add-on code combinations for CY 2015, along with all of the other proposed complexity adjustments, in Addendum J to the proposed rule (which is available via the Internet on the CMS Web site). One primary service code and add-on code combination (CPT code 37225 and 37233) that satisfied the frequency and cost criteria was not proposed for a complexity adjustment because we believe that these claims are miscoded. Of the 35 qualifying claims reporting this code combination, only 3 claims contained the appropriate base code (CPT code 37228) for CPT add-on code 37233.

We provided in Addendum J to the 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 the proposed rule also contained summary cost statistics for each of the code combinations proposed to be reassigned under a given primary code. 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 geometric mean cost listed in Addendum J for the code combination described by CPT code 33208A assigned to C–APC 0655 included all code combinations that were proposed to be reassigned to C–APC 0655 when CPT code 33208 is the primary code. Providing the information contained in Addendum J in the proposed rule allowed stakeholders the opportunity to better assess the impact associated with the proposed reassignment of each of the code combinations eligible for a complexity adjustment.

(b) Additional C–APCs

Several commenters to the CY 2014 OPPS/ASC proposed rule questioned why CMS only converted a subset of the device-dependent APCs to C–APCs (78 FR 74864). We responded that while we were initially adopting a subset of the most costly device-dependent services, we may extend comprehensive payments to other procedures in future years as part of a broader packaging initiative (78 FR 74864). Upon further review for CY 2015, we stated in the CY 2015 OPPS/ASC proposed rule (79 FR 40944 through 40945) that we believe that the entire set of the currently device-dependent APCs (after the proposed reorganization and consolidation of the current device-dependent APCs) are appropriate candidates for C–APC payment because the device-dependent APCs not included in last year's comprehensive APC payment proposal are similar to the original 29 device-dependent APCs that were proposed as C–APCs in CY 2014. Similar to the original 29 device-dependent APCs for CY 2014 that were converted to C–APCs, the additional device-dependent APCs that were proposed for conversion to C–APCs contain comprehensive services primarily intended for the implantation of costly medical devices. Therefore, in the CY 2015 OPPS/ASC proposed rule, we proposed to apply the comprehensive APC payment policy to the remaining device-dependent APCs for CY 2015.

In addition, since the publication of the CY 2014 OPPS/ASC final rule with comment period, stakeholders brought several services to our attention as appropriate candidates for C–APC payment. Stakeholders recommended that we create C–APCs for these procedures and technologies or assign them to a previously proposed C–APC. We agreed with the stakeholders. Similar to the other services designated as comprehensive in CY 2014, these procedures are comprehensive single-session services with high-cost implantable devices or high-cost equipment. For CY 2015, we proposed to convert the following existing APCs into C–APCs: APC 0067 (Single Session Cranial Stereotactic Radiosurgery) and APC 0351 (Level V Intraocular Surgery)). C–APC 0351 only contains one procedure—CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens). We also proposed to assign the CPT codes for IORT (CPT codes 77424 and 77425) to C–APC 0648 (Level IV Breast and Skin Surgery) because IORT is a single session comprehensive service that includes breast surgery combined with a special type of radiation therapy that is delivered inside the surgical cavity but is not technically brachytherapy. The HCPCS codes that we proposed to assign to these C–APCs in CY 2015 would be assigned to status indicator ''J1.''

(c) Reconfiguration and Restructuring of the C–APCs

Based on further examination of the structure of the C–APCs illustrated in the CY 2014 OPPS/ASC final rule with comment period and an evaluation of their comprehensive geometric mean costs (using the updated CY 2013 claims data), in the CY 2015 OPPS/ASC proposed rule (79 FR 40945), we proposed to reorganize, combine, and restructure some of the C–APCs. The purpose of this APC restructuring is to improve resource and clinical homogeneity among the services assigned to certain C–APCs and to eliminate APCs for clinically similar services, but with overlapping geometric mean costs. The services we proposed to assign to each of the C–APCs for CY 2015, along with the relevant cost statistics, were provided in Addendum J to the proposed rule. Addendum J is available at the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* Table 7 of the proposed rule (79 FR 40952) listed the additional 28 APCs proposed under the CY 2015 comprehensive APC policy.

In summary, our proposal to reorganize, combine, and restructure some of the C–APCs included the following proposed changes:

- Endovascular clinical family (renamed Vascular Procedures, VASCX). We proposed to combine C–APCs 0082, 0083, 0104, 0229, 0319, and 0656 illustrated for CY 2014 to form three proposed levels of comprehensive endovascular procedure APCs: C–APC 0083 (Level I Endovascular Procedures); C–APC 0229 (Level II Endovascular Procedures); and C–APC 0319 (Level IV Endovascular Procedures).
- Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices (AICDP). We proposed to combine C–APCs 0089, 0090, 0106, 0654, 0655, and 0680 as illustrated for CY 2014 to form three proposed levels of C–APCs within a broader series of APCs for pacemaker implantation and similar procedures as follows: APC 0105 (Level I Pacemaker and Similar Procedures), a non-comprehensive APC; C–APC 0090 (Level II Pacemaker and Similar Procedures); C–APC 0089 (Level III Pacemaker and Similar Procedures); and C–APC 0655 (Level IV Pacemaker and Similar Procedures).
- We proposed to delete the clinical family for Event Monitoring, which only had one C–APC (C–APC 0680 (Insertion of Patient Activated Event)) with a single CPT code 33282 as illustrated for CY 2014. We also proposed to reassign CPT code 33282 to C–APC 0090, which contains clinically similar procedures.
- In the urogenital family, we proposed two levels instead of three levels for urogenital procedures, and to reassign several codes from APC 0195 to C–APC 0202 (Level V Female Reproductive Procedures).

• We proposed to rename the arthroplasty family of APCs to ''Orthopedic Surgery.'' We also proposed to reassign several codes from APC 0052 to C–APC 0425, which we proposed to rename ''Level V Musculoskeletal Procedures Except Hand and Foot.''

• We proposed three levels of electrophysiologic procedures, using the current inactive APC ''0086'' instead of APC 0444, to have consecutive APC grouping numbers for this clinical family and to rename APC 0086 ''Level III Electrophysiologic Procedures.'' In addition, we proposed to replace composite APC 8000 with proposed C–APC 0086 as illustrated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74870).

We also proposed three new clinical families: Gastrointestinal Procedures (GIXXX) for gastrointestinal stents, Tube/Catheter Changes (CATHX) for insertion of various catheters, and Radiation Oncology (RADTX), which would include C–APC 0067 for single session cranial SRS.

(3) Public Comments

Comment: Commenters were generally supportive of the proposed changes to the comprehensive APC payment policy for CY 2015 when compared to the CY 2014 final policy, and urged CMS to monitor implementation for payment adequacy and access to quality care. Some commenters requested that CMS delay implementation until at least July 1, 2015, to allow time to fully test systems changes. Some commenters requested that CMS delay implementation for a year or more until CMS addresses assorted concerns or so that hospitals can continue to analyze the policy and budget for the financial impact.

Response: We appreciate the commenters' support. We plan to monitor the implementation of this C–APC payment policy and will consider future revisions as necessary. We will not further delay implementation of this policy. We have already delayed implementation of the C–APC payment policy for a year, which we believe provided ample time for hospitals to evaluate the policy.

Comment: We received feedback from commenters regarding the data resources that CMS provided to support the proposed rule. Some commenters commended CMS for the technical support and assistance provided that enabled the commenters to replicate CMS' methodology and match CMS' results. Other commenters expressed concern that the data resources were insufficient, inconsistent, and unclear. Some commenters also requested that CMS enhance transparency, expand the data resources available to the public, and engage stakeholders in future comprehensive APC payment policy development. Some commenters asked that CMS provide cost data on all of the code combinations that were evaluated for the complexity adjustments, including the code combinations that qualified for a complexity adjustment. One commenter stated that discrepancies in some of the number entries between Addendum J and Addendum B violate the Administrative Procedures Act (APA) because these discrepancies ''make it impossible to understand what CMS is proposing.''

Response: We appreciate the commenters' support for the proposed expansion of available data resources related to the comprehensive APC payment policy methodology. In response to the commenters who expressed concern regarding the insufficiency of the data files provided, we understand that the OPPS is technically complex. However, we believe that the data made available to the public as part of the proposed rule were appropriate, clear, and sufficient. We acknowledge the commenters' concerns regarding the transparency of related data and the desire for additional resources. Therefore, for this final rule with comment period, we are providing additional data in Addendum J, such as cost statistics related to code combinations that are not eligible for complexity adjustments. Regarding any indications of discrepancies in some of the number entries between Addendum J and Addendum B, as the commenter suggested, we understand and acknowledge that minor discrepancies may sometimes occur with complex payment rules that include various files with many different types of data. However, we do not believe any such discrepancies would limit commenters' ability to understand the proposed policies or to evaluate the impacts or effects of the proposed policy changes. The comprehensive APC payment policy has been open for public comment during three consecutive OPPS rulemaking cycles: the CY 2014 OPPS/ASC proposed rule; the CY 2014 OPPS/ASC final rule with comment period; and the CY 2015 OPPS/ASC proposed rule. Therefore, we do not believe that we provided insufficient notice of the policies that are a part of the comprehensive APC payment policy.

Comment: Commenters expressed concern regarding the misalignment between hospitals' billing practices and systems and the proposal to package all services (except for the few exceptions noted above) on a claim into the payment for the comprehensive service. The commenters observed that a significant number of comprehensive service claims spanned more than 5 days, with some claims spanning close to 30 days. The commenters recommended that CMS limit the payment bundle to services provided within 1 or 2 days of the primary service, or defining the bundle based on episodes of care. Commenters also requested that CMS clarify the guidance provided and educate providers on how to report comprehensive services that fall within the span of a recurring service claim. Some commenters expressed concern that policies which reduce or eliminate series billing for recurring services may create an operational burden for hospitals; increase claims processing activity for Medicare contractors; and increase the amount of paperwork sent to a beneficiary.

Response: Our intent is to capture all of the services associated with the primary service assigned to a C–APC, except those services that would still be separately paid under the OPPS, even when provided in conjunction with a comprehensive service. The 219 procedures assigned to the C–APCs are a small fraction of the total services provided in HOPDs. We believe that it would not be an undue hardship for some hospitals to alter their processes such that they file separate claims for services that are unrelated both clinically and in regard to time to the comprehensive service. With regard to recurring services, we have previously issued manual guidance in the Internet Only Manual, Pub. 100–4, Chapter 1, Section 50.2.2, that provides that only recurring services should be billed monthly. We also have specified that, in the event that a recurring service occurs on the same day as an acute service that falls within the span of the recurring service claim, hospitals should bill separately for recurring services on a monthly claim (repetitive billing) and submit a separate claim for the acute service. We also do not expect that these claims for comprehensive services in the outpatient setting would extend beyond a few days because the 219 procedures assigned to the 25 C–APCs are almost entirely surgical procedures. If a physician determined that furnishing one of these services would be medically necessary for the treatment of a Medicare beneficiary and expected the beneficiary to require hospital care for more than 2 midnights, inpatient admission would be appropriate.

Comment: Commenters generally supported the proposed packaging of all add-on codes reported in conjunction with comprehensive service claims with the allowance of complexity adjustments for add-on codes currently assigned to device-dependent APCs in CY 2014. One commenter requested that CMS assign add-on CPT code 57267 (Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (List separately in addition to code for primary procedure) to C–APC 0202 because this code has high device costs.

Response: We appreciate the commenters' support. According to 42 CFR 419.2(b)(18), add-on codes are packaged under the OPPS. Because implementation of the finalized comprehensive APC payment policy was delayed until CY 2015, for CY 2014 we maintained the structure and code assignments for the device-dependent APCs, which continued separate payment for add-on codes assigned to device-dependent APCs for CY 2014. We refer readers to Table 7 of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74859). The add-on code complexity adjustment policy is limited only to certain add-on codes that were previously assigned to device-dependent APCs and that, along with a primary comprehensive service, meet the complexity adjustment criteria. We refer readers to Table 9 of the CY 2015 OPPS/ASC proposed rule (79 FR 40959) for a listing of these add-on codes. Our intent is not to make a higher payment in every case that an add-on procedure results in higher costs. Therefore, we are finalizing the CY 2015 proposal to package all add-on codes reported on a claim in conjunction with a comprehensive service, and also to allow a limited number of add-on codes to be evaluated for a complexity adjustment when billed with a primary comprehensive service. We are not extending the complexity adjustment policy beyond those add-on codes that were assigned to device-dependent APCs. The list of add-on codes that we evaluated for a complexity adjustment is included later in this section in Table 8.

Comment: Some commenters requested that CMS divide the restructured C–APCs into more discrete groupings to increase clinical coherence and resource cost homogeneity. Some commenters believed that improved clinical coherence among the procedures within the C–APCs would increase the stability of C–APC payments from year-to-year and decrease opportunities for ''gaming'' the system. Some commenters also expressed concern with the high variation in geometric mean costs for services assigned to the C–APCs that do not create a violation of the 2 times rule, but would result in inadequate payment for the highest cost procedures assigned to the C–APC.

Response: We disagree with the commenters. We believe that the categorization of the restructured C–APCs better represents clinical and resource homogeneity when compared to the CY 2014 structure of the C–APCs. We also note that the OPPS is a prospective payment system that relies on groupings of procedures resulting in a weighted-average cost payment based on all of the procedures in the group. Too much discretization of APC groupings would move the OPPS more toward a fee schedule, which would have individual payments for each HCPCS code and presents an undesirable outcome for the OPPS. In addition, we encourage all members of the stakeholder public to report all suspected incidents of fraud and abuse to the Office of Inspector General or the CMS Center for Program Integrity. As required by statute, we will review and evaluate, on an annual basis, any year-to-year changes in APC and HCPCS geometric mean costs.

Comment: A few commenters disagreed with CMS' proposal to expand the C–APCs to include all of the current device-dependent APCs. The commenters noted that a significant percentage of claims for some of the lower paying C–APCs (specifically, C–APCs 0084 (Level I Electrophysiologic Procedures), 0427 (Level II Tube or Catheter Changes or Repositioning), 0622 (Level II Vascular Access Procedures), and 0652 (Insertion of Intraperitoneal and Pleural Catheters) report services assigned to noncomprehensive APCs that are significantly more costly than the primary service that is motivating the C–APC payment. Commenters believed that procedures assigned to these APCs are not infrequently performed as secondary procedures to other more costly procedures that are assigned to noncomprehensive APCs. Commenters recommended various approaches for addressing this concern: (1) Applying complexity adjustments to these claims; (2) excluding high-cost procedures from the comprehensive APC packaging policy; (3) paying for the higher-cost service and applying a multiple procedure reduction to the C–APC; or (4) eliminating the lower paying C–APCs from the comprehensive APC payment policy methodology.

Response: Our analysis shows a significant number of claims in APCs 0427 and 0622 that contain noncomprehensive services that are more costly than the procedures assigned to the proposed C–APC. In addition, similar to APCs 0427 and 0622, APC 0652 contains a total of three catheter-insertion procedures. These procedures are not similar to the other major procedures assigned to C–APCs, but are sometimes supportive of other procedures. For example, APC 0652 includes the procedure that describes the placement of a pleural catheter that can be used for drug delivery, but is not a definitive therapeutic procedure similar to most of the other procedures assigned to that C–APC. Also, APCs 0427, 0622, and 0652 are not device-intensive APCs, meaning that the device offsets are not greater than 40 percent. Therefore, we are accepting the commenters' recommendation. We are not converting APCs 0427, 0622, and 0652 into C–APCs for CY 2015. In addition, because we are not converting APC 0427 into a C–APC, we will not evaluate add-on CPT code 49435 for complexity adjustments because the APC that contains the base codes for CPT code 49435 are assigned to APC 0427. However, we are finalizing the proposal to convert APC 0084 into a C–APC. We did not find that a significant number of higher cost noncomprehensive procedures are performed in conjunction with the procedures assigned to APC 0084. Unlike many of the catheter insertion procedures assigned to APCs 0427, 0622, and 0652, the electrophysiology procedures assigned to APC 0084 are not supportive of other services, but are the definitive therapeutic procedures intended to treat a patient's cardiac condition.

Comment: Commenters urged CMS to develop adjustments to C–APC payments based on patient acuity or diagnosis to account for clinical complexity and patient characteristics, which could help mitigate the negative payment impact of expanding the comprehensive APC payment policy on hospitals that treat more clinically complex patients, such as academic medical centers, cancer hospitals, and trauma centers.

Response: As we stated in the CY 2015 OPPS/ASC proposed rule (79 FR 40951), section 1833(t)(2) of the Act provides a procedure-based payment methodology for the OPPS, which is unlike the IPPS that makes payments based on both diagnoses and procedures. Currently OPPS payments are not based on patient severity or diagnosis like payments under the IPPS. Therefore, we are unable to make

payment adjustments based on diagnoses.

Comment: Commenters expressed concern that not implementing C–APCs in the ASC setting distorts the payment relationship between ASCs and HOPDs and could result in incentives to direct patients from one setting to another. Commenters recommended that CMS reprogram the ASC payment system software, as soon as possible, to allow the system to perform the complex logic needed to implement and provide adequate payment for the C–APCs for ASCs.

Response: The commenters are correct that the comprehensive APC payment policy methodology is not being adopted under the ASC payment system. However, we do not believe that this policy decision will result in site-of-service shifts, but we will continue to monitor procedure volumes in both settings. Although OPPS payments for individual surgical procedures assigned to C–APCs are higher than ASC payments for the same procedures, under the standard noncomprehensive service payment methodology that applies in the ASC for all APCs and in the OPPS for noncomprehensive services, there remains separate payment for covered procedures and covered ancillary services that are not packaged under a general packaging policy. This continuation of separate payment for covered procedures and covered ancillary services performed in the ASC (which is not available in the OPPS for procedures performed in addition to the primary procedures assigned to C–APCs) should help mitigate any incentive to perform procedures assigned to C–APCs in the HOPD. However, given the significant difference between ASC and OPPS payment rates, we do not believe that separate payment (at the multiple procedure reduction reduced rate) for additional procedures performed in the ASC setting along with a procedure that is assigned to a C–APC will draw cases away from the HOPD because, in most cases, the overall HOPD will be higher than the ASC payment for the same set of procedures. We will consider the commenters' suggestion that we develop new payment software for the ASC payment system should an opportunity to do so arise in the future.

Comment: Commenters requested that CMS provide separate payment for certain services reported on a comprehensive claim. Some commenters requested that CMS exclude the following additional services from the packaging provision under the comprehensive APC payment policy:

- Dialysis and emergency dialysis services.
- Blood products.
- Expensive diagnostic tests, such as angiography.
- High-cost drugs and devices that account for a high percentage of the geometric mean cost of a C–APC.
- Outpatient services paid under a payment schedule, such as laboratory services.

The commenters believed that the C–APC payment would not adequately cover the cost of these services. One commenter believed that packaging payment for an otherwise separately payable drug when provided in conjunction with a comprehensive service may cause hospitals, in consultation with physicians, to choose a less-expensive alternative drug.

Response: We responded to similar comments that disagreed with CMS' proposal to package payment for various items and services into the C–APC payment in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74865 through 74910). As previously stated, we disagree with the commenters. We believe that the central attribute of the comprehensive APC payment policy is the packaging of all adjunctive services, with the exception of those services described above that, according to the statute, cannot be packaged or the list of preventive services that generally would not be provided at the time of a major procedure assigned to a C–APC. We note that (as stated above in section II.A.3.a. of this final rule with comment period) where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more expensive than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than routinely using a more expensive item, which often results if separate payment is provided for the items. Furthermore, packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services (including drugs) or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery.

Comment: Commenters asserted that the reliance on code combinations based on cost ranking of codes would lead to instability in the complexity adjustments from year to year, and overlook a large number of comprehensive claims with three or more ''J1'' services, which is common for the clinical complexity of procedures assigned to the endovascular revascularization family of APCs. Commenters suggested alternative methodologies for determining eligibility, such as applying a complexity adjustment to any claim that has three or more ''J1'' services or applying the cost and frequency criteria to all combinations of ''J1'' services.

Response: We disagree with the commenters that assigning complexity adjustments based on cost ranking of primary and secondary codes is either insufficient or would result in instability of the complexity adjustments in future years. We proposed complexity adjustments for certain code pairs to provide a higher payment in the next higher APC within a clinical family for high cost procedure pairs consisting of a primary comprehensive procedure and a secondary comprehensive procedure that represent sufficiently frequent and sufficiently costly comprehensive procedure pairs such that they are separated from and provided a higher payment than all of the cases that are accounted for in APC assignment of the primary service. We do not believe that providing a complexity adjustment to any claim that has three or more ''J1'' services or to all claims reporting pairs of ''J1'' services that meet the cost and frequency criteria would adequately serve the stated purpose of the policy. The intent of the complexity adjustment policy is to identify a limited number of costly procedure pairs for a higher payment at the next higher paying C–APC within the clinical family, not to unpackage and separately pay for all of the high cost cases that are associated with the primary ''J1'' procedure. Although such a policy as the commenters requested could be beneficial to the procedures assigned to the endovascular C–APC family because of the high number of codes that can be billed per case, we do not believe that this approach would serve the other clinical families that do not rely on component coding to the same extent as endovascular procedures. Therefore, we are finalizing our proposal to base the complexity adjustments on code pairs that include the two most costly ''J1'' services reported on the C–APC service claim.

Comment: Commenters believed that the cost threshold is too restrictive and would cause financial hardship for hospitals and jeopardize beneficiary access to care. Commenters suggested that CMS adjust the cost threshold to 1.5, 1.75, or within 2 percent of the 2 times rule limit.

Response: In response to comments to the CY 2014 OPPS/ASC final rule with comment period, we significantly

lowered the cost criterion for a complexity adjustment from two times the cost of the primary procedure to two times the cost of the lowest cost procedure in the APC to which the primary procedure is assigned. This change made it significantly easier for code combinations to qualify for a complexity adjustment based on higher cost. We do not believe that further lowering of the cost criterion would be consistent with the objective of the comprehensive APC payment policy. We believe that lowering the cost criterion would result in effectively unpackaging too many cases from the primary C–APC assignment and, therefore, defeat the purpose of the policy, which is to create a comprehensive prospective payment for major, primary device-intensive procedures.

Comment: Commenters expressed concern that claims assigned to the only level or the highest level C–APC within a clinical family are ineligible to receive a complexity adjustment because there is no higher paying APC in the clinical family in which to assign these code combinations. Commenters requested that CMS add an additional C–APC level to these clinical families to provide for more granular payment levels and accommodate potential complexity adjustments.

Response: As we stated in the CY 2015 OPPS/ASC proposed rule, we would not create new APCs with a geometric mean cost that is higher than the highest cost 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. We only found 7 code pairs out of the 219 procedures that are assigned to the 25 final C–APCs that would qualify for a complexity adjustment if a higher paying APC were available for assignment of the code combination. We do not believe that this small number of code combinations from the highest paying APCs in the final 12 clinical families of C–APCs that satisfy the complexity adjustment criteria necessitates creating additional APCs, especially if these APCs would be populated with only a few multiple procedure claims. In addition, in accordance with section 1833(t)(2)(B) of the Act, APCs are defined as ''groups of covered OPD services'' that are comparable clinically and with respect to the use of resources. If we created an additional new higher level APC within each C–APC clinical family that did not contain any primary comprehensive services and instead only contained a very small volume of complexity-adjusted code pairs, we do not believe that such APCs would constitute appropriate ''groups of covered OPD services.''

Comment: One commenter urged CMS to finalize the proposal to assign CPT code 0308T to APC 0351 and to convert APC 0351 into a C–APC.

Response: We appreciate the commenter's support. For this final rule with comment period, we are finalizing our proposal to assign CPT code 0308T to APC 0351 and to convert APC 0351 into a C–APC for CY 2015.

Comment: Commenters generally agreed with the proposed structure of the Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices (AICDP) C–APCs. One commenter specifically supported the assignment of CPT code 0319T to C–APC 108.

Response: We appreciate the commenters' support.

Comment: Several commenters supported CMS' proposed assignment of CPT codes 77424 and 77425 to C–APC 0648. Another commenter believed that the services assigned to C–APC 0648 are not similar clinically or similar in resource costs, and suggested that CMS divide this C–APC into two levels.

Response: We appreciate the commenters' support for our proposal regarding C–APC 0648. However, we disagree with the commenter that the services assigned to C–APC 0648 are not similar clinically or in regard to resource costs. All of the seven services proposed to be assigned to C–APC 0648 involve the breast. The current clinical application of intraoperative radiation therapy (IORT CPT codes 77424 and 77425) is for breast cancer following lumpectomy. In regard to resource costs of the services assigned to C–APC 0648, the range from the lowest cost significant procedure to the highest cost significant procedure is between approximately $5,584 and $9,325, which is well within the 2 times rule limit. In addition, C–APC 0648 is a small APC with only 7 services and a total of approximately 5,000 claims based on CY2013 claims data. To further divide this C–APC would be less consistent with a prospective payment system than its proposed structure. Therefore, we are finalizing our proposal to assign CPT codes 77424 and 77425 to C–APC 0648.

Comment: One commenter requested that CMS exclude C–APC 0259 from the comprehensive APC payment policy. The commenter believed that the change in the procedure-to-device claim edits policy would result in more incorrectly coded claims for the procedure described by CPT code 69930 (Cochlear device implantation, with or without mastoidectomy), which is the only service assigned to C–APC 0259.

Response: We do not believe that C–APC 0259 should be excluded from the comprehensive APC payment policy. The discussion of the device edits policy is in section II.A.2.d.1. of this final rule with comment period. We believe that hospitals will continue to report the cost of the cochlear implant when one of these devices is implanted into a Medicare beneficiary because the cost of this device is 84 percent of the total cost of the procedure. After consideration of this comment, we see no reason to exempt C–APC 0259 from the comprehensive APC payment policy. We are finalizing our proposal to convert APC 0259 into a C–APC for CY 2015.

Comment: Several commenters agreed with CMS' proposed structure of the cardiac electrophysiology C–APCs: C–APC 0084 (Level I Electrophysiologic Procedures); C–APC 0085; and C–APC 0086 (Level III Electrophysiologic Procedures). One commenter requested that CMS reassign CPT code 93603 (Right ventricular recording) from C–APC 0084 to C–APC 0085 because the commenter believed that the procedure described by CPT code 93603 is more similar to the procedures assigned to C–APC 0085 than the other procedures assigned to C–APC 0084.

Response: We appreciate the commenters' support. However, we disagree with the commenter that CPT code 93603 should be reassigned from C–APC 0084 to C–APC 0085. CPT code 93603 is a very low-volume procedure, with a total of 12 claims for CY 2013. The geometric mean cost for CPT code 93603 (based on these 12 claims) is $1,807. The geometric mean cost of the lowest cost significant service in C–APC 0085 is $4,064 (CPT code 93619). Therefore, we believe that CPT code 93603 lacks resource similarity to the procedures assigned to C–APC 0085. We are finalizing the structure of the cardiac electrophysiology C–APCs, as proposed for CY 2015.

Comment: Several commenters agreed with CMS' proposed structure of the neurostimulator APCs. Two commenters believed that the difference in cost between CPT code 61885 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array) and CPT code 61886 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode

arrays) is too low and that the device costs may not be adequately captured based on the accuracy of the claims data. Another commenter recommended that CMS restructure the neurostimulator APCs to improve clinical coherence by limiting C–APC 0318 to only certain full-system procedures, assigning all lead placement procedures to C–APC 0061, and assigning the remaining neurostimulator procedures to C–APC 0039.

Response: We appreciate the commenters' support. Regarding the commenters' concern about the geometric mean cost of CPT codes 61885 and 61886, the geometric mean cost of CPT code 61886 (dual channel procedure) is higher than CPT code 61885 (single channel procedure), which is to be expected. It is important to remember that the C–APC payment policy packages all procedures performed with the primary procedure, so the cost for the primary service in a C–APC may be higher than the cost associated with single claims for the same service. We note that APC groupings are based on two factors, clinical similarity and resource similarity. The OPPS requires that we group services into APCs for payment purposes based on these two factors. Clinical similarity in the APC grouping context is by definition, and by necessity, is much broader than the comparisons that distinguish individual CPT codes. All of the procedures assigned to C–APCs 0061, 0039, and 0318 include the various neurostimulator-related procedures. The neurostimulator family of C–APCs groups these procedures based on the geometric mean cost and clinical similarity of the primary service. In some cases, an APC includes implantation of a complete system of one type of neurostimulator and the implantation of either a generator alone or a complete system of other types. This is a function of the CPT coding system and the prospective nature of the comprehensive APC payment policy. Overall, we believe that the proposed structure of the neurostimulator family of C–APCs strikes the proper balance of both factors for APC construction and resource and clinical similarity. We are finalizing the proposed structure of the neurostimulator C–APCs, as proposed, and without modification.

Comment: One commenter requested that CMS divide C–APC 0425 into two APCs because the range of procedure costs in this APC is too significant. Another commenter requested that CMS reassign the following CPT codes from APC 0208 to C–APC 0425 based on more appropriate resource homogeneity to the other procedures assigned to C–APC 0425: CPT codes 22551, 22554, 22612, and 22856.

Response: We disagree with the commenters' recommendation to divide C–APC 0425 into two C–APCs. The cost range for significant procedures within C–APC 0425 (using the proposed rule code assignments) is between approximately $9,087 (for CPT code 69714) and $15,740 (for CPT code 24363), which is well within the 2 times rule limit. We agree with the commenters that CPT codes 22551 (with a geometric mean cost of $10,052), 22554 (with a geometric mean cost of $8,129), 22612 (with a geometric mean cost of $8,451), and 22856 (with a geometric mean cost of $12,958) should be reassigned from APC 0208 (with a geometric mean cost of $4,267) to C–APC 0425 (with a geometric mean cost of $10,606). We believe that assigning these four CPT codes to C–APC 0425 supports more appropriate resource and clinical similarity when compared to the current assignment to APC 0208. Otherwise, we are finalizing the proposed structure for C–APC 0425. With these additions to C–APC 0425, the cost range for significant procedures within C–APC 0425 (using the final rule code assignments) is between approximately $8,451 (for CPT code 22612) and $15,740 (for CPT code 24363).

Comment: One commenter believed that the proposed C–APCs that include drug pumps would provide inadequate payment for its developing therapy because the therapy uses an advanced technology drug pump and a very costly drug. The commenter requested that CMS either provide complexity adjustments for high-cost drugs or unpackage the payment for certain high-cost drugs.

Response: As we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74908 through 74909), we do not believe that drugs being supplied to the patient to fill the reservoir of a pump at the time of pump implantation should be excluded from the comprehensive APC payment policy because drugs supplied to fill the pump during implantation of the pump are adjunctive to the procedure. The costs of costly adjunctive services are included proportionally into the cost estimation for the primary services through our ability to use almost all claims for a service and adoption of the geometric mean cost upon which to establish relative payment weights. In addition, we do not believe that we should make complexity adjustments for higher cost drugs. Complexity adjustments are for more complex procedure variations that differ significantly from the primary ''J1'' procedure. Complexity adjustments are not intended as a way to provide separate payment for adjunctive drugs and supplies under the guise of a complexity adjustment. Therefore, we are not adopting this commenter's suggested changes to the comprehensive APC payment policy. We will continue to monitor the development of this technology and consider future revisions to this policy as needed.

Comment: Commenters opinions varied regarding CMS' proposal to include C–APCs 0202 (Level V Gynecologic Procedures), 0385 (Level I Urogenital Procedures), and 0386 (Level II Urogenital Procedures) in the urogenital procedures clinical family of C–APCs and to allow complexity adjustments from C–APC 0202 to C–APC 0385 and complexity adjustments from C–APC 0385 to C–APC 0386. Some commenters agreed with CMS' proposed structure of the urogenital procedures family of C–APCs, while other commenters opposed the proposal to reassign complexity adjustment code combinations from C–APC 0202 to C–APC 0385. The commenters believed that the procedures assigned to C–APC 0202, which are related to female urogenital anatomy, are not sufficiently clinically similar to the primary procedures assigned to C–APC 0385, which relate to the male urogenital anatomy.

Response: We appreciate the commenters' support for the proposed structure of the urogenital procedures C–APC clinical family and the proposed approach for complexity adjustments. However, we disagree with the commenters that complexity adjustments should not be made from C–APC 0202 to C–APC 0385 because of insufficient clinical similarity between the complex procedures with a primary code assigned to C–APC 0202 that have been reassigned according to the complexity adjustment policy to C–APC 0385 and the primary procedures assigned to C–APC 0385. Although we acknowledge that there are differences in the male and female human urogenital anatomy, we believe that many of these procedures involve relatively complex repairs of the urogenital region involving implantable medical devices and, therefore, it is appropriate to assign complexity adjusted code combinations from C–APC 0202 to the next higher paying APC in the urogenital procedures clinical family, which is C–APC 0385.

Comment: Some commenters supported the proposed structure of the C–APCs in the endovascular clinical

family. Other commenters noted that payments for some endovascular procedure code combinations would be negatively impacted by the proposed structure for C–APCs 0083 (Level I Endovascular Procedures), 0229 Level II Endovascular Procedures), and 0319 (Level III Endovascular Procedures). The commenters recommended reviewing and revising these C–APCs and creating more levels beyond the proposed three levels of endovascular C–APCs.

Response: We appreciate the commenters' support for the proposed structure of the endovascular C–APC clinical family. We do not believe that additional levels of endovascular C–APCs are necessary at this time. We believe that the restructured endovascular C–APCs better reflect resource homogeneity than the CY 2014 final structure of these C–APCs because the new structure has clearer delineations between the cost ranges of the procedures assigned to the three levels. In addition, in response to comments to the CY 2014 OPPS/ASC final rule with comment period (79 FR 40951), we proposed less stricter complexity adjustment criteria, which resulted in more code combinations qualifying for higher payment than would have qualified under the CY 2014 OPPS final rule complexity adjustment criteria. We also proposed evaluating certain add-on codes that are currently assigned to device-dependent APCs for complexity adjustments, and the overwhelming majority of these add-on codes are endovascular add-on codes. We believe that these two changes to the CY 2014 comprehensive APC payment policy sufficiently mitigate much of any negative payment impact for endovascular procedures in this transition from the current payment methodology to the comprehensive APC payment methodology. As we do annually, we will reevaluate the need for adjustments to the endovascular family of C–APCs.

Comment: In the CY 2015 OPPS/ASC proposed rule (79 FR 40950 through 40951) in response to a comment to the CY 2014 OPPS/ASC final rule with comment period, we proposed to continue to pay for stem cell transplant procedures as we have done for many years through APCs 0111 (Blood Product Exchange) and 0112 (Apheresis and Stem Cell Procedures). We stated that we would not create a C–APC for stem cell transplant procedures. Some commenters supported this approach. Other commenters requested that CMS create a C–APC for these procedures.

Response: Based on the rationale discussed in the CY 2015 OPPS/ASC proposed rule (79 FR 40950 through 40951), we will continue to pay for stem cell transplant procedures through APCs 0111 and 0112 in CY 2015.

(4) Statement of Final Policy and List of CY 2015 C–APCs.

As we discussed earlier, in the CY 2015 OPPS/ASC proposed rule (79 FR 40941 through 40953), we proposed to continue to define a comprehensive service as a classification for the provision of a primary service and all adjunctive services and supplies reported on the hospital Medicare Part B claim, with few exceptions, resulting in a single beneficiary copayment per claim. The comprehensive APC payment bundle policy includes all hospital services reported on the claim that are covered under Medicare Part B, except for the excluded services or services requiring separate payment by statute as noted above. We proposed to continue to define a clinical family of C–APCs as a set of clinically related C–APCs that represent different resource levels of clinically comparable services.

After consideration of the public comments we received, we are finalizing our proposals, with some minor modifications, for establishment of C–APCs. In this final rule with comment period, we are establishing a total of 25 C–APCs within 12 clinical families for CY 2015, as described below in Table 7.

We are establishing a comprehensive APC payment methodology that adheres to the same basic principles as those finalized in the CY 2014 OPPS/ASC final rule with comment period, with the following changes for CY 2015:

- We are reorganizing and consolidating several of the current device-dependent APCs and the CY 2014 C–APCs.
- We are expanding the comprehensive APC payment policy to include all device-dependent APCs, except for APCs 0427, 0622, and 0652.
- We are creating two other new C–APCs (C–APC 0067 and C–APC 0351).
- We are establishing new complexity adjustment criteria:
  - Frequency of 25 or more claims reporting the HCPCS code combination (the frequency threshold); and
  - Violation of the ''2 times'' rule (the cost threshold).
- We are establishing a policy to package all add-on codes, although we evaluate claims reporting a single primary service code reported in combination with an applicable add-on code (we refer readers to Table 8 below for the list of applicable add-on codes) for complexity adjustments.

Addendum J to this final rule with comment period (which is available via the Internet on the CMS Web site) contains all of the data related to the comprehensive APC payment policy, including the list of complexity adjustments.

TABLE 7—CY 2015 C–APCS

Clinical family *	C–APC	APC title	CY 2015 payment
AICDP	0090	Level II Pacemaker/Similar Procedures	$6,542.78
AICDP	0089	Level III Pacemaker/Similar Procedures	9,489.74
AICDP	0655	Level IV Pacemaker/Similar Procedures	16,400.98
AICDP	0107	Level I ICD and Similar Procedures	22,907.64
AICDP	0108	Level II ICD and Similar Procedures	30,806.39
BREAS	0648	Level IV Breast and Skin Surgery	7,461.40
ENTXX	0259	Level VII ENT Procedures	29,706.85
EPHYS	0084	Level I Electrophysiologic Procedures	872.92
EPHYS	0085	Level II Electrophysiologic Procedures	4,633.33
EPHYS	0086	Level III Electrophysiologic Procedures	14,356.62
EYEXX	0293	Level IV Intraocular Procedures	8,446.54
EYEXX	0351	Level V Intraocular Procedures	23,075.30
GIXXX	0384	GI Procedures with Stents	3,173.83
NSTIM	0061	Level II Neurostim./Related Procedures	5,288.58
NSTIM	0039	Level III Neurostim./Related Procedures	17,099.35
NSTIM	0318	Level IV Neurostim./Related Procedures	26,152.16
ORTHO	0425	Level V Musculoskeletal Procedures	10,220.00

TABLE 7—CY 2015 C–APCS—Continued

Clinical family *	C–APC	APC title	CY 2015 payment
PUMPS	0227	Implantation of Drug Infusion Device	15,566.34
RADTX	0067	Single Session Cranial SRS	9,765.40
UROGN	0202	Level V Gynecologic Procedures	3,977.63
UROGN	0385	Level I Urogenital Procedures	6,822.35
UROGN	0386	Level II Urogenital Procedures	13,967.97
VASCX	0083	Level I Endovascular Procedures	4,537.45
VASCX	0229	Level II Endovascular Procedures	9,624.10
VASCX	0319	Level III Endovascular Procedures	14,840.64

* **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.
NSTIM = Neurostimulators.
ORTHO = Orthopedic Surgery.
PUMPS = Implantable Drug Delivery Systems.
RADTX = Radiation Oncology.
UROGN = Urogenital Procedures.
VASCX = Vascular Procedures.

TABLE 8—CY 2015 PACKAGED CPT ADD–ON CODES THAT ARE EVALUATED FOR A COMPLEXITY ADJUSTMENT

CY 2015 CPT/ HCPCS add-on code	CY 2015 short descriptor
19297	Place breast cath for rad.
33225	L ventric pacing lead add-on.
37222	Iliac revasc add-on.
37223	Iliac revasc w/stent add-on.
37232	Tib/per revasc add-on.
37233	Tibper revasc w/ather add-on.
37234	Revsc opn/prq tib/pero stent.
37235	Tib/per revasc stnt & ather.
37237	Open/perq place stent ea add.
37239	Open/perq place stent ea add.
92921	Prq cardiac angio addl art.
92925	Prq card angio/athrect addl.
92929	Prq card stent w/angio addl.
92934	Prq card stent/ath/angio.
92938	Prq revasc byp graft addl.
92944	Prq card revasc chronic addl.
92998	Pul art balloon repr precut.
C9601	Perc drug-el cor stent bran.
C9603	Perc d-e cor stent ather br.
C9605	Perc d-e cor revasc t cabg b.
C9608	Perc d-e cor revasc chro add.

f. 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, cardiac electrophysiologic evaluation and ablation services, mental health services, multiple imaging services, and cardiac resynchronization therapy 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 the CY 2015 OPPS/ASC proposed rule (79 FR 40953), for CY 2015, we proposed to continue our composite APC payment policies for LDR prostate brachytherapy services, mental health services, and multiple imaging services, as discussed below. In addition, we noted that we finalized a policy in the CY 2014 OPPS/ASC final rule with comment period to modify our longstanding policy to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur (78 FR 74910 through 74912). For CY 2014, we created one new composite APC, entitled ''Extended Assessment and Management (EAM) Composite'' (APC 8009), to provide payment for all qualifying extended assessment and management encounters rather than recognize two levels of EAM composite APCs (78 FR 74910 through 74912). Under this policy, we allow any visits, a Level 4 or 5 Type A ED visit or a Level 5 Type B ED visit furnished by a hospital in conjunction with observation services of substantial duration to qualify for payment through EAM composite APC 8009. In the CY 2015 OPPS/ASC proposed rule (79 FR 40953 to 40954), we proposed to pay for qualifying extended assessment and management services through composite APC 8009.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40953), we also proposed to discontinue our composite APC payment policies for cardiac electrophysiologic evaluation and ablation services (APC 8000), and to pay for these services through comprehensive 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. As such, in the CY 2015 OPPS/ASC proposed rule, we proposed to delete APC 8000 for CY 2015 (79 FR 40953).

We note that we finalized a policy to discontinue and supersede the cardiac resynchronization therapy composite APC with comprehensive APC 0108 (Level II Implantation of Cardioverter-Defibrillators (ICDs)), as discussed in section II.A.2.e. of the CY 2014 OPPS/ASC final rule with comment period (78

FR 74902). For CY 2014, APC 0108 is classified as a composite APC, as discussed in the CY 2014 OPPS/ASC final rule with comment period, because comprehensive APCs were not made effective until CY 2015 (78 FR 74925). For CY 2015, with the implementation of our new comprehensive APC policy, in the CY 2015 OPPS/ASC proposed rule, we proposed to effectuate the policy finalized in the CY 2014 OPPS/ASC final rule with comment period, and pay for cardiac resynchronization therapy services through comprehensive APC 0108 (proposed to be renamed ''Level II ICD and Similar Procedures''), which is discussed in section II.A.2.e. of the CY 2015 proposed rule (79 FR 40953).

(1) Extended Assessment and Management Composite APC (APC 8009)

Beginning in CY 2008, we included composite APC 8002 (Level I Extended Assessment and Management (EAM) Composite) and composite APC 8003 (Level II Extended Assessment and Management (EAM) Composite) in the OPPS to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur (an extended visit). In most of these circumstances, observation services are furnished in conjunction with evaluation and management services as an integral part of a patient's extended encounter of care. From CY 2008 through CY 2013, in the circumstances when 8 or more hours of observation care was provided in conjunction with a high level visit, critical care, or direct referral for observation, was an integral part of a patient's extended encounter of care, and was not furnished on the same day as surgery or post-operatively, a single OPPS payment was made for the observation and evaluation and management services through one of the two composite APCs, as appropriate. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163 through 74165) for a full discussion of this longstanding policy for CY 2013 and prior years. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74910), we created one new composite APC, APC 8009 (Extended Assessment and Management (EAM) Composite), to provide payment for all qualifying extended assessment and management encounters rather than recognizing two levels of EAM composite services. Under the CY 2014 finalized policy, we no longer recognize composite APC 8002 or APC 8003. Beginning in CY 2014, we allowed services identified by the new single 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), 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 post-operatively) (78 FR 74910 through 74912) to qualify for payment through EAM composite APC 8009.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40953 through 40954), for CY 2015, we proposed to continue our CY 2014 finalized policy to provide payment for all qualifying extended assessment and management encounters through composite APC 8009. As we did for CY 2014, in the CY 2015 OPPS/ASC proposed rule, for CY 2015, we proposed to allow a clinic visit and certain high level ED visits furnished by a hospital in conjunction with observation services of substantial duration (8 or more hours) to qualify for payment through the EAM composite APC 8009 (provided the observation is not furnished on the same day as surgery or post-operatively). Specifically, we proposed to continue to allow a clinic visit, a Level 4 or Level 5 Type A ED visit, or a Level 5 Type B ED visit furnished by a hospital or a direct referral for observation (identified by HCPCS code G0379) performed in conjunction with observation services of substantial duration to qualify for payment through composite APC 8009 (provided the observation is not furnished on the same day as surgery or post-operatively). We note that, for CY 2015, we also proposed to continue our current policy where one service code describes all clinic visits. We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74910 through 74912) for a full discussion of the creation of composite APC 8009.

As we noted in the CY 2014 OPPS/ASC final rule with comment period, the historical cost data used annually to calculate the geometric mean costs and payment rate for composite APC 8009 would not reflect the single clinic visit code that was new for CY 2014 (HCPCS code G0463) until our CY 2016 rulemaking cycle. We stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74910 through 74912) that when hospital claims data for the CY 2014 clinic and ED visit codes become available, we would calculate the geometric mean cost for EAM composite APC 8009 using CY 2014 single and ''pseudo'' single procedure claims that meet each of 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 1 day earlier than the date of service associated with HCPCS code G0378. (By selecting these claims from single and ''pseudo'' single claims, we ensure that they would not contain a code for a service with status indicator ''T'' on the same date of service.)
- 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 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.

Because we have no available cost data for HCPCS code G0463, for CY 2015, we proposed to calculate the geometric mean cost for procedures assigned to APC 8009 using CY 2013 single and ''pseudo'' single procedure claims that met each of the following criteria:

- The claim did not contain a HCPCS code to which we have assigned status indicator ''T'' that is reported with a date of service 1 day earlier than the date of service associated with HCPCS code G0378. (By selecting these claims from single and ''pseudo'' single claims, we assured that they would not contain a code for a service with status indicator ''T'' on the same date of service.)
- The claim contained 8 or more units of services described by HCPCS code G0378 (Observation services, per hour.)
- The claim contained 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; or CPT code 99201 (Office or other outpatient visit for the evaluation and management of a new patient (Level 1)); CPT code 99202 (Office or other outpatient visit for the evaluation and management of a new patient (Level 2)); CPT code 99203 (Office or other outpatient visit for the evaluation and management of a new patient (Level 3)); CPT code 99204 (Office or other outpatient visit for the evaluation and management of a new patient (Level 4)); CPT code 99205 (Office or other outpatient visit for the evaluation and management of a new patient (Level 5)); CPT code 99211

(Office or other outpatient visit for the evaluation and management of an established patient (Level 1)); CPT code 99212 (Office or other outpatient visit for the evaluation and management of an established patient (Level 2)); CPT code 99213 (Office or other outpatient visit for the evaluation and management of an established patient (Level 3)); CPT code 99214 (Office or other outpatient visit for the evaluation and management of an established patient (Level 4)); CPT code 99215 (Office or other outpatient visit for the evaluation and management of an established patient (Level 5)); 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)); HCPCS code G0384 (Type B emergency department visit (Level 5)); or CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) provided on the same date of service or 1 day before the date of service for HCPCS code G0378.

The proposed CY 2015 geometric mean cost resulting from this methodology for EAM composite APC 8009 was approximately $1,287.

Comment: One commenter urged CMS to consider options to minimize the financial burden for the beneficiary associated with self-administered drugs while the beneficiary is receiving observation services. The commenter also supported efforts to count outpatient observation toward the Medicare skilled nursing facility (SNF) 3-day stay requirement. Another commenter expressed concern that paying for all qualifying EAM encounters through a single composite APC is likely to penalize certain outpatient facilities, such as those that are attached to safety-net or teaching hospitals, which treat more complex patients and populations. The commenter urged CMS to monitor and accept provider feedback concerning the impact of this coding change to ensure that it does not create financial pressure or incentives to admit borderline cases, deny treatment, or otherwise negatively affect clinical decision making.

Response: The comments related to beneficiary liability associated with self-administered drugs and counting outpatient observation toward the SNF 3-day qualifying stay are outside the scope of the proposed regulations. We do not believe that paying for all qualifying EAM encounters through a single composite APC is likely to penalize certain outpatient facilities that treat more complex patients and populations. We believe that this proposal accurately accounts for the cost of providing an extended assessment and management service and that this proposal does not have any substantial impact on any particular type of facility or patient type. We also do not believe that paying for all qualifying EAM encounters through a single composite APC creates any financial pressure or incentives to admit borderline cases, deny treatment, or otherwise negatively affect clinical decision making. We continue to expect hospitals to provide the appropriate medical care to all beneficiaries.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue our CY 2014 finalized policy to provide payment for all qualifying extended assessment and management encounters through composite APC 8009 for CY 2015. We also are finalizing our proposal, without modification, to continue to allow a clinic visit and certain high level ED visits furnished by a hospital in conjunction with observation services of substantial duration (8 or more hours) to qualify for payment through EAM composite APC 8009 (provided the observation is not furnished on the same day as surgery or post-operatively). The final CY 2015 geometric mean cost resulting from this methodology for EAM composite APC 8009 is approximately $1,281.

(2) Low Dose Rate (LDR) Prostate Brachytherapy Composite APC (APC 8001)

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.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40955), for CY 2015, we proposed to continue to pay for LDR prostate brachytherapy services using the composite APC payment methodology proposed and implemented for CY 2008 through CY 2014. That is, we proposed to use CY 2013 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 2014 practice, in the CY 2015 OPPS/ASC proposed rule (79 FR 40955), we proposed 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) and APC 0651 (Complex Interstitial Radiation Source Application), the APCs to which CPT codes 55875 and 77778 are assigned, respectively. We proposed to continue to calculate the geometric mean costs of procedures or services assigned to APCs 0163 and 0651 using single and ''pseudo'' single procedure claims. We continue to believe that this composite APC 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 2013 claims data available for the CY 2015 OPPS/ASC proposed rule, we were able to use 379 claims that contained both CPT codes 55875 and 77778 to calculate the

proposed geometric mean cost of approximately $3,669 for these procedures upon which the proposed CY 2015 payment rate for composite APC 8001 is based.

Comment: Several commenters expressed concern that the proposed payment rate for APC 8001 is based only on 379 claims that reported both CPT codes 55875 and 77778 on the same date of service, a significant decrease from the CY 2014 final rule claims data used for ratesetting when 591 claims were available. Commenters also noted that the proposed payment rate of $3,504.02 yields an 8.9 percent decrease in payment compared to the CY 2014 payment rate of $3,844.64. One commenter opined that the decrease in payment for these services is partially due to the number of brachytherapy procedures provided in the hospital outpatient setting. A few commenters urged CMS to closely monitor the number of claims used to set the payment rate for this APC and to consider other ratesetting methodologies if the number of claims continues to decrease. Several commenters expressed that the low volume of claims reporting outpatient brachytherapy services also affected other APCs, notably APC 0312 (Radioelement Applications) and APC 0651 (Complex Interstitial Radiation Source Application), and cited additional decreases in the volume of claims used for ratesetting for these APCs.

Response: The CY 2015 final rule claims data show that 406 claims were available and used to set the payment rate for APC 8001, with a geometric mean cost of approximately $3,745, compared to the proposed rule claims data that showed 379 claims available and used for ratesetting, with a geometric mean cost of approximately $3,669. In response to comments regarding the decrease in the number of claims available for CY 2015 ratesetting and the geometric mean cost relative to the number of claims available for CY 2014 ratesetting and the geometric mean cost, we note that there is typically some fluctuation in costs from year to year. We acknowledge that the number of claims available and used for ratesetting for APC 8001 has decreased over recent years. However, the percentage of single frequency claims compared to total claims that we were able to use for ratesetting in this final rule with comment period is comparable to prior years. In addition, evaluation of the claims data for the 4 years prior to CY 2014 indicated that the mean or median costs used for ratesetting for APC 8001 were lower in those years than CY 2014 or CY 2015 cost levels. For APC 0651, based on final rule claims data, there are 62 single frequency claims out of a total of 3,785 claims, with a geometric mean cost of approximately $988. For APC 0312, based on final rule claims data, there are 26 single frequency claims out of a total of 378 claims, with a geometric mean cost of approximately $411. We agree with the commenters' assertion that it appears that there are an increasing number of radiation oncological technologies that are competing with prostate brachytherapy, which may be contributing to a decreased number of claims available for ratesetting for these APCs. As we stated in the CY 2014 OPPS/ASC final rule with comment period, we will continue to evaluate additional refinements and improvements to our ratesetting methodologies in order to maximize the use of claims data (78 FR 74913). In addition, we will continue to explore means by which we can use a larger volume of claims to establish the payment rate for APC 0312 and APC 0651.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue use of composite APC 8001 for CY 2015 and to set the payment rate for this APC using our established methodology. The final geometric mean cost for composite APC 8001 for CY 2015 is approximately $3,745.

(3) Mental Health Services Composite APC (APC 0034)

In the CY 2015 OPPS/ASC proposed rule (79 FR 40955), for CY 2015, we proposed 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, in the CY 2015 OPPS/ASC proposed rule (79 FR 40955), we proposed 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 APC 0034 (Mental Health Services Composite). We also proposed to continue to set the payment rate for APC 0034 at the same payment rate that we proposed to establish for APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs), which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid one unit of APC 0034 (79 FR 40955). 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 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.

We did not receive any public comments on this proposal. Therefore, we are finalizing our CY 2015 proposal, without modification, to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to a single beneficiary by a hospital to the payment rate for APC 0176, which is the maximum partial hospitalization per diem payment for a hospital for CY 2015.

(4) 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 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 the CY 2015 OPPS/ASC proposed rule, for CY 2015, we proposed 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 (79 FR 40956). 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 2015 payment rates for the five multiple imaging composite APCs (APC 8004, APC 8005, APC 8006, APC 8007, and APC 8008) were based on geometric mean costs calculated from a partial year of CY 2013 claims available for the 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 2013 and CY 2014 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, pursuant to 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 the CY 2015 OPPS/ASC 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 that proposed rule.

For the CY 2015 OPPS/ASC proposed rule, we were able to identify approximately 636,000 ''single session'' claims out of an estimated 1.6 million potential composite APC cases from our ratesetting claims data, approximately 40 percent of all eligible claims, to calculate the proposed CY 2015 geometric mean costs for the multiple imaging composite APCs.

Table 8 of the proposed rule (79 FR 40956 through 40958) listed the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC geometric mean costs for CY 2015.

Comment: A few commenters expressed concern that the multiple imaging composite APCs may undercompensate providers for imaging procedures. These commenters recommended that CMS provide an analysis of the effects of reductions in imaging payments due to the composite APC policy on utilization. The commenters recommended that CMS provide separate payment for each imaging procedure in light of reductions to payment for imaging procedures.

Response: We continue to believe that our multiple imaging composite policies reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session, and some of those efficiencies result in lower payments due to cost savings from furnishing multiple imaging services on the same date. We will continue to monitor the multiple imaging composite APC ratesetting methodology and the cost of providing imaging services. If appropriate, we may report any information to the HOP Panel, or discuss and propose changes to the multiple imaging composite APCs in rulemaking in the future.

After consideration of the public comments received, we are finalizing our proposal to continue the use of multiple imaging composites without modification. We were able to identify approximately 661,000 million ''single session'' claims out of an estimated 1.68 million potential composite cases from our CY 2013 ratesetting claims data, approximately 39 percent of all eligible claims, to calculate the final CY 2015 geometric mean costs for the multiple imaging composite APCs.

Table 9 below lists the HCPCS codes that will be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC geometric mean costs for CY 2015.

TABLE 9—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1—Ultrasound	
CY 2015 APC 8004 (Ultrasound composite)	CY 2015 Approximate 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.

TABLE 9—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

76856	Us exam, pelvic, complete.
76870	Us exam, scrotum.
76857	Us exam, pelvic, limited.

Family 2—CT and CTA with and without Contrast

CY 2015 APC 8005 (CT and CTA without Contrast Composite)*	CY 2015 Approximate 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 2015 APC 8006 (CT and CTA with Contrast Composite)	CY 2015 Approximate 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 2015 APC 8007 (MRI and MRA without Contrast Composite)*	CY 2015 Approximate 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 9—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 2015 APC 8008 (MRI and MRA with Contrast Composite)	CY 2015 Approximate 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. 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 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 expensive 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 items.

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 we originally paid as primary services. 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 five packaging policies that were added in CY 2014 (78 FR 74925). 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 in the OPPS to determine which OPPS services can be packaged to achieve the objective of advancing the OPPS as a prospective payment system.

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 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 general, in the CY 2015 OPPS/ASC proposed rule (79 FR 40958 through 40961), we proposed to package the costs of selected HCPCS codes into payment for services reported with other HCPCS codes where we believe that one code reported an item or service that was integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by another HCPCS code. Below we discuss categories and classes of items and services that we proposed to package beginning in CY 2015. 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), and the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925).

b. Revisions of a Packaging Policy Established in CY 2014—Procedures Described by Add-On Codes

In the CY 2014 OPPS/ASC final rule with comment period, we packaged add-on codes in the OPPS, with the exception of add-on codes describing drug administration services (78 FR 74943; 42 CFR 419.2(b)(18)). With regard to the packaging of add-on procedures that use expensive medical devices, we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74943) that the most expensive medical devices used in procedures to insert or implant devices in the hospital outpatient setting are included in procedures that are assigned to comprehensive APCs. Comprehensive APCs are discussed in section II.A.2.e. of this final rule with comment period. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74864), we discussed the comprehensive APC policy, which we adopted, with modification, but delayed the implementation of, until CY 2015. We stated that, for CY 2014, we would continue to pay separately for only those add-on codes (except for drug administration add-on codes) that were assigned to device-dependent APCs in CY 2014, but that, after CY 2014, these device-dependent add-on codes would be paid under the comprehensive APC policy. According to the proposed changes to the comprehensive APC policy described in section II.A.2.e. of this final rule with comment period, we proposed to package all of the procedures described by add-on codes that are currently assigned to device-dependent APCs, which will be replaced by comprehensive APCs. The device-dependent add-on codes that are separately paid in CY 2014 that we proposed to package in CY 2015 were listed in Table 9 of the CY 2015 OPPS/ASC proposed rule (79 FR 40959).

Comment: A few commenters disagreed with the proposal to package payment for the add-on codes listed in Table 9 of the proposed rule for the following reasons:

- Some commenters requested that CMS delay packaging the device-dependent add-on codes remaining for CY 2015 while additional data analysis is performed and refinements are adopted to ensure accurate payment for the full range of add-on procedures, including those not assigned to comprehensive APCs.
- A few commenters suggested that add-on codes are separate and distinct clinical procedures having unique, independent values determined by the American Medical Association (AMA)

and, therefore, should not be treated as ancillary services.

• Some commenters requested that CMS establish exceptions to its proposal to package add-on codes for specific add-on procedures with high cost supply items that commenters believed would be underpaid under the policy and impede patient access to care.

Response: We disagree with the commenters that oppose packaging these remaining add-on codes. We received similar public comments during the CY 2014 rulemaking cycle and responded to those comments in the CY 2014 OPPS/ASC final rule with comment period. Generally, we disagree because add-on codes describe services that are integral, ancillary, supportive, dependent, or adjunctive to the primary service. In other words, add-on codes do not represent a stand-alone procedure and are inclusive to other procedures performed at the same time. For a full discussion of our response to these public comments, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74942 through 74943).

We also disagree with commenters' assertion that add-on code services are separate and distinct clinical procedures and should not be treated as ancillary services. We received a similar public comment last year where commenters suggested that procedures described by add-on codes are not integral, ancillary, supportive, dependent, or adjunctive to the primary service. As we noted previously (78 FR 74942 through 74943), the fundamental nature of an add-on code procedure is that it typically describes some form of a related extension of or addition to the primary procedure or service described by the primary procedure. The definition of an add-on code is that it is an extension of a primary, base service. CPT defines add-on codes as codes that describe ''procedures [that] are commonly carried out in addition to the primary procedure performed'' (2014 CPT Codebook Professional Edition, page xiv). Further, CPT states that ''add-on codes describe additional intra-service work *associated with the primary procedure* (emphasis added) (2014 CPT Codebook Professional Edition, page xiv). We also disagree with commenters that some add-on codes are not related to the primary procedure but represent a separate procedure that should be paid separately from the primary procedure. If such procedures were in fact separate procedures, they would not be described by an add-on code. Thus, we believe that add-on code procedures are not always separate and distinct clinical procedures, but rather are related extensions, supportive, integral, or adjunctive of the primary procedure and, therefore, it is appropriate to package the cost of the add-on codes into the payment calculation for the primary procedure. Finally, in response to commenters who requested that CMS establish exceptions to its proposal for add-on code with high cost supply items, we are allowing certain add-on codes to be evaluated for a complexity adjustment when billed with a comprehensive APC primary procedure. We refer readers to section II.A.2.e. of this final rule with comment period for further discussion of that policy. We see no reason to grant exceptions to the add-on code packaging policy to specifically account for add-on procedures with high cost supply items, as any associated costs are accounted for in the payment for the primary procedure. The only reason we did not package the add-on codes listed in Table 9 of the proposed rule was that implementation of the comprehensive APC policy was delayed for 1 year (78 FR 74943). Because the comprehensive APC policy will be implemented in CY 2015, we are packaging these remaining add-on codes.

After consideration of the public comments we received, we are finalizing our proposal to package all of the procedures described by add-on codes that are currently assigned to device-dependent APCs, which will be replaced by comprehensive APCs, as listed in Table 9 of the CY 2015 OPPS/ASC proposed rule (79 FR 40959) and included in Table 10 below. The current device-dependent add-on codes that are separately paid in CY 2014 that will be packaged in CY 2015 are included in Table 8 under section II.A.2.e. of this final rule with comment period, which addresses the comprehensive APC policy.

TABLE 10—ADD-ON CODES ASSIGNED TO DEVICE-DEPENDENT APCS FOR CY 2014 THAT ARE PACKAGED IN CY 2015

CY 2015 add-on code	Short descriptor
19297	Place breast cath for rad.
33225	L ventric pacing lead add-on.
37222	Iliac revasc add-on.
37223	Iliac revasc w/stent add-on.
37232	Tib/per revasc add-on.
37233	Tibper revasc w/ather add-on.
37234	Revsc opn/prq tib/pero stent.
37235	Tib/per revasc stnt & ather.
37237	Open/perq place stent ea add.
37239	Open/perq place stent ea add.
49435	Insert subq exten to ip cath.
92921	Prq cardiac angio addl art.
92925	Prq card angio/athrect addl.
92929	Prq card stent w/angio addl.
92934	Prq card stent/ath/angio.
92938	Prq revasc byp graft addl.
92944	Prq card revasc chronic addl.
92998	Pul art balloon repr precut.
C9601	Perc drug-el cor stent bran.
C9603	Perc d-e cor stent ather br.
C9605	Perc d-e cor revasc t cabg b.
C9608	Perc d-e cor revasc chro add.

c. Packaging Policies for CY 2015

(1) Ancillary Services

Under the OPPS, we currently pay separately for certain ancillary services. Some of these ancillary services are currently assigned to status indicator ''X,'' which is defined as ''ancillary services,'' but some other ancillary services are currently assigned to status indicators other than ''X.'' This is because the current use of status indicator ''X'' in the OPPS is incomplete and imprecise. Some procedures and services that are ancillary, for example, a chest X-ray, are assigned to an APC with services assigned status indicator ''S.'' As discussed in the CY 2015 OPPS/ASC proposed rule (79 FR 40959 through 40961), we reviewed all of the covered services provided in the HOPD and identified those that are commonly performed when provided with other HOPD services, and also provided as ancillary to a primary service in the HOPD. These 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.

As discussed in section II.A.3.a. of this final rule with comment period, our intent is that the OPPS be more of a prospective payment system with expanded packaging of items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service. Given that the longstanding OPPS policy is to package items and services that are integral, ancillary, supportive, dependent, or adjunctive to a primary service, we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74945) that we believe that ancillary services should be packaged when they are performed with another service, but should continue to be separately paid when performed alone. We indicated that this packaging approach is most consistent with a prospective payment system and the regulation at 42 CFR 419.2(b) that packages many ancillary services into primary services while preserving separate payment for those instances in which one of these ancillary services is provided alone (not with any other service paid under the OPPS) to a hospital outpatient. We did not finalize the ancillary packaging policy for CY 2014 because we believed that further evaluation was necessary (78 FR 74946).

In the CY 2015 OPPS/ASC proposed rule (79 FR 40959 through 40961), we proposed to conditionally package certain ancillary services for CY 2015. Specifically, we proposed to limit the initial set of APCs that contain conditionally packaged services to those ancillary service APCs with a proposed geometric mean cost of less than or equal to $100 (prior to application of the conditional packaging status indicator). We limited this initial set of packaged ancillary service APCs to those with a proposed geometric mean cost of less than or equal to $100 in response to public comments on the CY 2014 ancillary service packaging proposal in which commenters 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 that the proposed $100 geometric mean cost limit for selecting this initial group of conditionally packaged ancillary service APCs is less than the geometric mean cost of APC 0634, which contains the single clinic visit HCPCS code G0463, which is a single payment rate for clinic visits beginning in CY 2014, and had a CY 2015 OPPS/ASC proposed rule geometric mean cost of approximately $103. This proposed $100 geometric mean cost limit is part of the methodology of selecting the initial set of conditionally packaged ancillary service APCs under this proposed packaging policy. It is not meant to represent a threshold above which ancillary services will not be packaged, but as a basis for selecting this initial set of APCs, which will likely be updated and expanded in future years. In future years, we may package ancillary services assigned to APCs with geometric mean costs higher than $100. In addition, geometric mean costs can change over time. An increase in the geometric mean cost of any of the proposed APCs to above $100 in future years would not change the conditionally packaged status of services assigned to the APCs selected in CY 2015 in a future year. We would continue to consider these APCs to be conditionally packaged. However, we would review the conditionally packaged status of ancillary services annually.

We proposed to exclude certain services from this packaging policy even though they are assigned to APCs with a geometric mean cost of less than or equal to $100. Preventive services will continue to be paid separately, and include the following services listed in Table 11 below that would otherwise be packaged under this policy.

TABLE 11—PREVENTIVE SERVICES EXEMPTED FROM THE ANCILLARY SERVICE PACKAGING POLICY

HCPCS Code	Short descriptor	APC
76977	Us bone density measure	0340
77078	Ct bone density axial	0260
77080	Dxa bone density axial	0261
77081	Dxa bone density/peripheral	0260
G0117	Glaucoma scrn hgh risk direc	0260
G0118	Glaucoma scrn hgh risk direc	0230
G0130	Single energy x-ray study	0230
G0389	Ultrasound exam aaa screen	0265
G0404	Ekg tracing for initial prev	0450
Q0091	Obtaining screen pap smear	0450

In addition, we did not propose to package certain psychiatry and counseling-related services as we see similarities to a visit and, at the time of issuance of the CY 2015 OPPS/ASC proposed rule, did not consider them to be ancillary services. We also did not propose to package certain low cost drug administration services as we are examining various alternative payment policies for drug administration services, including the associated drug administration add-on codes.

Finally, we proposed to delete status indicator ''X'' (Ancillary Services) because the majority of the services assigned to status indicator ''X'' were proposed to be assigned to status indicator ''Q1'' (STV-Packaged Codes). For the services that are currently

assigned status indicator ''X'' that were not proposed to be conditionally packaged under this policy, we proposed to assign those services status indicator ''S'' (Procedure or Service, Not Discounted When Multiple), indicating separate payment and that the services are not subject to the multiple procedure reduction. The APCs that we proposed for conditional packaging as ancillary services in CY 2015 were listed in Table 11 of the CY 2015 OPPS/ASC proposed rule (79 FR 40960 through 40961).

The HCPCS codes that we proposed to conditionally package as ancillary services for CY 2015 were displayed in Addendum B to the CY 2015 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.*

We also proposed to revise the regulations at 42 CFR 419.2(b)(7) to replace the phrase ''Incidental services such as venipuncture'' with ''Ancillary services'' to more accurately reflect the proposed packaging policy discussed above.

Comment: A number of commenters, which included hospital associations, health systems, and individual hospitals, supported conditionally packaging ancillary services with a geometric mean cost of $100 prior to application of the ''Q1'' status indicator.

Response: We appreciate the commenters' support.

Comment: A few commenters expressed concern that conditionally packaging ancillary services would disproportionately affect teaching hospitals because of the types of patients these hospitals serve and the types of services that they typically provide. One commenter submitted results from its data analysis that estimated major teaching hospitals will lose approximately −0.4 percent on average as a result of this packaging proposal, compared to nonteaching hospitals, which would gain approximately 0.2 percent. The commenter's concern was that the negative impact is a direct result of academic medical centers' caring for unique and complex patient populations, for example, trauma patients who are seen in teaching hospital emergency departments. The commenter's analysis suggested that a large proportion of certain APCs listed on Table 11 of the proposed rule (APCs 0012, 0099, 0260, 0261, 0340, and 0420) are packaged into emergency department visits and related services.

Response: Conditional packaging of ancillary services results in packaging of these services when provided with other primary services and separate payment for the services when they are performed alone. It is possible that, as the commenter asserted, the case-mix at teaching hospitals results in greater packaging of ancillary services than at nonteaching hospitals. This may be due to teaching hospitals being more likely to provide services in addition to the ancillary service, which would result in packaging of the ancillary service into the other primary service or services provided to the patient. Even if the commenter's observation is reflective of a difference between teaching and nonteaching hospitals, we do not believe that such an observation is a sufficient reason to not package ancillary services in the OPPS. Packaging is a fundamental element of a prospective payment system. As stated above, in the OPPS, we packaged items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service. We believe that the ancillary services proposed for conditional packaging are ancillary when provided with other primary services and, therefore, are appropriately conditionally packaged in the OPPS. As for the impact of the CY 2015 OPPS policies on teaching hospitals, we refer the commenter to the impact table (Table 49) in section XXI. of this final rule with comment period, which shows that teaching hospitals will receive an overall 2.3 percent payment update compared to a 2.0 percent payment update for nonteaching hospitals. Therefore, overall teaching hospitals stand to benefit more than nonteaching hospitals from the policies adopted in this final rule with comment period, despite any relative negative impacts from the ancillary packaging policy.

Comment: Several commenters requested clarification of the methodology used to identify APCs with a geometric mean cost less than or equal to $100 prior to application of the ''Q1'' status indicator, given that the geometric mean cost of some of the APCs listed in Table 11 of the proposed rule exceeds $100. Also, commenters requested that the $100 threshold be held constant for future years or updated annually based on inflation akin to the drug threshold methodology.

Response: As we stated in the CY 2015 OPPS/ASC proposed rule (79 FR 40960), the ancillary services APCs proposed for conditional packaging were those with a geometric mean cost of less than or equal to $100 *prior* to application of the ''Q1'' status indicator to the APC. In other words, it was ancillary service APCs with a geometric mean cost of $100 or less with all of the services assigned to the APC that had either status indicator ''X'' or ''S.'' Once status indicator ''Q1'' was assigned, some of the geometric mean costs of some of the APCs increased to above $100 due to conditional packaging according to the ''Q1'' status indicator logic. We remind the commenters that the APCs listed in Table 11 of the proposed rule (79 FR 40960 through 40961) displayed the APC geometric mean costs after application of the ''Q1'' status indicator, which resulted in some of the APC geometric mean costs that were below $100 prior to application of the ''Q1'' status indicator to exceed $100 after application of the ''Q1'' status indicator. We also clarify that the $100 geometric mean cost initial selection criteria for this packaging policy is not a threshold above which ancillary services will not be conditionally packaged. As we stated in the CY 2015 OPPS/ASC proposed rule, ''[the $100 limit] is not meant to represent a threshold above which ancillary services will not be packaged, but as a basis for selecting this initial set of APCs, which will likely be updated and expanded in future years'' (79 FR 40960). As we stated in the proposed rule, in future years, we may package additional ancillary services in APCs with a geometric mean cost (prior to the application of the conditional packaging status indicator) that exceeds $100.

Comment: One commenter expressed concern regarding the composition of APC 0077 (Level I Pulmonary Treatment), which was proposed to be conditionally packaged. The commenter believed that HCPCS code G0424 (Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day) is not clinically similar to HCPCS code G0237 (Therapeutic procedures to increase strength or endurance of respiratory muscles, face to face, one on one, each 15 minutes (includes monitoring) and HCPCS code G0238 (Therapeutic procedures to improve respiratory function, other than described by G0237, one on one, face to face, per 15 minutes (includes monitoring), which also are assigned to APC 0077. In addition, the commenter stated that the assignment of HCPCS code G0424 to APC 0077 would create a 2 times rule violation. The commenter recommended that CMS reassign HCPCS code G0424 to APC 0078 (Level II Pulmonary Treatment).

Response: We disagree with the commenter's assertion that the assignment of HCPCS code G0424 to

APC 0077 would create a 2 times rule violation. Section 1833(t)(9) of the Act requires that we annually review all the items and services within an APC group and revise the APC structures accordingly. Included in this review is the identification of any 2 times rule violations as provided under section 1833(t)(2) of the Act and, to the extent possible, rectification of these violations. We review our claims data and determine whether we need to make changes to the current APC assignment for the following year. For HCPCS codes G0238 and G0424, we evaluated their APC assignment for the CY 2015 update and determined that APC 0340 (Level II Minor Procedures) is the more appropriate assignment for these services based on resource similarity to the other services assigned to APC 0340. In addition, with the reassignment of HCPCS codes G0424 and G0238 to APC 0340, only four HCPCS codes (31270, 94668, 94669, and G0237) remained in APC 0077, one (HCPCS code 94669) of which did not have any claims volume in CY 2013. The commenter suggested that we reassign HCPCS code G0424 to APC 0078. APC 0078 has a mean cost of approximately $90, which is under the $100 initial selection criteria for conditionally packaged ancillary services. With the reduced size of APC 0077 and the mean cost of APC 0078 being less than $100, we are reassigning the procedure codes remaining in APC 0078 to APC 0077 and revising the title of APC 0077 to read ''Pulmonary Treatment.'' The new combined APC 0077 is assigned status indicator ''Q1'' under the conditional packaging policy. We note that the mean cost of this revised APC 0077 (after application of the ''Q1'' status indicator) is approximately $154.

Comment: One commenter requested that CMS continue separate payment, by assigning status indicator ''S,'' for CPT codes 92557 (comprehensive hearing test), 92601 through 92604 (cochlear implant programming), and 92640 (auditory brainstem implant programming) which are assigned to APC 0364, an APC that is proposed for conditional packaging. The commenter stated that these CPT codes are primary audiology services and are not dependent or incident to other services in the hospital.

Response: We do not believe that it is necessary to change the status indicator to ''S'' as we disagree that these CPT codes represent primary audiology services. Conditional packaging provides separate payment when the otherwise packaged services are provided alone without other primary services. Therefore, these services will continue to be separately paid when performed without other primary services.

Comment: Some commenters expressed concern that packaging payment for ancillary services could have a negative impact on patient access because hospitals will not have an incentive to perform ancillary services at the time of other therapeutic or evaluation/management services, even when providing such services at the same encounter would be efficient and offer patients the most appropriate and complete care. Commenters cautioned that expanded packaging policies will impede the accuracy and stability of future ratesetting under the OPPS.

Response: We appreciate stakeholders' concerns and predictions about the effect that this conditional packaging policy may have on patient access to ancillary services. We will continue to monitor service utilization trends in the HOPD. We disagree with commenters that packaging services impedes the accuracy and stability of future OPPS ratesetting. As a reminder, hospitals include HCPCS codes and charges for packaged services on their claims, and the costs associated with those packaged services are included in the costs of the separately payable procedure on the claim. We also continue to emphasize that hospitals should report all HCPCS codes for all services, including those for packaged services, according to correct coding principles.

Comment: One commenter disagreed with the proposed assignment of status indicator ''Q1'' to CPT code 95012 (Expired nitric oxide gas determination). The commenter requested that CMS assign status indicator ''S'' to CPT code 95012 because the code describes an independent, primary procedure that is not ancillary to any other procedure. The commenter also requested that CMS reassign CPT code 95012 to APC 0078 (Level II Pulmonary Treatment) because of its clinical homogeneity to other services assigned to that APC.

Response: We disagree with the commenter. We believe the procedure or service described by CPT code 95012 to be an ancillary diagnostic test and, therefore, appropriate for conditional packaging under the ancillary services policy. We believe that existing assignment to APC 0340 (Level II Minor Procedures) is appropriate in that CPT code 95012 is a minor test and that its mean cost of approximately $41 is similar to the mean cost of APC 0340 of approximately $53. Therefore, we are finalizing our proposal to maintain assignment of CPT code 95012 to APC 0340 with a ''Q1'' status indicator for CY 2015.

Comment: A few commenters requested that CMS make an exception to the ancillary packaging policy for pathology services, specifically those services assigned to APC 0342 (Level I Pathology) and APC 0433 (Level II Pathology). These commenters were concerned about inadequate payment for pathology services.

Response: We disagree with commenters' concern regarding inadequate payment for pathology services and do not believe that an exception to this packaging policy for the pathology services assigned to APCs 0342 and 0433 is appropriate at this time. We remind the commenters that this policy only affects the facility payment for the technical aspect of the services and does not affect the physician fee schedule payment to the pathologist for the physician work in performing pathology services. We believe that pathology services are some of the best examples of ancillary services as they typically follow a surgical or other specimen-generating procedure for the purposes of diagnosis. We also remind the commenters that in the event a patient receives a pathology test in isolation from other primary HOPD services, the test would be separately paid because the ancillary services packaging policy is a conditional packaging policy. Therefore, we are not creating an exception to this ancillary packaging policy for pathology services.

After consideration of the public comments we received, we are finalizing our ancillary services packaging policy as proposed, including deletion of status indicator ''X.'' We also are adopting as final our proposed revision of the regulations at 42 CFR 419.2(b)(7) to replace the phrase ''Incidental services such as venipuncture'' with ''Ancillary services'' to more accurately reflect the final packaging policy for CY 2015.

The APCs that we are conditionally packaging as ancillary services in CY 2015 are listed in Table 12 below.

TABLE 12—APCS FOR CONDITIONALLY PACKAGED ANCILLARY SERVICES FOR CY 2015

APC	CY 2015 OPPS Geometric mean cost (with application of Q1 status indicator)	Final CY 2015 OPPS SI	Group title
0012	$102.18	Q1	Level I Debridement & Destruction.
0060	20.57	Q1	Manipulation Therapy.
0077	170.77	Q1	Level I Pulmonary Treatment.
0099	81.40	Q1	Electrocardiograms/Cardiography.
0215	98.52	Q1	Level I Nerve and Muscle Services.
0230	54.01	Q1	Level I Eye Tests & Treatments.
0260	61.59	Q1	Level I Plain Film Including Bone Density Measurement.
0261	98.56	Q1	Level II Plain Film Including Bone Density Measurement.
0265	95.12	Q1	Level I Diagnostic and Screening Ultrasound.
0340	54.33	Q1	Level II Minor Procedures.
0342	56.31	Q1	Level I Pathology.
0345	78.91	Q1	Level I Transfusion Laboratory Procedures.
0364	44.94	Q1	Level I Audiometry.
0365	122.36	Q1	Level II Audiometry.
0367	167.31	Q1	Level I Pulmonary Tests.
0420	136.66	Q1	Level III Minor Procedures.
0433	190.55	Q1	Level II Pathology.
0450	30.33	Q1	Level I Minor Procedures.
0624	81.76	Q1	Phlebotomy and Minor Vascular Access Device Procedures.
0690	36.47	Q1	Level I Electronic Analysis of Devices.
0698	104.61	Q1	Level II Eye Tests & Treatments.

The HCPCS codes that we are conditionally package as ancillary services for CY 2015 are displayed in Addendum B to this CY 2015 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site). The supporting documents for this final rule with comment period are available at the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

(2) Prosthetic Supplies

We have a longstanding policy of providing payment under the OPPS for implantable DME, implantable prosthetics, and medical and surgical supplies, as provided at sections 1833(t)(1)(B)(i) and (t)(1)(B)(iii) of the Act and 42 CFR 419.2(b)(4), (b)(10), and (b)(11). In the CY 2014 OPPS/ASC final rule with comment period, we clarified that medical and surgical supplies under § 419.2(b)(4) include (but are not limited to) all supplies on the DMEPOS Fee Schedule except prosthetic supplies (78 FR 74947). Under 42 CFR 419.22(j), prosthetic supplies are currently excluded from payment under the OPPS and are paid under the DMEPOS Fee Schedule, even when provided in the HOPD. However, as we discussed in the CY 2015 OPPS/ASC proposed rule (79 FR 40961), under section 1833(t)(1)(B)(i) of the Act, the Secretary has the authority to designate prosthetic supplies provided in the hospital outpatient setting as covered OPD services payable under the OPPS.

As we stated in the CY 2015 OPPS/ASC proposed rule (79 FR 40961) and as mentioned above, implantable prosthetic devices are packaged in the OPPS under 42 CFR 419.2(b)(11). It is common for implantable prosthetic devices to be provided as a part of a device system. Such device systems include the implantable part or parts of the overall device system and also certain nonimplantable prosthetic supplies that are integral to the overall function of the medical device, part of which is implanted and part of which is external to the patient. These prosthetic supplies are integral to the implantable prosthetic because typically shortly after the surgical procedure to implant the implantable prosthetic device in the hospital, the surgeon and/or his or her colleagues will have to attach, fit, and program certain prosthetic supplies that are not surgically implanted into the patient but are a part of a system and that are essential to the overall function of an implanted device. Because these supplies are integral to the overall function of the implanted prosthetic, and because, as mentioned above, we package in the OPPS items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service, we believe that it is most consistent with a prospective payment system to package the payment of prosthetic supplies (along with the implantable prosthetic device) into the surgical procedure that implants the prosthetic device, as all of the components are typically necessary for the performance of the system and the hospital typically purchases the system as a single unit. Patients requiring replacement supplies at a time later than the initial surgical procedure and outside of the hospital would obtain them as they typically do from a DMEPOS supplier with payment for such supplies made under the DMEPOS Fee Schedule.

In addition to prosthetic supplies that are components of device systems, part of which are implanted, many other prosthetic supplies on the DMEPOS Fee Schedule are typical medical and surgical supplies and of the type that are packaged in the OPPS under § 419.2(b)(4). Consistent with our change from status indicator ''A'' to ''N'' for all nonprosthetic DMEPOS supplies in the CY 2014 OPPS final rule with comment period (78 FR 74947), in the CY 2015 OPPS/ASC proposed rule (79 FR 40961), we proposed to package and change the status indicator from ''A'' to ''N'' for all DMEPOS prosthetic supplies. With this proposed change, all medical and surgical supplies would be packaged in the OPPS.

Therefore, we proposed to delete ''prosthetic supplies'' from the regulations at § 419.22(j) because we proposed that prosthetic supplies be packaged covered OPD services in the OPPS for CY 2015. Prosthetic supplies provided in the HOPD would be included in ''medical and surgical supplies'' (as are all other supplies currently provided in the HOPD) under § 419.2(b)(4). The HCPCS codes for prosthetic supplies that we proposed to

package for CY 2015 were displayed in Addendum B to the CY 2015 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site). The supporting documents for the proposed rule, including but not limited to Addendum B, are available at the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Comment: Many commenters agreed with CMS' proposal to conditionally package prosthetic supplies furnished in the HOPD.

Response: We appreciate the commenters' support.

Comment: A few commenters requested to be informed of the fund transfer amount from the DMEPOS Fee Schedule to the OPPS as a result of this proposed policy.

Response: Our CY 2013 claims analysis shows that packaging payment for prosthetic supplies under the OPPS would redistribute approximately $1 million.

Comment: Some commenters recommended that CMS implement an exception to the ''unbundling'' rule that currently exists for the inpatient prospective payment systems (IPPS). (We refer readers to the Medicare Claims Processing Manual, Pub. 100–04, Chapter 20—Durable Medical Equipment, Prosthetics, Orthotic Devices, and Supplies, Section 110—General Billing Requirements—for DME, Prosthetics, Orthotic Devices, and Supplies.) The commenters believed that such an exception would allow DME suppliers to bill Medicare directly for prosthetic supplies furnished to patients during an outpatient visit when the supplies are intended primarily for home use.

Response: We do not believe that an additional exception to the ''unbundling'' rule is necessary for the provision of prosthetic supplies in the HOPD. We remind commenters that DME, prosthetics, and orthotics can be billed by hospitals for outpatients and are paid according to the DMEPOS Fee Schedule. Only prosthetic supplies are packaged in the OPPS. Unlike inpatient stays, hospital outpatient stays are typically brief and the need for replacement supplies during a hospital outpatient stay should be minimal. If a hospital wants to provide a patient with some basic supplies for immediate home use (for example, tape, a syringe, or gauze), such supplies are packaged into the payment for whatever service the patient received at the hospital. DME suppliers can furnish additional or replacement prosthetic supplies to the patient's home and receive payment under the DMEPOS Fee Schedule.

After consideration of the public comments we received, we are adopting as final our proposed deletion of ''prosthetic supplies'' from the regulations at § 419.22(j) because prosthetic supplies are packaged covered OPD services in the OPPS for CY 2015. Prosthetic supplies provided in the HOPD will be included in the packaged category of ''medical and surgical supplies'' (as are all other supplies currently provided in the HOPD) under § 419.2(b)(4). The HCPCS codes for prosthetic supplies that we are packaging for CY 2015 are displayed in Addendum B to this CY 2015 OPPS/ASC final rule with comment period (which is available via Internet on the CMS Web site). The supporting documents for this final rule with comment period, including but not limited to Addendum B, are available at the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

4. Calculation of OPPS Scaled Payment Weights

In the CY 2015 OPPS/ASC proposed rule (79 FR 40961 through 40962), for CY 2015, we proposed to calculate the relative payment weights for each APC shown in Addenda A and B to the 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 the proposed rule. Prior to CY 2007, we standardized all 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 the relative payment weight for each APC.

Beginning with the CY 2007 OPPS (71 FR 67990), we standardized all of the relative payment weights to 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 five levels). For the CY 2013 OPPS (77 FR 68283), we established a policy of using geometric mean-based APC costs rather than median-based APC costs to calculate relative payment weights. For CY 2015, we proposed to continue this policy.

For the CY 2014 OPPS, we standardized all of the relative payment weights to clinic visit APC 0634 as discussed in section VII. of the CY 2015 OPPS/ASC proposed rule (79 FR 41008). For CY 2015, we proposed to continue this policy to maintain consistency in calculating unscaled weights that represent the cost of some of the most frequently provided services. We proposed to assign APC 0634 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the proposed geometric mean cost for APC 0634 to derive the proposed unscaled relative payment weight for each APC. The choice of the APC on which to base 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 2015 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 proposed to compare the estimated aggregate weight using the CY 2014 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2015 unscaled relative payment weights.

We did not receive any public comments on our proposed policy for the CY 2015 unscaled relative payment weights. Therefore, we are finalizing our proposed policy to maintain consistency in calculating unscaled weights that represent the cost of some of the most frequently provided services by assigning APC 0634 a relative payment weight of 1.00 and dividing the geometric mean cost of each APC by the geometric mean cost for APC 0634 to derive the unscaled relative payment weight for each APC for CY 2015.

For CY 2014, we multiplied the CY 2014 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2013 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 2015, we proposed to apply the same process using the CY 2015 unscaled relative payment weights rather than scaled relative payment weights. We proposed to calculate the weight scaler by dividing the CY 2014 estimated aggregate weight by the CY 2015 estimated aggregate weight (79 FR

40962). The service-mix is the same in the current and prospective years because we use the same set of claims for service volume in calculating the aggregate weight for each year. We note that the CY 2014 OPPS scaled relative weights incorporate the estimated payment weight from packaged laboratory tests previously paid at CLFS rates.

For a detailed discussion of the weight scaler 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 2015 OPPS final rule link, then open the claims accounting document link at the bottom of the page.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40962), we proposed to include estimated payments to CMHCs in our comparison of the estimated unscaled relative payment weights in CY 2015 to the estimated total relative payment weights in CY 2014 using CY 2013 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we proposed to adjust the proposed CY 2015 unscaled relative payment weights for purposes of budget neutrality. The proposed CY 2015 unscaled relative payment weights were adjusted by multiplying them by a weight scaler of 1.3220 to ensure that the proposed CY 2015 relative payment weights are budget neutral.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act states 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 final rule with comment period) is included in the budget neutrality calculations for the CY 2015 OPPS.

Comment: One commenter expressed concern that CMS did not provide detailed data on the weight scaling process. The commenter noted that it could not find the claims accounting document to which the proposed rule referenced.

Response: The direct link to the proposed rule claims accounting document is located on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1613-P-claims-accounting-narrative.pdf.*

After consideration of the public comments we received, we are finalizing our proposed methodology for calculating the OPPS scaled relative payment weights without modification, including updating of the budget neutrality scaler for this final rule with comment period. Under this methodology, the final unscaled relative payment weights were adjusted by a weight scaler of 1.2977 for this final rule with comment period. The CY 2015 unscaled relative payment weights listed in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site) incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this final rule with comment period.

B. 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 2015 IPPS/LTCH PPS final rule (79 FR 49994), consistent with current law, based on IHS Global Insight, Inc.'s second quarter 2014 forecast of the FY 2015 market basket increase, the FY 2015 IPPS market basket update is 2.9 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 2015.

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 2015 IPPS/LTCH PPS final rule (79 FR 49994), we discussed the calculation of the MFP adjustment for FY 2015, which is 0.5 percentage point.

As we proposed, based on more recent data that became subsequently available after the publication of the CY 2015 OPPS/ASC proposed rule (for example, a more recent estimate of the market basket increase and the MFP adjustment), we are using such updated data, if appropriate, to determine the CY 2015 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 this CY 2015 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 2015, 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, as we proposed, we are applying a 0.2 percentage point reduction to the OPD fee schedule increase factor for CY 2015.

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 finalizing an OPD fee schedule increase factor of 2.2 percent for the CY 2015 OPPS (which is 2.9 percent, the estimate of the hospital inpatient market basket percentage increase, less the 0.5 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 final rule with comment period.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40963), we proposed to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (*6*) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2015, 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 2015.

We did not receive any public comments on our proposed adjustments to the OPD fee schedule increase factor or the proposed amendment to § 419.32(b)(1)(iv)(B) by adding a new paragraph (*6*) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act. Therefore, for the reasons discussed above, we are adjusting the OPD fee schedule increase factor for CY 2015 as proposed. We also are finalizing the amendment to § 419.32(b)(1)(iv)(B) as proposed.

To set the OPPS conversion factor for CY 2015, we proposed to increase the CY 2014 conversion factor of $72.672 by 2.1 percent. In accordance with section 1833(t)(9)(B) of the Act, we further adjusted the conversion factor for CY 2015 to ensure that any revisions made to the wage index and rural adjustment were made on a budget neutral basis. We proposed a calculated overall budget neutrality factor of 0.9998 for wage index changes by comparing total estimated payments from our simulation model using the FY 2015 IPPS wage indexes to those payments using the FY 2014 IPPS wage indexes, as adopted on a calendar year basis for the OPPS.

For CY 2015, we proposed to maintain current rural adjustment policy, as discussed in section II.E. of this final rule with comment period. Therefore, the budget neutrality factor for the rural adjustment would be 1.0000.

For CY 2015, we proposed 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 final rule with comment period. We calculated a CY 2015 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2015 payments under section 1833(t) of the Act, including the CY 2015 cancer hospital payment adjustment, to estimated CY 2015 total payments using the CY 2014 final cancer hospital payment adjustment as required under section 1833(t)(18)(B) of the Act. The CY 2015 estimated payments applying the CY 2015 cancer hospital payment adjustment are identical to estimated payments applying the CY 2014 final cancer hospital payment adjustment. Therefore, we applied a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment.

For the proposed rule, we estimated that pass-through spending for drugs, biologicals, and devices for CY 2015 would equal approximately $15.5 million, which represented 0.03 percent of total projected CY 2015 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.02 percent estimate of pass-through spending for CY 2014 and the 0.03 percent estimate of pass-through spending for CY 2015, resulting in a proposed adjustment for CY 2015 of 0.01 percent. Finally, estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2015.

For the proposed rule, we proposed 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 would make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of 0.2 percent (that is, the OPD fee schedule increase factor of 2.1 percent further reduced by 2.0 percentage points). This resulted in a proposed reduced conversion factor for CY 2015 of $72.692 for hospitals that fail to meet the Hospital OQR requirements (a difference of −$1.484 in the conversion factor relative to hospitals that met the requirements).

Comment: MedPAC noted that CMS is required by law to implement the 2015 update to the conversion factor as stated in the Affordable Care Act. In its March 2014 Report to Congress, MedPAC recommended an update of 3.25 percent and Congressional action to direct the Secretary to reduce or eliminate differences in payment rates between HOPDs and physician offices, which is different from the Affordable Care Act requirement.

Response: As discussed above, 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. Section 1833(t)(3)(C)(iv) provides that the OPD fee schedule increase factor, subject to sections 1833(t)(3)(F) and 1833(t)(3)(G)(iv) of the Act, is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act.

After consideration of the public comment we received, we are finalizing the calculation of the CY 2015 OPPS conversion factor as proposed. We are finalizing the proposed amendment to § 419.32(b)(1)(iv)(B) by adding a new paragraph (*6*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2015 to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(iv) of the Act. We are using a reduced conversion factor of $72.661 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −$1.483 in the conversion factor relative to hospitals that met the requirements).

For CY 2015, we are finalizing our proposal 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 final rule with comment period.

For this final rule with comment period, we estimate that pass-through spending for drugs, biologicals, and devices for CY 2015 will equal approximately $82.8 million, which represents 0.15 percent of total projected CY 2015 OPPS spending. Therefore, the conversion factor is also adjusted by the difference between the 0.02 percent estimate of pass-through spending for CY 2014 and the 0.15 percent estimate of pass-through spending for CY 2015, resulting in an adjustment for CY 2015 of −0.13 percent. Finally, estimated payments for outliers remain at 1.0 percent of total OPPS payments for CY 2015.

As a result of these final policies, the OPD fee schedule increase factor for the CY 2015 OPPS is 2.2 percent (which is 2.9 percent, the estimate of the hospital inpatient market basket percentage increase, less the 0.5 percentage point MFP adjustment, and less the 0.2 percentage point additional adjustment). For CY 2015, we are using a conversion factor of $74.144 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 OPD fee schedule increase factor of 2.2 percent for CY 2015, the required wage index budget neutrality adjustment of

approximately 0.9996, the cancer hospital payment adjustment of 1.0000, and the adjustment of −0.13 percent of projected OPPS spending for the difference in the pass-through spending result in a conversion factor for CY 2015 of $74.144.

C. 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 final rule with comment period.

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, in the CY 2015 OPPS/ASC proposed rule (79 FR 40964), we proposed to continue this policy for the CY 2015 OPPS. We refer readers to section II.H. of this final rule with comment period for a description and 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 final rule with comment period, for estimating APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2015 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 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). As discussed in that final rule with comment period, 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. In the CY 2015 OPPS/ASC proposed rule (79 FR 40964), we proposed to implement this provision in the same manner as we have since CY 2011. That is, 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. Similar to our current policy for HOPDs that are affiliated with multicampus hospital systems, we proposed that the HOPD would receive a wage index based on the geographic location of the specific inpatient hospital with which it is associated. Therefore, if the associated hospital is located in a frontier State, the wage index adjustment applicable for the hospital also will apply for the affiliated 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 FY 2015 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 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28054 through 28084 and 79 FR 49950 through 49991, respectively) for a detailed discussion of all changes to the FY 2015 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 proposed rule and final rule (79 FR 28054 through 28055 and 79 FR 49951 through 49957, respectively), the Office of Management and Budget (OMB) issued revisions to the current labor market area delineations on February 28, 2013, that included a number of significant changes such as new Core Based Statistical Areas (CBSAs), urban counties that become rural, rural counties that become urban, and existing CBSAs that are 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*. As we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50586), in order to allow for sufficient time to assess the new revisions and their ramifications, we intended to propose changes to the IPPS wage index based on the newest CBSA delineations in the FY 2015 IPPS/LTCH PPS proposed rule. Similarly, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74951), we stated that we intended to propose changes in the OPPS, which uses the IPPS wage index, based on the new OMB delineations in the CY 2015 OPPS/ASC proposed rule, consistent with any proposals in the FY 2015 IPPS/LTCH PPS proposed rule. We refer readers to proposed changes based on the new OMB delineations in the FY 2015 IPPS/LTCH proposed rule at 79 FR 28054 through 28084 and the final changes based on the new OMB delineations in the FY 2015 IPPS/LTCH PPS final rule at 79 FR 49950 through 49966.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40964), we proposed to use the FY 2015 hospital IPPS wage index for urban and rural areas as the wage index for the OPPS hospital to determine the wage adjustments for the OPPS payment rate and the copayment standardized amount for CY 2015. (We

refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49850) and the final FY 2015 hospital wage index files posted on the CMS Web site.) We note that the final FY 2015 IPPS wage indexes reflect a number of changes as a result of the new OMB delineations as well as a 1-year extension of the imputed rural floor. We proposed that the CY 2015 OPPS wage index (for hospitals paid under the IPPS and OPPS) would be the final FY 2015 IPPS wage index. Thus, any adjustments, including the adjustments related to the new OMB delineations, that were finalized for the IPPS wage index would be reflected in the OPPS wage index. As stated earlier in this section, we continue to 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. Therefore, we did not propose to change our existing regulations, which require that we use the FY 2015 IPPS wage indexes for calculating OPPS payments in CY 2015.

Hospitals that are paid under the OPPS but not under the IPPS do not have a hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, we 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 proposed to adopt the final wage index changes from the FY 2015 IPPS/LTCH PPS final rule for these hospitals. The following is a brief summary of the major changes in the FY 2015 IPPS wage indexes and any adjustments that we proposed to apply to these hospitals under the OPPS for CY 2015. We refer the reader to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49950 through 49991) for a detailed discussion of the changes to the wage indexes.

For CY 2015, we proposed 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 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173)). We stated in the proposed rule that applying this adjustment is consistent with our proposed 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. Table 4J from the FY 2015 IPPS/LTCH PPS final 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 will receive the adjustment for FY 2015.

As we have done in prior years, we are including Table 4J from the FY 2015 IPPS/LTCH PPS final rule as Addendum L to this final rule with comment period with the addition of non-IPPS hospitals that would receive the section 505 out-migration adjustment under the CY 2015 OPPS. Addendum L is available via the Internet on the CMS Web site.

In the FY 2015 IPPS/LTCH PPS proposed rule, we proposed to adopt the new 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. In the FY 2015 IPPS/LTCH PPS final rule, we finalized the adoption of the new OMB delineations. For IPPS wage index purposes, for hospitals that are designated as rural under the new OMB labor market area delineations that currently are located in urban CBSAs, we generally assigned them the urban wage index value of the CBSA in which they are physically located for FY 2014 for a period of 3 fiscal years (79 FR 28060 through 28061 and 79 FR 49957 through 49960). To be consistent, we proposed to apply 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 are physically located for FY 2014 for the next 3 calendar years. As stated in the CY 2015 OPPS/ASC proposed rule (79 FR 40965), this proposed policy would impact six hospitals for purposes of OPPS payment.

We believe that adopting the new OMB labor market area delineations creates a more accurate wage index system, but we also recognize that implementing the new OMB delineations may cause some short-term instability in hospital payments. Therefore, similar to the policy we adopted in the FY 2005 IPPS final rule (69 FR 49033), in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49960 through 49962), we finalized a 1-year blended wage index for all hospitals that experience any decrease in their actual payment wage index exclusively due to the implementation of the new OMB delineations. Under this final IPPS policy, a post-reclassified wage index with the rural and imputed floors applied is computed based on the hospital's FY 2014 CBSA (that is, using all of its FY 2014 constituent county/ies), and another post-reclassified wage index with the rural and imputed floors applied is computed based on the hospital's new FY 2015 CBSA (that is, the FY 2015 constituent county/ies). We then compare these two wage indexes. If the FY 2015 wage index with FY 2015 CBSAs is lower than the FY 2015 wage index with FY 2014 CBSAs, we compute a blended wage index consisting of 50 percent of each of the two wage indexes added together. This blended wage index will be the IPPS hospital's wage index for FY 2015. In the CY 2015 OPPS/ASC proposed rule, for purposes of the OPPS, we proposed to apply this 50-percent transition blend to hospitals paid under the OPPS but not under the IPPS. We stated that we believe a 1-year, 50/50 blended wage index would mitigate the short-term instability and negative payment impacts due to the implementation of the new OMB delineations, providing hospitals with a transition period during which they may adjust to their new geographic CBSA. We believe that a longer transition period would reduce the accuracy of the overall labor market area wage index system, and generally would not be warranted for hospitals moving from one urban geographic labor market area to another.

In addition, for the FY 2015 IPPS, we are continuing the extension of the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2015 (79 FR 49969 through 49971). For purposes of the CY 2015 OPPS, we also proposed to apply the imputed floor policy to hospitals paid under the OPPS but not under the IPPS.

For CMHCs, we proposed 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, we proposed to apply a 1-year, 50/50 blended wage index to CMHCs that would receive a lower wage index due to the new CBSA delineations. In addition, as with OPPS hospitals and for the same reasons, for CMHCs currently located in urban CBSAs that are designated as rural under the new OMB labor market area delineations, we proposed to maintain the urban wage index value of the CBSA in which they are physically located for

CY 2014 for the next 3 calendar years. 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 out-migration wage adjustment table (Addendum L to this final rule with comment period, 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 FY 2015 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 final FY 2015 IPPS wage index tables.

Comment: One commenter suggested that the IPPS rural floor should utilize State-specific budget neutrality rather than national budget neutrality to prevent it from being susceptible to gaming by hospitals. The commenter suggested that, under the current policy, an urban hospital can reclassify to rural status to improve the rural wage index in the State, which in some cases is used as a floor for urban hospitals.

Response: As we stated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50370), section 3141 of Public Law 111–148 requires that a national budget neutrality adjustment be applied in implementing the rural floor policy under the IPPS. Therefore, absent a legislative change enacted by Congress, we are unable to change the rural floor budget neutrality adjustment from a national adjustment to a State-specific adjustment. In this final rule with comment period, we are adopting the final fiscal year IPPS wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50370 through 50372) for further discussion and a detailed response to a similar comment.

After considering the public comment we received, we are finalizing our proposals to use the FY 2015 IPPS final wage index as the CY 2015 wage index for OPPS hospitals and CMHCs, as discussed above and as set forth in the CY 2015 OPPS/ASC proposed rule (79 FR 40963 through 40965), without modification.

D. 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 the CY 2015 OPPS/ASC proposed rule (79 FR 40966), we proposed to update the default ratios for CY 2015 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 2015, we proposed 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 CY 2015 OPPS relative payment weights. Table 12 published in the proposed rule (79 FR 40966 through 40968) listed the proposed CY 2015 default urban and rural CCRs by State and compared them to the CY 2014 default CCRs. These proposed CCRs represented 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 proposed 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 proposed 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.

We did not receive any public comments on our CY 2015 proposal. Therefore, we are finalizing our proposal, without modification, to apply our standard methodology of calculating the statewide average default CCRs using the same hospital overall CCRs that we used to adjust charges to costs on claims data for setting the CY 2015 OPPS relative payment weights. We used this methodology to calculate the statewide average default CCRs listed in Table 13 below.

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 2014 and CY 2015 are modest and the few significant changes are associated with areas that have a small number of hospitals.

Table 13 below lists the statewide average default CCRs for OPPS services furnished on or after January 1, 2015.

TABLE 13—CY 2015 STATEWIDE AVERAGE CCRS

State	Urban/rural	CY 2015 default CCR	Previous default CCR (CY 2014 OPPS final rule)
ALABAMA	RURAL	0.235	0.229
ALABAMA	URBAN	0.186	0.188
ALASKA	RURAL	0.439	0.473
ALASKA	URBAN	0.294	0.302
ARIZONA	RURAL	0.228	0.254
ARIZONA	URBAN	0.181	0.182
ARKANSAS	RURAL	0.262	0.244
ARKANSAS	URBAN	0.239	0.220
CALIFORNIA	RURAL	0.178	0.190
CALIFORNIA	URBAN	0.196	0.206
COLORADO	RURAL	0.410	0.393
COLORADO	URBAN	0.219	0.221
CONNECTICUT	RURAL	0.339	0.343
CONNECTICUT	URBAN	0.273	0.276
DELAWARE	URBAN	0.314	0.356
DISTRICT OF COLUMBIA	URBAN	0.299	0.279
FLORIDA	RURAL	0.180	0.160
FLORIDA	URBAN	0.156	0.160
GEORGIA	RURAL	0.256	0.260
GEORGIA	URBAN	0.211	0.205
HAWAII	RURAL	0.337	0.345
HAWAII	URBAN	0.307	0.298
IDAHO	RURAL	0.353	0.359
IDAHO	URBAN	0.463	0.478
ILLINOIS	RURAL	0.252	0.252
ILLINOIS	URBAN	0.217	0.222
INDIANA	RURAL	0.334	0.326
INDIANA	URBAN	0.262	0.288
IOWA	RURAL	0.321	0.308
IOWA	URBAN	0.269	0.266
KANSAS	RURAL	0.300	0.313
KANSAS	URBAN	0.231	0.239
KENTUCKY	RURAL	0.231	0.221
KENTUCKY	URBAN	0.212	0.225
LOUISIANA	RURAL	0.272	0.257
LOUISIANA	URBAN	0.209	0.222
MAINE	RURAL	0.430	0.452
MAINE	URBAN	0.432	0.438
MARYLAND	RURAL	0.296	0.283
MARYLAND	URBAN	0.244	0.248
MASSACHUSETTS	RURAL	0.326	0.395
MASSACHUSETTS	URBAN	0.333	0.336
MICHIGAN	RURAL	0.371	0.341
MICHIGAN	URBAN	0.320	0.322
MINNESOTA	RURAL	0.485	0.462
MINNESOTA	URBAN	0.347	0.349
MISSISSIPPI	RURAL	0.247	0.233
MISSISSIPPI	URBAN	0.181	0.200
MISSOURI	RURAL	0.267	0.263
MISSOURI	URBAN	0.274	0.280
MONTANA	RURAL	0.501	0.481
MONTANA	URBAN	0.386	0.384
NEBRASKA	RURAL	0.290	0.323
NEBRASKA	URBAN	0.255	0.243
NEVADA	RURAL	0.241	0.220
NEVADA	URBAN	0.149	0.154
NEW HAMPSHIRE	RURAL	0.362	0.326
NEW HAMPSHIRE	URBAN	0.280	0.287
NEW JERSEY	URBAN	0.202	0.213
NEW MEXICO	RURAL	0.296	0.291
NEW MEXICO	URBAN	0.294	0.304
NEW YORK	RURAL	0.333	0.345
NEW YORK	URBAN	0.340	0.351
NORTH CAROLINA	RURAL	0.280	0.258
NORTH CAROLINA	URBAN	0.246	0.256
NORTH DAKOTA	RURAL	0.660	0.661
NORTH DAKOTA	URBAN	0.395	0.400
OHIO	RURAL	0.317	0.327

TABLE 13—CY 2015 STATEWIDE AVERAGE CCRS—Continued

State	Urban/rural	CY 2015 default CCR	Previous default CCR (CY 2014 OPPS final rule)
OHIO	URBAN	0.222	0.232
OKLAHOMA	RURAL	0.282	0.258
OKLAHOMA	URBAN	0.203	0.205
OREGON	RURAL	0.287	0.311
OREGON	URBAN	0.352	0.357
PENNSYLVANIA	RURAL	0.283	0.257
PENNSYLVANIA	URBAN	0.197	0.198
PUERTO RICO	URBAN	0.577	0.614
RHODE ISLAND	URBAN	0.297	0.295
SOUTH CAROLINA	RURAL	0.191	0.190
SOUTH CAROLINA	URBAN	0.207	0.203
SOUTH DAKOTA	RURAL	0.286	0.287
SOUTH DAKOTA	URBAN	0.214	0.219
TENNESSEE	RURAL	0.203	0.207
TENNESSEE	URBAN	0.188	0.190
TEXAS	RURAL	0.251	0.235
TEXAS	URBAN	0.203	0.197
UTAH	RURAL	0.481	0.474
UTAH	URBAN	0.335	0.334
VERMONT	RURAL	0.439	0.456
VERMONT	URBAN	0.353	0.397
VIRGINIA	RURAL	0.219	0.226
VIRGINIA	URBAN	0.241	0.238
WASHINGTON	RURAL	0.300	0.330
WASHINGTON	URBAN	0.330	0.360
WEST VIRGINIA	RURAL	0.312	0.283
WEST VIRGINIA	URBAN	0.300	0.319
WISCONSIN	RURAL	0.328	0.344
WISCONSIN	URBAN	0.294	0.291
WYOMING	RURAL	0.429	0.400
WYOMING	URBAN	0.262	0.269

E. 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 2014. 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.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40968), for the CY 2015 OPPS, we proposed 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.

Comment: Several commenters supported the proposed continuation of the 7.1 percent rural SCH adjustment. Several commenters, including MedPAC, also recommended that CMS update the analysis in the near future to assess if the 7.1 percent payment adjustment remains a valid figure.

Response: We appreciate the commenters' support. We agree that it is appropriate to continue the 7.1 percent

adjustment for rural SCHs (including EACHs) as we proposed for CY 2015. As we indicated in the proposed rule (79 FR 40968), we may reassess the 7.1 percent rural adjustment in the near future by examining differences between urban hospitals' costs and rural hospitals' costs using updated claims, cost reports, and provider information.

After consideration of the public comments we received, we are finalizing our CY 2015 proposal 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. 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 under the OPPS than the payment 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 and 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.

2. Payment Adjustment for Certain Cancer Hospitals for CY 2015

In the CY 2015 OPPS/ASC proposed rule (79 FR 40968), for CY 2015, we proposed to continue our policy to provide additional payments to 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 were available at the time of the development of the proposed rule. To calculate the proposed CY 2015 target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A. of the proposed rule, used to estimate costs for the CY 2015 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 2013 claims data that we used to model the impact of the proposed CY 2015 APC relative payment weights (3,881 hospitals) because it is appropriate to use the same set of hospitals that we used to calibrate the modeled CY 2015 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2012 to 2013. 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 27 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 3,807 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 were approximately 89 percent of reasonable cost (weighted average PCR of 0.89). Therefore, we proposed 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 0.89 for each cancer hospital. Table 13 of the proposed rule (79 FR 40969) indicated the estimated percentage increase in OPPS payments to each cancer hospital for CY 2015 due to the cancer hospital payment adjustment policy.

Comment: Several commenters noted that cancer hospitals have significantly higher costs than other OPPS hospitals and agreed with CMS' proposal to provide the proposed payment adjustment.

Response: We appreciate the commenters' support of our proposal. As described in detail below, we performed the same analysis as in previous years comparing the PCR for these cancer hospitals relative to other OPPS hospitals. That study indicates that there is a difference in PCRs between these hospital types. Accordingly, we are finalizing a cancer hospital adjustment with a target PCR of 0.89 based on that analysis.

After consideration of the public comments we received, we are finalizing our proposal to establish the target PCR equal to 0.89 for each cancer hospital. For this final rule with comment period, we have rerun our calculations to determine the target PCR using the latest available cost data and have determined that 0.89 is still the correct target PCR. We limited the dataset to the hospitals with CY 2013 claims data that we used to model the impact of the final CY 2015 APC relative payment weights (3,808 hospitals). The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2011 to 2013. We removed the cost report data of the 47 hospitals located in Puerto Rico from our dataset and also removed the cost report data of 14 hospitals that had cost report data that were not complete, leading to a final analytic file of 3,747 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 89 percent of reasonable cost (weighted average PCR of 0.89). Therefore, we are finalizing 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 target PCR equal to 0.89 for each cancer hospital.

Table 14 below indicates the estimated percentage increase in OPPS payments to each cancer hospital for CY 2015 due to the cancer hospital payment adjustment policy. The actual amount of the CY 2015 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2015 payments and costs. 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 will be assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 14—ESTIMATED CY 2015 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider No.	Hospital name	Estimated percentage increase in OPPS payments for CY 2015
050146	City of Hope Comprehensive Cancer Center	15.5
050660	USC Norris Cancer Hospital	22.0
100079	Sylvester Comprehensive Cancer Center	15.8
100271	H. Lee Moffitt Cancer Center & Research Institute	19.9
220162	Dana-Farber Cancer Institute	47.6
330154	Memorial Sloan-Kettering Cancer Center	46.7
330354	Roswell Park Cancer Institute	16.6
360242	James Cancer Hospital & Solove Research Institute	35.1
390196	Fox Chase Cancer Center	18.5
450076	M.D. Anderson Cancer Center	60.1
500138	Seattle Cancer Care Alliance	53.9

G. 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 2014 OPPS/ASC final rule with comment period (78 FR 74958 through 74960), 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 2014, 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 $2,900 (the fixed-dollar amount threshold). 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 OPPS. Our current estimate of total outlier payments as a percent of total CY 2013 OPPS payment, using available CY 2013 claims and the revised OPPS expenditure estimate for the FY 2015 President's Budget Mid-Session Review, is approximately 1.4 percent of the total aggregated OPPS payments. Therefore, for CY 2013, we estimate that we paid 0.4 percent above the CY 2013 outlier target of 1.0 percent of total aggregated OPPS payments.

Using CY 2013 claims data and CY 2014 payment rates, we currently estimate that the aggregate outlier payments for CY 2014 will be approximately 0.8 percent of the total CY 2014 OPPS payments. The difference between 0.8 percent and the 1.0 percent target is reflected in the regulatory impact analysis in section XXII. of this final rule with comment period. We provide estimated CY 2015 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. Outlier Calculation

In the CY 2015 OPPS/ASC proposed rule (79 FR 40970), for CY 2015, we proposed to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We proposed that a portion of that 1.0 percent, an amount equal to 0.47 percent of outlier payments (or 0.0047 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 the proposed rule, for CMHCs, we proposed to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) or APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs), exceeds 3.40 times the payment rate for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. For further discussion of CMHC outlier payments, we refer readers to section VIII.D. of the proposed rule and this final rule with comment period.

To ensure that the estimated CY 2015 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we proposed 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 $3,100.

We calculated the proposed fixed-dollar threshold of $3,100 using the standard methodology most recently used for CY 2014 (78 FR 74959 through 74960). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2014 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 2015 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2013 claims using the same inflation factor of 1.1146 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28321). We used an inflation factor of 1.0557 to estimate CY 2014 charges from the CY 2013 charges reported on CY 2013 claims. The methodology for determining this charge inflation factor is discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28321) and final rule (79 FR 50374). 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 proposed to apply the same CCR inflation adjustment factor that we proposed to apply for the FY 2015 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2015 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2015, we proposed to apply an adjustment factor of 0.9813 to the CCRs that were in the April 2014 OPSF to trend them forward from CY 2014 to CY 2015. The methodology for calculating this proposed adjustment was discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28321) and finalized in the FY 2015 IPPS/LTCH PS final rule (79 FR 50374).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2014 OPSF file after adjustment (using the proposed CCR inflation adjustment factor of 0.9813 to approximate CY 2015 CCRs) to charges on CY 2013 claims that were adjusted (using the proposed charge inflation factor of 1.1146 to approximate CY 2015 charges). We simulated aggregated CY 2015 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 2015 OPPS payments. We estimated that a proposed fixed-dollar threshold of $3,100, 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 proposed that, if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment rate for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 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 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 proposed 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 final rule with comment period.

Comment: A few commenters suggested that CMS not increase the outlier payment fixed dollar threshold from $2,900 to $3,100. One commenter suggested that CMS maintain the CY 2014 fixed-dollar threshold of $2,900, while another commenter suggested that CMS lower the CY 2014 fixed-dollar threshold because CMS' projection of CY 2014 outlier payments in the proposed rule estimated that outlier payments would be below the target of 1.0 percent of OPPS payments.

Response: We set the proposed CY 2015 outlier payment fixed-dollar threshold at $3,100 so that projected outlier payments would equal 1.0 percent of total OPPS payments. We projected that CY 2014 outlier payments would fall below the 1.0 percent target with the $2,900 threshold. However, we estimated that changes to recalibrate APCs and other payment policy changes would result in outlier payments greater than the 1.0 percent target in CY 2015 if we did not increase the fixed-dollar threshold. As discussed below, based on the more recent data available for this final rule with comment period, the CY 2015 outlier payment fixed-dollar threshold will be $2,775. When combined with the multiple threshold of 1.75 times the APC payment rate, this fixed-dollar threshold will allocate an estimated 1.0 percent of projected total OPPS payments to outlier payments for CY 2015.

3. Final Outlier Calculation

Consistent with historical practice, we used updated data for this final rule with comment period. For CY 2015, we are applying the overall CCRs from the July 2014 OPSF file after adjustment (using the CCR inflation adjustment factor of 0.9821 to approximate CY 2015 CCRs) to charges on CY 2013 claims that were adjusted (using the charge inflation factor of 1.1044 to approximate CY 2015 charges). These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed-dollar threshold for the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379 through 50380). We simulated aggregated CY 2015 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payments will 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 2015 OPPS payments. We estimate that a fixed-dollar threshold of $2,775, combined with the multiple threshold of 1.75 times the APC payment rate, will allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment rate for APC 0173, the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate.

H. 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 2015 OPPS/ASC final rule with comment period, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this final rule with comment period and the relative payment weight determined under section II.A. of this final rule with comment period. Therefore, the national unadjusted payment rate for most APCs contained in Addendum A to this final rule with comment period (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 final rule with comment period (which is available via the Internet on the CMS Web site) was calculated by multiplying the CY 2015 scaled weight for the APC by the CY 2015 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 final rule with comment period.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40971 through 40972), we demonstrated 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,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''U,'' or ''V'' (as defined in Addendum D1 to the proposed rule), 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 are finalizing the methodology as proposed and demonstrate below how to calculate final CY 2015 OPPS payments using the same parameters.

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 we are creating new status indicator ''J1'' to reflect the comprehensive APCs discussed in section II.A.2.e. of this final rule with comment period. We also note that we are deleting status indicator ''X'' as part of the CY 2015 packaging policy for ancillary services, discussed in section II.A.3. of this final rule with comment period.

We did not receive any public comments on the proposed calculation of an adjusted Medicare payment. Therefore, we are finalizing the calculation of an adjusted Medicare payment, where appropriate, in the manner described as follows. Individual providers interested in calculating the payment amount that they will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this final rule with comment period (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 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 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 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 full CY 2015 OPPS fee schedule increase factor of 2.2 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 CY 2015 OPPS policy for transitioning wage indexes into the new OMB labor market area delineations, a hold harmless policy for the wage index may apply, as discussed in section II.C. of this final rule with comment period. The wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2015 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 Public Law 98–21. (For further discussion of the changes to the FY 2015 IPPS wage indices, as applied to the CY 2015 OPPS, we refer readers to section II.C. of this final rule with comment period.) As we proposed, we are continuing 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 final rule with comment period (which is available via the Internet on the CMS Web site) contains the qualifying counties and the associated wage index increase developed for the FY 2015 IPPS and listed as Table 4J in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49854) 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.

X_a 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 = $Y + X_a$.

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 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 APC 0019 (Level I Excision/Biopsy). The CY 2015 full national unadjusted payment rate for APC 0019 is approximately $378.41. The reduced national unadjusted payment rate for APC 0019 for a hospital that fails to meet the Hospital OQR Program requirements is approximately $370.84. This reduced rate is calculated by multiplying the reporting ratio of 0.980 by the full unadjusted payment rate for APC 0019.

The FY 2015 wage index for a provider located in CBSA 35614 in New York is 1.2973. This is based on the 1-year 50/50 transition blend between the wage index under the old CBSA 35644 (1.3115) and the wage index under the new CBSA 35614 (1.2831). The labor-related portion of the full national unadjusted payment is approximately $294.55 (.60 * $378.41 * 1.2973). The labor-related portion of the reduced national unadjusted payment is approximately $288.65 (.60 * $370.84 * 1.2973). The nonlabor-related portion of the full national unadjusted payment is approximately $151.36 (.40 * $378.41). The nonlabor-related portion of the reduced national unadjusted payment is approximately $148.34 (40 * $370.84). The sum of the labor-related and nonlabor-related portions of the full national adjusted payment is approximately $445.91 ($294.55 + $151.36). The sum of the reduced national adjusted payment is approximately $436.99 ($288.65 + $148.34).

I. 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. OPPS Copayment Policy

In the CY 2015 OPPS/ASC proposed rule (79 FR 40973), for CY 2015, we proposed 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 proposed 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, 2015, were shown in Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site). As discussed in section XII.G. of the proposed rule, for CY 2015, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies equals 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/ASC 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).

We did not receive any public comments regarding the proposed methodology for calculating copayments for CY 2015. Therefore, for the reasons set forth in this final rule with comment period, we are finalizing our proposed CY 2015 copayment methodology without modification.

3. 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 APC 0019, approximately $75.68 is 20 percent of the full national unadjusted payment rate of approximately $378.41. For APCs with only a minimum unadjusted copayment in Addenda A and B to this final rule with comment period (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 final rule with comment period. Calculate the rural adjustment for eligible providers as indicated in Step 6 under section II.H. of this final rule with comment period.

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 final rule with comment period, 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 unadjusted copayments for services payable under the OPPS that will be effective January 1, 2015, are shown in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site). We note that the national unadjusted payment rates and copayment rates shown in Addenda A and B to this final rule with comment period reflect the full CY 2015 OPD fee schedule increase factor discussed in section II.B. of this final rule with comment period.

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. OPPS Ambulatory Payment Classification (APC) Group Policies

A. 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/or provides payment or more accurate payment for these items or services in a timelier manner than if CMS 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. Items, procedures, or services not paid separately under the hospital OPPS are assigned to the appropriate status indicators. Section XI. of the CY 2015 OPPS/ASC proposed rule provided a discussion of the various status indicators used under the OPPS. Assigning procedures to certain status indicators would generate separate payment for the service furnished, while assignment to other status indicators would not.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40974), in Table 14 (Table 15 of this final rule with comment period), we summarized our process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing their treatment under the OPPS. We noted that because the payment rates associated with codes effective July 1 were not available to us in time for incorporation into the Addenda to the proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2014 OPPS quarterly update CR were not included in Addendum B of the proposed rule (which is available via the Internet on the CMS Web site), while those codes based upon the April 2014 OPPS quarterly update were included in Addendum B. Nevertheless, we requested public comments on the codes included in the July 2014 OPPS quarterly update and included these codes in the preamble of the proposed rule.

TABLE 15—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April I, 2014	Level II HCPCS Codes	April 1, 2014	CY 2015 OPPS/ASC proposed rule.	CY 2015 OPPS/ASC final rule with comment period.
July 1, 2014	Level II HCPCS Codes	July 1, 2014	CY 2015 OPPS/ASC proposed rule.	CY 2015 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2014	CY 2015 OPPS/ASC proposed rule.	CY 2015 OPPS/ASC final rule with comment period.
October 1, 2014	Level II HCPCS Codes	October 1, 2014	CY 2015 OPPS/ASC final rule with comment period.	CY 2016 OPPS/ASC final rule with comment period.
January 1, 2015	Level II HCPCS Codes	January 1, 2015	CY 2015 OPPS/ASC final rule with comment period.	CY 2016 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes.	January 1, 2015	CY 2015 OPPS/ASC final rule with comment period.	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 solicited public comments in the CY 2015 OPPS/ASC proposed rule or whether we will be soliciting public comments in this CY 2015 OPPS/ASC final rule with comment period. We note that we will be seeking public comments in this CY 2015 OPPS/ASC final rule with comment period on the interim APC and status indicator assignments for new CPT and Level II HCPCS codes that will be effective January 1, 2015. In the CY 2015 OPPS/ASC proposed rule (79 FR 40977), we also noted that we sought public comments in the CY 2014 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, 2013, or January 1, 2014. These new and revised codes, with an effective date of October 1, 2013, or January 1, 2014, 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 2014 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 2014 OPPS/ASC final rule with comment period. We are responding to public comments and finalizing our interim OPPS treatment of these codes in this CY 2015 OPPS/ASC final rule with comment period.

We received public comments on some new codes that were assigned to comment indicator ''NI'' in Addendum B of the CY 2014 OPPS/ASC final rule with comment period. We respond to those comments in sections III.C. of this CY 2015 OPPS/ASC final rule with comment period.

1. Treatment of New CY 2014 Level II HCPCS and CPT Codes Effective April 1, 2014 and July 1, 2014 for Which We Solicited Public Comments in the CY 2015 OPPS/ASC Proposed Rule

Through the April 2014 OPPS quarterly update CR (Transmittal 2903, Change Request 8653, dated March 11, 2014) and the July 2014 OPPS quarterly update CR (Transmittal 2971, Change Request 8776, dated May 23, 2014), we recognized several new HCPCS codes for separate payment under the OPPS.

Effective April 1, 2014, we made effective four new Level II HCPCS codes and also assigned them to appropriate interim OPPS status indicators and APCs. Through the April 2014 OPPS quarterly update CR, we allowed separate payment for three of the four new Level II HCPCS codes. Specifically, as displayed in Table 15 in the proposed rule (79 FR 40975), we provided separate payment for HCPCS codes C9021, C9739, and C9740. HCPCS code Q2052 was assigned to status indicator ''N'' to indicate the service described by this code is packaged under the OPPS.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40974), we solicited public comments on the proposed APC and status indicator assignments, where applicable, for the Level II HCPCS codes listed in Table 15 of that proposed rule (HCPCS codes C9021, C9739, C9740, and Q2052). We did not receive any public comments on the proposed APC and status indicator assignments for HCPCS codes C9021 and Q2052. Because HCPCS code Q2052 will only be billed by pharmacy suppliers, we are modifying our CY 2015 proposal to continue to assign HCPCS code Q2052 to status indicator ''N.'' Instead, for CY 2015, we are reassigning HCPCS code Q2052 from OPPS status indicator ''N'' to ''E'' (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)). We are adopting as final, without modification, the proposed APC and status indicator assignments for HCPCS code C9021 for CY 2015. We note that we received some public comments on HCPCS codes C9739 and C9740, which we address in section III.C.3.e. of this final rule with comment period.

Effective for CY 2015, the HCPCS Workgroup replaced HCPCS code C9021 with HCPCS code J9301. Table 16 below shows the complete long descriptor for HCPCS code J9301. Consistent with our general policy of using permanent HCPCS codes (that is, ''J'' codes) rather than using temporary HCPCS codes (that is, ''C'' codes and ''Q'' codes) for the reporting of drugs under the OPPS in order to streamline coding, we are showing the replacement HCPCS code for C9021, which is effective January 1, 2015, in Table 16.

In this final rule with comment period, we are assigning the Level II HCPCS codes listed in Table 16 below to the specified APCs and status indicators for CY 2015. The final payment rates for these codes, where applicable, can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 16—FINAL CY 2015 STATUS INDICATORS AND APC ASSIGNMENTS FOR THE LEVEL II HCPCS CODES THAT WERE NEWLY IMPLEMENTED IN APRIL 2014

CY 2014 HCPCS Code	CY 2015 HCPCS Code	CY 2015 long descriptor	Final CY 2015 status indicator	Final CY 2015 APC
C9021	J9301	Injection, obinutuzumab, 10mg	G	1476
C9739	C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants	T	0162
C9740	C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants	T	1564
Q2052	Q2052	Services, supplies and accessories used in the home under the Medicare intravenous immune globulin (IVIG) demonstration.	E	N/A

Effective July 1, 2014, 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 2014 OPPS quarterly update CR, we allowed separate payment under the OPPS for four new Level II HCPCS codes and 17 new Category III CPT codes effective July 1, 2014. Specifically, as displayed in Table 16 in the proposed rule, we allowed separate payment for HCPCS codes C2644, C9022, C9134, and Q9970. We note that HCPCS code Q9970 replaced HCPCS code C9441 (Injection, ferric carboxymaltose, 1 mg), beginning July 1, 2014. HCPCS code C9441 was made effective January 1, 2014, but the code was deleted June 30, 2014, because it was replaced with HCPCS code Q9970. HCPCS code C9441 was granted pass-through payment status when the code was implemented on January 1, 2014. Because HCPCS code Q9970 describes the same drug as HCPCS code C9441, in the CY 2015 OPPS/ASC proposed rule (79 FR 40975), we proposed to continue the pass-through payment status for HCPCS code Q9970, and assign the HCPCS Q-code to the same APC and status indicator as its predecessor HCPCS C-code, as shown in Table 16 of the proposed rule. Specifically, we proposed to assign HCPCS code Q9970 to APC 9441 (Inj, Ferric Carboxymaltose) and status indicator ''G.''

In addition, the HCPCS Workgroup established HCPCS code Q9974, effective July 1, 2014, to replace HCPCS codes J2271 (Injection, morphine sulfate, 100mg) and J2275 (Injection, morphine sulfate (preservative-free sterile solution), per 10 mg). Both of these HCPCS J-codes were assigned to status indicator ''N'' (Packaged Services). As a result of the establishment of new HCPCS code Q9974 as a replacement for HCPCS codes J2271 and J2275, the payment indicator for HCPCS codes J2271 and J2275 was changed to ''E'' (Not Payable by Medicare), effective July 1, 2014. Also, because HCPCS code Q9974 describes the same services that were described by HCPCS codes J2271 and J2275, in the CY 2015 OPPS/ASC proposed rule (79 FR 40975), we proposed to continue to assign HCPCS code Q9974 to the same status indicator as its predecessor HCPCS J-codes. Specifically, we proposed to assign HCPCS code Q9974 to status indicator ''N,'' effective July 1, 2014.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40975), we also proposed to assign the Level II HCPCS codes listed in Table 16 to the specified proposed APCs and status indicators set forth in Table 16 of the proposed rule. This table included a complete list of the Level II HCPCS codes that were made effective July 1, 2014. The codes that were made effective July 1, 2014, did not appear in Addendum B to the proposed rule, and as a result, the proposed payment rates along with the proposed status indicators and proposed APC assignments, where applicable, for CY 2015 were provided in Table 16 of the proposed rule.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40975), we solicited public comments on the proposed status indicators and APC assignments for the HCPCS codes that were listed in Table 16 of the proposed rule. We did not receive any public comments on the proposed APC and status indicator assignments for HCPCS codes C9022, C9134, Q9970, and Q9974 for CY 2015. Therefore, we are adopting as final, without modification, the proposed APC and status indicator assignments for these four Level II HCPCS codes for CY 2015. We note that we received a public comment on HCPCS code C2644, which is addressed in section II.A.2.d.3. of this final rule with comment period.

The HCPCS Workgroup replaced HCPCS code C9022 with HCPCS code J1322, effective January 1, 2015. Because HCPCS code J1322 describes the same drug with the same dosage descriptor as its predecessor code, HCPCS code C9022, this drug will continue to receive pass-through payment status in CY 2015. Therefore, we are assigning HCPCS code J1322 to the same APC and status indicator as its predecessor code, HCPCS code C9022, as shown in Table 17 below.

In addition, the HCPCS Workgroup replaced HCPCS code C9134 with HCPCS code J7181, effective January 1, 2015. Because HCPCS code J7181 does not describe the same dosage descriptor as its predecessor code, HCPCS code J7181 has been assigned to a new APC. Specifically, HCPCS code C9134 had a dosage descriptor of ''10 i.u.,'' while HCPCS code J7181 has a dosage descriptor of ''i.u.'' Therefore, effective January 1, 2015, we are assigning HCPCS code J7181 to APC 1746, which is a different APC assignment than the APC assignment for HCPCS code C9134, to maintain data consistency for future rulemakings. Because the predecessor code, HCPCS code C9134, was granted pass-through payment status, HCPCS code J7181 will continue to be assigned to status indicator ''G'' for CY 2015.

We also note that the HCPCS Workgroup replaced HCPCS code Q9970 with HCPCS code J1439, effective January 1, 2015. Because HCPCS code J1439 describes the same drug with the same dosage descriptor as its predecessor code, HCPCS code Q9970, this drug will continue to receive pass-through payment status in CY 2015. Therefore, we are assigning HCPCS code J1439 to the same APC and status indicator as its predecessor code, HCPCS code Q9970, as shown in Table 17 below.

Further, the HCPCS Workgroup replaced HCPCS code Q9974 with HCPCS code J2274, effective January 1, 2015. Because HCPCS code J2274 describes the same drug with the same dosage descriptor as its predecessor code, HCPCS code Q9974, this drug will continue its packaged status indicator. Therefore, we are assigning HCPCS code J2274 to the same status indicator as its predecessor code, HCPCS code Q9974, as also shown in Table 17 below.

Table 17 below includes a complete list of the Level II HCPCS codes that were made effective July 1, 2014, with their final status indicators and APC assignments for CY 2015. The final payment rates for these codes, where applicable, can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 17—FINAL CY 2015 STATUS INDICATORS AND APC ASSIGNMENTS FOR THE LEVEL II HCPCS CODES THAT WERE NEWLY IMPLEMENTED IN JULY 2014

CY 2014 HCPCS Code	CY 2015 HCPCS Code	CY 2015 long descriptor	Final CY 2015 status indicator	Final CY 2015 APC
C2644	C2644	Brachytherapy source, cesium-131 chloride solution, per millicurie	U	2644
C9022	J1322	Injection, elosulfase alfa, 1mg	G	1480
C9134	J7181	Factor XIII A-Subunit (Recombinant), Per IU	G	1746
Q9970	J1439	Injection, ferric carboxymaltose, 1mg	G	9441
Q9974	J2274	Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10 mg.	N	N/A

In the CY 2015 OPPS/ASC proposed rule (79 FR 40975), for CY 2015, we proposed to continue our established policy of recognizing Category I CPT vaccine codes for which FDA approval is imminent and Category III CPT codes that the AMA releases in January of each year for implementation in July through the OPPS quarterly update process. Under the OPPS, Category I CPT vaccine codes and Category III CPT codes that are released on the AMA Web site in January are made effective in July of the same year through the July quarterly update CR, consistent with the AMA's implementation date for the codes. For the July 2014 update, there were no new Category I CPT vaccine codes.

Through the July 2014 OPPS quarterly update CR (Transmittal 2971, Change Request 8776, dated May 23, 2014), we assigned interim OPPS status indicators and APCs for 17 of the 27 new Category III CPT codes that were made effective July 1, 2014. Specifically, as displayed in Table 17 in the proposed rule, we made interim OPPS status indicators and APC assignments for Category III CPT codes 0347T, 0348T, 0349T, 0350T, 0355T, 0356T, 0358T, 0359T, 0360T, 0362T, 0364T, 0366T, 0368T, 0370T, 0371T, 0372T, and 0373T. Table 17 of the proposed rule listed the Category III CPT codes that were implemented on July 1, 2014, along with the proposed status indicators, proposed APC assignments, and proposed payment rates, where applicable, for CY 2015. We did not receive any public comments on the proposed APC and status indicator assignments for Category III CPT codes 0347T, 0348T, 0349T, 0350T, 0356T, 0358T, 0359T, 0360T, 0362T, 0364T, 0366T, 0368T, 0370T, 0371T, 0372T, and 0373T. Therefore, we are adopting as final, without modification, the proposed APC and status indicator assignments for these 16 CPT codes for CY 2015. We received a public comment on CPT codes 0335T, which we address

in section III.C.2.6. of this final rule with comment period. We also received specific public comments on CPT codes 0351T, 0352T, 0353T, and 0354T, which are addressed in section II.C.6.b. of this final rule with comment period. Table 18 below lists the Category III CPT codes that were implemented in July 2014, along with their final status indicators and APC assignments for CY 2015. The final payment rates for these codes, where applicable, can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 18—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2014

CY 2014 CPT code	CY 2015 CPT code	CY 2015 long descriptor	Final CY 2015 status indicator	Final CY 2015 APC
0347T	0347T	Placement of interstitial device(s) in bone for radiostereometric analysis (RSA)	Q1	0420
0348T	0348T	Radiologic examination, radiostereometric analysis (RSA); spine, (includes, cervical, thoracic and lumbosacral, when performed).	Q1	0261
0349T	0349T	Radiologic examination, radiostereometric analysis (RSA); upper extremity(ies), (includes shoulder, elbow and wrist, when performed).	Q1	0261
0350T	0350T	Radiologic examination, radiostereometric analysis (RSA); lower extremity(ies), (includes hip, proximal femur, knee and ankle, when performed).	Q1	0261
0351T	0351T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; real time intraoperative.	N	N/A
0352T	0352T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; interpretation and report, real time or referred.	B	N/A
0353T	0353T	Optical coherence tomography of breast, surgical cavity; real time intraoperative	N	N/A
0354T	0354T	Optical coherence tomography of breast, surgical cavity; interpretation and report, real time or referred.	B	N/A
0355T	0355T	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report.	T	0142
0356T	0356T	Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each.	Q1	0698
0358T	0358T	Bioelectrical impedance analysis whole body composition assessment, supine position, with interpretation and report.	Q1	0340
0359T	0359T	Behavior identification assessment, by the physician or other qualified health care professional, face-to-face with patient and caregiver(s), includes administration of standardized and non-standardized tests, detailed behavioral history, patient observation and caregiver interview, interpretation of test results, discussion of findings and recommendations with the primary guardian(s)/caregiver(s), and preparation of report.	V	0632
0360T	0360T	Observational behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by one technician; first 30 minutes of technician time, face-to-face with the patient.	V	0632
0361T	0361T	Observational behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by one technician; each additional 30 minutes of technician time, face-to-face with the patient (List separately in addition to code for primary service).	N	N/A
0362T	0362T	Exposure behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by physician or other qualified health care professional with the assistance of one or more technicians; first 30 minutes of technician(s) time, face-to-face with the patient.	V	0632
0363T	0363T	Exposure behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by physician or other qualified health care professional with the assistance of one or more technicians; each additional 30 minutes of technician(s) time, face-to-face with the patient (List separately in addition to code for primary procedure).	N	N/A
0364T	0364T	Adaptive behavior treatment by protocol, administered by technician, face-to-face with one patient; first 30 minutes of technician time.	S	0322
0365T	0365T	Adaptive behavior treatment by protocol, administered by technician, face-to-face with one patient; each additional 30 minutes of technician time (List separately in addition to code for primary procedure).	N	N/A
0366T	0366T	Group adaptive behavior treatment by protocol, administered by technician, face-to-face with two or more patients; first 30 minutes of technician time.	S	0325
0367T	0367T	Group adaptive behavior treatment by protocol, administered by technician, face-to-face with two or more patients; each additional 30 minutes of technician time (List separately in addition to code for primary procedure).	N	N/A
0368T	0368T	Adaptive behavior treatment with protocol modification administered by physician or other qualified health care professional with one patient; first 30 minutes of patient face-to-face time.	S	0322
0369T	0369T	Adaptive behavior treatment with protocol modification administered by physician or other qualified health care professional with one patient; each additional 30 minutes of patient face-to-face time (List separately in addition to code for primary procedure).	N	N/A

TABLE 18—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2014—Continued

CY 2014 CPT code	CY 2015 CPT code	CY 2015 long descriptor	Final CY 2015 status indicator	Final CY 2015 APC
0370T	0370T	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present).	S	0324
0371T	0371T	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present).	S	0324
0372T	0372T	Adaptive behavior treatment social skills group, administered by physician or other qualified health care professional face-to-face with multiple patients.	S	0325
0373T	0373T	Exposure adaptive behavior treatment with protocol modification requiring two or more technicians for severe maladaptive behavior(s); first 60 minutes of technicians' time, face-to-face with patient.	S	0323
0374T	0374T	Exposure adaptive behavior treatment with protocol modification requiring two or more technicians for severe maladaptive behavior(s); each additional 30 minutes of technicians' time face-to-face with patient (List separately in addition to code for primary procedure).	N	N/A

Further, in the CY 2015 OPPS/ASC proposed rule, we solicited public comments on the proposed CY 2015 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, 2014, and July 1, 2014. These codes were listed in Tables 15, 16, and 17 of the proposed rule. We also proposed to finalize the status indicator and APC assignments and payment rates for these codes, if applicable, in this CY 2015 OPPS/ASC final rule with comment period. Because the new Category III CPT and Level II HCPCS codes that became effective for July were not available to us in time for incorporation into the Addenda to the proposed rule, our policy is to include the codes, the proposed status indicators, proposed APCs (where applicable), and proposed payment rates (where applicable) in the preamble of the proposed rule, but not in the Addenda to the proposed rule. These codes were listed in Tables 16 and 17, respectively, of the proposed rule. We also proposed to incorporate these codes into Addendum B to this CY 2015 OPPS/ASC final rule with comment period, which is consistent with our annual OPPS update policy. The Level II HCPCS codes implemented or modified through the April 2014 OPPS update CR and displayed in Table 15 were included in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site), where the proposed CY 2015 payment rates for these codes were also shown.

We did not receive any additional public comments on this process. The final APC and status indicator assignments and payment rates, if applicable, for the Level II HCPCS codes and the Category III CPT codes that were implemented or modified through the April 2014 or July 2014 OPPS update CR can be found in Tables 16, 17, and 18, or in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

2. Process for New Level II HCPCS Codes That Became Effective October 1, 2014 and New CPT and Level II HCPCS Codes That Will Become Effective January 1, 2015 for Which We Are Soliciting Public Comments in This CY 2015 OPPS/ASC Final Rule with Comment Period

As has been our practice in the past, we incorporate those new Category I and III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the OPPS for the following calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January OPPS quarterly update CRs. In the past, we also have 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 updating the OPPS for the following calendar year. For CY 2015, these codes are flagged with comment indicator ''NI'' in Addendum B to this 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, the CPT and Level II HCPCS codes that will become effective January 1, 2015, are flagged with comment indicator ''NI'' in Addendum B to this CY 2015 OPPS/ASC final rule with comment period. Specifically, the status indicator and the APC assignment and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in this final rule with comment period, and we will respond to these public comments in the OPPS/ASC final rule with comment period for the next year's OPPS/ASC update. In the CY 2015 OPPS/ASC proposed rule (79 FR 40977), we proposed to continue this process for CY 2015. Specifically, for CY 2015, we proposed to include in Addendum B to the CY 2015 OPPS/ASC final rule with comment period the following new HCPCS codes:

- New Level II HCPCS codes effective October 1, 2014, that would be incorporated in the October 2014 OPPS quarterly update CR;
- New Category I and III CPT codes effective January 1, 2015, that would be incorporated in the January 2015 OPPS quarterly update CR; and
- New Level II HCPCS codes effective January 1, 2015, that would be incorporated in the January 2015 OPPS quarterly update CR.

As stated above, the October 1, 2014 and January 1, 2015 codes are flagged with comment indicator ''NI'' in Addendum B to this CY 2015 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2015. We are inviting public comments on the interim status indicator and APC assignments and payment rates for these codes, if applicable, that will be finalized in the CY 2016 OPPS/ASC final rule with comment period.

3. Process for Soliciting Public Comments for New and Revised CPT Codes Released by the AMA

We generally incorporate the new CPT codes that are effective January 1 in the OPPS/ASC final rule with comment period. We establish interim APC and status indicator assignments for these new codes for the coming year, and

request comments on the interim assignments in the OPPS/ASC final rule with comment period. Similarly, we establish interim APC and status indicator assignments for existing CPT codes that have substantial revision to their code descriptors that necessitate a change in the current APC assignments, and request comments on the interim assignments in the OPPS/ASC final rule with comment period. In both cases, we assign these new and revised codes to OPPS comment indicator ''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.) in the OPPS/ASC final rule with comment period. We respond to comments and finalize the APC and status indicator assignments for these CPT codes in the following year's OPPS/ASC final rule with comment period.

a. Current Process for Accepting Comments on New and Revised CPT Codes for a Year

As described above, under the hospital OPPS, our current process for both new CPT codes and existing CPT codes with substantial revisions to the code descriptors that are released by the AMA for use beginning January 1 is to flag these codes with comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to indicate that the codes are new for the calendar year and have been assigned interim APCs and status indicators, and that we are accepting public comments on the interim APC and status indicator assignments. We address public comments received and finalize the APC and status indicator assignments for the codes in the next year's OPPS/ASC final rule with comment period. For example, the new CPT codes that were effective January 1, 2014, were assigned to comment indicator ''NI'' in Addendum B to the CY 2014 OPPS/ASC final rule with comment period. We respond to public comments received on the CY 2014 OPPS/ASC final rule with comment period and finalize the APC and status indicator assignments for these codes in this CY 2015 OPPS/ASC final rule with comment period. We include the final APC and status indicator assignments for these codes in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

Many stakeholders have expressed concern with the process we use to recognize new and revised CPT codes. They believe that CMS should publish proposed APC and status indicator assignments for the new and revised CPT codes that will be effective January 1 in the OPPS/ASC proposed rule for that calendar year, and request public comments prior to finalizing the assignments. Further, the stakeholders believe that seeking public input on the APC and status indicator assignments for these new and revised codes would assist CMS in assigning the CPT codes to appropriate APCs. Similar concerns have been expressed regarding our process for assigning interim payment values for revalued, and new and revised codes, under the Medicare Physician Fee Schedule (MPFS). We refer readers to the CY 2015 MPFS proposed rule for a detailed discussion of this issue as it relates to the MPFS (79 FR 40359 through 40364).

Like the MPFS, the OPPS and the ASC payment system rely principally upon the Current Procedural Terminology (CPT®) coding system maintained by the AMA to identify specific services for billing and payment purposes. 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. However, the OPPS/ASC proposed rules are published prior to the publication of the CPT codes that are made public in the Fall with a January 1 effective date, and we are currently unable to include these codes in the OPPS/ASC proposed rules. Consequently, we establish in the final rule with comment period interim APC and status indicator assignments for new and revised CPT codes that have an effective date of January 1, and we make payment based on those interim designations for one year, while accepting public comments on the final rule with comment period. We then respond to those public comments received and make final APC and status indicator assignments in the next year's final rule with comment period.

b. Modification of Process for New and Revised CPT Codes That Are Effective January 1

In the CY 2015 OPPS/ASC proposed rule (79 FR 40977 through 40979), we proposed to make changes in the process we use to establish APC assignments and status indicators for new and revised codes. We proposed that, for new and revised CPT codes that we receive from the AMA's 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 proposed to adopt these conforming coding and payment policies on an interim basis pending the result of our specific proposals for status indicator and APC assignments 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 CMS would not have established status indicator or APC assignments for these new or revised codes, it would not be practicable for Medicare to use those CPT codes. In this circumstance, we proposed 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, but that we did not receive in time to include proposed APC and status indicator assignments in the proposed rule. However, if certain CPT codes are revised in a manner that would not affect the cost of inputs (for example, a minor change to CPT code descriptors), we would use these revised codes and continue to assign those codes to their current APC. 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 2015, we would assign each of those CPT codes to status indicator ''B'' in the final rule with comment period, to indicate that an alternate code is recognized under the OPPS. Hospitals could not use those two new CPT codes to bill Medicare for outpatient services the first year after the CPT 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 APC and status indicator assignment for the new G-code during the year. We would propose APC and status indicator assignments for the two new CPT codes during rulemaking in CY 2016, accept and respond to public comments on the proposed assignments, and establish final APC and status indicator assignments for the codes in the final rule for payment beginning in CY 2017.

For new codes that describe wholly new services, as opposed to new or revised codes that describe services for which APC and status indicator assignments are already established, we would make every effort to work with the AMA's 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 APC and status indicator assignments in the proposed rule for a year, we would need to establish interim APC and status indicator assignments for the initial year because there would be no predecessor code we could use as a reference to establish a G-code in order to continue current payment policies for such a service. We proposed to continue to establish the initial APC and status indicator assignments for these wholly new services as interim final assignments, and to follow our current process to solicit and respond to public comments and finalize the APC and status indicator assignments in the subsequent year.

We recognize that the use of HCPCS G-codes may place an administrative burden on those providers that bill for services under the OPPS and the ASC payment system. However, the proposed use of G-codes would permit us to propose and accept public comment on the APC and status indicator assignments for the vast majority of new and revised codes before they take effect. We are hopeful that the AMA's 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 before the new and revised CPT codes take effect on January 1. If the AMA's CPT Editorial Committee can make adjustments to its schedule, we would not need to use G-codes as described above for the purpose of maintaining outdated coding and APC and status indicator assignments for a year until we can include proposed APC and status indicator assignments for the new and revised codes in a proposed rule. We proposed to implement the revised CMS process for establishing APC and status indicator assignments for new and revised codes for CY 2016. However, we indicated in the proposed rule that we would consider alternative implementation dates if that would allow time for the AMA's CPT Editorial Panel to adjust its schedule in order to avoid the necessity to use numerous HCPCS G-codes.

In summary, in conjunction with the proposals presented in the CY 2015 MPFS proposed rule to revise the process used to address new, revised, and potentially misvalued codes under the MPFS, in the CY 2015 OPPS/ASC proposed rule (79 FR 40977 through 40979), we proposed to include in the OPPS/ASC proposed rule 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 and 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 APC and status indicator assignments for the codes. Otherwise, we will 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 APC and status indicator assignments until the following year when we would include proposed assignments for the new and revised codes in the proposed rule. We proposed 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 OPPS. For codes that describe wholly new services for which we do not receive timely information from the AMA, we proposed to establish interim APC and status indicator assignments 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 APC and status indicators for the vast majority of new and revised CPT codes that take effect on January 1 each year. We invited public comments on this proposal. We indicated in the proposed rule that we were specifically interested in receiving public comments on the following topics:

- Is this proposal preferable to the present process? Are there other alternatives?
- If we were to implement this proposal, is it better to move forward with the changes or is more time needed to make the transition and, therefore, implementation should be delayed beyond CY 2016?
- Are there alternatives other than the use of HCPCS G-codes that would allow us to address the annual CPT code changes through notice and comment rather than interim final rulemaking?
- Is the process we have proposed for wholly new services appropriate? How should we define new services?
- Are there any classes of services, other than new services, that should remain on an interim final schedule?

Comment: The majority of the commenters supported the proposal to modify the current process of recognizing new and revised CPT codes because it would provide an opportunity for the public to comment on specific APC and status indicator assignments prior to those assignments being finalized. However, several commenters disagreed with our proposed implementation date of CY 2016 and requested that CMS work with the AMA to determine an appropriate implementation date. Other commenters suggested that CMS finalize the proposal but urged CMS to work with the AMA on an appropriate timeline that considers the AMA's CPT and RUC (Specialty Society Relative Value Update Committee) meeting dates as well as CMS' OPPS and MPFS regulation schedule. The AMA supported the proposal but requested that CMS finalize the proposal for CY 2017 rather than CY 2016 because the CPT codes for the CY 2016 update are almost complete.

Response: We appreciate the commenters' support for our proposal. We believe that publishing our proposed status indicator and APC assignments for the new and revised CPT codes in the proposed rule would alleviate some concerns expressed by stakeholders in the past that some of our interim APC assignments were not appropriate, and that the APC assignment process could be improved if we had the benefit of public comments before adopting final APC and status indicator assignments for new and revised codes. This new process of proposing and requesting public comments before finalizing the APC and status indicator assignments for new and revised codes allows both CMS and stakeholders the benefit of public notice and comment prior to the use of the new and revised codes for payment purposes. When we receive information on the new and revised codes from the AMA in time to include proposals for new and revised codes in the proposed rule before the codes are effective the following January 1, the revised process allows public notice and comment before finalizing APC and status indicator assignments for the codes during the calendar year before the CPT codes become effective. In addition, this new process eliminates the need to make interim APC and status indicator assignments for new and revised CPT codes, which has been unpopular among some providers because the interim assignments are used for payment for a year before we address public comments and make any appropriate changes to an APC or status indicator assignment in the subsequent year's final rule.

Although the AMA and several commenters requested that we modify our proposal by finalizing this new process for the CY 2017 OPPS update, we disagree with this recommendation. We believe the new process that permits an opportunity for public comment on

proposed APC and status indicator assignments for the vast majority of new and revised codes before they are finalized and used for payment purposes will be beneficial to CMS and to hospitals and other stakeholders, and we see no reason to delay implementation of this policy change. Therefore, beginning with the CY 2016 OPPS update, we will publish proposed APC and status indicator assignments for any new and revised CPT codes for January 1, 2016 that are publicly released by the AMA in time for us to consider them for inclusion in the OPPS/ASC proposed rule. After review of the public comments received on the proposed rule, we will finalize the status indicator and APC assignments for those new and revised CPT codes in the CY 2016 OPPS/ASC final rule. Because the APC assignments would be final, we would no longer request comments in the OPPS/ASC final rules for these new and revised CPT codes that are included in the proposed rule. For any new and revised codes released too late for us to consider them for inclusion in the CY 2016 OPPS/ASC proposed rule, we will create HCPCS G-codes that reflect the same description(s), and APC and status indicator assignments, as their predecessor codes. These HCPCS G-codes will be used during CY 2016, and then we will include proposals for the corresponding new and revised codes and APC and status indicator assignments in the CY 2017 OPPS/ASC proposed rule.

Comment: Most commenters opposed the use of temporary HCPCS G-codes and requested that CMS not implement the HCPCS G-code process if it finalizes the proposal to change to process for new and revised CPT codes. The commenters recommended not establishing temporary HCPCS G-codes because these codes would be extremely burdensome for providers to use. The commenters stated that establishing HCPCS G-codes for services or procedures that are already described by existing CPT codes would be too confusing for hospitals, physicians, and other third party insurers to accurately claim costs for these procedures, and that using two different sets of codes for the same procedure or service could result in erroneous claims.

Response: As described above, we plan to publish the new and revised CPT codes that are publicly available and provided to us in time for evaluation in the CY 2016 OPPS/ASC proposed rule. Specifically, in the CY 2016 OPPS/ASC proposed rule, we expect to publish new and revised CPT codes that would be effective January 1, 2016, with the proposed status indicator and APC assignments, and request public comments on these proposed assignments as long as we receive them in time for inclusion in the proposed rule. We would finalize the status indicator and APC assignments for these new and revised CPT codes in the CY 2016 OPPS/ASC final rule.

However, for those new and revised CPT codes that are not publicly available in time for the OPPS/ASC proposed rule, we will create HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can include proposed status indicator and APC assignments in the following year's proposed rule. These HCPCS G-codes will be assigned to comment indicator ''NI'' to indicate that the codes are new and open for comment for 60 days after display of the OPPS/ASC final rule with comment period. This is consistent with our current policy of seeking public comments on new CPT and Level II HCPCS codes with interim APC and status indicator assignments that were not previously published in the proposed rule. For new and revised codes, we recognize that there is a trade-off between the benefit of considering public comments on the proposed APC and status indicator assignments before they take effect and the potential confusion caused by the use of HCPCS G-codes. We anticipate that the use of HCPCS G-codes will be largely a temporary solution or may not be necessary in the OPPS, and we expect to work closely with the AMA to minimize the need for them. We note that, under the MPFS, we generally do not develop values for new and revised CPT codes until we receive recommendations provided by the AMA's RUC. In contrast, under the OPPS, we use only the publicly available new and revised CPT codes and their descriptors to develop APC and status indicator assignments. As such, we anticipate that the need to use HCPCS G-codes under the OPPS will be less frequent than under the MPFS.

After consideration of the public comments we received, we are finalizing our proposal. For the new and revised CPT codes that we receive timely from the AMA's CPT Editorial Panel, we are finalizing our proposal to include these 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 and revised CPT codes that we receive too late for inclusion in the OPPS/ASC proposed rule, we are finalizing our proposal to create 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. We also are finalizing 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.

B. 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 final rule with comment period.

In CY 2008, we implemented 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 (72 FR 66650 through 66652). For CY 2014, we provided composite APC payments for nine categories of services:

- Mental Health Services Composite (APC 0034)
- Cardiac Electrophysiologic Evaluation and Ablation Composite (APC 8000)
- Low Dose Rate (LDR) Prostate Brachytherapy Composite (APC 8001)
- Ultrasound Composite (APC 8004)
- CT and CTA without Contrast Composite (APC 8005)
- CT and CTA with Contrast Composite (APC 8006)
- MRI and MRA without Contrast Composite (APC 8007)
- MRI and MRA with Contrast Composite (APC 8008)
- Extended Assessment & Management Composite (APC 8009)

A further discussion of composite APCs is included in section II.A.2.f. of this final rule with comment period. We note that, as a consequence of the new comprehensive APC policy, APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite) is being deleted.

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. 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 APC 0634 (Hospital Clinic Visits). The APC relative payment weights are scaled to APC 0634 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

Section 1833(t)(9)(A) of the Act requires the Secretary to review, no less than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments 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. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights (the Panel recommendations for specific services for the CY 2015 OPPS and our responses to them are discussed in the relevant specific sections throughout this final rule with comment period).

Finally, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same 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).

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 cost of the highest cost item or service within an APC group is more than 2 times greater than the cost of the lowest cost item or service within that same group. In making this determination, 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 bills 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 the CY 2015 OPPS/ASC proposed rule (79 FR 40981), for CY 2015, we proposed 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.

In the CY 2015 OPPS/ASC proposed rule, we identified the APCs with violations of the 2 times rule for CY 2015 (79 FR 40980). Therefore, we proposed changes to the procedure codes assigned to these APCs in Addendum B to the CY 2015 OPPS/ASC proposed rule. We noted that Addendum B did not appear in the printed version of the **Federal Register** as part of the CY 2015 OPPS/ASC proposed rule. Rather, it was 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 proposed 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 2015 included in the proposed rule are related to changes in costs of services that were observed in the CY 2013 claims data newly available for CY 2015 ratesetting. We also proposed changes to the status indicators for some procedure codes that were not specifically and separately discussed in the proposed rule. In these cases, we proposed 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 proposed for CY 2015. In addition, we proposed to rename existing APCs or create new clinical APCs to complement the proposed procedure code reassignments. Addendum B to the CY 2015 OPPS/ASC

proposed rule identified with a comment indicator ''CH'' those procedure codes for which we proposed a change to the APC assignment or status indicator, or both, that were initially assigned in the April 2014 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*). In contrast, Addendum B to this final rule with comment period (available via the Internet on the CMS Web site) identifies with the ''CH'' comment indicator the final CY 2015 changes compared to the HCPCS codes' status as reflected in the October 2014 Addendum B update.

3. Exceptions to the 2 Times Rule

As discussed earlier, we may make exceptions to the 2 times rule limit on the variation of costs within each APC group in unusual cases such as low-volume items and services. Taking into account the APC changes that we proposed for CY 2015, 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 2013 claims data available for the CY 2015 OPPS/ASC proposed rule, we found 9 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs that we proposed to make exceptions for under the 2 times rule for CY 2015, and identified 9 APCs that met the criteria for an exception to the 2 times rule based on the CY 2013 claims data available for the proposed rule. We did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 0375 (Ancillary Outpatient Services when Patient Expires), which has an APC cost set based on multiple procedure claims. Therefore, we only identified those APCs, including those with criteria-based costs, such as device-dependent APCs, 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 18 of the proposed rule (79 FR 40981) listed the 9 APCs that we proposed to make exceptions for under the 2 times rule for CY 2015 based on the criteria cited above and claims data submitted between January 1, 2013, and December 31, 2013, and processed on or before December 31, 2013. For the final rule with comment period, we stated that we intend to use claims data for dates of service between January 1, 2013, and December 31, 2013, that were processed on or before June 30, 2014, and updated CCRs, if available. Therefore, after considering the public comments we received on the CY 2015 OPPS/ASC proposed rule and making changes to APC assignments based on those comments, we analyzed the CY 2013 claims data used for this final rule with comment period to identify the APCs with violations of the 2 times rule. Based on the final CY 2013 claims data, we found 12 APCs with violations of the 2 times rule for this final rule with comment period, which is 3 more APCs that violated the 2 times rule compared to those indicated in the proposed rule. We applied the criteria as described earlier to identify the APCs that are exceptions to the 2 times rule for CY 2015, and identified three new APCs that meet the criteria for exception to the 2 times rule for this final rule with comment period, but that did not meet the criteria using proposed rule claims data. Specifically, we found that the following three new APCs violated the 2 times rule:

- APC 0095 (Cardiac Rehabilitation);
- APC 0388 (Discography); and
- APC 0420 (Level III Minor Procedures).

After consideration of the public comments we received and our review of the CY 2013 costs from hospital claims and cost report data available for this final rule with comment period, we are finalizing our proposals with some modifications. Specifically, we are finalizing our proposal to except 7 of the 9 proposed APCs from the 2 times rule for CY 2015: APCs 0057, 0066, 0330, 0433, 0450, 0634, and 0661. In contrast, we are not finalizing our proposal to except 2 of the 9 proposed APCs from the 2 times rule: APC 0012 (Level I Debridement & Destruction) and APC 0015 (Level II Debridement & Destruction). Our data analysis for this final rule with comment period revealed that these two APCs no longer violate the 2 times rule. Table 19 below lists 10 APCs that we are excepting from the 2 times rule for CY 2015 based on the criteria above and a review of updated claims data. We note that, for cases in which a recommendation by the HOP 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 of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates. The geometric mean costs for hospital outpatient services for these and all other APCs that were used in the development of this final rule with comment period 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 19—FINAL APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2015

CY 2015 APC	CY 2015 APC Title
0057	Bunion Procedures.
0066	Level V Radiation Therapy.
0095	Cardiac Rehabilitation.
0330	Dental Procedures.
0388	Discography.
0420	Level III Minor Procedures.
0433	Level II Pathology.
0450	Level I Minor Procedures.
0634	Hospital Clinic Visits.
0661	Level III Pathology.

The final costs for hospital outpatient services for these and all other APCs that were used in the development of this final rule with comment period can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

C. OPPS APC-Specific Policies

1. Cardiovascular and Vascular Services: Cardiac Telemetry (APC 0213)

For CY 2015, we proposed to reassign CPT code 93229 (External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and

transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional) from APC 0209 (Level II Extended EEG, Sleep, and Cardiovascular Studies), with a proposed rule payment rate of approximately $239 to APC 0213 (Level I Extended EEG, Sleep, and Cardiovascular Studies), with a proposed payment rate of approximately $175.

Comment: One commenter opposed CMS' proposal to reassign CPT code 93229 to APC 0213 and stated that the hospital costs used to set the CY 2015 proposed payment rate is based on faulty claims data, which include miscoded claims reporting the service submitted by hospitals. The commenter indicated that based on its internal analysis of the CY 2013 hospital claims data, which were used as the basis for the CY 2015 proposed APC reassignment, several hospitals reported costs of under $100 for the procedure described by CPT code 93229. The commenter stated that the service described by CPT code 93229 involves the use of sophisticated technology requiring attended surveillance on a 24-hour, 7 days a week basis by a technician for up to 30 days. According to the commenter, this particular service requires resources that are greater than $100. The commenter further explained that the service described by CPT code 93229 requires up to 30 days of electrocardiogram (ECG) monitoring through an external device worn by the patient at home that captures, stores, and transmits ECG data in real-time through wireless technology to a receiving or monitoring center (the hospital outpatient facility). These data are then reviewed by certified cardiac technicians and the ordering physician is provided with daily reports. The commenter added that this procedure is performed primarily (approximately 90 percent of the time) by independent diagnostic testing facilities (IDTFs) and infrequently performed by hospitals, typically under arrangements with IDTFs. The commenter believed that the CY 2015 proposed payment rate of approximately $175 for APC 0213 is significantly lower than the CY 2014 MPFS payment rate of $669. The commenter stated that the actual cost of providing the service is approximately $795. Therefore, the commenter recommended that CMS either reassign CPT code 93229 to APC 0435 (Level III Extended EEG, Sleep, and Cardiovascular Studies), which has a proposed payment rate of approximately $853, or establish a new APC for outpatient cardiac telemetry services that accurately reflects the costs associated with providing this service.

Response: CPT code 93229 became effective January 1, 2009. We believe that 5 years is sufficient time to understand what procedure CPT code 93229 describes and how to appropriately report this service on hospital claims. Based on our analysis of the CY 2013 hospital outpatient claims data used for this final rule with comment period, we are unable to determine whether hospitals are miscoding the claims reporting this service. For all APCs whose payment rates are based upon relative payment weights, we note that the quality and accuracy of reported units and charges influence the geometric mean costs that are the basis for our payment rates, especially the geometric mean costs for low volume items and services. Beyond our standard OPPS trimming methodology (described in section II.A.2. of this final rule with comment period) that we apply to those claims that have passed various types of claims processing edits, it is not our general policy to determine the accuracy of hospital coding and charging practices for the purposes of ratesetting (75 FR 71838). We rely on hospitals to accurately report all of the services provided to beneficiaries using the established HCPCS and CPT codes that appropriately describe the procedures performed in accordance with their code descriptors and the CPT Editorial Panel's and CMS' instructions, as applicable, and to include these charges and costs on their Medicare hospital cost report appropriately. In addition, we do not specify the methodologies that hospitals must use to set charges for this or any other service.

We recognize that the MPFS pays separately for CPT code 93229. However, the MPFS and the OPPS are very different payment systems. Each system is established under a different set of statutory and regulatory principles, and the policies established under the MPFS do not necessarily affect the payment policies under the OPPS. Moreover, we do not agree with the commenter that CPT code 93229 should be reassigned to APC 0435. Based on the claims data available for this final rule with comment period, we believe that APC 0213 is the most appropriate APC to reassign CPT code 93229 based on the clinical homogeneity and resource costs in relation to the other procedures assigned to this APC. Our analysis of the latest hospital outpatient CY 2013 claims data shows a final geometric mean cost of approximately $105 for CPT code 93229 based on 3,505 single claims (out of 3,579 total claims), which is not inconsistent with the geometric mean cost of approximately $183 for APC 0213, which is the lowest cost APC in the extended EEG, sleep, and cardiovascular studies series of APCs.

In response to the commenter's concern regarding miscoding of hospital claims reporting the service described by CPT code 93229, we remind hospitals that CPT code 93229 is not the appropriate procedure code to use to report Holter monitoring (CPT codes 93224 through 93227), or event monitoring (CPT codes 93268 through 93278) procedures. CPT code 93229 should be used to report continuous outpatient cardiovascular monitoring that includes up to 30 consecutive days of real-time cardiac monitoring. In particular, the 2014 CPT Code Book describes the procedure described by CPT code 93229 as a mobile cardiovascular telemetry service and defines it as:

''Mobile cardiovascular telemetry (MCT): Continuously records the electrocardiographic rhythm from external electrodes placed on the patient's body. Segments of the ECG data are automatically (without patient intervention) transmitted to a remote surveillance location by cellular or landline telephone signal. The segments of the rhythm, selected for transmission, are triggered automatically (MCT device algorithm) by rapid and slow heart rates or by the patient during a symptomatic episode. There is continuous real time data analysis by preprogrammed algorithms in the device and attended surveillance of the transmitted rhythm segments by a surveillance center technician to evaluate any arrhythmias and to determine signal quality. The surveillance center technician reviews the data and notifies the physician or other qualified health care professional depending on the prescribed criteria'' (2014 CPT Professional Edition; page 549).

We expect that hospitals would only report CPT code 93229 on hospital claims for providing the mobile telemetry service that is described above.

In summary, after consideration of the public comment we received, we are finalizing our CY 2015 proposal, without modification, to reassign CPT code 93229 to APC 0213 for CY 2015. Consistent with our policy of reviewing APC assignments annually, we will reevaluate the cost of CPT code 93229 and its APC assignment for the CY 2016 rulemaking.

2. Gastrointestinal (GI) Services: Upper GI Procedures (APCs 0142, 0361, 0419, and 0422)

In the CY 2014 OPPS/ASC final rule with comment period, we assigned CPT codes 43211 (Esophagoscopy, flexible transoral; with endoscopic mucosal resection), and 43254 (Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection) to APC 0141 (Level I Upper GI Procedures) on an interim basis. In addition, we assigned CPT code 43240 (Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with transmural drainage of pseudocyst) to APC 0419 (Level II Upper GI Procedures), CPT code 91035 (Esophagus, gastroesophageal reflux test; with mucosal attached telemetry ph electrode placement, recording, analysis and interpretation) to APC 0361 (Level II Alimentary Tests), and CPT code 0355T (Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report) to APC 0142 (Level I Small Intestine Endoscopy).

For CY 2015, we proposed to reassign CPT codes 43211 and 43254 from APC 0141 to APC 0419. We also proposed to continue to assign CPT code 43240 to APC 0419; CPT code 91035 to APC 0361; and CPT code 0355T to APC 0142.

Comment: Several commenters requested that CMS reassign CPT codes 43211 and 43254 from APC 0141 to APC 0419 in response to the CY 2014 OPPS/ASC final rule with comment period. The commenters believed that the reassignment would be consistent with the resource and clinical homogeneity principles used to assign services to appropriate classification groupings. In response to the CY 2015 OPPS/ASC proposed rule, the same commenters supported CMS' proposal to reassign CPT codes 43211 and 43254 to APC 0419 for the CY 2015 OPPS update, and applauded CMS for considering the suggestions made in response to the commenters' concerns. One commenter requested that CMS consider reassigning CPT codes 43211 and 43254 from APC 0141 to APC 0422 (Level III Upper GI Procedures) instead of from APC 0141 to APC 0419 as proposed. Based on an analysis of the CY 2013 OPPS claims data performed by the commenter, the commenter believed that the geometric mean costs associated with endoscopic mucosal resection (EMR) procedures are more closely aligned with the geometric mean cost of APC 0422 than APC 0419.

Response: EMR CPT codes 43211 and 43254 became effective January 1, 2014. As with all new codes, our policy has been to assign the service to an APC based on input from a variety of sources, including but not limited to, a review of the clinical similarity of the service in comparison to existing procedures; input from CMS medical advisors; information from interested specialty societies; and a review of all other information available to us. Based on the complexity of these procedures and input from our medical advisors, we believe that APC 0419 appropriately reflects the clinical homogeneity and resource costs associated with performing EMR procedures. Therefore, after consideration of the public comments we received, we are finalizing our CY 2015 proposal, without modification, to reassign CPT codes 43211 and 43254 from APC 0141 to APC 0419 for the CY 2015 OPPS update. As we do every year, we will review our claims data for these services for the CY 2016 OPPS rulemaking.

Comment: Several commenters expressed concern with CMS' proposal to continue to assign CPT code 43240 to APC 0419, and requested that CMS reassign the CPT code to APC 0384 (GI Procedures with Stents) based on the clinical similarity of the service to other procedures assigned to this APC.

Response: Based on our analysis of the latest hospital outpatient claims data used for this final rule with comment period, we agree with the commenters that a more appropriate APC reassignment is necessary for CPT code 43240. However, we believe that the most appropriate APC reassignment is APC 0422 (Level III Upper GI Procedures) rather than APC 0384. Our claims data show a geometric mean cost of approximately $1,574 for CPT code 43240 based on 44 single claims (out of 142 total claims), which is more comparable to the geometric mean cost of approximately $1,987 for APC 0422 than to the geometric mean cost of approximately $3,294 for APC 0384. Therefore, after consideration of the public comments we received, we are modifying our proposal regarding the APC reassignment of CPT code 43240. Specifically, we are reassigning CPT code 43240 from APC 0419 to APC 0422 for CY 2015.

Comment: Several commenters expressed concern regarding the inadequate payment rate for CPT code 91035 under Medicare's ASC payment system, and requested that CMS reassign CPT code 91035 from APC 0361 to APC 0142 as a means to increase the payment rate in the ASC setting. The commenters noted that APC 0142 includes other capsule-based procedures that are clinically similar to the procedure described by CPT code 91035, such as the procedure described by CPT code 91112 (Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report). The commenters further explained that the procedures described by CPT codes 91035 and 91112 both involve the use of a capsule to collect pH and other data from the patient's gastrointestinal tract over a period of several days.

Response: Based on our analysis of the latest hospital outpatient claims data used for this final rule with comment period, we believe that CPT code 91035 is appropriately assigned to APC 0361 to ensure adequate payment for the service in any hospital outpatient setting. Our claims data show a geometric mean cost of approximately $466 for CPT code 91035 based on 1,272 single claims (out of 5,099 total claims), while claims data for CPT code 91112 show a geometric mean cost of approximately $774 based on 353 single claims (out of 412 total claims). The geometric mean cost of APC 0361 is approximately $341 and the geometric mean cost of APC 0142 is approximately $884, which is almost twice the geometric cost of CPT code 91035. In addition, assigning CPT code 91035 to APC 0142 would create a violation of the 2 times rule within APC 0142 because the geometric mean cost of the highest cost significant procedure assigned to APC 0142 (CPT code 44361, with a geometric mean cost of approximately $1,019) is 2.2 times the geometric mean cost of CPT code 91035. Therefore, APC 0142 would not be an appropriate assignment for CPT code 91035. We are finalizing our CY 2015 proposal to continue to assign CPT code 91035 to APC 0361.

Comment: In response to the CY 2014 OPPS/ASC final rule with comment period, several commenters requested that CMS assign CPT code 0355T, which became effective July 1, 2014, to APC 0142 for the CY 2015 OPPS update. The commenters believed that the procedure described by CPT code 0355T is similar to the procedures described by existing GI capsule endoscopy CPT codes 91110 (Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report), 91111 (Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with interpretation and report), and 91112 (Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report), which are all assigned to APC 0142.

Response: As published in Table 17 of the CY 2015 OPPS/ASC proposed rule (79 FR 40976), we proposed to continue

to assign this new code to APC 0142. We agree with the commenters that GI endoscopy CPT codes 0355T, 91110, 91111, and 91112 are clinically similar. Therefore, we are finalizing our CY 2015 proposal, without modification, to continue to assign CPT code 0355T to APC 0142, As a result, all four GI endoscopy procedures described by CPT codes 0355T, 91110, 91111, and 91112 will be assigned to APC 0142 for the CY 2015 OPPS update.

We remind hospitals that because the payment rates associated with new codes that become effective July 1 are not available to us in time for incorporation into the Addenda to the proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2014 OPPS quarterly update CR were not included in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site). However, we listed the codes and their proposed APC assignments in the preamble of the proposed rule.

The final CY 2015 payment rate for all of the CPT codes discussed can be found in Addendum B to this CY 2015 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

3. Genitourinary Services

a. Gynecologic Procedures (APCs 0188, 0189, 0192, 0193, and 0202)

For the CY 2014 OPPS update, we made several changes to specific APC assignments, which included the female reproductive APCs; APC 0192, APC 0193, and APC 0195. These proposed changes were listed in Addendum B to the CY 2014 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site). With respect to these three APCs, based on claims data available for the CY 2014 OPPS/ASC proposed rule, only APC 0193 showed a violation of the 2 times rule. We note that, under the OPPS, we may make exceptions to the 2 times rule based on the variation of costs within each APC group in unusual cases such as low-volume items and services. In the case of APC 0193, we believed that it was necessary to make an exception to the 2 times rule for the CY 2014 OPPS update because this APC sufficiently reflected the clinical and resource coherence of the Level V female reproductive procedures.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40982), we discussed our proposal to make further changes to the existing female reproductive APCs; APC 0188, APC 0189, APC 0191, APC 0192, APC 0193, APC 0195, and APC 0202 based on a presentation made at the March 10, 2014 Panel meeting. Specifically, one presenter expressed concern regarding the reassignment of the female reproductive procedures within existing APCs 0192 (Level IV Female Reproductive Procedures), 0193 (Level V Female Reproductive Procedures), and 0195 (Level VI Female Reproductive Procedures) that became effective with the CY 2014 OPPS update. The presenter stated that the proposed changes would compromise beneficiary access to pelvic floor repair procedures, and urged the Panel to request that CMS reconsider its packaging policy for the procedures assigned to APCs 0193 and 0195 and allow stakeholders the opportunity to work with CMS to appropriately reassign these procedures to accurately account for the clinical complexity associated with providing these services. In addition, the presenter requested that CMS delay the conversion of existing APC 0202 (Level VII Female Reproductive Procedures) to a C–APC to allow for further study of the complexity of pelvic floor repair procedures. After review of the information provided by the presenter and examination of the hospital outpatient claims data available for the CY 2015 OPPS/ASC proposed rule, the Panel did not make any recommendations regarding any of the female reproductive APCs.

For the CY 2015 OPPS update, based on our review of the latest hospital outpatient claims data available for the CY 2015 OPPS/ASC proposed rule, there were no violations of the 2 times rule within any of the female reproductive APCs (79 FR 40982). However, we proposed to restructure the female reproductive APCs to more appropriately reflect the resource and clinical characteristics of the procedures assigned to each APC. The proposed restructuring resulted in the use of five APCs for the CY 2015 OPPS update, as compared to the seven APCs used for the CY 2014 OPPS update. We believe that the proposed five-level APC structure will provide more accurate payments for the female reproductive procedures furnished to Medicare beneficiaries.

Tables 21 and 22 of the proposed rule (79 FR 40983) showed the current CY 2014 and proposed CY 2015 female reproductive APCs. Specifically, Table 21 showed the female reproductive APCs, APC titles, and their status indicator assignments for CY 2014, while Table 22 showed the proposed female reproductive APCs, APC titles, and their status indicator assignments for CY 2015. In the proposed rule, we noted that one of the five levels of the female reproductive APCs, APC 0202, is proposed to be converted to a C–APC. We refer readers to section II.A.2.e. of this final rule with comment period for further discussion of our comprehensive APC policy.

In addition, for CY 2015, we proposed to consolidate the two existing hysteroscopy APCs; APC 0190 (Level I Hysteroscopy) and APC 0387 (Level II Hysteroscopy). Specifically, we proposed to delete APC 0387 and to reassign the procedures currently assigned to this APC to APC 0190. In conjunction with this proposed reassignment, we proposed to rename APC 0190 from ''Level II Hysteroscopy'' to ''Hysteroscopy.'' Based on the hospital outpatient claims data available for the CY 2015 OPPS/ASC proposed rule, we believe that the two-leveled structure of the hysteroscopy APCs is no longer necessary because the single-leveled hysteroscopy APC sufficiently reflects the resources and clinical similarities of all the hysteroscopic procedures. We note that, for CY 2014, the payment rates for APCs 0190 and 0387 are $1,763 and $2,818, respectively. For CY 2015, the proposed payment rate for APC 0190 was approximately $2,014.

Comment: Many commenters supported CMS' proposal to reassign several of the female reproductive procedures to APC 0202 and stated that the proposed restructuring of these APCs more appropriately reflects clinical and resource homogeneity among similar procedures.

Response: We appreciate the commenters' support.

Comment: Some commenters opposed CMS' proposal to reassign CPT code 57155 (Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy) from APC 0193 (Level IV Female Reproductive Procedures) to APC 0192 (Level III Female Reproductive Procedures) for the CY 2015 OPPS update. According to the commenters, the proposed CY 2015 OPPS payment rate of approximately $501 for CPT code 57155 is significantly lower than the CY 2014 OPPS payment rate of approximately $1,375, which represents a 63-percent reduction in the payment for this service. The commenters noted that the APC assignment for this procedure has varied between APC 0192 and APC 0193 since the inception of the code, and recommended that CMS reexamine the procedures assigned to APCs 0192, 0193, and 0202 to ensure that the proposed structure of these APCs provides the most appropriate payment for the services assigned to each APC.

Some commenters requested that CMS continue to assign CPT code 57155 to APC 0193 for the CY 2015 update. The commenters also recommended that CMS closely monitor medical practice patterns to ensure beneficiary access to this treatment if CMS finalizes the proposal to reassign CPT code 57155 to APC 0192.

Response: CPT code 57155 became effective January 1, 2002. Since that time, CPT code 57155 has been assigned to either APC 0192 or APC 0193. For CYs 2002, 2003, and 2006 through 2013, CPT code 57155 was assigned to APC 0192. For CYs 2004, 2005, and 2014, CPT code 57155 was assigned to APC 0193. Consistent with CMS' statutory requirement under section 1833(t)(9) of the Act to review and revise APC assignments annually and to construct the most appropriate APC groupings as well as, to the extent desirable, correct any 2 times rule violations, we evaluated the resource consumption and clinical coherence associated with the female reproductive APCs for the CY 2015 OPPS update. Based on an analysis of the latest hospital outpatient claims data for this final rule with comment period, CPT code 57155 has a geometric mean cost of approximately $731 based on 858 single claims (out of 2,461 total claims). The geometric mean costs for the significant procedures assigned to APC 0192 range between approximately $398 (for CPT code 56605) and $731 (for CPT code 57155). Therefore, we believe that CPT code 57155 is appropriately assigned to APC 0192 based on the comparable resource costs associated with the other procedures assigned to this APC and are not making any changes to our proposal for this final rule with comment period. We note that APC 0192 had a proposed payment rate of approximately $501, which was based on hospital outpatient claims data submitted between January 1, 2013, and December 31, 2013, and processed on or before December 31, 2013. For this final rule with comment period, the final payment rate for APC 0192 is approximately $487, which is based on hospital outpatient claims data submitted between January 1, 2013, and December 31, 2013, and processed on or before June 30, 2014.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to reassign CPT code 57155 from APC 0193 to APC 0192 for CY 2015.

Comment: Several commenters requested that CMS not finalize the proposal to consolidate the two existing hysteroscopy APCs. Instead, the commenters suggested that CMS maintain the two-leveled structure of the hysteroscopy APCs to differentiate the less costly diagnostic hysteroscopic services from the more resource-intensive hysteroscopic procedures. One commenter stated that the reconfiguration of these APCs for CY 2015 is premature and warrants more discussion prior to finalizing a proposal regarding this issue. Another commenter believed that it is not clinically coherent to combine the diagnostic hysteroscopy procedure described by CPT code 58555 with a significant therapeutic procedure, such as a hysteroscopic myomectomy described by CPT code 58561. The commenter explained that all of the gynecology specialty societies recommend minimally invasive alternatives to hysterectomy when available. In addition, the commenter believed that the proposal to consolidate the hysteroscopy APCs would provide incentives for hospitals to encourage treatment that is not the standard of care.

Response: Based on a review of the latest hospital outpatient claims data for the CY 2015 OPPS update, we believe that restructuring and consolidating the gynecology APCs is prudent in order to improve the comparability of resource and clinical similarity of all the hysteroscopy procedures assigned to a specific APC. In addition, we disagree with the commenter's assertion regarding hospitals' incentives to deliver substandard care for the purposes of financial gain. We believe that hospitals and physicians will offer their patients the appropriate care and treatment, which may or may not employ an expensive medical device.

Comment: Several commenters suggested that modifications to the proposed APC assignments for certain related procedures be considered if CMS finalizes the proposal to restructure and consolidate the female reproductive APCs. One commenter suggested that CMS reassign CPT codes 58561 and 58563 to APC 0202 instead of APC 0190 based on the clinical similarities in relation to the other procedures assigned to APC 0202.

Response: Based on input from our medical advisors, we agree with the commenter that APC 0202 is the most appropriate APC assignment for CPT codes 58561 and 58563 based on their clinical similarity in relation to the other procedures assigned to this APC. We note that APC 0202 is designated as a C–APC for the CY 2015 OPPS update. Further information on C–APCs can be found in section II.A.2.e. of this final rule with comment period.

Comment: One commenter suggested that CMS reconsider the proposal to consolidate the hysteroscopy APCs and establish two separate APCs for female reproductive procedures; one for the more resource-intensive hysteroscopic procedures and another for the lower-cost and less complex hysteroscopic procedures. Specifically, the commenter recommended assigning the following seven resource-intensive female reproductive procedures to a higher-paying APC, with a geometric mean cost ranging between approximately $3,010 and $4,350: CPT codes 58353, 58356, 58561, 58563, 58565, 58559, and 58560. The commenter also suggested assigning the following four less complex female reproductive procedures to a lower-paying APC, with a geometric mean cost ranging between approximately $1,758 and $2,099: CPT codes 58555, 58558, 58562, and 58579. Another commenter believed that the necessary resources required to provide the service described by CPT code 58555 are significantly less than the resources required to provide the service described by CPT code 58561. The commenter stated that the resource costs for providing the services described by CPT codes 58353, 58561, 58563, and 58565 are similar and recommended that these procedures be assigned to the same APC.

Response: We reviewed our latest hospital outpatient claims data used for this final rule with comment period for all of the hysteroscopic procedures. Based on our review and after consideration of the public comments we received, we are modifying our proposal regarding the proposed APC assignments for several of the hysteroscopic procedures for the CY 2015 OPPS update. Specifically, we are deleting APC 0190 and reassigning the eight procedures that were proposed to be assigned to this APC to APC 0188, APC 0193, or APC 0202.

In summary, after consideration of the public comments received, we are finalizing our proposals with some modifications. For the hysteroscopy procedure APCs, we proposed to reassign all of the procedures assigned to APC 0387 to APC 0190, which resulted in a one-leveled APC containing all of the hysteroscopy procedures. Specifically, we proposed to delete APC 0387 (Level II Hysteroscopy), and to rename APC 0190 ''Hysteroscopy.'' However, based on our analysis of the hospital outpatient claims data available for this final rule with comment period, we are modifying our proposal. Instead, we are reassigning all of the hysteroscopy procedures that we proposed to assign

to APC 0190 to one of the female reproductive APCs. That is, we are reassigning all of the procedures proposed for reassignment to APC 0190 to APC 0188, APC 0193, or APC 0202. Consequently, with no procedures remaining in APC 0190, we deleted this APC for CY 2015. In addition, we are finalizing our proposal to restructure the female reproductive APCs to more appropriately reflect the resource and clinical characteristics of the procedures assigned to each APC. Specifically, we are finalizing our proposal to assign all of the female reproductive procedures to APCs 0188, 0189, 0192, 0193, or 0202. In addition, because of our revision to the hysteroscopy procedures APCs, we are revising the APC titles for the five female reproductive APCs; APC 0188, APC 0189, APC 0192, APC 0193, and APC 0202, from ''Female Reproductive Procedures'' to ''Gynecologic Procedures'' to more appropriately describe the procedures assigned to these APCs. Table 20 below lists the hysteroscopic procedures CPT codes, along with their long descriptors, proposed CY 2015 OPPS status indicators and APC assignments, as well as their final CY 2015 OPPS status indicators and APC assignments. Table 21 below lists the final APC titles and status indicators for the gynecologic procedure APCs. The final CY 2015 payment rates for the gynecologic procedures APCs, as well as the hysteroscopic procedures CPT codes listed in Table 21 can be found in Addendum B to this CY 2015 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 20—FINAL CY 2015 APC ASSIGNMENTS FOR THE HYSTEROSCOPIC PROCEDURES

CPT Code	Long descriptor	Proposed CY 2015 OPPS SI	Proposed CY 2015 OPPS APC	Final CY 2015 OPPS SI	Final CY 2015 OPPS APC
58353	Endometrial ablation, thermal, without hysteroscopic guidance	J1	0202	J1	0202
58356	Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed.	J1	0202	J1	0202
58555	Hysteroscopy, diagnostic (separate procedure)	T	0190	T	0193
58558	Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without d & c.	T	0190	T	0193
58559	Hysteroscopy, surgical; with lysis of intrauterine adhesions (any method).	T	0190	J1	0202
58560	Hysteroscopy, surgical; with division or resection of intrauterine septum (any method).	T	0190	J1	0202
58561	Hysteroscopy, surgical; with removal of leiomyomata	T	0190	J1	0202
58562	Hysteroscopy, surgical; with removal of impacted foreign body	T	0190	T	0193
58563	Hysteroscopy, surgical; with endometrial ablation (eg, endometrial resection, electrosurgical ablation, thermoablation).	T	0190	J1	0202
58565	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants.	J1	0202	J1	0202
58579	Unlisted hysteroscopy procedure, uterus	T	0190	T	0188

TABLE 21—FINAL CY 2015 APC TITLES FOR GYNECOLOGIC PROCEDURES

CY 2015 APC	Proposed CY 2015 APC title	Final CY 2015 APC title	Final CY 2015 status indicator
0188	Level I Female Reproductive Procedures	Level I Gynecologic Procedures	T
0189	Level II Female Reproductive Procedures	Level II Gynecologic Procedures	T
0192	Level III Female Reproductive Procedures	Level III Gynecologic Procedures	T
0193	Level IV Female Reproductive Procedures	Level IV Gynecologic Procedures	T
0202	Level V Female Reproductive Procedures	Level V Gynecologic Procedures	J1

b. Cystourethroscopy, Transprostatic Implant Procedures, and Other Genitourinary Procedures (APCs 0160, 0161, 0162, 0163, and 1564)

For the CY 2015 OPPS update, based on our review of the latest hospital outpatient claims data available for the CY 2015 OPPS/ASC proposed rule, we proposed to restructure the APCs containing cystourethroscopy and other genitourinary procedures to more appropriately reflect the resource costs and clinical characteristics of the procedures assigned within each APC (79 FR 40987). We note that, for the CY 2014 OPPS update, there are five levels of APCs that contain cystourethroscopy and genitourinary procedures. These APCs were listed in Table 26 of the CY 2015 OPPS/ASC proposed rule (79 FR 40986), along with their status indicator assignments for CY 2014. The proposed restructuring resulted in the use of four APCs for the CY 2015 OPPS update, as compared to the five APCs used for the CY 2014 OPPS update. Specifically, based on our review and evaluation of the procedures assigned to these APCs and the latest hospital outpatient claims data available, in the CY 2015 OPPS/ASC proposed rule, we proposed to delete APC 0429 (Level V Cystourethroscopy and Other Genitourinary Procedures) and reassign the procedures that were previously assigned to this APC to either APC 0161 (Level I Cystourethroscopy and Other Genitourinary Procedures) or APC 0163 (Level IV Cystourethroscopy and Other Genitourinary Procedures). We believe that the procedures currently assigned to APC 0429 would be more appropriately assigned to either APC 0161 or APC 0163 based on their geometric mean costs for the CY 2015 OPPS update. Further, we believe that this proposed restructuring appropriately categorizes all of the cystourethroscopy and other genitourinary procedures that are comparable clinically and with respect to resource use within an APC group. We also proposed to delete APC 0169 (Lithotripsy) because the one procedure,

specifically the procedure described by CPT code 50590 (Lithotripsy, extracorporeal shock wave), that was assigned to this APC was proposed for reassignment to APC 0163 (79 FR 40987). Table 27 of the CY 2015 OPPS/ASC proposed rule (79 FR 40987) listed the proposed APCs that contain cystourethroscopy and other genitourinary procedures, the APC titles, and the proposed status indicator assignments for CY 2015. The proposed payment rates for the specific APCs listed in Table 27 were listed in Addendum A to the proposed rule. The proposed payment rates for the specific cystourethroscopy and other genitourinary procedure codes were listed in Addendum B to the proposed rule. (Addenda A and B to the proposed rule are available via the Internet on the CMS Web site.)

Comment: Several commenters opposed CMS' proposal to delete APC 0169 and reassign the extracorporeal shock wave lithotripsy (ESWL) CPT code 50590 to APC 0163. The commenters noted that the procedure described by CPT code 50590 is classified as a noninvasive therapy and is not similar, clinically or with respect to resource costs, to the other more invasive surgical urological procedures that are proposed for assignment to APC 0163. One commenter stated that the ESWL procedure does not involve the use of an endoscope and, therefore, should not be assigned to APC 0163. This commenter believed that the payment rate for APC 0163 would be influenced by dominating the claims data for CPT code 50590 because ESWL is a commonly performed procedure resulting in a significant high volume of single frequency claims. The commenter requested that CMS delay finalizing this proposal or, alternatively, reassign CPT code 50590 to APC 0162 (Level III Cystourethroscopy and Other Genitourinary Procedures) because this APC encompasses a broader and more diverse grouping of procedures than APC 0163.

Response: As part of our standard annual OPPS update process, we review each APC assignment for the clinical similarity and resource homogeneity of the procedures assigned to each APC. An analysis of our latest hospital outpatient claims data available for this final rule with comment period revealed a geometric mean cost of approximately $3,094 based on 32,370 single claims (out of 44,816 total claims) for CPT code 50590, which is comparable to the geometric mean cost of approximately $3,230 for APC 0163. The significant procedures assigned to APC 0163 have geometric mean costs ranging between $2,946 and $4,088. We do not agree with the commenters that APC 0162 is the more appropriate APC assignment because the geometric mean cost for this APC, approximately $2,163, is significantly lower than the geometric mean cost of approximately $3,094 for CPT code 50590. In addition, the geometric mean cost of APC 0163 (using proposed rule data) and without CPT code 50590 assigned to this APC was approximately $3,058, which is close to the final rule geometric mean cost of CPT code 50590 of $3,094. Although the ESWL procedure does not involve the use of an endoscope, we note that not every procedure proposed for reassignment, or ultimately reassigned, to APC 0163 uses an endoscope. In addition, we do not agree with the commenters that the ESWL procedure is not clinically similar to the other procedures assigned to APC 0163. There are no general rules for clinical similarity that apply to all APCs. Instead, the evaluation of clinical similarity depends upon the particular characteristics of the services being evaluated for a particular APC assignment. The use of single procedure APCs, like APC 0169, the APC to which CPT code 50590 is assigned for CY 2014, generally is not considered appropriate under the OPPS because payment rates based on a single procedure code's geometric mean cost is more consistent with a fee schedule than a prospective payment system. However, there are limited circumstances in which we assign a single procedure code to an APC; for example, the intraocular procedures assigned to an APC series. Specifically, APC 0673 (Level III Intraocular Procedures) has a geometric mean cost of approximately $3,239. APC 0293 (Level IV Intraocular Procedures) is the next higher level APC in the intraocular procedures APC series, and it has a single procedure (CPT code 65770 (Keratoprosthesis)) assigned to it, which has a geometric mean cost of approximately $8,766. The highest cost procedure assigned to APC 0673 is CPT code 67113 (Repair of complex retinal detachment), which has a geometric mean cost of approximately $4,065. The geometric mean cost of CPT code 65770 is significantly higher, 2.2 times the geometric mean cost of CPT code 67113. Therefore, we assigned CPT code 65770 to a different APC because the resource costs are not similar. Because the procedure described by CPT code 65770 is an intraocular surgery and there are no other APCs that contain clinically similar procedures, we assigned CPT code 65770 to APC 0293 without any other procedures. Continuing in this series, we assigned CPT code 0308T (Insertion of intraocular telescope prosthesis including removal of crystalline lens) to APC 0351 (Level V Intraocular Procedures) without any other procedures. CPT code 0308T has a geometric mean cost of approximately $23,947, which is 2.73 times the geometric mean cost of the procedure described by CPT code 65770, which is assigned to APC 0293, which is one level lower than APC 0351 in the intraocular procedures APC series. CPT code 0308T is the only procedure code assigned to APC 0351 because there are no other procedures that are similar in terms of resource costs. We do not believe that similar APC series assignment is applicable to CPT code 50590. Therefore, we proposed to reassign CPT code 50590 to APC 0163 and delete APC 0169 (79 FR 40986 through 40987). In summary, based on our review of the latest hospital outpatient claims data for this final rule with comment period, we believe that CPT code 50590 would be appropriately assigned to APC 0163 based on its clinical and resource similarity to the other procedures assigned to APC 0163, several of which are dedicated to kidney stone removal. Therefore, we are finalizing our proposal, without modification, to assign CPT code 50590 to APC 0163 for CY 2015.

Comment: One commenter requested that CMS not finalize the proposal to delete APC 0429, and suggested that CMS maintain this APC until data become available for CPT code 52356 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (eg., Gibbons or double-J type)), which became effective January 1, 2014.

Response: We believe that CPT code 52356 is appropriately categorized by APC 0163 based on its similarity to the other procedures assigned to this APC. Because CPT code 52356 became effective January 1, 2014, we expect to have claims data for the procedure described by this code available for the CY 2016 OPPS rulemaking cycle. We note that, consistent with CMS' policy of reviewing APC assignments annually in accordance with the statutory requirement, we will reevaluate the APC assignment for CPT code 52356 for the CY 2016 OPPS update. Therefore, after consideration of the public comment we received, we are finalizing our proposals, without modification, to delete APC 0429 and to assign CPT code 52356 to APC 0163 for CY 2015.

Comment: Some commenters disagreed with CMS' proposal to

reassign CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) from APC 0163 to APC 0162. The commenters stated that the proposal would result in a 28-percent reduction in the payment for this service when the CY 2014 payment rate of approximately $2,905 for APC 0163 is compared to the CY 2015 proposed payment rate of approximately $2,091 for APC 0162. The commenters noted that CPT code 55875 has been assigned to APC 0163 since the code's inception in CY 2007, and believed that the proposed payment rate for APC 0163 more accurately reflects the resources necessary to provide this service. The commenters urged CMS to maintain the APC assignment of CPT code 55875 to APC 0163.

Response: Analysis of our latest hospital claims data used for this final rule with comment period revealed a geometric mean cost of approximately $2,501 for CPT code 55875 based on 703 single claims (out of 4,681 total claims), which is comparable to the geometric mean cost of approximately $2,163 for APC 0162. We do not agree with the commenters that APC 0163 is the more appropriate APC because its geometric mean cost of approximately $3,230 is significantly higher than the geometric mean cost of approximately $2,501 for CPT code 55875. We believe that CPT code 55875 is appropriately assigned to APC 0162 based on its clinical homogeneity and resource costs to the procedures currently assigned to this APC. Therefore, after consideration of the public comments we received, we are finalizing our proposal, without modification, to reassign CPT code 55875 to APC 0162 for CY 2015.

Comment: One commenter opposed CMS' proposal to reassign CPT code 53850 (Transurethral destruction of prostate tissue; by microwave thermotherapy) from APC 0429 to APC 0161. The commenter stated that the CY 2015 proposed payment rate for APC 0161 is approximately $1,235, which is significantly lower than the CY 2014 payment rate of approximately $3,304 for APC 0429. The commenter suggested that CMS reassign CPT code 53850 to APC 0163, the APC to which CPT code 53852 (Transurethral destruction of prostate tissue; by radiofrequency thermotherapy) is proposed to be reassigned. The commenter explained that both procedures are similar in clinical technique because both procedures use a thermal approach as an alternative to open prostatectomy or transurethral resection of the prostate for the treatment of benign prostatic hyperplasia (BPH).

Response: As has been our practice since the implementation of the OPPS in 2000, we review, on an annual basis, the APC assignments for the procedures and services paid under the OPPS. Based on the latest hospital outpatient claims data used for this final rule with comment period, our analysis does not support the reassignment of CPT code 53850 to APC 0163. Our analysis of the claims data shows a geometric mean cost of approximately $1,542 for CPT code 53850 based on 107 single claims (out of 142 total claims), which is relatively similar to the geometric mean cost of approximately $1,273 for APC 0161. While we acknowledge that both procedures are similar, our analysis of the claims data shows that the resource costs of providing the procedure described by CPT code 53852 is significantly higher than the resource cost of providing the procedure described by CPT code 53850. Specifically, the geometric mean cost for CPT code 53852 is approximately $3,339 based on 98 single claims (out of 156 total claims), which is comparable to the geometric mean cost of APC 0163 of approximately $3,230. We do not agree with the commenters that APC 0163 is the more appropriate APC assignment because its geometric mean cost is significantly higher than the geometric mean cost of CPT code 53850 of approximately $1,542. We believe that CPT code 53850 would be appropriately assigned to APC 0161 based on its clinical homogeneity and resource costs to the procedures currently assigned to this APC. Therefore, after consideration of the public comment we received, we are finalizing our proposal, without modification, to reassign CPT code 53850 from APC 0429 to APC 0161 for CY 2015.

In addition, effective April 1, 2014, we created HCPCS codes C9739 (Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants) and C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants) as a result of an application to assign the transprostatic implant procedures (TIPs) to a New Technology APC. We assigned HCPCS codes C9739 and C9740 to APCs 0162 (Level III Cystourethroscopy and other Genitourinary Procedures) and 1564 (New Technology—Level XXVII), respectively, based on the estimated costs of the procedures, which include 1 to 3 implants in the case of procedures described by HCPCS code C9739, and 4 or more implants in the case of procedures described by HCPCS code C9740. We based the number of implants for HCPCS codes C9739 and C9740 on the number of implant utilization data per patient that the New Technology applicant provided within its approved application. The CY 2014 payment rates for APCs 0162 and 1564 are $2,007.32 and $4,750.00, respectively.

The AMA's CPT Editorial Panel recently created two new codes for this technology, which become effective on January 1, 2015: CPT codes 52441 (Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant) and 52442 (Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)).

Comment: One commenter stated that the TIPs described by HCPCS codes C9739 and C9740 do not receive adequate payment under the OPPS because of the code descriptors for these procedure codes as they relate to the number of implants allowed in each respective code (1 to 3 implants for HCPCS code C9739 and 4 or more implants for HCPCS code C9740), when categorized by the APCs in which these services are assigned. The commenter also believed that the TIPs are unable to be performed in the ASC setting because of the inadequate payment rate for the specific APCs. The commenter believed that the procedures described by HCPCS codes C9739 and C9740 are device dependent because a majority of the procedures' costs are associated with the costs of the implants, with a mean of 4.9 implants per procedure. The commenter also believed that there is considerable variation in the number of implants used for each procedure. The commenter believed that the ASC payment is extremely low because the procedures are not designated as ''device intensive'' in the ASC setting (that is, the procedures are not assigned to ASC payment indicator ''J8''), nor are the procedures assigned to a C–APC under the OPPS, which would most likely allow for the performance of the device-intensive treatment in the ASC setting, similar to most of the proposed C–APCs that are defined as device-intensive APCs. The commenter stated that the proposed OPPS payments for HCPCS codes C9739 and C9740 are inadequate to cover both the costs of the number of implants required and the cost of the procedure. The commenter recommended several possible APC assignments to improve the payments for TIPs. The commenter recommended using new CPT codes 52441 and 52442

to report the TIPs under the OPPS, and assigning the procedures to C–APC 0385 (Level I Urogenital Procedures) because the proposed payment rate for C–APC 0385 of approximately $7,659 is comparable to the estimated cost of performing TIPs using 5 implants, which is approximately $7,519. The commenter's second recommendation was to continue to report the performance of the TIPs using HCPCS codes C9739 and C9740, and to assign HCPCS code C9740 to APC 0385, as described previously, and HCPCS code C9739 to APC 0202 (Level V Female Reproductive Procedures) and remove ''Female'' from the title of APC 0202. According to the commenter, the proposed payment for APC 0202 of approximately $4,366 is equivalent to the cost of a TIP using 2 or 3 implants. The commenter believed that because APC 0202 is designated as a C–APC, the ASC payment for the procedure would also prove to be adequate. The commenter's third recommendation was to use new CPT codes 52441 and 52442 to report TIPs and to assign the procedure codes to APC 0168 (Level II Urethral Procedures) on an interim basis until OPPS claims data are available for these codes. The commenter believed that the proposed payment rate for APC 0168 of approximately $2,533 more appropriately equates to the cost of a single implant procedure described by CPT code 52441, while additional implant procedures described by CPT code 52442 would be paid at 50 percent, or approximately $1,267, because APC 0168 is subject to the multiple procedure discount (that is, the APC is assigned to status indicator ''T''), which, the commenter claimed, more appropriately equates to the estimated cost of providing the procedure described by CPT code 52442 of approximately $1,248. However, the commenter noted that, because APC 0168 is not a C–APC, payment for the procedure may not be designated as ''device intensive'' to ensure adequate ASC payment. The commenter recommended that CMS consider any procedure that has device costs that are greater than 40 percent as device intensive.

Response: We agree with the commenter that the cost of the implants associated with the procedures described by HCPCS codes C9739 and C9740 represents the majority of the costs of the procedures. We considered those costs and the variation in the number of implants per procedure when we created HCPCS codes C9739 and C9740 and assigned the procedure codes to APCs 0162 and 1564, respectively. We believe that HCPCS codes C9739 and C9740 are preferable to the new CPT codes 52441 and 52442 with respect to OPPS and ASC payments because the new codes describe complete procedures instead of the insertion of individual implants, which are almost always incomplete procedures because patients usually receive multiple implants. We do not believe that any of the APCs recommended by the commenter are appropriate for assignment of HCPCS codes C9739 and C9740 at this time because our usual policy with new codes is to wait until we have OPPS claims data available before making an APC reassignment. In regard to the ASC payment for the procedures, neither APC 0162 nor APC 1564 is designated as device intensive. Therefore, the multiple procedure payment reduction under OPPS applies to the entire payment amount under the ASC payment as well. Currently, there is no policy regarding designating services that are assigned to a New Technology APC as device intensive for the ASC setting. We may consider such a policy in future rulemakings.

We will maintain payment for the cystourethroscopy with insertion of TIPs using HCPCS codes C9739 and C9740 because we believe that the code descriptors more appropriately reflect complete procedures and the distribution of implant utilization per patient. For CY 2015, we are maintaining our APC assignments for HCPCS codes C9739 and C9740 to APCs 0162 and 1564, respectively. The APC assignments for HCPCS codes C9739 and C9740 are initial APC assignments until we obtain claims data for these two codes for the CY 2016 OPPS update. The final CY 2015 geometric mean costs for APC 0162 is approximately $2,163, and the final CY 2015 payment rate (there are no geometric mean costs for New Technology APCs, only payment bands) for APC 1564 is approximately $4,750. CPT codes 52441 and 52442 will not be payable under the OPPS for CY 2015; we are assigning these two CPT codes to status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)).

After consideration of the public comments we received, we also are finalizing our proposal to restructure the APCs containing cystourethroscopy, transprostatic implant procedures, and other genitourinary procedures, and to use a four-level APC grouping to classify the procedures based on our analysis of the latest hospital outpatient claims data available for this final rule with comment period. The final payment rates for the cystourethroscopy, transprostatic implant procedures, and other genitourinary procedure codes, as well as the specific CPT codes on which we received public comments and that are discussed in this section, can be found in Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site. The final payment rates for APCs 0160, 0161, 0162, and 0163, which are the final CY 2015 cystourethroscopy, transprostatic implant procedures, and other genitourinary APCs, can be found in Addendum A to this final rule with comment period, which is also available via the Internet on the CMS Web site.

We remind commenters that every year we revise, if necessary, the APC assignments for procedure codes based on our analysis of the latest hospital outpatient claims data. We anticipate that there will be further significant revisions to the urology-related APCs in futures years because the current overall APC structure is suboptimal and can be improved with respect to the clinical similarity and resource similarity of the groupings. In addition, we note that section 1833(t)(9)(A) of the Act requires the Secretary to review, on a recurring basis occurring no less than annually, and revise the groups, the relative payment weights, and the wage and other adjustments 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. Although we do not discuss every APC change in the proposed and final rules with comment period, these changes are listed in Addendum B to the proposed and final rules with comment period. Specifically, procedure codes with proposed revisions to the APC and/or status indicator assignments are assigned to comment indicator ''CH'' (Active HCPCS code in current year and next calendar year, status indicator and/or APC assignment has changed) in Addendum B to the proposed rule.

c. Level IV Anal/Rectal Procedures (APC 0150)

We created HCPCS code C9735 (Anoscopy; with directed submucosal injection(s), any substance) effective April 1, 2013, and assigned the service to APC 0150 (Level IV Anal/Rectal Procedures) for CY 2013, which had a payment rate of $2,365.97. We maintained the assignment of HCPCS code C9735 to APC 0150 for CY 2014, with a payment rate of $2,501.31. HCPCS code C9735 involves injection of a bulking agent, L8605 (Injectable bulking agent dextranomer/hyaluronic

acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies). One commenter in response to the CY 2014 OPPS/ASC proposed rule believed that the proposed assignment for HCPCS code C9735 to APC 0150 was inappropriate, and asserted that the entire HCPCS code C9735 procedure costs far more than the proposed payment rate for APC 0150. The commenter recommended creating a new Level V Anal/Rectal Procedures APC, composed of HCPCS code C9735, and two other procedures. CMS responded in the CY 2014 OPPS/ASC final rule with comment period that HCPCS code C9735 became effective April 1, 2013, so there were no claims data yet on this procedure, and that our longstanding policy is to wait until there are claims data on a new procedure before reassigning the service to another clinical APC (78 FR 74981). We did not agree with the commenters that creating a Level V Anal/Rectal Procedures APC was warranted for CY 2014. We believed that the suggested Level V APC would have a low volume of single frequency claims, and HCPCS code C9735 had no claims volume at that time. We stated that the low volume of claims for such an APC would contribute to APC cost and payment volatility.

For CY 2015, we proposed to maintain the assignment of HCPCS code C9735 to APC 0150, which had a proposed payment rate of $2,612.71. The AMA's CPT Editorial Panel created new Category III CPT code 0377T (Anoscopy with directed submucosal injection of bulking agent for fecal incontinence), which describes the procedure performed by HCPCS code C9735, to be effective January 1, 2015.

Comment: A few commenters recommended that CMS divide APC 0150 into two APCs by creating a higher cost Level V Anal/Rectal Procedures APC. The commenters stated that there are four procedure codes that have a geometric mean cost that is more than $500 higher than the proposed geometric mean cost of APC 0150, which is $2,735.52, and one procedure code that has a geometric mean cost that is approximately $300 higher than the proposed geometric mean cost of APC 0150. One commenter specifically stated that the proposed payment rate for APC 0150 is insufficient to cover the cost of the procedure described by HCPCS code C9735, which is one of the five procedure codes recommended for assignment to the suggested Level V Anal/Rectal Procedures APC, because the proposed payment rate for APC 0150 is lower than the total cost of the procedure. The commenter pointed out that the proposed geometric mean cost of HCPCS code C9735 is $3,241.32, which is considerably higher that the proposed geometric mean cost of APC 0150, which is $2,735.52. The commenter also recommended creating a Level V Anal/Rectal Procedures APC, and assigning HCPCS code C9735 and other codes to this recommended APC. In addition, the commenter recommended that CMS use new CPT code 0377T for hospitals to report the anoscopy with directed submucosal injection of bulking agent for fecal incontinence procedure, effective January 1, 2015.

Response: The claims data available for this final rule with comment period, which are used to establish final payment rates for the CY 2015 OPPS, show a geometric mean cost of approximately $2,698 for APC 0150, while the geometric mean cost for HCPCS code C9735 is approximately $2,863 based on 56 single frequency claims. We believe that the geometric mean cost of HCPCS code C9735 is similar to the geometric mean cost of APC 0150. Further, the procedure described by HCPCS code C9735 is no longer one of the five highest cost procedures assigned to APC 0150 based on claims data available for this final rule with comment period. Similarly, there are other higher cost, lower volume procedures with geometric mean costs that are greater than the geometric mean cost of APC 0150, but do not create a violation of the 2 times rule because of the APC assignment. For instance, CPT code 46762 (Sphincteroplasty, anal, for incontinence, adult; implantation artificial sphincter) has a final rule geometric mean cost of approximately $11,873 based on 9 single frequency claims. The volume of claims for this CPT code is too low to consider this procedure significant for purposes of evaluating a potential violation of the 2 times rule. Therefore, we do not believe that the range of costs for the significant procedures assigned to APC 0150 warrants the creation of a higher level APC. Based on claims data available for this final rule with comment period, the five highest cost procedures assigned to APC 0150 have a total number of single frequency claims that equals less than 220 claims. The suggested Level V Anal/Rectal Procedures APC would have a low volume of single frequency claims and would contribute to APC cost and payment volatility, as was the case when based on CY 2014 claims data. As we stated in the CY 2014 OPPS/ASC final rule with comment period, we are not accepting the commenter's recommendation because a low volume APC will contribute to the APC's cost volatility, which in turn contributes to payment volatility for the procedures assigned to the low volume APC (78 FR 74981).

After consideration of the public comments we received regarding the composition of APC 0150, we are finalizing our proposal to continue to assign HCPCS code C9735 to APC 0150 for CY 2015. The CY 2015 final geometric mean cost of APC 0150 is approximately $2,698. In addition, new CPT code 0377T also is assigned to APC 0150 for CY 2015 because we agree with the commenters that HCPCS code C9735 should be deleted after December 31, 2014. We are instructing hospitals to use CPT code 0377T to report this service beginning with the code's effective date, January 1, 2015.

d. Percutaneous Renal Cryoablation (APC 0423)

For CY 2014, we assigned CPT codes 50593 (Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy) and 0340T (Ablation, pulmonary tumor(s), including pleura or chest wall when involved by tumor extension, percutaneous, cryoablation, unilateral, includes imaging guidance) to APC 0423 (Level II Percutaneous Abdominal and Biliary Procedures), which has a payment rate of $4,106.19. For CY 2015, we proposed to continue to assign these two CPT codes to APC 0423, with a proposed payment rate of $4,053.32.

Comment: One commenter believed that CMS' proposal to continue to assign CPT codes 50593 and 0340T to APC 0423 does not accurately reflect the costs incurred when performing these cryoablation procedures. The commenter noted that APC 0423 includes several other radiofrequency ablation and endoscopy procedures, which do not include high-cost device systems like the cryoablation procedures described by CPT codes 50593 and 0340T. Although the commenter acknowledged that there is no violation of the 2 times rule, the commenter stated that the proposed geometric mean cost of CPT code 50593 is significantly higher than the proposed geometric mean cost of APC 0423. In addition, the commenter asserted that the cryoablation procedures described by CPT codes 50593 and 0340T are not clinically similar to other procedures assigned to APC 0423. The commenter further noted that less than half of claims used to establish the proposed geometric mean cost of CPT code 50593 were correctly coded, and did not include the device HCPCS code C2618 (Probe, cryoablation). The commenter

recommended that CMS create a new Level III Percutaneous Abdominal and Biliary Procedures APC, and assign CPT codes 50593 and 0340T to this APC.

Response: We disagree with the commenter that the proposed geometric mean cost of CPT code 50593, which is $4,937.12 is significantly higher than the proposed geometric mean cost of APC 0423, which is $4,243.84. The claims data available for this final rule with comment period show a geometric mean cost of approximately $4,249 for APC 0423, and approximately $4,985 for CPT code 50593, which is based on 749 single frequency claims. The geometric mean cost of CPT code 50593 is the highest cost procedure assigned to APC 0423, but is well within a normal range of costs associated with the other procedures assigned to this APC, and does not approach the 2 times limit that would create a violation of the 2 times rule. CPT code 0340T has no claims at this time because the procedure code became effective beginning in CY 2014. Therefore, we do not believe that a new Level III Percutaneous Abdominal and Biliary Procedures APC is warranted based on the geometric mean cost of CPT code 50593 relative to the geometric mean cost of APC 0423. We also remind the commenter that we typically do not investigate allegations of hospital cost underreporting or incorrect coding. As we stated in the CY 2011 OPPS/ASC final rule with comment period, ''Beyond our standard OPPS trimming methodology . . . that we apply to those claims that have passed various types of claims processing edits, it is not our general policy to judge the accuracy of hospital coding and charging for purposes of ratesetting'' (75 FR 71838). We believe that the cryoablation procedures described by CPT codes 50593 and 0340T are clinically similar to the other procedures assigned to APC 0423. Many of the procedures assigned to APC 0423 are ablative procedures, and all of the procedures assigned to this APC are abdominal or biliary. Therefore, we are finalizing the CY 2015 proposal, without modification, to continue to assign CPT codes 50593 and 0340T to APC 0423. We will specifically review the APC assignment of CPT code 0340T when claims data for this service become available.

4. Nervous System Services

a. Chemodenervation (APC 0206)

For CY 2015, we proposed to continue to assign CPT code 64616 (Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)) to APC 0204 (Level I Nerve Injections), with a proposed payment rate of approximately $218. We note that CPT code 64616 became effective January 1, 2014.

Comment: One commenter requested that CMS reassign CPT code 64616 from APC 0204 to APC 0206 (Level II Nerve Injections), which had a proposed payment rate of approximately $375. The commenter noted that this recommendation for APC reassignment was also submitted in response to the CY 2014 OPPS/ASC final rule with comment period. The commenter stated that APC 0206 is the APC that was assigned to CPT code 64613 (Chemodenervation of muscle(s); neck muscle(s) (eg, for spasmodic torticollis, spasmodic dysphonia), which is the predecessor code for CPT code 64616 in effect prior to January 1, 2014. Based on the commenter's analysis of the CY 2013 hospital outpatient claims data that was used for the CY 2015 OPPS/ASC proposed rule, the commenter believed that APC 0206 is the most appropriate APC assignment for CPT code 64616 based on the resource costs and clinical homogeneity of the predecessor code, CPT code 64613, in relation to the other procedures assigned to APC 0206.

Response: We reviewed the latest hospital outpatient claims data reporting the service described by predecessor code, CPT code 64613, and the replacement code, CPT code 64616. We acknowledge that the procedure described by CPT code 64616 was previously described by CPT code 64613. Based on our analysis of the latest hospital outpatient claims data available for this final rule with comment period, we agree with the commenter's recommendation that CPT code 64616 should be reassigned from APC 0204 to APC 0206 for the CY 2015 update. Specifically, we reviewed the latest hospital outpatient claims data for CPT code 64613 based on claims submitted by hospitals for dates of service between January 1, 2013, and December 31, 2013, that were processed on or before June 30, 2014. Our review of the latest claims data shows a geometric mean cost of approximately $322 for CPT code 64613 based on 11,177 single claims (out of 13,743 total claims), which is comparable to the geometric mean cost of approximately $387 for APC 0206. There are 21 procedures assigned to APC 0206 and the geometric mean costs for the procedures with significant claims data range approximately between $322 (for CPT code 64613) and $536 (for CPT code 62270). Based on these data, we agree with the commenter that APC 0206 is the most appropriate APC assignment for CPT code 64616 based on clinical homogeneity to the other procedures assigned to this APC and the resource similarity of the predecessor code, CPT code 64613, to the other procedures assigned to APC 0206.

Therefore, after consideration of the public comment we received, we are not adopting our proposal to continue to assign CPT code 64616 to APC 0204. Instead, we are reassigning CPT code 64616 to APC 0206 for the CY 2015 OPPS update. The final CY 2015 payment rate for CPT code 64616 can be found in Addendum B to this CY 2015 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

b. Epidural Lysis (APCs 0203 and 0207)

For CY 2015, we proposed to continue to assign CPT code 62263 (Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days) to APC 0203 (Level IV Nerve Injections), with a proposed payment rate of approximately $1,524. We also proposed to continue to assign CPT code 62264 (Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 1 day) to APC 0207 (Level III Nerve Injections), with a proposed payment rate of approximately $683.

Comment: One commenter opposed CMS' proposals to continue to assign CPT code 62263 to APC 0203 and CPT code 62264 to APC 0207. The commenter stated that CMS has overcompensated for the cost of providing the service described by CPT code 62263 by assigning the procedure to APC 0203. Alternatively, the commenter believed that CMS has undercompensated the cost of providing the service described by CPT code 62264 by assigning the procedure to APC 0207. The commenter stated that the resources utilized during the performance of the services described by both CPT codes are comparable, and each CPT code should be reassigned to a more appropriate APC to ensure adequate payment for the services provided.

Response: We reviewed the latest hospital outpatient claims data reporting services described by CPT codes 62263 and 62264 for dates of service between January 1, 2013, and December 31, 2013, that were processed

on or before June 30, 2014. For CPT code 62263, our analysis of the claims data shows a geometric mean cost of approximately $1,215 based on 70 single claims (out of 88 total claims), which is comparable to the geometric mean cost of approximately $1,525 for APC 0203. For CPT code 62264, our analysis of the claims data shows a geometric mean cost of approximately $798 based on 1,971 single claims (out of 4,174 total claims), which is comparable to the geometric mean cost of approximately $697 for APC 0207. Therefore, we believe that the procedures described by CPT code 66263 and CPT code 62264 are appropriately assigned to APCs 0203 and 0207, respectively, based on clinical and resource similarities in relation to the other procedures assigned to these APCs. We remind the commenter that the OPPS is a system of averages, in which the costs of services, calculated from the most recent year's claims data, are weighted relative to the other services in the system, for that given year. Furthermore, as has been our practice since the implementation of the OPPS, we annually review all the items and services within an APC group to determine, with respect to comparability of the use of resources, any violations of the 2 times rule. In making this determination, we review our claims data and determine whether we need to make changes to the current APC assignments for the following year. We will reevaluate the APC assignment for CPT codes 62263 and 62264 for the CY 2016 OPPS rulemaking.

After consideration of the public comment that we received, we are finalizing our CY 2015 proposal, without modification, to continue to assign CPT code 62263 to APC 0203 and CPT code 62264 to APC 0207. The final CY 2015 payment rates for the two procedures can be found in Addendum B to this CY 2015 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

c. Transcranial Magnetic Stimulation (TMS) Therapy (APC 0218)

Since July 2006, CPT codes have existed to describe Transcranial Magnetic Stimulation (TMS) therapy. The initial CPT codes were temporary Category III CPT codes, specifically, CPT codes 0160T (Therapeutic repetitive transcranial magnetic stimulation treatment planning) and 0161T (Therapeutic repetitive transcranial magnetic stimulation treatment delivery and management, per session), that became effective July 1, 2006. For CY 2011, the CPT Editorial Panel deleted CPT code 0160T on December 31, 2010, and replaced this procedure code with CPT code 90867 (Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; initial, including cortical mapping, motor threshold determination, delivery and management), effective January 1, 2011. Similarly, CPT code 0161T was deleted on December 31, 2010, and was replaced with CPT code 90868 (Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent delivery and management, per session), effective January 1, 2011. In CY 2012, the CPT Editorial Panel established an additional TMS therapy code, specifically, CPT code 90869 (Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent motor threshold re-determination with delivery and management), that became effective January 1, 2012.

For the CY 2014 update, CPT codes 90867 and 90868 were assigned to APC 0216 (Level II Nerve and Muscle Tests), with a payment rate of $216.79, and CPT code 90869 was assigned to APC 0218 (Level II Nerve and Muscle Tests), with a payment rate of $127.75. For the CY 2015 update, as listed in Addendum B to the CY 2015 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 90869 to APC 0218, with a proposed payment rate of approximately $160. In addition, we proposed to reassign CPT codes 90867 and 90868 from APC 0216 to APC 0218, the same APC assignment for CPT code 90869.

Comment: One commenter disagreed with CMS' proposal to reassign CPT codes 90867 and 90868 from APC 0216 to APC 0218, and to continue to assign CPT code 90869 to APC 0218. The commenter stated that the proposed addition of certain nerve conduction study codes to APC 0218 for the CY 2015 update has negatively affected the proposed payment rate for APC 0218. The commenter believed that this proposal resulted in a decreased payment rate of approximately $160 for APC 0218, compared to the CY 2014 payment rate of approximately $217; thereby effectuating a potential financial loss for the provider with each treatment because a typical course of TMS therapy includes a total of 25 daily treatment sessions. In addition, the commenter stated that assigning CPT codes 90867, 90868, and 90869 to APC 0218 is clinically inappropriate because these CPT codes describe therapy services, whereas the other procedure codes assigned to APC 0218 describe diagnostic tests (simple nerve conduction and electromyography studies). To correct the perceived clinical and resource discrepancies, the commenter suggested that CMS establish a new APC specifically for the TMS therapy codes, and that CMS title the APC ''Transcranial Magnetic Stimulation.''

Response: We believe that APC 0218 is the most appropriate APC assignment for the three TMS therapy CPT codes. The CPT codes describing the procedures assigned to APC 0218 all describe noninvasive services that affect the nervous system. Based on the latest hospital outpatient claims data used for this final rule with comment period, our analysis revealed that the resources associated with providing the services described by CPT codes 90867, 90868, and 90869 are comparable to the other services assigned to APC 0218. Specifically, based on CY 2013 claims data used for this final rule with comment period, the geometric mean cost for CPT code 90867 is approximately $210 based on 72 single claims (out of 72 total claims), the geometric mean cost for CPT code 90868 is approximately $201 based on 2,513 single claims (out of 2,516 total claims), and the geometric mean cost for CPT code 90869 is approximately $194 based on 28 single claims (out of 30 total claims). In addition, a review of the procedures assigned to APC 0218 shows that the range of geometric mean cost for the services assigned to APC 0218 is approximately between $95 (for CPT code 95937) and $327 (for CPT code 95875), which is comparable to the geometric mean costs for all three TMS therapy CPT codes. Based on the clinical and resource similarities in relation to the other procedures currently assigned to APC 0218, we believe that the TMS therapy codes would be appropriately assigned to APC 0218.

After consideration of the public comment we received, we are finalizing our CY 2015 proposal, without modification, to reassign CPT codes 90867 and 90868 from APC 0216 to APC 0218, and to continue to assign CPT code 90869 to APC 0218 for CY 2015.

5. Ocular Services: Ophthalmic Procedures and Services

For the CY 2015 OPPS update, based on our evaluation of the latest hospital outpatient claims data, we proposed to restructure all of the ophthalmic APCs to better reflect the costs and clinical characteristics of the procedures within each APC. This proposed restructuring resulted in the use of 13 APCs for the ophthalmology-related procedures for the CY 2015 OPPS update, as compared to the 24 APCs used for the CY 2014 OPPS update. We believe that this major

restructuring and consolidation of APCs more appropriately categorizes all of the ophthalmology-related procedures and services within an APC group, such that the services within each newly-configured APC are more comparable clinically and with respect to resource use. Tables 19 and 20 in the proposed rule showed the current CY 2014 and proposed CY 2015 ophthalmology-related APCs. Specifically, Table 19 of the CY 2015 OPPS/ASC proposed rule (79 FR 40981) showed the CY 2014 ophthalmology-related APCs and status indicator assignments, while Table 20 showed the proposed restructured ophthalmology-related APCs and their status indicator assignments for CY 2015 (79 FR 40981 through 40982). The proposed payment rates for the ophthalmology-related APCs listed in Table 20 were listed in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site).

In the CY 2015 OPPS/ASC proposed rule, we invited public comments on this proposal.

Comment: Several commenters stated that the proposed restructuring and consolidation of the CY 2015 ophthalmic APC is substantial, and requested that CMS not finalize this proposal. The commenters also stated that CMS has not provided information regarding the criteria used to differentiate the various levels of treatments or procedures for the restructured 13 ophthalmic APCs. The commenters stated that the configuration and structure of the existing 24 APCs do not appear to be inconsistent with the requirements for clinical coherence or resource use. The commenters disagreed with CMS' proposal to establish broader categories within these APCs, and indicated that such a change in APC groupings has the potential to aggregate procedures that vary significantly in resource costs and clinical coherence. In addition, the commenters stated that some of the procedures in the restructured ophthalmic APCs appear to be inappropriately categorized. For example, the restructuring of the ophthalmic APCs has resulted in the consolidation of cornea procedures within one of the restructured APCs, and the procedures are no longer assigned to a separate classification grouping based on the previous APC configurations. The commenters pointed out that the major cornea transplant codes have been reassigned to restructured APC 0673 (Level III Intraocular Procedures), along with procedures that treat glaucoma and retina conditions. The commenters further explained that the equipment used for these services when performed in alternative settings and the depths of the condition of the eye and the appropriate treatments vastly differ, as does the time and other resources necessary to perform these types of surgeries. As a result, the commenters believed that additional APCs are needed to appropriately categorize ophthalmic procedures based on clinical homogeneity and resource consumption. The commenters also requested the opportunity to work with CMS to make appropriate adjustments to the restructured ophthalmic APC groupings to ensure clinical coherence and to minimize payment variances for these procedures.

Response: Consistent with CMS' statutory requirement under section 1833(t)(9) of the Act to review and revise APC assignments annually and to construct the most appropriate APC groupings, as well as, to the extent desirable, correct any 2 times rule violations, we evaluated the resource consumption and clinical coherence associated with the ophthalmic APCs for the CY 2015 update. Based on our analysis of the latest hospital outpatient claims data used for this final rule with comment period and understanding of the clinical aspects of these procedures, we believe that the restructured and consolidated ophthalmic APCs more appropriately group these ophthalmology-related services according to their current resource costs, as well as their clinical characteristics. The former ophthalmic procedures APC structure unnecessarily separated, from a clinical and resource similarity prospective, ophthalmic procedures based on disease state or traditional subdivisions within ophthalmic surgery. APC groupings were never intended to precisely track traditional ophthalmology subspecialty divisions, such as cornea surgery, retina surgery, or glaucoma surgery, as the commenters suggested. We also believe that larger APC groupings are more consistent with a prospective payment system than smaller groupings. We note that we regularly accept meetings from interested parties throughout the year, and we encourage stakeholders to continue a dialogue with us during the rulemaking cycle and throughout the year on our continuing efforts to improve the coherence of the OPPS APC groupings.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to restructure and consolidate the ophthalmic APCs. Table 22 below shows the final ophthalmology-related APCs and their status indicator assignments for CY 2015. The final payment rates for these APCs can be found in Addendum B to this CY 2015 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site). We also remind the public that we review the OPPS and APC structures and assignments annually and may propose additional restructurings of the APCs and procedure code assignments for other clinical areas and APC groupings in CY 2016 and future rulemakings.

TABLE 22—FINAL CY 2015 APC ASSIGNMENTS FOR THE OPHTHALMIC PROCEDURES AND SERVICES

Final CY 2015 APC	Final CY 2015 APC title description	Final CY 2015 status indicator
0230	Level I Eye Tests & Treatments	S
0231	Level III Eye Tests & Treatments	S
0233	Level II Intraocular Procedures	T
0238	Level I Extraocular, Repair, and Plastic Eye Procedures	T
0239	Level II Extraocular, Repair, and Plastic Eye Procedures	T
0240	Level III Extraocular, Repair, and Plastic Eye Procedures	T
0242	Level IV Extraocular, Repair, and Plastic Eye Procedures	T
0247	Laser Eye Procedures	T
0255	Level I Intraocular Procedures	T
0293	Level IV Intraocular Procedures	J1
0351	Level V Intraocular Procedures	J1
0673	Level III Intraocular Procedures	T

TABLE 22—FINAL CY 2015 APC ASSIGNMENTS FOR THE OPHTHALMIC PROCEDURES AND SERVICES—Continued

Final CY 2015 APC	Final CY 2015 APC title description	Final CY 2015 status indicator
0698	Level II Eye Tests & Treatments	S

6. Imaging

a. Echocardiography Services Without Contrast (APCs 0269, 0270, and 0697)

We proposed to continue to use for the CY 2015 update the three APCs that describe echocardiography services without contrast, APC 0697 (Level I Echocardiogram Without Contrast), APC 0269 (Level II Echocardiogram Without Contrast), and APC 0270 (Level III Echocardiogram Without Contrast), and to maintain the CY 2014 HCPCS code assignments for these APCs.

Comment: One commenter requested that CMS reexamine the services assigned to the APCs for echocardiography services without contrast. In particular, the commenter requested that CMS reassign CPT codes 76825 (Echocardiography, fetal, cardiovascular system, real time with image documentation (2D), with or without M-mode recording); and 76826 (Echocardiography, fetal, cardiovascular system, real time with image documentation (2D), with or without M-mode recording; follow-up or repeat study) from APC 0697 to APC 0269 based on the clinical and resource similarities to the other echocardiography procedures assigned to APC 0269.

Response: Based on our review of the latest hospital outpatient claims data available for this final rule with comment period, we agree with the commenter that CPT codes 76825 and 76826 should be reassigned to APC 0269, which more appropriately supports the clinical and resource homogeneity of the APCs rather than reassigning the procedure codes to APC 0697. The geometric mean cost of CPT code 76825 is approximately $384, and the geometric mean cost of CPT code 76826 is approximately $285. These costs are sufficiently close to the geometric mean cost of CPT code 93306 (Echocardiography, transthoracic, real time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography), which is approximately $430. CPT code 93306 comprises 93 percent of the service volume within APC 0269. By reassigning CPT codes 76825 and 76826 to APC 0269, only one procedure code would remain in APC 0697. Therefore, we also are reassigning CPT code 93308 (Echocardiography, transthoracic, real time with image documentation (2D), includes M-mode recording, when performed, follow-up or limited study) from APC 0697 to APC 0267 (Level III Diagnostic and Screening Ultrasound) for CY 2015. We are deleting APC 0697 for the CY 2015 OPPS update because all of the procedure codes previously assigned to APC 0697 have been reassigned to more appropriate APCs to ensure adequate payment for the services provided and the clinical and resource homogeneity of APCs.

b. Optical Coherence Tomography (OCT) Procedures of the Breast

For the July 2014 quarterly update, the CPT Editorial Panel established four new Category III CPT codes to describe optical coherence tomography (OCT) procedures of the breast: CPT code 0351T (Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; real time intraoperative); CPT code 0352T (Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; interpretation and report, real time or referred); CPT code 0353T (Optical coherence tomography of breast, surgical cavity; real time intraoperative); and CPT code 0354T (Optical coherence tomography of breast, surgical cavity; interpretation and report, real time or referred). As listed in Table 17 of the CY 2015 OPPS/ASC proposed rule (79 FR 40976), we proposed to assign CPT codes 0351T and 0353T to OPPS status indicator ''N'' (paid under OPPS; payment is packaged into payment for other services; there is no separate APC payment), and CPT codes 0352T and 0354T to OPPS status indicator ''B'' (codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)).

Comment: Some commenters expressed concern regarding CMS' proposal to assign CPT codes 0351T and 0353T to OPPS status indicator ''N'' and noted that both procedures describe independent, unique services and should be assigned to specific APCs. The commenters recommended assigning CPT codes 0351T and 0353T to any one of the following APCs: APC 0028 (Level I Breast and Skin Surgery), which had a proposed payment rate of approximately $2,176; APC 0029 (Level II Breast and Skin Surgery), which had a proposed payment rate of approximately $3,018; or APC 0030 (Level III Breast and Skin Surgery), which had a proposed payment rate of approximately $4,150.

Response: Consistent with our packaging policy for intraoperative procedures, we proposed to assign CPT codes 0351T and 0353T to OPPS status indicator ''N'' because both procedure codes describe supportive dependent services that are performed during independent procedures. As clarified in the CY 2008 OPPS final rule with comment period (72 FR 66627), we define ''intraoperative'' procedures as services that are provided during and, therefore, on the same date of service as another procedure that is separately payable under the OPPS. We further define intraoperative as services that support the performance of an independent procedure and are provided in the same operative session as the independent procedure. Both of the procedures described by CPT codes 0351T and 0353T must always be performed in conjunction with another procedure; specifically, the surgical procedure is performed followed by the breast OCT to improve the surgical outcome. We believe that these procedure codes clearly describe services that conform to the definition of ''intraoperative'' procedures. For further information on our policy for intraoperative services under the hospital OPPS, we refer readers to the CY 2008 OPPS final rule with comment period (72 FR 66627 through 66630).

In summary, we believe that CPT codes 0351T and 0353T are procedures that support the performance of an independent procedure and are provided in the same operative session as the independent procedure. Specifically, we believe that both procedures are provided during and, therefore, on the same date of service as another procedure that is separately payable under the OPPS. In addition, we believe that CPT codes 0351T and 0353T are always integral to, and dependent upon, the independent procedure that they support. Therefore, payment for these services will be

packaged because the procedures would generally be performed on the same date as another procedure that is separately payable under the OPPS. After consideration of the public comments we received, we are finalizing our proposals to assign CPT codes 0351T and 0353T to OPPS status indicator ''N'' and CPT codes 0352T and 0354T to OPPS status indicator ''B'' for CY 2015.

c. Parathyroid Planar Imaging (APCs 0263, 0317, 0406, and 0414)

For CY 2015, we proposed to assign CPT code 78071 (Parathyroid planar imaging (including subtraction, when performed); with tomographic (SPECT)) to APC 0263 (Level I Miscellaneous Radiology Procedures), for which we proposed a CY 2015 geometric mean cost of approximately $357. We also proposed to assign CPT code 78072 (Parathyroid planar imaging (including subtraction, when performed); with tomographic (SPECT), and concurrently acquired computed tomography (CT) for anatomical localization) to APC 0317 (Level II Miscellaneous Radiology Procedures), for which we proposed a CY 2015 geometric mean cost of approximately $577. In addition, we proposed to change the status indicators for CPT codes 78071 and 78072 from ''X'' to ''S.''

Comment: Commenters agreed with CMS' proposal to assign CPT codes 78071 and 78072 to status indicator ''S,'' but opposed the proposal to assign CPT code 78071 to APC 0263. The commenters believed that CPT codes 78071 and 78072 should be assigned to the nuclear medicine APCs instead of the radiology APCs because the nuclear medicine APCs are more representative of the resources utilized in the performance of these procedures. The commenters suggested that CMS assign CPT codes 78071 and 78072 to either APC 0414 (Level II Tumor/Infection Imaging) or 0408 (Level III Tumor/Infection Imaging).

Response: We agree with the commenters that the resources utilized in the performance of the procedures described by CPT codes 78071 and 78072 are more comparable to the procedures assigned to the nuclear medicine APCs. However, we do not agree with the commenters that CPT codes 78071 and 78072 are more appropriately assigned to either APC 0408 or APC 0414. We believe that APC 0406 (Level I Tumor/Infection Imaging) is the most appropriate APC assignment for CPT codes 78071 and 78072 because the procedures currently assigned to APC 0406 are similar to the procedures described by CPT codes 78071 and 78072 in clinical nature and resource utilization. The final CY 2015 APC geometric mean costs of approximately $362 for CPT code 78071 and approximately $427 for CPT code 78072 are similar to the geometric mean costs of the significant procedures assigned to APC 0406, which range between approximately $307 and approximately $427.

After consideration of the public comments we received, we are not finalizing our CY 2015 proposal to assign CPT codes 78071 and 78072 to APCs 0263 and 0317, respectively. Instead, based on consideration of the public comments we received, for CY 2015, we are assigning CPT codes 78071 and 78072 to APC 0406, which has a final CY 2015 APC geometric mean cost of approximately $391.

7. Radiology Oncology

a. Proton Beam Therapy and Magnetoencephalography (MEG) Services (APCs 0065, 0412, 0446, 0664, and 0667)

In the CY 2015 OPPS/ASC proposed rule (79 FR 40989), we proposed several changes to the radiation therapy APCs for CY 2015. To correct a violation of the 2 times rule within APC 0664 (Level I Proton Beam Radiation Therapy), we proposed to reassign CPT code 77520 from APC 0664 to APC 0412 (Level III Radiation Therapy). We believe that CPT code 77520 is both clinically similar and comparable in geometric mean cost to the other services assigned to APC 0412. We also proposed to reassign CPT code 77522 from APC 0664 to proposed newly renamed APC 0667 (Level IV Radiation Therapy) because we believe that the procedure described by CPT code 77522 is both clinically similar and comparable in geometric mean cost to the other services assigned to APC 0667. Because there would be no other codes assigned to APC 0664 if these proposed reassignments are finalized, we also proposed to delete APC 0664 for CY 2015 (79 FR 40989). In addition, we proposed to rename existing APC 0667 to ''Level IV Radiation Therapy'' (instead of using the existing title of ''Level II Proton Beam Radiation Therapy''), to make the title consistent with other APCs in the radiation therapy series. In conjunction with this proposed change, we proposed to reassign the following three services to proposed newly renamed APC 0667 for CY 2015: CPT codes 77522, 77523, and 77525.

Comment: Commenters generally supported CMS' proposals regarding the radiation therapy APCs, with one exception. The commenters supported the proposal to reassign CPT code 77520 from APC 0664 to APC 0412. However, the commenters expressed concern regarding the proposal to reassign CPT code 77522 from APC 0664 to proposed newly renamed APC 0667. Commenters disagreed with CMS' determination that the procedure described by CPT code 77522 is clinically similar and comparable in geometric mean cost to the other services assigned to APC 0667 in 2014, specifically the procedures described by CPT codes 77523 and 77525. The commenters recommended that CMS maintain the assignment of CPT code 77522 to APC 0664 and not delete the classification grouping, which would result in CPT code 77522 being the only service assigned to this APC.

Response: We appreciate the commenters' support for our proposals regarding the radiation therapy APCs, specifically our proposal to reassign CPT code 77520 from APC 0664 to APC 0412. In regard to the proposed reassignment of CPT code 77522 from APC 0664 to APC 0667, we disagree with the commenters for the following reasons. The three CPT codes, 77522, 77523, and 77525, are similar clinically. All three of these CPT codes describe procedures that involve proton beam therapy delivery services with a continuum of complexity. The procedure described by CPT code 77520 is the least complex. The procedure described by CPT code 77522 is more complex than the procedure described by CPT code 77520, and the procedure described by CPT code 77523 is more complex than the procedure described by CPT code 77522. The procedure described by CPT code 77525 is the most complex procedure of the series proposed to be reassigned to APC 0667. We proposed to reassign CPT code 77520 from APC 0664 to APC 0412 because of the resource comparability with respect to the other procedures involving proton beam therapy delivery services assigned to APC 0412, not based on the clinical dissimilarity with respect to the procedures assigned to APC 0664. In regard to the remaining three procedures involving proton beam therapy delivery services (the procedures described by CPT codes 77522, 77523, and 77525), we believe that these procedures are clinically similar, but each has a slightly varying level of complexity relative to the others. The proposed configuration of APC 0667 only contains the three proton beam therapy delivery services described by CPT codes 77522, 77523, and 77525, and does not include any other service codes. APC 0667 is the most clinically homogeneous APC

under the OPPS to assign these services that would ensure adequate payment, with the exception of single service APCs. With regard to the resource comparability of the procedures described by CPT codes 77522, 77523 and 77525, the lowest geometric mean cost among these procedures is associated with the procedure described by CPT code 77522, which is approximately $1,033, and the highest geometric mean cost is associated with the procedure described by CPT code 77525, which is approximately $1,244. The statutory prong that dictates when resources become dissimilar between two services is the 2 times rule. Based on the limitations imposed by the 2 times rule, the highest cost significant service assigned to an APC cannot exceed the lowest cost by greater than two times. In this case, the geometric mean cost of the procedure described by CPT code 77525 is only 1.2 times the geometric mean cost of the procedure described by CPT code 77522, which is well within the 2 times limit. Therefore, we determined that the resource similarity among the services proposed to be reassigned to APC 0667 is comparable. In addition, we generally prefer to assign procedures to the most appropriate APC that would ensure adequate payment, as opposed to using single-service APCs, which the commenters recommended for the procedure described by CPT code 77522, unless no other reasonable options exist, because single-service APCs are more consistent with a fee schedule than a prospective payment system.

Therefore, we are finalizing the following proposals affecting the proton beam therapy services for CY 2015: (1) We are reassigning CPT code 77520 from APC 0664 to APC 0412; (2) we are reassigning CPT code 77522 from 0664 to APC 0667;(3) we are reassigning CPT codes 77523 and 77525 to APC 0667; (4) we are deleting APC 0664; and (5) we are renaming APC 0667 to ''Level IV Radiation Therapy.''

In the CY 2015 OPPS/ASC proposed rule (79 FR 40989), we also proposed to delete APC 0065 (IORT, MRgFUS, and MEG) because we proposed to reassign the services assigned to this APC to more appropriate APCs based on clinical similarities and comparable geometric mean cost. With respect to MEG services, we proposed to reassign the MEG CPT codes 95965 and 95966 from APC 0065 to APC 0446 (Level IV Nerve and Muscle Services), which would only contain MEG services.

Comment: One commenter applauded CMS for the establishment of new APC 0446, the APC to which the MEG procedures are proposed to be reassigned. The commenter believed that the reassignment of CPT codes 95965 and 95966 would produce more accurate data related to MEG usage. Alternatively, one commenter expressed concern that the current proposal does not adequately cover the costs associated with providing MEG services, and urged CMS to work with hospitals and other stakeholders to ensure that HOPDs submit claims correctly to capture the full costs of providing these services.

Response: Based on our analysis of the latest hospital outpatient claims data used for this final rule with comment period, we believe that the establishment of APC 0446 is necessary to ensure clinical and resource homogeneity and adequate payment for MEG services. Therefore, after consideration of the public comments we received, we are finalizing our CY 2015 proposal without modification. As we do every year, we will review our claims data for these services for the CY 2016 OPPS rulemaking.

b. Stereotactic Radiosurgery Services (SRS) and Magnetic Resonance Image Guided Focused Ultrasound (MRgFUS) (APC 0066)

For CY 2015, for SRS, we proposed to continue to assign CPT code 77373 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions) to APC 0066, with a proposed payment rate of approximately $1,893. We also proposed to rename APC 0066 from ''Level I Stereotactic Radiosurgery'' to ''Level V Radiation Therapy'' (79 FR 40989).

In addition, we proposed to continue to assign 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) and 77372 (Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based) to APC 0067 (Single Session Cranial Stereotactic Radiosurgery), with a proposed payment rate of approximately $9,768. We also proposed to rename APC 0067 from ''Level II Stereotactic Radiosurgery'' to ''Single Session Cranial Stereotactic Radiosurgery,'' which we proposed as a C–APC. For further discussion regarding C–APCs and SRS CPT codes 77371 and 77372 assigned to C–APC 0067, we refer readers to section II.A.2.e. of this final rule with comment period.

Comment: Several commenters requested that CMS reinstate the use of SRS G-codes because the SRS CPT codes do not accurately describe current clinical practices or adequately cover the cost of providing fractionated linac-based SRS.

Response: For the CY 2014 update, we finalized our proposal to adopt the full range of SRS CPT codes and to discontinue the use of the remaining SRS G-codes under the OPPS. HOPDs must use and report SRS CPT codes 77371, 77372, and 77371 to describe the delivery of stereotactic radiosurgery treatment services under the OPPS. For a full discussion of this issue, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74989 through 749995). In addition, for the CY 2015 update, HCPCS code G0173 (Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session), and HCPCS code G0251 ((Linear accelerator based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum five sessions per course of treatment)) will be deleted, effective December 31, 2014, because these codes will no longer be used under the MPFS. However, HCPCS code G0339 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment) and HCPCS code G0340 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment) will continue to be used under the MPFS and, therefore, will continue to be active codes for the CY 2015 MPFS update. However, HCPCS codes G0339 and G0340 will not be active codes for the CY 2015 OPPS update. Instead, HOPDs must use and report SRS CPT codes 77371, 77372, and 77373 to describe the delivery of stereotactic radiosurgery treatment services under the OPPS.

Comment: Many commenters requested that CMS reassign HCPCS code G0251 to a different APC to resolve a violation of the 2 times rule within APC 0066. Several commenters recommended excluding the claims data for HCPCS code G0251 prior to determining the final payment rate for APC 0066. The commenters indicated that HCPCS code G0251 is used most often for fractionated cranial SRS, not for stereotactic body radiation therapy (SBRT), as described by CPT code 77373.

Response: Both HCPCS code G0251 and CPT code 77373 describe fractionated cranial stereotactic radiosurgery services that involve between 2 and 5 fractions of treatment. Single-session cranial SRS are reported using either CPT code 77371 or 77372. Based on the code descriptor, we believe that the service described by HCPCS code G0251 is appropriately crosswalked to the service described by CPT code 77373. We explained the code crosswalk in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74991).

We note that, under the OPPS, we may make exceptions to the 2 times rule in unusual cases, such as low-volume items or services. For the CY 2015 update (taking into consideration the APC changes that we proposed for CY 2015), we reviewed all of the APCs to determine which APCs would not satisfy the requirement of the 2 times rule. In the case of APC 0066, we believe that it is necessary to make an exception to the 2 times rule for this APC because the three G-codes that caused the violation of the 2 times rule to occur have been crosswalked to CPT code 77373. We expect to have claims data for only CPT code 77373 available for the CY 2016 rulemaking. At that time, we will reevaluate the APC assignments for all of the SRS CPT codes.

In addition to our proposal to continue to assign SRS CPT code 77373 to APC 0066, we proposed to assign all four of the MRgFUS procedures to APC 0066 because in the past MRgFUS services were assigned to the same APC as some of the former SRS G-codes for fractionated linac-based SRS. Specifically, for CY 2015, we proposed to reassign HCPCS codes 0071T (Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume less than 200 cc of tissue), 0072T (Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume greater or equal to 200 cc of tissue), C9734 (Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance), and 0301T (Destruction/reduction of malignant breast tumor with externally applied focused microwave, including interstitial placement of disposable catheter with combined temperature monitoring probe and microwave focusing sensocatheter under ultrasound thermotherapy guidance) from APC 0065 (IORT, MRgFUS, and MEG) to APC 0066. We proposed to delete APC 0065 for CY 2015.

Comment: Several commenters stated that the proposed payment rate for APC 0066 of approximately $1,893 does not adequately reflect the level of resources required to perform MRgFUS procedures. Instead, the commenters believed that the MRgFUS procedures are similar to the stereotactic radiosurgery procedures that are assigned to C–APC 0067 in terms of treatment set-up, delivery of radiation, and post-procedure recovery. The commenters further believed that the MRgFUS procedures would be more appropriately assigned to a C–APC from a clinical and resource perspective. The commenters explained that certain procedures are commonly reported in conjunction with MRgFUS procedures, similar to stereotactic radiosurgery procedures. Therefore, the commenters recommended that CMS reassign the MRgFUS procedures to C–APC 0067.

Response: CPT codes 0071T and 0072T became effective January 1, 2005. CPT code 0301T became effective January 1, 2012. HCPCS code C9734 became effective April 1, 2013. Currently, we do not have any single claims reporting any of the four MRgFUS procedures. However, because we are deleting APC 0065, we believe that reassigning these procedures to APC 0066 for the CY 2015 update is more appropriate because, in the past, MRgFUS services were assigned to the same APC as some of the former fractionated linac-based SRS G-codes. We also believe that the MRgFUS procedures are clinically dissimilar to single-session cranial SRS because MRgFUS procedures may involve more than one treatment session. However, we will review and consider the comments related to C–APC 0067 in a future annual update.

After consideration of the public comments we received, we are finalizing our proposal without modification. Specifically, for SRS CPT code 77373, we are finalizing our proposal to continue to assign this code to APC 0066 for the CY 2015 update. In addition, we are finalizing our proposal to reassign MRgFUS HCPCS codes 0071T, 0072T, 0301T, and C9734 from APC 0065 to APC 0066 for CY 2015. We are deleting APC 0065 for CY 2015. Because we are deleting APC 0065, we are renaming APC 0066 from ''Level I Stereotactic Radiosurgery'' to ''Level V Radiation Therapy.'' The final payment rates for SRS CPT code 77373 and MRgFUS HCPCS codes 0071T, 0072T, 0301T, and C9734 can be found in Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site.

8. Respiratory Services: Level II Endoscopy Lower Airway (APC 0415)

In the CY 2015 OPPS/ASC proposed rule, we proposed to continue the APC assignment of the procedure codes that have been historically assigned to APC 0415 (Level II Endoscopy Lower Airway). Commenters responding to the CY 2014 OPPS/ASC proposed rule had recommended that CMS split the procedure codes assigned to APC 0415 into two levels of lower airway endoscopy APCs. We did not split APC 0415 into two levels for CY 2014, as the commenters suggested, because the geometric mean costs would have been based on a relatively low volume of single frequency claims and would have potentially effectuated APC and cost volatility (78 FR 74996). In the CY 2015 OPPS/ASC proposed rule, we did not propose any changes to the composition of APC 0415. There were not any violations of the 2 times rule for the services assigned to APC 0415 based on claims data available for the proposed rule. The proposed geometric mean cost of APC 0415 was approximately $2,368.

Comment: Several commenters recommended that CMS create a Level III Lower Airway Endoscopy APC and assign the procedure codes currently assigned and proposed for continued assignment to APC 0415 to this newly created APC based on geometric mean costs, procedure complexity, and clinical similarity. Specifically, one commenter recommended that CMS assign CPT code 31647 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe) to the recommended Level III APC. Another commenter recommended that CMS assign CPT code 31626 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple) to the recommended Level III APC. One commenter recommended that seven specific procedure codes be assigned to the newly created Level III APC, namely: CPT codes 31634 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (eg, fibrin glue), if performed), 31638 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with revision of tracheal or bronchial stent inserted at previous session (includes tracheal/bronchial dilation as required)), 31626, 31631

(Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of tracheal stent(s) (includes tracheal/bronchial dilation as required)), 31636 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of bronchial stent(s) (includes tracheal/bronchial dilation as required), initial bronchus), 31660 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe), and 31661 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes). The commenters believed that a new Level III Lower Airway Endoscopy APC would more accurately reflect the costs of expensive lower airway procedures that utilize new technologies.

Response: We believe that there is considerable clinical similarity in regard to the procedures assigned to APC 0415. All of the procedures are lower airway bronchoscopy procedures and are generally clinically more complex than the lower airway endoscopy procedures assigned to APC 0076 (Level I Endoscopy Lower Airway). We do not believe that the range of costs for the significant procedures assigned to APC 0415 warrants the creation of a Level III lower airway endoscopy APC. The final rule geometric mean cost for APC 0415 is approximately $2,341. Several of the procedures that the commenters recommended for assignment to the recommended Level III APC have final rule geometric mean costs comparable to the geometric mean cost of APC 0415. For CY 2015, CPT code 31634 has a final geometric mean cost of approximately $1,539; CPT code 31638 has a final geometric mean cost of approximately $2,320; and CPT code 31626 has a final geometric mean cost of approximately $2,897. The other CPT codes recommended by the commenters have somewhat higher approximate geometric mean costs, namely: CPT code 31631 (which has a geometric mean cost of approximately $3,488), CPT code 31661 (which has a geometric mean cost of approximately $3,789), CPT code 31660 (which has a geometric mean cost of approximately $3,840), and CPT code 31636 (which has a geometric mean cost of approximately $4,090). Assigning any of these procedures to APC 0415 does not create a violation of the 2 times rule when compared to the geometric mean cost of the lowest significant procedure assigned to this APC, CPT code 31629 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i)), which is approximately $2,186. Among the procedures discussed above, CPT codes 31626 and 31660 describe the only significant procedures assigned to this APC and are the procedures that we would normally apply the 2 times rule provisions. There are not any violations of the 2 times rule in regard to these procedures' costs. Although CPT code 31647 has a considerably higher geometric mean cost of approximately $5,373 based on 11 single frequency claims, it is not a significant procedure. We would not reassign this procedure to another APC based on a violation of the 2 times rule. Moreover, considering the final rule claims data for the five highest cost procedures assigned to APC 0415, the total number of single frequency claims is 649. The possible composition of a Level III lower airway endoscopy APC would still be based on a low volume of claims, similar to the low volume of claims in regard to the Level III lower airway endoscopy APC recommended by the commenters in CY 2014. As we stated in the CY 2014 OPPS/ASC final rule with comment period, a low-volume APC would contribute to the APC's cost volatility, which in turn contributes to payment volatility for the procedures assigned to the low-volume APC (78 FR 74996).

After consideration of the public comments we received regarding the composition of APC 0415, we are finalizing our proposal to continue the assignment of the procedure codes that have been historically assigned to APC 0415 for CY 2015. However, for CY 2016, we will explore possible changes to the lower airway endoscopy APCs as a part of our broader efforts to thoroughly review, revise, and consolidate APCs to improve both clinical and resource homogeneity. The CY 2015 final geometric mean cost of APC 0415 is approximately $2,341.

9. Other Services

a. Epidermal Autograft (APC 0327)

In the CY 2014 OPPS/ASC final rule with comment period, we assigned CPT code 15110 to APC 0329 (Level IV Skin Repair), with a payment rate of approximately $2,260. The payment rate for CPT code 15110 was derived from the latest hospital outpatient claims data used for the CY 2014 ratesetting, which showed a geometric mean cost of approximately $2,174 based on 10 single claims (out of 29 total claims).

As stated in section III.B. of this final rule with comment period, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS. Analysis of the latest hospital outpatient claims data available for the CY 2015 OPPS/ASC proposed rule showed a geometric mean cost for CPT code 15110 of approximately $774 based on 90 single claims (out of 122 total claims). Therefore, in the CY 2015 OPPS/ASC proposed rule (79 FR 40987), we proposed to reassign CPT code 15110 from APC 0329 to APC 0327 (Level II Skin Procedures), which has a geometric mean cost of approximately $451. We believe that APC 0327 is the most appropriate APC assignment for CPT code 15110 when considering the similarities in relation to the other procedures assigned to this APC.

In addition, we proposed to revise the APC titles for the four skin repair APCs (79 FR 40987). Specifically, we proposed to rename APC 0326 from ''Level I Skin Repair'' to ''Level I Skin Procedures,'' APC 0327 from ''Level II Skin Repair'' to ''Level II Skin Procedures,'' APC 0328 from ''Level III Skin Repair'' to ''Level III Skin Procedures,'' and APC 0329 from ''Level IV Skin Repair'' to ''Level IV Skin Procedures.''

Table 28 of the proposed rule (79 FR 40987) showed the long descriptor, as well as the proposed CY 2015 APC and status indicator assignment for CPT code 15110. The proposed CY 2015 payment rate for CPT code 15110 can be found in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site).

Comment: Several commenters requested that CMS reevaluate the claims data for CPT code 15110, and recommended that CMS not finalize the proposal to reassign the procedure code to APC 0327. The commenters stated that the procedure described by CPT code 15110 allows patients with chronic or non-healing wounds to recover much sooner and without the use of expensive surgical interventions, which has resulted in cost savings for hospitals, patients, and payers. Other commenters suggested that CMS reassign CPT code 15110 to APC 0328 (Level III Skin Procedures), which has a proposed CY 2015 payment rate of approximately $1,408. The commenters believed that APC 0328 has clinically similar procedures and is more comparable to the geometric mean costs of CPT code 15110. Another commenter believed that the low volume of claims data for CPT code 15110 is attributable to providers and hospitals miscoding the performance of the service by not including the cost of the device.

Response: We reviewed the historical claims data for CPT code 15110, dating

back to CY 2008, which is the first year that claims data for this code became available. As listed in Table 23 below, for CY 2008 through CY 2013, the payment rate for CPT code 15110 has ranged between $288.30 and $393.38 based on a range of single claims between 3 and 8. In addition, for the CY 2014 update, which was based on hospital outpatient claims data that were submitted between January 1, 2012, and December 31, 2012, and processed on or before June 30, 2013, the payment rate for CPT code 15110 was significantly higher (approximately $2,260.46) based on 10 single claims. However, as has been our practice since the implementation of the OPPS in 2000, we review, on an annual basis, the APC assignments for the procedures and services paid under the OPPS. Based on the latest hospital outpatient claims data used for this final rule with comment period, our analysis does not support the continued assignment of CPT code 15110 to APC 0329, which is the APC to which the procedure was assigned during CY 2014, or the suggested APC 0328. We examined the latest hospital outpatient claims data for CPT code 15110 for dates of service between January 1, 2013, and December 31, 2013, that were processed on or before June 30, 2014. Our analysis of the claims data shows a geometric mean cost for CPT code 15110 of approximately $748 based on 127 single claims (out of 165 total claims). We do not believe that APC 0328 is the most appropriate APC assignment because the geometric mean cost for this APC is approximately $1,460, which is significantly higher than the geometric mean cost for CPT code 15110, which is approximately $748. Assigning CPT code 15110 to APC 0328 would result in an overpayment for the service provided. We believe that APC 0327 is the most appropriate APC assignment for CPT code 15110 based on clinical homogeneity to the other skin-related procedures assigned to this APC.

TABLE 23—HISTORICAL AND CURRENT OPPS CLAIMS AND PAYMENT INFORMATION FOR CPT CODE 15110

Calendar year (CY)	OPPS payment rate	Single claims	Total claims
2008	$288.30	3	16
2009	292.68	3	15
2010	299.19	8	22
2011	319.74	5	16
2012	344.98	4	19
2013	393.38	4	30
2014	2,260.46	10	29
2015	429.95	127	165

Further, based on our analysis of the CY 2013 hospital outpatient claims data used for this final rule with comment period, we are unable to determine whether hospitals are miscoding claims reporting this service. For all APCs whose payment rates are based upon relative payment weights, we note that the quality and accuracy of reported units and charges influence the geometric mean costs that are the basis for our payment rates, especially for low-volume items and services. Beyond our standard OPPS trimming methodology (described in section II.A.2. of this final rule with comment period) that we apply to those claims that have passed various types of claims processing edits, it is not our general policy to determine the accuracy of hospital coding and charging practices for purposes of ratesetting (75 FR 71838). We rely on hospitals to bill all HCPCS codes accurately in accordance with their code descriptors and CPT and CMS instructions, as applicable, and to report charges on claims and charges and costs on their Medicare hospital cost report appropriately. In addition, we do not specify the methodologies that hospitals must use to set charges for this or any other service.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to reassign CPT code 15110 to APC 0327 for CY 2015. The final payment rate for CPT code 15110 can be found in Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site.

b. Image-Guided Breast Biopsy Procedures and Image-Guided Abscess Drainage Procedures (APCs 0005 and 0007)

For the CY 2014 OPPS update, the AMA's CPT Editorial Panel deleted the image-guided breast biopsy CPT codes 19102 and 19103 and replaced these procedure codes with six new CPT codes that ''bundled'' payment for associated imaging services, effective January 1, 2014. As shown in Table 23 of the proposed rule (79 FR 40983), CPT codes 19102 and 19103 described percutaneous image-guided breast biopsies using specific devices. Specifically, CPT code 19102 described a breast biopsy performed using a core needle, and CPT code 19103 described a breast biopsy performed using either a vacuum-assisted or rotating device.

In CY 2013, to appropriately report the performance of an image-guided breast biopsy using a core needle, an automated vacuum-assisted device, or a rotating biopsy device, multiple procedure codes were required to identify the specific service performed. That is, a procedure code describing the device-related breast biopsy procedure was required to be reported in combination with the procedure code describing the localization device used during the procedures, as well as the specific image-guidance procedure codes describing the imaging service. Table 23 of the proposed rule showed how image-guided breast biopsy procedures were reported prior to CY 2014. Table 23 of the proposed rule also showed the CY 2013 OPPS status indicators, APC assignments, and payment rates for the breast biopsy procedure codes, the localization devices used during the procedures, and the specific image-guidance procedure codes describing the imaging service.

For the CY 2014 OPPS update, the AMA's CPT Editorial Panel grouped the multiple procedures that describe these imaging services into single comprehensive service codes; specifically, CPT codes 19081, 19082, 19083, 19084, 19085, and 19086. Table 24 of the proposed rule showed the six new CPT codes that replaced obsolete CPT codes 19102 and 19103. These comprehensive breast biopsy procedure codes are differentiated based on the use of specific imaging-guidance devices—specifically imaging services performed using stereotactic guidance, ultrasound

guidance, or magnetic-resonance guidance.

As has been our practice since the implementation of the OPPS in 2000, we review all new procedure codes before assigning the codes to an APC. Consistent with our longstanding policy for the treatment of new codes, we assigned these new replacement CPT codes to interim APCs for CY 2014. Based on our understanding of the resources required to furnish the service as defined in the code descriptor, as well as input from our medical advisors, we assigned replacement CPT codes 19081, 19083, and 19085 to APC 0005 (Level II Needle Biopsy/Aspiration Except Bone Marrow) for the CY 2014 OPPS update. In addition, we assigned new CPT codes 19081, 19083, and 19085 to comment indicator ''NI'' in Addendum B to the CY 2014 OPPS/ASC final rule with comment period (which is available via the CMS Web site) to indicate that the codes were new with an interim APC assignment that was subject to public comment. We note that, for the CY 2014 OPPS update, we finalized our policy to package all add-on codes (except those for drug administration), effective January 1, 2014. Consequently, payment for replacement CPT codes 19082, 19084, and 19086, which describe add-on procedures, was packaged for CY 2014.

At the Panel's March 10, 2014 meeting, one presenter requested that CMS reassign comprehensive CPT codes 19081, 19083, and 19085 from APC 0005 (Level II Needle Biopsy/Aspiration Except Bone Marrow), which has a CY 2014 OPPS payment rate of $702.08, to APC 0037 (Level IV Needle Biopsy/Aspiration Except Bone Marrow), which has a CY 2014 OPPS payment rate of $1,223.25. The presenter indicated that it is inappropriate to combine all of the new replacement CPT codes into one APC without regard for the imaging modality or device used to perform the procedure. The presenter also requested that CMS maintain the historic assignment of the predecessor CPT codes cost data until claims data become available for the new comprehensive CPT codes. The Panel agreed with the presenter and recommended that CMS reassign the new replacement comprehensive CPT codes, as the presenter suggested.

In light of the public presentation, the Panel's recommendation, and our longstanding policy of reviewing, on an annual basis, the APC assignments for all services and items paid under the OPPS, we evaluated the geometric mean costs associated with all of the procedures assigned to the existing four needle biopsy APCs, specifically, APCs 0004 (Level I Needle Biopsy/Aspiration Except Bone Marrow), 0005, 0685 (Level III Needle Biopsy/Aspiration Except Bone Marrow), and 0037. In the CY 2015 OPPS/ASC proposed rule (79 FR 40984), based on our review of the latest hospital outpatient claims data available for the proposed rule, we proposed to reassign all of the procedures assigned to APCs 0685 and 0037 to either APC 0004 or APC 0005 based on clinical and resource homogeneity. If CMS finalizes this proposed revision, there would be no procedures assigned to APCs 0685 or 0037. Therefore, in the CY 2015 OPPS/ASC proposed rule (79 FR 40984), we proposed to delete APCs 0685 and 0037 for CY 2015.

Consequently, for the CY 2015 OPPS update, we proposed to only use two needle biopsy APCs, specifically, APCs 0004 and 0005. The proposed reassignment of all of the procedures assigned to APCs 0685 and 0037 results in increased payment rates for both APCs 0004 and 0005. For CY 2015, the proposed payment rate for APC 0004 is approximately $494, which is 20 percent higher than the CY 2014 OPPS payment rate of approximately $411. Similarly, the proposed payment rate for APC 0005 is approximately $1,062, which is 51 percent higher than the CY 2014 OPPS payment rate of approximately $702. Therefore, we proposed to continue to assign CPT codes 19081, 19083, and 19085 to APC 0005 for the CY 2015 OPPS update (79 FR 40985). In addition, we proposed to continue to package payment for add-on CPT codes 19082, 19084, and 19086 under the OPPS for CY 2015, consistent with our packaging policy for add-on codes that was implemented on January 1, 2014. Because we proposed to delete APC 0037 we believe that the proposed increased payment rate for APC 0005 is consistent with the Panel's recommendation to reassign CPT codes 19081, 19083, and 19085 to an appropriate APC based on resource utilization and clinical coherence.

Comment: Commenters supported CMS' proposal to continue to assign CPT codes 19081, 19083, and 19085 to APC 0005. The commenters stated that the assignment of these CPT codes to APC 0005 is clinically coherent and more accurately captures the resource cost associated with providing these services when compared to the CY 2014 APC assignment.

Response: We appreciate the commenters' support.

Comment: Some commenters expressed concern regarding the inadequate payment for ancillary services associated with multiple biopsies that may be performed on the same date of service. The commenters indicated that patients sometimes present with multiple lesions, which requires a biopsy of each lesion. According to the commenters, prior to the establishment of the comprehensive CY 2014 breast biopsy CPT codes, hospitals would report each biopsy, imaging guidance, and marker or localization placements separately. The commenters requested that CMS provide guidance on how to report multiple biopsies performed on the same date of service.

Response: We expect hospitals to report the performance of breast biopsies using the comprehensive breast biopsy CPT codes, consistent with the latest CPT coding guidelines. As stated in the CY 2014 CPT code book, image-guided breast biopsies, including the placement of localization devices when performed, are reported using the comprehensive breast biopsy CPT codes 19081 through 19086. Image-guided placement of localization devices without the performance of a biopsy are required to be reported using CPT codes 19281 through 19288. In addition, when more than one biopsy is performed using the same imaging modality, hospitals are required to report each biopsy using an add-on code. However, if more than one biopsy is performed using different imaging modalities, hospitals are required to report a separate primary code for each additional imaging modality.

We note that it is extremely important that hospitals use all of the required HCPCS codes to report the performance of all services they furnish, consistent with the code descriptors, CPT and/or CMS instructions, and correct coding principles, whether payment for the services is made separately or packaged. The accuracy of the OPPS payment rates depends on the quality and completeness of the claims data that hospitals submit for the services they furnish to Medicare beneficiaries.

After consideration of the public comments we received, we are finalizing our proposal to continue to assign CPT codes 19081, 19083, and 19085 to APC 0005 for CY 2015. In addition, we are finalizing our proposal to continue to package payment for add-on CPT codes 19082, 19084, and 19086 under the OPPS for CY 2015, consistent with our packaging policy for add-on codes that was implemented on January 1, 2014. Furthermore, we are finalizing our proposal to delete APC 0037 because we believe that the proposed increased payment rate for APC 0005 is consistent with the Panel's recommendation to reassign CPT codes 19081, 19083, and 19085 to an

appropriate APC based on resource utilization and clinical coherence. Table 24 below shows the final status indicators, APC assignments, and payment rates for the image-guided breast biopsy CPT codes 19081 through 19086.

TABLE 24—FINAL CY 2015 APCS TO WHICH IMAGE-GUIDED BREAST BIOPSY PROCEDURE CODES ARE ASSIGNED

CPT Code	Long descriptor	CY 2014 SI	CY 2014 APC	CY 2014 Payment	Final CY 2015 SI	Final CY 2015 APC	Final CY 2015 payment
19081	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including stereotactic guidance.	T	0005	702.08	T	0005	$1,052.22
19082	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including stereotactic guidance (List separately in addition to code for primary procedure).	N	N/A	N/A	N	N/A	N/A
19083	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including ultrasound guidance.	T	0005	$702.08	T	0005	1,052.22
19084	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including ultrasound guidance (List separately in addition to code for primary procedure).	N	N/A	N/A	N	N/A	N/A
19085	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including magnetic resonance guidance.	T	0005	$702.08	T	0005	1,052.22
19086	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including magnetic resonance guidance (List separately in addition to code for primary procedure).	N	N/A	N/A	N	N/A	N/A

In addition to the proposal to maintain the APC assignment of the breast biopsy comprehensive CPT codes to APC 0005, we also discussed in the CY 2015 OPPS/ASC proposed rule our proposal to reassign CPT code 10030 from APC 0006 (Level I Incision & Drainage) to APC 0007 (Level II Incision and Drainage). We note that, for the CY 2014 OPPS update, the AMA's CPT Editorial Panel established CPT code 10030 to report the bundled service of image-guided fluid collection drainage by catheter for percutaneous soft tissue, and CPT code 49407 to report the bundled service of image-guided fluid collection drainage by catheter for peritoneal, retroperitoneal, transvaginal or transrectal collections, effective January 1, 2014. As shown in Table 25 of the CY 2015 OPPS/ASC proposed rule, which showed the long descriptors for CPT codes 10030 and 49407, and as listed in Addendum B to the CY 2014 OPPS/ASC final rule with comment period, we assigned CPT code 10030 to APC 0006, with a payment rate of $159.66 and CPT code 49407 to APC 0685, with a payment rate of $757.76. As listed in Addendum B to the CY 2014 OPPS/ASC final rule with comment period, both procedure codes were assigned to comment indicator ''NI'' to indicate that the codes were new codes and assigned interim APC and status indicator assignments that were subject to public comment.

At the Panel's March 10, 2014 meeting, one presenter requested that CMS reassign CPT codes 10030 and 49407 from APC 0006 and APC 0685, respectively, to APC 0037 (Level IV Needle Biopsy/Aspiration Except Bone Marrow), which has a CY 2014 OPPS payment rate of $1,223.25. The

commenter noted that similar procedures also are assigned to APC 0037. Specifically, the presenter indicated that all the image-guided fluid collection drainage procedures should be treated as one clinically cohesive group and assigned to APC 0037. The Panel agreed with the presenter and recommended that CMS reassign CPT code 49407 to APC 0037. However, the Panel did not agree with the presenter that CPT code 10030 would be more appropriately assigned to APC 0037. Rather, the Panel believed that the most appropriate APC assignment for CPT code 10030 would be APC 0007. We agreed with the Panel's recommendation that CPT code 10030 should be assigned to APC 0007. Therefore, in the CY 2015 OPPS/ASC proposed rule (79 FR 40986), we proposed to reassign CPT code 10030 from APC 0006 to APC 0007 for the CY 2015 OPPS update. In light of the Panel's recommendation to reassign CPT code 49407 and the image-guided breast biopsy procedures to APC 0037 and APC 0007, respectively, and our longstanding policy of reviewing, on an annual basis, the APC assignments for all services and items paid under the OPPS, we evaluated the geometric mean costs associated with the procedures assigned to the existing four needle biopsy APCs, as previously stated, and proposed to reassign the procedures assigned to APCs 0685 and 0037 to either APC 0004 or APC 0005 based on clinical and resource homogeneity and to delete APCs 0685 and 0037 for CY 2015. Specifically, we proposed to reassign CPT code 49407 from APC 0685 to APC 0005 for CY 2015, and to delete APCs 0037 and 0685. Table 25 of the proposed rule also showed the long descriptors for CPT codes 10030 and 49407, and their proposed status indicator and APC assignments for the CY 2015 OPPS update. The proposed CY 2015 payment rate for CPT codes 10030 and 49407 can be found in Addendum B to this CY 2015 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site).

Comment: Some commenters recommended that CMS reassign CPT code 10030 from APC 0006 to APC 0005. The commenters stated that, according to an internal analysis, CPT code 10030 is comparable with respect to clinical and resource characteristics and costs to the other abscess drainage procedures assigned to APC 0005.

Response: In light of the Panel's recommendation to reassign the procedure to APC 0007 and because CPT code 10030 is a new code for CY 2014, we are not accepting the commenters' suggestion to assign this procedure to APC 0005. Rather, we are reassigning CPT code 10030 from APC 0006 to APC 0007 for the CY 2015 OPPS update, as recommended by the Panel. We note that we will have CY 2014 hospital claims data available for CPT codes 10030 and 49407 in preparation for the CY 2016 OPPS rulemaking. At that time, we will reevaluate the APC assignments for all the abscess drainage CPT codes.

Therefore, after consideration of the public comments we received, we are finalizing our proposal, without modification, to reassign CPT code 10030 from APC 0006 to APC 0007. In addition, we are finalizing our proposal to reassign the procedures assigned to APCs 0685 and 0037 to either APC 0004 or APC 0005 based on clinical and resource homogeneity. Because there would be no other procedures assigned to APCs 0685 and 0037 as a result of this reassignment, we are finalizing our proposal to delete APCs 0685 and 0037 for CY 2015. The final CY 2015 payment rate for CPT codes 10030 and 49407 can be found in Addendum B to this CY 2015 OPPS/ASC final rule (which is available via the Internet on the CMS Web site).

c. Negative Pressure Wound Therapy (NPWT) (APCs 0012, 0013, 0015 and 0016)

For CY 2015, we proposed to assign all of the NPWT services to APC 0015 (Level II Debridement & Destruction), with a proposed payment rate of $141.66. We proposed to continue to assign CPT code 97606 (Negative pressure wound therapy (eg, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters) to APC 0015. In addition, for the CY 2015 OPPS update, we proposed to reassign CPT code 97605 (Negative pressure wound therapy (eg, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters) from APC 0013 (Level II Debridement & Destruction), the APC to which the procedure is assigned for CY 2014, to APC 0015. As listed in Table 29 of the CY 2015 OPPS/ASC proposed rule (79 FR 40916), we also proposed to reassign HCPCS codes G0456 (Negative pressure wound therapy (e.g. vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wounds(s) surface area less than or equal to 50 square centimeters) and G0457 (Negative pressure wound therapy (e.g. vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wounds(s) surface area greater than 50 square centimeters) from APC 0016 (Level III Debridement & Destruction) to APC 0015.

We note that CPT codes 97605 and 97606 became effective on January 1, 2005, and describe the type of NPWT services that employ durable medical equipment (DME). Alternatively, HCPCS codes G0456 and G0457, which are relatively new codes that became effective on January 1, 2013, were established by CMS to provide a payment mechanism for NPWT services furnished using disposable supplies instead of DME. We proposed to maintain the assignment of status indicator ''T'' to these two codes.

For the CY 2013 OPPS update, we assigned CPT code 97605 to APC 0013 (Level II Debridement & Destruction), with a payment rate of $71.54 and CPT code 97606 to APC 0015 (Level III Debridement & Destruction), with a payment rate of $106.96. In addition, we assigned HCPCS codes G0456 and G0457 to APC 0016 (Level IV Debridement & Destruction), with a payment rate of $209.65.

For the CY 2014 OPPS update, we continued to assign CPT code 97605 to APC 0013 and CPT code 97606 to APC 0015. We also continued to assign HCPCS codes G0456 and G0457 to APC 0016, with a payment rate of $274.81. We note that we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75001) that some commenters requested the reassignment of HCPCS codes G0456 and G0457 to a higher paying APC, with a payment rate specifically ranging between $450 and $500. The commenters believed that a higher paying APC would be more reflective of the cost of providing NPWT services using disposable supplies. We further stated that because HCPCS codes G0456 and G0457 were new codes for the CY 2013 OPPS update, we expected to have claims data available for these codes during the CY 2015 rulemaking cycle and, at that time, we would reevaluate the APC assignments for these services in preparation for the CY 2015 OPPS update.

For the CY 2015 OPPS update, we analyzed the latest hospital outpatient claims data available for the CY 2015 OPPS/ASC proposed rule, which was based on claims submitted between January 1, 2013 and December 31, 2013, and processed on or before December 31, 2013. The data indicated that the geometric mean cost of APC 0013 was comparable to the geometric mean cost of APC 0015. Therefore, in the CY 2015 OPPS/ASC proposed rule (79 FR 40988), we proposed to combine these APCs by reassigning all of the procedures from APC 0013 to APC 0015; delete APC 0013, and retain APC 0015 for the CY 2015 OPPS update. In addition, we proposed to rename the Debridement and Destruction APC series (excluding APC 0012) as follows: APC 0015 (Level II Debridement and Destruction); APC 0016 (Level III Debridement and Destruction); and APC 0017 (Level IV Debridement and Destruction).

Furthermore, the CY 2013 claims data available for the proposed rule also indicated that the geometric mean cost for HCPCS code G0456 was approximately $152 based on 4,509 single claims (out of 5,772 total claims), and approximately $193 for HCPCS code G0457 based on 386 single claims (out of 591 total claims). The claims data also showed that the geometric mean cost for CPT code 97605 was approximately $101 based on 58,901 single claims (out of 75,378 total claims), and approximately $140 for CPT code 97606 based on 6,722 single claims (out of 9,063 total claims). The proposed geometric mean costs of HCPCS codes G0456 and G0457, and CPT codes 97605 and 97606 were all comparable to the proposed geometric mean cost for APC 0015 of approximately $148. Based on analysis of the most recent claims data available for the proposed rule, we stated that we believed that the most appropriate assignment for all of the NPWT services was APC 0015 based on the clinical and resource homogeneity of the services assigned to this APC. The next higher cost APC in the series, APC 0016, had a proposed geometric mean cost of approximately $284, which was significantly higher than the proposed geometric mean cost of any of the NPWT services. Therefore, in the CY 2015 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 97606 to APC 0015, reassign CPT code 97605 from APC 0013 to APC 0015, and reassign HCPCS codes G0456 and G0457 from APC 0016 to APC 0015 for the CY 2015 OPPS update.

Comment: Most commenters requested that CMS continue to assign the disposable NPWT HCPCS codes G0456 and G0457 to APC 0016 for the CY 2015 OPPS update, which is the same APC to which these services are assigned for CY 2014. The commenters believed that hospitals may have miscoded claims reporting these services and, consequently, the CY 2015 proposed payment rate of approximately $142 for HCPCS codes G0456 and G0457 is insufficient because the CY 2013 OPPS claims data do not accurately capture the cost of the disposable supplies that is included in providing the service. One commenter stated that the cost of the disposable NPWT supplies range between $200 and $700 per case. The commenter provided copies of individual invoices that were forwarded to various hospitals from the manufacturer that showed a cost of approximately $220 for one disposable NPWT system. In addition, based on its analysis of charges reported by hospitals, the commenter believed that hospitals failed to understand the differences between the type of NPWT services that employ DME, which are described by CPT codes 97605 and 97606, and the type of disposable NPWT services described by HCPCS G-codes. The commenter stated that, according to its data analysis, there was no difference in hospital charges for the two types of NPWT services reported on claims. The commenter believed that hospitals miscoded these claims because they may have believed that the services described by the CPT codes for the type of NPWT services that use DME are similar to the services described by the disposable NPWT HCPCS G-codes. Several commenters explained that the cost of the type of NPWT services that use DME does not include the cost of the devices and supplies that are used to provide the services described by the HCPCS G-codes. The commenter speculated that, although it appeared that hospitals did not include the cost of the disposable devices when reporting their charges for the services described by the disposable NPWT HCPCS G-codes, hospitals should have included such costs. Therefore, the commenters urged CMS to continue to assign HCPCS codes G0456 and G0457 to APC 0016 for the CY 2015 OPPS update.

Response: Based on the significant number of claims that are available for this final rule with comment period, we believe that APC 0015 best reflects the clinical characteristics and resource costs of HCPCS codes G0456 and G0457. In addition, we do not believe that continuing to assign HCPCS codes G0456 and G0457 to APC 0016 would be appropriate for CY 2015. Our analysis of the latest hospital outpatient claims data available for this CY 2015 OPPS/ASC final rule with comment period, which is based on claims submitted between January 1, 2013 and December 31, 2013, and processed on or before June 30, 2014, indicates that the geometric mean costs for both HCPCS codes (G0456 and G0457) are very similar to the geometric mean cost of APC 0015. Specifically, our latest hospital outpatient claims data for this final rule with comment period show a geometric mean cost of approximately $158 for HCPCS code G0456 based on 5,198 single claims (out of 6,645 total claims), which is close to the geometric mean cost of APC 0015, which is approximately $152. Similarly, our claims data show a geometric mean cost of approximately $202 for HCPCS code G0457 based on 476 single claims (out of 676 total claims), which is also closer to the geometric mean cost of APC 0015, which is approximately $152 than the geometric mean cost of APC 0016, which is approximately $294.

In addition, we are not convinced that hospitals are reporting the same charges for the two types of NPWT services (DME-based and disposable) because a review of the latest claims data shows that the geometric mean costs for the most highly utilized procedures described by HCPCS code G0456 (geometric mean cost of approximately $158) and CPT code 97605 (geometric mean cost of approximately $101) are significantly different. This difference in costs captured in the claims data demonstrates that hospitals are not reporting identical charges for the different types of NPWT services, DME and disposable-based. Furthermore, we note that for all APCs whose payment rates are based upon relative payment weights, the quality and accuracy of reported units and charges influence the geometric mean costs that are the basis for our payment rates, especially for low volume items and services. However, beyond our standard OPPS trimming methodology (described in section II.A.2. of this final rule with comment period) that we apply to those claims that have passed various types of claims processing edits, it is not our general policy to judge the accuracy of hospital coding and charging for purposes of ratesetting (75 FR 71838). We rely on hospitals to bill all HCPCS codes accurately in accordance with their code descriptors and CPT and CMS instructions, as applicable, and to report charges on claims and charges and costs on their Medicare hospital cost reports appropriately. In addition, we do not specify the methodologies that hospitals

must use to set charges for this or any other service. Therefore, based on the latest hospital outpatient claims data available for this final rule with comment period, we believe that APC 0015 best reflects the clinical characteristics and resource costs of HCPCS codes G0456 and G0457.

Comment: One commenter recommended that CMS make certain changes to APCs 0015 and 0016. Specifically, the commenter recommended that CMS lower the geometric mean cost for APC 0016 to $190, which would result in reassigning certain codes that were in APC 0015 whose geometric mean cost met or exceeded this amount to APC 0016. This commenter stated that such reassignment would retain HCPCS codes G0456 and G0457 in APC 0016.

Response: We believe that the proposed structures of APCs 0015 and 0016 (aside from the few code reassignments that are being made for the purpose of resolving a violation of the 2 times rule in APC 0015 that are discussed below) are optimal in terms of clinical and resource homogeneity. The geometric mean cost range for significant procedures assigned to APC 0015 is between approximately $110 (for CPT code 17250) and approximately $201 (for CPT code 11100). The geometric mean cost range for significant procedures assigned to APC 0016 is between approximately $230 (for CPT code 17282) and approximately $368 (for CPT code 11043). Reassigning HCPCS code G0456 from APC 0015 to APC 0016 would either violate the 2 times rule in APC 0016 or necessitate dividing APC 0016 into two APCs, which we do not believe is appropriate or necessary. Both of these options are undesirable, especially given that the geometric mean cost of HCPCS code G0456 (approximately $158) is comparable to the geometric mean cost of APC 0015 (approximately $152).

In summary, based on the latest claims data used for this final rule with comment period, we believe that HCPCS codes G0456 and G0457 are appropriately assigned in APC 0015 for the CY 2015 update based on the clinical and resource similarity to the other procedures in APC 0015. As has been our practice since the implementation of the OPPS in 2000, we review, on an annual basis, the APC assignments for the procedures and services paid under the OPPS. We will again review the APC assignments for all the NPWT services in light of the CY 2014 claims data and the proposed APC structures for clinically relevant APCs and determine whether an APC reassignment for any of the NPWT codes would be appropriate in the CY 2016 rulemaking.

In addition, in the CY 2015 OPPS/ASC proposed rule, there were violations of the 2 times rule noted for both APCs 0012 and 0015 (79 FR 40981). Every year we make every effort to minimize the number of APCs that are listed as exceptions to the 2 times rule. To resolve the violations of the 2 times rule in APCs 0012 and 0015, we are making the following code reassignments:

- CPT codes 11719, 11720, 11721, 11740, and 17340, and HCPCS code G0127 from APC 0012 to APC 0340.
- CPT codes 11901, 12014, 96920, and 97605 from APC 0015 to APC 0012.

These code reassignments eliminated the 2 times rule violations that existed in APCs 0012 and 0015 in the CY 2015 OPPS/ASC proposed rule. We note that APC 0012 is one of the APCs included in the ancillary services packaging policy that is discussed in section II.A.3.c.(1) of this final rule with comment period. Because CPT code 97605 is assigned to APC 0012, the code will be conditionally packaged and assigned to status indicator ''Q1'' for CY 2015.

After consideration of the public comments we received, we are finalizing our CY 2015 proposal, with modification. Specifically, we are finalizing our proposal to assign CPT code 97606 and HCPCS codes G0456 and G0457 to APC 0015. However, we are reassigning CPT code 97605 from our proposed APC 0015 to APC 0012 for the CY 2015 update to eliminate the violation of the 2 times rule that existed in APC 0015 based on claims data available for the proposed rule.

In addition, for the CY 2015 update, the CPT Editorial Panel established two new CPT codes to describe disposable NPWT services and revised the long descriptors for existing CPT codes 97605 and 97606, effective January 1, 2015. Consistent with our general policy of using permanent codes rather than using temporary HCPCS G-codes in order to streamline coding, we are deleting HCPCS codes G0456 and G0457 because they are replaced with two new CPT codes effective January 1, 2015. Table 25 below shows the replacement CPT codes for HCPCS codes G0456 and G0457 as well as the revised long descriptors for existing CPT codes 97605 and 97606. The final CY 2015 payment rate for the NPWT services codes can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site). Like all new codes effective January 1, 2015, the APC assignments for the new disposable NPWT CPT codes are open for comment for 60 days after display of this CY 2015 OPPS/ASC final rule with comment period.

TABLE 25—FINAL APC ASSIGNMENTS FOR THE NPWT SERVICES FOR CY 2015

CY 2014 CPT/ HCPCS Code	CY 2015 CPT Code	CY 2015 Long descriptor	Proposed CY 2015 OPPS SI	Proposed CY 2015 OPPS APC	Final CY 2015 OPPS SI	Final CY 2015 OPPS APC
97605	97605	Negative pressure wound therapy (eg, vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.	T	0015	Q1	0012
97606	97606	Negative pressure wound therapy (eg, vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.	T	0015	T	0015

TABLE 25—FINAL APC ASSIGNMENTS FOR THE NPWT SERVICES FOR CY 2015—Continued

CY 2014 CPT/ HCPCS Code	CY 2015 CPT Code	CY 2015 Long descriptor	Proposed CY 2015 OPPS SI	Proposed CY 2015 OPPS APC	Final CY 2015 OPPS SI	Final CY 2015 OPPS APC
G0456	97607	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.	T	0015	T	0015
G0457	97608	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.	T	0015	T	0015

d. Platelet Rich Plasma (PRP) (APC 0327)

For CY 2015, we proposed to continue to assign HCPCS code G0460 (Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment) to APC 0327 (Level II Debridement & Destruction), with a proposed payment rate of approximately $431. We note that HCPCS code G0460, which became effective July 1, 2013, describes both the procedure and product components associated with the autologous platelet rich plasma service.

Comment: One commenter requested that CMS exempt HCPCS code G0460 from the geographic wage index variations to enable hospitals to more willingly participate in the AutoloGel Coverage with Evidence Development (CED) protocols. According to the commenter, HOPDs are reluctant to enroll in the CED protocols because they are concerned that the proposed APC payment rate will not cover the cost of the product, the procedure, the overhead, and the additional administrative effort associated with CED data collection requirements. In addition, the commenter requested that CMS establish a final payment rate for APC 0327 based on the geometric mean cost of $496.99 to help achieve some stability regarding the payment for the procedures assigned to this APC.

Response: We note that comments related to CED protocols or data collection are outside the scope of the proposed rule. With regard to the geographic wage index exemption requested by the commenter, we have never made such an exception. Under the hospital OPPS, all procedures and services that include devices are wage adjusted. Moreover, the payment rates for procedures and APCs are not based on a specific projected amount. The final payment rate for APC 0327 is based on the geometric mean cost of all the procedures described by the HCPCS codes assigned to this APC. We believe that the procedure described by HCPCS code G0460 is appropriately assigned to APC 0327 for the CY 2015 OPPS update based on the clinical and resource similarities in relation to the other procedures assigned to APC 0327. We note that, for this final rule with comment period, which is based on hospital outpatient claims submitted between January 1, 2013, and December 31, 2013, that were processed on or before June 30, 2014, our latest hospital outpatient claims data show no claims reporting the service described by HCPCS code G0460. As has been our practice since the implementation of the OPPS in 2000, we review, on an annual basis, the APC assignments for the procedures and services paid under the OPPS. We will review the APC assignment for HCPCS code G0460 when sufficient claims data become available to determine whether a reassignment to a more appropriate APC is necessary for the CY 2016 update. After consideration of the public comment we received, we are finalizing our proposal, without modification, to continue to assign HCPCS code G0460 to APC 0327 for CY 2015. The final CY 2015 payment rate for HCPCS code G0460 can be found in Addendum B to this CY 2015 OPPS/ASC final rule (which is available via the Internet on the CMS Web site).

IV. OPPS Payment for Devices

A. 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. We may establish a new device category for pass-through payment in any quarter, and 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. CY 2015 Policy

There currently is one device category eligible for pass-through payment, which we established effective October 1, 2013: HCPCS code C1841 (Retinal

prosthesis, includes all internal and external components). Recognizing that this device category has been eligible for at least 2 years, but not more than 3 years, of pass-through status by the end of CY 2015, in the CY 2015 OPPS/ASC proposed rule (79 FR 40989), we proposed the expiration of pass-through payment for HCPCS code C1841 devices on December 31, 2015. Therefore, in accordance with our established policy, beginning with CY 2016, we proposed 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 (79 FR 40989 through 40990).

Comment: A few commenters requested that CMS extend the pass-through payment period for the device described by HCPCS code C1841 due to delay of the first date of sale of the device until January 2014. The commenters asserted that the delay was due to various regulatory delays, including the Food and Drug Administration's (FDA's) Humanitarian Device Exemption (HDE) approval process and Federal Communications Commission (FCC) regulations regarding utilization of a radiofrequency (RF) band approval. The commenters therefore requested that CMS use the date of the first sale or the date of the first HCPCS code C1841 device implant (January 16, 2014) to ''reset'' the start date for pass-through payment eligibility, which would result in another year of pass-through payment status.

Response: According to 42 CFR 419.66(g), ''CMS limits the eligibility for a pass-through payment established under this section to a period of at least 2 years, but not more than 3 years, *beginning on the date that CMS establishes a category of devices*'' (emphasis added). We cannot extend the pass-through payment status of HCPCS code C1841 beyond CY 2015 because such an extension would make the pass-through payment status effective longer than the maximum 3-year period permitted under 42 CFR 419.66(g). Moreover, the HCPCS code C1841 device category was made effective in the OPPS on October 1, 2013. The HCPCS code C1841 device category will have had more than 2 years of pass-through payment status as of December 31, 2015. Extending pass-through payment status through December 31, 2016, as requested by the commenter, would afford the HCPCS code C1841 device category longer than the 3-year maximum pass-through payment period. Therefore, after consideration of the public comments we received, we are finalizing our proposal to expire HCPCS code C1841 device category from pass-through payment status after December 31, 2015. We are finalizing our proposal to package the costs for devices described by HCPCS code C1841 into the costs of the procedure with which the device is reported in the hospital claims data used in the development of the OPPS relative payment weights that will be used to establish the ASC payment rates for CY 2016.

With the expiration of HCPCS code C1841 device category from pass-through payment status at the end of CY 2015, there are no other currently active categories for which we would expire pass-through status in CY 2015. If we create new device categories for pass-through payment status during the remainder of CY 2014 or during CY 2015, we will propose future expiration dates in accordance with 42 CFR 419.66(g).

2. 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.

We published a list of all procedural APCs with the CY 2014 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 in CY 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).

b. CY 2015 Policy

In the CY 2015 OPPS/ASC proposed rule (79 FR 40990), we proposed to continue, for CY 2015, 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 proposed to continue our policy, for CY 2015, that the pass-through evaluation process and pass-through 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, be the device pass-through process and payment methodology only. The rationale for this policy is provided in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60471 through 60477). We also proposed 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

proposed 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 proposed 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 the CY 2015 OPPS/ASC proposed rule (79 FR 40990), for CY 2015, we also proposed to continue our policy established in CY 2010 to include implantable biologicals in our calculation of the device APC offset amounts. In addition, we proposed to continue to calculate and set any device APC offset amount for any new device pass-through category that includes a newly eligible implantable biological beginning in CY 2015, using the same methodology we have historically used to calculate and set device APC offset amounts for device categories eligible for pass-through payment, and to include the costs of implantable biologicals in the calculation of the device APC offset amounts (79 FR 40990).

In addition, in the CY 2015 OPPS/ASC proposed rule (79 FR 40900), we proposed to update the list of all procedural APCs with the final CY 2015 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 2015 device pass-through payment applications and by CMS in reviewing those applications.

Comment: One commenter objected to CMS' proposal to continue its policy of evaluating implantable biological pass-through applications through the device evaluation process. The commenter believed that all biologicals should be evaluated through the drug and biological pass-through process, which is intended for the evaluation of drugs and biologicals.

Response: We have discussed our rationale for this policy in the CY 2010 OPPS/ASC final rule (74 FR 60463). Implantable biologicals function as implantable medical devices and are used in the HOPD in surgical procedures in a manner similar to implantable medical devices. Therefore, since CY 2010, we have treated them as medical devices for pass-through payment purposes. In addition, like implantable medical devices, implantable biologicals are treated as packaged surgical supplies in the OPPS under 42 CFR 419.2(b)(16). For these reasons, we will continue to treat implantable biologicals as devices for pass-through payment purposes in CY 2015.

After consideration of the public comment we received, we are finalizing, without modification, the aforementioned proposed policies for calculation of the device APC offset amounts for CY 2015. In addition, we are updating, on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html,* the list of all procedural APCs with the final CY 2015 portions of the APC payment amounts that we determine are associated with the cost of devices so that this information is available for use by the public in developing potential CY 2015 device pass-through payment applications and by CMS in reviewing those applications.

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

1. 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 are 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, the hospital is 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, the hospital is instructed to report as the device charge the difference between its usual charge for the device being implanted and its 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 are 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'' 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.

2. Policy for CY 2015

In the CY 2015 OPPS/ASC proposed rule (79 FR 40990 through 40992), for CY 2015, we proposed 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 2015, we proposed to continue to reduce the OPPS payment, for the applicable APCs listed in Table 31 of the proposed rule, 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 ''FD'' when the

hospital receives a credit for a replaced device listed in Table 32 of the proposed rule that is 50 percent or greater than the cost of the device.

In the CY 2015 OPPS/ASC proposed rule (79 FR 40990 through 40992), for CY 2015, we also proposed 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 2015 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 device offset amount must be significant, which, for purposes of this policy, is defined as exceeding 40 percent of the APC cost. We also proposed to continue to restrict the devices to which the APC payment adjustment would apply to a specific set of costly devices to ensure that the adjustment would not be triggered by the implantation of an inexpensive device whose cost would not constitute a significant proportion of the total payment rate for an APC. We stated that 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.

Comment: One commenter urged CMS to discontinue its current policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. The commenter stated that procedures which involve the replacement of a device are of greater complexity than the original insertion of the device. The commenter recommended that, because the replacement procedures are not paid at a higher rate, CMS not further penalize the hospital by reducing the OPPS payment when the device is furnished without cost or with a full or partial credit to the hospital.

Response: We do not agree with the commenter and believe that it is appropriate to reduce the OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit.

After consideration of the public comments we received, we are finalizing our proposals 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, and to continue using 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.

We examined the offset amounts calculated from the CY 2015 final rule with comment period data and the clinical characteristics of the final CY 2015 APCs to determine which APCs meet the criteria for CY 2015. Table 26 below lists the APCs to which the payment adjustment policy for no cost/full credit and partial credit devices will apply in CY 2015. Table 27 below lists the devices to which the payment adjustment policy for no cost/full credit and partial credit devices will apply in CY 2015.

Based on the final CY 2013 claims data available for this CY 2015 OPPS/ASC final rule with comment period, we have updated the lists of APCs and devices to which the no cost/full credit and partial credit device adjustment policy will apply for CY 2015, consistent with the three criteria discussed earlier in this section.

TABLE 26—APCS TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WILL APPLY IN CY 2015

CY 2015 APC	CY 2015 APC title
0039	Level III Neurostimulator & Related Procedures.
0061	Level II Neurostimulator & Related Procedures.
0064	Level III Treatment Fracture/Dislocation.
0089	Level III Pacemaker and Similar Procedures.
0090	Level II Pacemaker and Similar Procedures.
0107	Level I ICD and Similar Procedures.
0108	Level II ICD and Similar Procedures.
0227	Implantation of Drug Infusion Device.
0229	Level II Endovascular Procedures.
0259	Level VII ENT Procedures.
0293	Level IV Intraocular Procedures.

TABLE 26—APCS TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WILL APPLY IN CY 2015—Continued

CY 2015 APC	CY 2015 APC title
0318	Level IV Neurostimulator & Related Procedures.
0319	Level III Endovascular Procedures.
0351	Level V Intraocular Procedures.
0385	Level I Urogenital Procedures.
0386	Level II Urogenital Procedures.
0425	Level V Musculoskeletal Procedures Except Hand and Foot.
0655	Level IV Pacemaker and Similar Procedures.

TABLE 27—DEVICES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WILL APPLY IN CY 2015

CY 2015 Device HCPCS code	CY 2015 Short descriptor
C1721	AICD, dual chamber.
C1722	AICD, single chamber.
C1728	Cath, brachytx seed adm.
C1764	Event recorder, cardiac.
C1767	Generator, neurostim, imp.
C1771	Rep dev, urinary, w/sling.
C1772	Infusion pump, programmable.
C1776	Joint device (implantable).
C1777	Lead, AICD, endo single coil.
C1778	Lead, neurostimulator.
C1779	Lead, pmkr, transvenous VDD.
C1785	Pmkr, dual, rate-resp.
C1786	Pmkr, single, rate-resp.
C1789	Prosthesis, breast, imp.
C1813	Prosthesis, penile, inflatab.
C1815	Pros, urinary sph, imp.
C1818	Integrated keratoprosthesis.
C1820	Generator, neuro rechg bat sys.
C1840	Lens, intraocular (telescopic).
C1881	Dialysis access system.
C1882	AICD, other than sing/dual.
C1891	Infusion pump, non-prog, perm.
C1895	Lead, AICD, endo dual coil.
C1896	Lead, AICD, non sing/dual.
C1897	Lead, neurostim, test kit.
C1898	Lead, pmkr, other than trans.
C1899	Lead, pmkr/AICD combination.
C1900	Lead coronary venous.
C2619	Pmkr, dual, non rate-resp.
C2620	Pmkr, single, non rate-resp.
C2621	Pmkr, other than sing/dual.
C2622	Prosthesis, penile, non-inf.
C2626	Infusion pump, non-prog, temp.
C2631	Rep dev, urinary, w/o sling.

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

A. 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 final rule with comment period, the term ''biological'' is used because this is the term that appears in section 1861(t) of the Act. ''Biological'' as used in this final rule with comment period includes ''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. CY 2015 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this final rule with comment period, 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 2015.

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 final rule with comment period, 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. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2014

In the CY 2015 OPPS/ASC proposed rule (79 FR 40992), we proposed that the pass-through status of 9 drugs and biologicals would expire on December 31, 2014, as listed in Table 33 of the proposed rule (79 FR 40993). 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, 2014. 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, 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), 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 $95 for CY 2015), as discussed further in section V.B.2. of this final rule with comment period. 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 ASP+6 percent for CY 2015, as discussed further in section V.B.3. of this final rule with comment period).

Comment: Commenters, including several hospitals, physicians, and a manufacturer, requested that CMS continue to pay separately for Exparel® (bupivacaine liposome injectable suspension) described by HCPCS code C9290 (Injection, bupivicaine liposome, 1 mg) once pass-through payment status expires on December 31, 2014. Commenters disagreed with CMS' proposal to package Exparel® as a surgical supply and stated that the drug is used to control postoperative pain and is not used in the actual surgical procedure. In addition, commenters noted that the product cost of Exparel® exceeds the proposed CY 2015 packaging threshold of $90 and is not FDA-approved as a local anesthetic.

Response: We disagree with the commenters' characterization of Exparel® as not functioning as a surgical supply because it is indicated for the alleviation of postoperative pain. The indications and usage of Exparel® as listed in the FDA-approved label are as follows: ''Exparel® is a liposome injection of bupivacaine, an amide-type local anesthetic, indicated for administration into the surgical site to produce postsurgical analgesia.''

Exparel® is injected immediately after the surgical procedure while the patient is still on the operating room table at the surgical wound site to control postoperative pain, which is an important part of the surgical care of the patient affecting the surgical outcome. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925 through 74939), we finalized our policy at 42 CFR 419.2(b)(16) to unconditionally package all drugs and biologicals that function as supplies in a surgical procedure. According to OPPS policy, drugs, biologicals, radiopharmaceuticals, implantable medical devices, and other items and products that are not equipment can be supplies in the OPPS (78 FR 43571 and 43575). While the commenter stated that the cost of Exparel® exceeds the drug packaging threshold, we emphasize that cost consideration is not a factor in determining whether an item is a surgical supply. We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy. Therefore, for CY 2015, we are finalizing our proposal to package Exparel® described by HCPCS code C9290 and to assign status indicator ''N'' to the code for CY 2015.

Comment: A few commenters recommended that CMS continue pass-through payment status for new drugs, specifically diagnostic radiopharmaceuticals and contrast agents, for a full 3 years. The commenters asserted that providing pass-through payment status for 3 years would help provide a more current and accurate data set on which to base payment amounts of the procedure when the diagnostic radiopharmaceutical or contrast agent is subsequently packaged. The commenters further recommended that CMS expire pass-through payment status for drugs and biologicals on a quarterly as opposed to an annual basis.

Response: As we stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74287), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68363), and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75010), and as described in section V.A. of this final rule with comment period, section 1833(t)(6)(c)(i)(II) of the Act permits CMS to make pass-through payments for a period of at least 2 years, but not more than 3 years, after the product's first payment as a hospital outpatient service under Medicare Part B OPPS. We continue to believe that this period of payment appropriately facilitates dissemination of these new products into clinical practice and facilitates the collection of sufficient hospital claims data reflective of their costs for future OPPS ratesetting. Our longstanding practice has been to provide pass-through payment for a period of 2 to 3 years, with expiration of pass-through payment status proposed and finalized through the annual rulemaking process. Each year, when proposing to expire the pass-through payment status of certain drugs and biologicals, we examine our claims data for these products. We observe that hospitals typically have incorporated these products into their chargemasters based on the utilization and costs observed in our claims data. Under the existing pass-through payment policy, we begin pass-through payment on a quarterly basis, depending on when applications are submitted to us for consideration. We are confident that the period of time for which drugs, biologicals, contrast agents, and radiopharmaceuticals receive pass-through payment status, which is at least 2 but no more than 3 years, is appropriate for CMS to collect the sufficient amount of data to make a packaging determination.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to expire the pass-through payment status of the nine drugs and biologicals listed in Table 28 below. Table 28 lists the drugs and biologicals for which pass-through payment status will expire on December 31, 2014, the status indicators, and the assigned APCs for CY 2015.

TABLE 28—DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2014

CY 2015 HCPCS Code	CY 2015 Long descriptor	Final CY 2015 SI	Final CY 2015 APC
C9290	Injection, bupivicaine liposome, 1 mg	N	N/A
C9293	Injection, glucarpidase, 10 units	K	9293
J0178	Injection, aflibercept, 1 mg vial	K	1420
J0716	Injection, centruroides (scorpion) immune f(ab)2, up to 120 milligrams	K	1431
J9019	Injection, asparaginase (erwinaze), 1,000 iu	K	9289
J9306	Injection, pertuzumab, 1 mg	K	1471
Q4131	EpiFix, per square centimeter	N	N/A
Q4132	Grafix core, per square centimeter	N	N/A
Q4133	Grafix prime, per square centimeter	N	N/A

3. Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Payment Status in CY 2015

In the CY 2015 OPPS/ASC proposed rule (79 FR 40993), we proposed to continue pass-through payment status in CY 2015 for 22 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, 2014. These drugs and biologicals, which were approved for pass-through status between January 1, 2013 and July 1, 2014, were listed in Table 34 of the proposed rule (79 FR 40994). The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through July 1, 2014 were assigned status indicator ''G'' in Addenda A and B to the proposed rule. Addenda A and B to the 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 stated in the proposed rule that 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 rate of ASP+6 percent in CY 2015, which is the amount that drugs and biologicals receive under section 1842(o) of the Act.

Therefore, for CY 2015, we proposed 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 2015. We proposed that a $0.00 pass-through payment amount would be paid for most pass-through drugs and biologicals under the CY 2015 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is 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 proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2015 because, if not on pass-through status, payment for these products would be packaged into the associated procedure.

In addition, we proposed to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2015 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 2015, as is consistent with our CY 2014 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed 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 2015, we proposed 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 ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed 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 proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

Comment: Several commenters supported CMS' proposal to provide payment at ASP+6 percent for drugs, biologicals, contrast agents, and radiopharmaceuticals that are granted pass-through payment status. A few commenters requested that CMS provide an additional payment for radiopharmaceuticals that are granted pass-through payment status.

Response: As discussed above, the statute provides that mandated pass-through payment for pass-through drugs and biologicals for CY 2015 equals the amount determined under section 1842(o) of the Act minus the portion of the otherwise applicable APC payment that CMS determines is associated with the drug or biological. Therefore, the pass-through payment is determined by subtracting the otherwise applicable payment amount under the OPPS (ASP+6 percent for CY 2015) from the amount determined under section 1842(o) of the Act (ASP+6 percent).

Regarding the commenters' request that CMS provide an additional payment for radiopharmaceuticals that are granted pass-through payment status, we note that, for CY 2015, consistent with our CY 2014 payment policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to provide payment for both diagnostic and therapeutic radiopharmaceuticals with pass-through payment status based on the ASP methodology. As stated above, the ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the WAC if the ASP is unavailable, and 95 percent of the radiopharmaceutical's most recent AWP if the ASP and WAC are unavailable. 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 2015, we proposed to follow the standard ASP methodology to determine its pass-through payment rate under the OPPS to account for the acquisition and pharmacy overhead costs, including compounding costs. We continue to believe that a single payment is appropriate for diagnostic radiopharmaceuticals with pass-through payment status in CY 2015, and that the payment rate of ASP+6 percent (or payment based on the ASP methodology) is appropriate to provide payment for both the radiopharmaceutical's acquisition cost and any associated nuclear medicine handling and compounding costs. We refer readers to section V.B.3. of this final rule with comment period for further discussion of payment for therapeutic radiopharmaceuticals based on ASP information submitted by manufacturers, and readers also may refer to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

After consideration of the public comments we received, we are finalizing our proposal to provide payment for drugs, biologicals, diagnostic and therapeutic radiopharmaceuticals, and contrast agents that are granted pass-through payment status based on the ASP methodology. If a diagnostic or therapeutic radiopharmaceutical receives pass- through status during CY 2015, we will follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we will 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 will 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 final rule with comment period, we implemented a policy whereby payment for the following nonpass-through items is packaged into payment for the associated procedure: 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 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 final rule with comment period. It follows that the copayment for the nonpass-through payment portion (the otherwise applicable fee schedule amount that we would also 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 2014, in the CY 2015 OPPS/ASC proposed rule, we proposed to continue to set the associated copayment amount to zero for CY 2015 for pass-through drugs and biologicals that would otherwise be packaged if the item did not have pass-through payment status. The 22 drugs and biologicals that we proposed would continue to have pass-through payment status for CY 2015 or have been granted pass-through payment status as of January 2015 were shown in Table 34 of the proposed rule (79 FR 40994).

Comment: Commenters supported the CY 2015 proposal to continue to set the associated copayment amounts for pass-through diagnostic radiopharmaceuticals and contrast agents that would otherwise be packaged if the product did not have pass-through payment status to zero. The commenters noted that this policy is consistent with statutory requirements and provides cost-saving benefits to Medicare beneficiaries.

Response: We appreciate the commenters' support of our proposal. As discussed in the CY 2015 OPPS/ASC proposed rule (79 FR 40993 through 40994), we believe that for drugs and biologicals that are ''policy-packaged,'' the copayment for the nonpass-through payment portion of the total OPPS payment for this subset of drugs and biologicals is accounted for in the copayment of 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, we believe that the copayment amount should be zero for drugs and biologicals that are ''policy-packaged,'' including diagnostic radiopharmaceuticals and contrast agents. We also believe that the copayment amount should be zero for anesthesia drugs that would otherwise be packaged if the item did not have pass-through payment status.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to set the associated copayment amount for pass-through diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs that would otherwise be packaged if the item did not have pass-through payment status to zero for CY 2015.

The 35 drugs and biologicals that will continue to have pass-through payment status for CY 2015 or have been granted pass-through payment status as of January 1, 2015 are shown in Table 29 below. As is our standard methodology, we annually review new permanent HCPCS codes and delete temporary HCPCS C-codes if an alternate permanent HCPCS code is available for purposes of OPPS billing and payment. Table 29 below includes those coding changes.

TABLE 29—DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2015

CY 2014 HCPCS code	CY 2015 HCPCS code	CY 2015 Long descriptor	Final CY 2015 SI	Final CY 2015 APC
A9520	A9520	Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries	G	1463
N/A	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	1664
C9021	J9301	Injection, obinutuzumab, 10 mg	G	1476
C9022	J1322	Injection, elosulfase alfa, 1mg	G	1480
C9023	J3145	Injection, testosterone undecanoate, 1 mg	G	1487
C9025	C9025	Injection, ramucirumab, 5 mg	G	1488
C9026	C9026	Injection, vedolizumab, 1 mg	G	1489
N/A	C9027	Injection, pembrolizumab, 1 mg	G	1490
C9132	C9132	Prothrombin complex concentrate (human), Kcentra, per i.u. of Factor IX activity	G	9132
C9133	J7200	Factor ix (antihemophilic factor, recombinant), Rixubus, per i.u	G	1467
C9134	J7181	Injection, Factor XIII A-subunit, (recombinant), per i.u	G	1746
C9135	J7201	Injection, factor ix, fc fusion protein (recombinant), per i.u	G	1486
N/A	C9136	Injection, factor viii, fc fusion protein, (recombinant), per i.u	G	1656
C9441	J1439	Injection, ferric carboxymaltose, 1 mg	G	9441
N/A	C9349	FortaDerm, and FortaDerm Antimicrobial, any type, per square centimeter	G	1657
N/A	C9442	Injection, belinostat, 10 mg	G	1658
N/A	C9443	Injection, dalbavancin, 10 mg	G	1659
N/A	C9444	Injection, oritavancin, 10 mg	G	1660
N/A	C9446	Injection, tedizolid phosphate, 1 mg	G	1662
N/A	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	1663
C9497	C9497	Loxapine, inhalation powder, 10 mg	G	9497
J1446	J1446	Injection, tbo-filgrastim, 5 micrograms	G	1477
J1556	J1556	Injection, immune globulin (Bivigam), 500 mg	G	9130
J3060	J3060	Injection, taliglucerase alfa, 10 units	G	9294
J7315	J7315	Mitomycin, ophthalmic, 0.2 mg	G	1448
J7316	J7316	Injection, Ocriplasmin, 0.125 mg	G	9298
J7508	J7508	Tacrolimus, Extended Release, Oral, 0.1 mg	G	1465
J9047	J9047	Injection, carfilzomib, 1 mg	G	9295
J9262	J9262	Injection, omacetaxine mepesuccinate, 0.01 mg	G	9297
J9354	J9354	Injection, ado-trastuzumab emtansine, 1 mg	G	9131
J9371	J9371	Injection, Vincristine Sulfate Liposome, 1 mg	G	1466

TABLE 29—DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2015—Continued

CY 2014 HCPCS code	CY 2015 HCPCS code	CY 2015 Long descriptor	Final CY 2015 SI	Final CY 2015 APC
J9400	J9400	Injection, Ziv-Aflibercept, 1 mg	G	9296
Q4121	Q4121	Theraskin, per square centimeter	G	1479
Q4122	Q4122	Dermacell, per square centimeter	G	1419
Q4127	Q4127	Talymed, per square centimeter	G	1449

4. 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 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 nonpass-through diagnostic radiopharmaceuticals and contrast agents were packaged as a matter of policy.

For CY 2014, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), we continued to package payment for all nonpass-through diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs, and we began packaging 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. These packaging policies are codified at 42 CFR 419.2(b).

b. 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 2015, as we did in CY 2014, we proposed to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals.

There is currently one diagnostic radiopharmaceutical with pass-through status under the OPPS. HCPCS code A9520 (Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries) was granted pass-through payment status beginning October 1, 2013. We currently apply the established radiopharmaceutical payment offset policy to pass-through payment for this product.

Table 35 of the CY 2015 OPPS/ASC proposed rule (79 FR 40995) displayed the proposed APCs to which nuclear medicine procedures would be assigned in CY 2015 and for which we expect that an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

Comment: A few commenters requested that CMS reinstate the ''FB'' modifier to specified nuclear medicine procedures in cases in which the diagnostic radiopharmaceutical is received at no cost or full credit. The commenters requested that the policy be maintained for CY 2015 and beyond.

Response: As we discussed in the CY2014 OPPS/ASC final rule with comment period (78 FR 75016), our review of claims data showed that hospitals rarely received diagnostic radiopharmaceuticals at no cost or full credit. Therefore, we do not believe that the ''FB'' modifier policy is warranted for diagnostic radiopharmaceuticals.

Comment: A few commenters agreed that pass-through payment status for HCPCS code A9520 should be extended for CY 2015.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals, as described in the CY 2015 OPPS/ASC proposed rule (79 FR 40994 through 40995). We will continue to reduce the payment amount for procedures in the APCs listed in Table 30 in this final rule with comment period by the full policy-packaged offset amount appropriate for diagnostic radiopharmaceuticals.

Table 30 below displays the APCs to which nuclear medicine procedures will be assigned in CY 2015 and for which we expect that an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through payment status.

TABLE 30—APCS TO WHICH A DIAGNOSTIC RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2015

CY 2015 APC	CY 2015 APC title
0308	Positron Emission Tomography (PET) Imaging.
0377	Level II Cardiac Imaging.
0378	Level II Pulmonary Imaging.
0389	Level I Non-imaging Nuclear Medicine.
0390	Level I Endocrine Imaging.
0391	Level II Endocrine Imaging.
0392	Level II Non-imaging Nuclear Medicine.
0393	Hematologic Processing & Studies.
0394	Hepatobiliary Imaging.
0395	GI Tract Imaging.
0396	Bone Imaging.
0398	Level I Cardiac Imaging.
0400	Hematopoietic Imaging.
0401	Level I Pulmonary Imaging.
0402	Level II Nervous System Imaging.
0403	Level I Nervous System Imaging.
0404	Renal and Genitourinary Studies.
0406	Level I Tumor/Infection Imaging.
0408	Level III Tumor/Infection Imaging.
0414	Level II Tumor/Infection Imaging.

c. 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, in the CY 2015 OPPS/ASC proposed rule (79 FR 40995), we proposed 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 2015, as we did in CY 2014, we proposed to continue to apply our standard contrast agents offset policy to payment for pass-through contrast agents (we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75017) for the final CY 2014 policy and the CY 2015 OPPS/ASC proposed rule (79 FR 40995 through 40996) for the proposed 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 2015 in order to provide an appropriate transitional pass-through payment for new contrast agents. We proposed 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 35 of the proposed rule, and these APCs were displayed in Table 36 of the proposed rule. 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 2015, we proposed to continue to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 36 of the proposed rule (79 FR 40995 through 40996), 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.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal for CY 2015 without modification. We will continue to recognize that when a contrast agent with pass-through payment status is billed with any procedural APC listed in Table 31 below, a specific offset based on the procedural APC will be applied to the payment for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

TABLE 31—APCS TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2015

CY 2015 APC	CY 2015 APC title
0080	Diagnostic Cardiac Catheterization.
0083	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization.
0093	Vascular Reconstruction/Fistula Repair.
0152	Level I Percutaneous Abdominal and Biliary Procedures.
0177	Level I Echocardiogram With Contrast.
0178	Level II Echocardiogram With Contrast.
0229	Level II Endovascular Revascularization of the Lower Extremity.
0278	Diagnostic Urography.
0279	Level II Angiography and Venography.
0280	Level III Angiography and Venography.
0283	Computed Tomography with Contrast.
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast.
0333	Computed Tomography without Contrast followed by Contrast.
0334	Combined Abdomen and Pelvis CT with Contrast.
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast.
0375	Ancillary Outpatient Services When Patient Expires.
0383	Cardiac Computed Tomographic Imaging.
0388	Discography.
0442	Dosimetric Drug Administration.
0662	CT Angiography.
0668	Level I Angiography and Venography.
8006	CT and CTA with Contrast Composite.
8008	MRI and MRA with Contrast Composite.

d. Payment Offset Policy for 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

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). In the CY 2015 OPPS/ASC proposed rule (79 FR 40996), for CY 2015, as we did in CY 2014, we proposed to continue to apply the skin substitute and stress agent offset policy to payment for pass-through skin substitutes and stress agents.

There are currently six skin substitutes (HCPCS codes Q4121, Q4122, Q4127, Q4131, Q4132, and Q4133) with pass-through payment status under the OPPS. We currently apply the established skin substitute payment offset policy to pass-through payment for these products. Table 37 of the CY 2015 OPPS/ASC proposed rule (79 FR 40996) displayed the proposed APCs to which skin substitute procedures would be assigned in CY 2015 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 2015 in order to provide an appropriate transitional pass through payment for new stress agents. Table 38 of the CY 2015 OPPS/ASC proposed rule (79 FR 40996) displayed the proposed APCs to which MPI procedures would be assigned in CY 2015 and for which we expect that an APC offset could be applicable in the case of a stress agent with pass-through status.

We did not receive any public comments on these proposals. Therefore, we are finalizing our proposal, without modification, to recognize that when a skin substitute with pass-through payment status is billed with any procedural APC listed in Table 32 below, a specific offset based on the procedural APC will be applied to the payment for the skin substitute to ensure that duplicate payment is not made for the skin substitute. In addition, when a stress agent with pass-through payment status is billed with any procedural APC listed in Table 33 below, a specific offset based on the procedural APC will be applied to the payment for the stress agent to ensure that duplicate payment is not made for the stress agent. Table 32 below displays the APCs to which skin substitute procedures will be assigned in CY 2015 and for which we expect that an APC offset could be applicable in the case of skin substitutes with pass-through payment status. Table 33 below displays the APCs to which MPI procedures will be assigned in CY 2015 and for which we expect that an APC offset could be applicable in the case of a stress agent with pass-through payment status.

TABLE 32—APCS TO WHICH A SKIN SUBSTITUTE OFFSET MAY BE APPLICABLE FOR CY 2015

CY 2015 APC	CY 2015 APC title
0328	Level III Skin Repair.
0329	Level IV Skin Repair.

TABLE 33—APCS TO WHICH A STRESS AGENT OFFSET MAY BE APPLICABLE FOR CY 2015

CY 2015 APC	CY 2015 APC title
0100	Cardiac Stress Tests.
0377	Level II Cardiac Imaging.

As we proposed, we will 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. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Background

Under 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: as a packaged payment included in the payment for the associated service, or 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. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Background

As indicated in section V.B.1. of this final rule with comment period, 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 $90 for CY 2014.

Following the CY 2007 methodology, for the CY 2015 OPPS/ASC proposed rule (79 FR 40997), 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 2015 and rounded the resulting dollar amount ($91.46) to the nearest $5 increment, which yielded a figure of $90. 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 proposed a packaging threshold for CY 2015 of $90. (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).)

Following the CY 2007 methodology, for this CY 2015 OPPS/ASC final rule with comment period, 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 2015 and rounded the resulting dollar amount ($93.48) to the nearest $5 increment, which yielded a figure of $95. 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). Therefore, for this CY 2015 OPPS/ASC final rule with comment period, using the CY 2007 OPPS methodology, we are establishing a packaging threshold for CY 2015 of $95.

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

In the CY 2015 OPPS/ASC proposed rule (79 FR 40997), to determine the proposed CY 2015 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 2013 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2013 claims processed before January 1, 2014 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 the proposed rule, or for the following policy-packaged items that we proposed to continue to package in CY 2015: 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.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2015, 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 proposed for separately payable drugs and biologicals for CY 2015, as discussed in more detail in section V.B.3.b. of the proposed rule) to calculate the CY 2015 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2013 (data that were used for payment purposes in the physician's office setting, effective April 1, 2014) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2015, we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2013 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site) because these were the most recent data available for use at the time of development of the proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2014. 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 2013 hospital claims data to determine their per day cost.

We proposed to package items with a per day cost less than or equal to $90, and identify items with a per day cost greater than $90 as separately payable. Consistent with our past practice, we crosswalked historical OPPS claims data from the CY 2013 HCPCS codes that were reported to the CY 2014 HCPCS codes that we displayed in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site) for payment in CY 2015.

Comment: The majority of the commenters opposed the continuation of the OPPS packaging threshold of $90 for CY 2015. The commenters believed that, over the past 5 years, CMS has rapidly increased the packaging threshold, which contradicts Congressional intent. As such, the commenters recommended that CMS eliminate the packaging threshold and provide separate payment for all drugs with HCPCS codes or freeze the packaging threshold at the current level ($90).

Response: As stated in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68086), we believe that packaging certain items is a fundamental component of a prospective payment system, that updating the packaging threshold of $50 for the CY 2005 OPPS is consistent with industry and government practices, and that the PPI for Prescription Drugs is an appropriate mechanism to gauge Part B drug inflation. Therefore, because of our continued belief that packaging is a fundamental component of a prospective payment system that continues to provide important flexibility and efficiency in the delivery of high quality hospital outpatient services, we are not adopting commenters' recommendations to pay separately for all drugs, biologicals, and radiopharmaceuticals for CY 2015 or to eliminate the packaging threshold or to freeze the packaging threshold at $90.

Since publication of the CY 2015 OPPS/ASC proposed rule, consistent with our policy of updating the packaging threshold with more recently available data for this final rule with comment period, we have again followed the CY 2007 methodology for CY 2015 and used updated four quarter moving average PPI index levels provided by the CMS Office of the Actuary to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2015. We then rounded the resulting updated dollar amount ($93.48) to the nearest $5 increment, which yielded a figure of $95. Therefore, after consideration of the public comments we received, and consistent with our methodology for establishing the packaging threshold using the most recent PPI forecast data, we are adopting a CY 2015 packaging threshold of $95.

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 2015 OPPS/ASC final rule with comment period, we used ASP data from the first quarter of CY 2014, 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, 2014, along with updated hospital claims data from CY 2013. We note that we also used these data for budget neutrality estimates and impact analyses for this CY 2015 OPPS/ASC final rule with comment period.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B to this final rule with comment period are based on ASP data from the second quarter of CY 2014. These data are the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2014. These payment rates will then be updated in the January 2015 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2015. For items that do not currently have an ASP-based payment rate, we recalculated their mean unit cost from all of the CY 2013 claims data and updated cost report information available for this CY 2015 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 the CY 2015 OPPS/ASC proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for this CY 2015 OPPS/ASC final rule with comment period. Under such circumstances, we proposed 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 2015 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2014. Specifically, for CY 2015, consistent with our historical practice, we proposed 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 2014 and that were proposed for separate payment in CY 2015, and that then have per day costs equal to or less than the CY 2015 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2015 final rule, would continue to receive separate payment in CY 2015.
- HCPCS codes for drugs and biologicals that were packaged in CY 2014 and that were proposed for separate payment in CY 2015, and that then have per day costs equal to or less than the CY 2015 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2015 final rule, would remain packaged in CY 2015.
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2015 but then have per day costs greater than the CY 2015 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2015 final rule, would receive separate payment in CY 2015.

We did not receive any public comments on our proposal to apply 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 CY 2015 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2013. Therefore, we are finalizing our proposal, without modification, for CY 2015.

c. 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. The adoption of this policy, to package all drugs and biologicals that function as supplies when used in a surgical procedure, followed these packaging policies: (1) Packaging of medical and surgical supplies into the related procedure under 42 CFR 419.2(b)(4) (68 FR 18543); (2) packaging of implantable devices (68 FR 18444); and (3) packaging of implantable biologicals (73 FR 68634). As noted in the CY 2014 OPPS/ASC final rule with comment period, we believe these policies represented an example of a broader category of drugs and biologicals that should be packaged in the OPPS, that is, drugs and biologicals that function as supplies in a surgical procedure (78 FR 74930). 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 is $32 per cm². Skin substitutes that had a July 2013 ASP+6 percent amount above $32 per cm² were classified in the high cost group, and skin substitutes that had a July 2013 ASP+6 percent amount at or below $32 per cm² were classified in the low cost group. Any new skin substitutes without pricing information are assigned to the low cost category until pricing information is available to compare to the $32 per cm² threshold for CY 2014. Skin substitutes with pass-through payment status are 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), 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 cm²). Large size skin substitute products are primarily used for burns that are treated on an inpatient basis. These manufacturers contend that nonlinear pricing for skin substitute products sold in both large and small sizes results in lower per cm² 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 cm²) 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.

As stated in the CY 2015 OPPS/ASC proposed rule (79 FR 40998), we agree 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, we believe that establishing 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) may provide more stable high/low cost categories and will resolve the issue associated with large sized products because the MUC will be derived from hospital outpatient claims only. The threshold would be 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.

Therefore, in the CY 2015 OPPS/ASC proposed rule (79 FR 40999), we proposed to maintain the high cost/low cost APC structure for skin substitute procedures in CY 2015. However, we proposed to revise the current methodology used to establish the high cost/low cost threshold, and to establish the high cost/low cost threshold based on the weighted average MUC for all skin substitutes using CY 2013 claims (which was proposed to be $27 per cm²). Skin substitutes with an MUC above $27 per cm² using CY 2013 claims were proposed to be classified in the high cost group and those with an MUC at or below $27 per cm² were proposed to be classified in the low cost group. Table 39 of the CY 2015 OPPS/ASC proposed rule (79 FR 40999) showed the CY 2014 high cost/low cost status for each skin substitute product and the proposed CY 2015 high cost/low cost status based on the weighted average MUC threshold of $27. We proposed to continue the CY 2014 policy that skin substitutes with pass-through payment status would be assigned to the high cost category for CY 2015. Skin substitutes with pricing information but without claims data to calculate an MUC would be assigned to either the high or low cost category based on the product's ASP+6 percent payment rate. 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. We also proposed that any new skin substitute without pricing information be assigned to the low cost category until pricing information is available to compare to the CY 2015 threshold.

Comment: Several commenters supported CMS' proposal to revise the methodology used to establish the high cost/low cost threshold from an ASP-based methodology to a methodology based on the weighted average MUC for all skin substitutes using CY 2013 claims data. The commenters agreed that the MUC methodology would promote stability of assignments to the high and low cost categories and not disadvantage certain skin substitutes that are sold in especially large sizes.

Response: We appreciate the commenters' support.

Comment: Other commenters requested that CMS retain the ASP-based methodology for calculating the high cost/low cost threshold because, in their opinion, the ASP is a better metric for skin substitute costs than hospital outpatient claims data.

Response: We disagree with the assertion that ASP better represents the hospital costs for skin substitutes than hospital claims data. ASP is a blend of sales prices from a variety of purchasers, including various nonhospital entities. ASP also excludes a significant number of hospital sales, for example sales to 340B hospitals. Hospital claims data are specific to hospitals, and are used in assessing the costs of almost all other items and services in the OPPS, including other similar surgical supplies, such as implantable devices and implantable biologicals, which we package for payment purposes in the OPPS. Furthermore, as stated in the CY 2015 OPPS/ASC proposed rule (79 FR 40998), we believe that using MUC will better promote stability versus ASP for high and low cost category assignments for skin substitutes, because ASP can be set very high by skin substitute manufacturers and disproportionally impact the threshold calculation.

Comment: Two commenters recommended an alternative high cost/low cost threshold calculation methodology. Instead of basing the threshold on the unit cost the commenters urged CMS to calculate the high cost/low cost threshold based on the total skin substitute costs per

patient, per day, which is currently the mechanism used to set the general OPPS drug, biological, and radiopharmaceutical packaging threshold, which was proposed as $90 for CY 2015. These commenters believed that calculating the threshold cost per cm² does not accurately reflect the true cost of products as they are used clinically, and could result in displacing larger single-size skin substitutes approved through a Premarket Approval (PMA) into the low-cost skin substitute group beginning in CY 2016. They believed that this is partly a consequence of CMS' broad categorization of products as skin substitutes that, according to the commenters, includes 510(k)-cleared wound dressings and human cell, tissue, and cellular and tissue-based products (HCT/Ps) under section 361 of the Public Health Service Act (PHSA) (for example, cadaver skin or placental tissue). According to these commenters, manufacturers of products regulated through these processes can market different sizes of their skin substitutes with greater ease than can manufacturers of skin substitutes approved through a PMA, who must reapply for an updated label through the FDA to change or add a different product size. The commenters are concerned that a unit cost threshold may result in large products with lower per cm² costs, but with higher total costs per case, being assigned to the low cost category in the future. One of these commenters, although generally supportive of the change from an ASP-based methodology to an MUC-based methodology, also submitted a hypothetical predictive model comparing per unit high cost/low cost calculations with per day threshold calculations for the various skin substitutes and requested that CMS adopt a per day high cost/low cost calculation methodology beginning in CY 2016 to prevent their skin substitutes from moving from the high cost to the low cost group in CY 2016.

Response: As we explained in the CY 2014 OPPS/ASC final rule with comment period, the FDA treatment of the various skin substitutes does not affect how skin substitutes are treated under our policy of packaging drugs and biologicals that function as supplies in a surgical procedure (78 FR 74932 through 74933). The 61 skin substitutes listed in Table 34 below are available in many different sizes. Product sizing, product packaging, quantity per package, and other such individual product attributes are manufacturer business decisions that do not concern the agency. We also believe that the commenters' analogy between the general drug, biological, and radiopharmaceutical packaging threshold and the high cost/low cost skin substitute threshold is imperfect. Per day costs are used for the general drug, biological, and radiopharmaceutical packaging threshold because this threshold applies to the entire spectrum of drugs, biologicals, and radiopharmaceuticals, which have a wide variety of dosing units and dose descriptors, among others, such that per unit comparisons are not possible and therefore a total per day dollar amount is calculated. On the contrary, skin substitutes divided into the high and low cost categories are all dosed per cm², which is also the standard measurement for sizing wounds. Therefore, notwithstanding the various sizes of the 61 skin substitutes listed in Table 34, meaningful unit cost comparisons can be made for skin substitutes. As discussed earlier, we believe that the MUC methodology will help mitigate or eliminate the effect of high skin substitute ASPs on the high cost/low cost threshold. However, using a per day cost methodology as suggested by the commenters could adversely affect the majority of products that are tailored to the wound size. We will evaluate the per day cost methodology and compare it to the MUC methodology next year once CY 2014 claims data are available.

After consideration of the public comments we received, we are finalizing our proposal to maintain the high cost/low cost APC structure for skin substitute procedures in CY 2015, and our proposal to revise the current methodology used to establish the high/low cost threshold with the alternative MUC methodology. We also are finalizing for CY 2015 the policy that skin substitutes with pass-through payment status would be assigned to the high cost category. Skin substitutes with pricing information but without claims data to calculate an MUC will 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 will use WAC+6 percent or 95 percent of AWP to assign a product to either the high cost or low cost category. We also are finalizing our proposal 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. 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 OPPS update and designated as included in the high cost group, verifiable pricing information must be provided to CMS no later than April 15. Table 34 below shows the CY 2014 high cost/low cost status for each skin substitute product and the final CY 2015 high cost/low cost status based on the weighted average MUC threshold of $25, which decreased slightly from the proposed $27 threshold due to updated final rule claims data. Skin substitutes with an MUC above $25 are assigned to the high cost group for CY 2015. For 2014 there are 16 high cost skin substitutes and 27 low cost skin substitutes. For CY 2015, there are 62 skin substitute codes, which represent the following products: 30 high cost skin substitutes; 24 low cost skin substitutes; 7 powdered, liquid, or micronized skin substitutes; and 1 miscellaneous skin substitute code.

TABLE 34—SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS

CY 2015 HCPCS Code	CY 2015 Short descriptor	HCPCS Code dosage	CY 2015 SI	CY 2014 High/low status based on weighted ASP	CY 2015 High/low status based on weighted MUC
C9358	SurgiMend, fetal	0.5 cm²	N	Low	Low.
C9360	SurgiMend, neonatal	0.5 cm²	N	Low	Low.
C9363	Integra Meshed Bil Wound Mat	1 cm²	N	Low	High.
Q4100	Skin substitute, NOS	N/A	N	Low	Low.
Q4101	Apligraf	1 cm²	N	High	High.

TABLE 34—SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS—Continued

CY 2015 HCPCS Code	CY 2015 Short descriptor	HCPCS Code dosage	CY 2015 SI	CY 2014 High/low status based on weighted ASP	CY 2015 High/low status based on weighted MUC
Q4102	Oasis wound matrix	1 cm^2	N	Low	Low.
Q4103	Oasis burn matrix	1 cm^2	N	Low	Low.
Q4104	Integra BMWD	1 cm^2	N	Low	High.
Q4105	Integra DRT	1 cm^2	N	Low	High.
Q4106	Dermagraft	1 cm^2	N	High	High.
Q4107	Graftjacket	1 cm^2	N	High	High.
Q4108	Integra Matrix	1 cm^2	N	Low	High.
Q4110	Primatrix	1 cm^2	N	High	High.
Q4111	Gammagraft	1 cm^2	N	Low	Low.
Q4112	Cymetra injectable	1 cc	N	N/A	N/A.
Q4113	GraftJacket Xpress	1 cc	N	N/A	N/A.
Q4114	Integra Flowable Wound Matrix	1 cc	N	N/A	N/A.
Q4115	Alloskin	1 cm^2	N	Low	Low.
Q4116	Alloderm	1 cm^2	N	High	High.
Q4117	Hyalomatrix	1 cm^2	N	Low	Low.
Q4118	Matristem Micromatrix	1 mg	N	N/A	N/A.
Q4119	Matristem Wound Matrix	1 cm^2	N	Low	Low.
Q4120	Matristem Burn Matrix	1 cm^2	N	Low	Low.
Q4121	Theraskin	1 cm^2	G	High	High.
Q4122	Dermacell	1 cm^2	G	High	High.
Q4123	Alloskin	1 cm^2	N	Low	High.
Q4124	Oasis Tri-layer Wound Matrix	1 cm^2	N	Low	Low.
Q4125	Arthroflex	1 cm^2	N	High	High.
Q4126	Memoderm/derma/tranz/integup	1 cm^2	N	High	High.
Q4127	Talymed	1 cm^2	G	High	High.
Q4128	Flexhd/Allopatchhd/matrixhd	1 cm^2	N	Low	High.
Q4129	Unite Biomatrix	1 cm^2	N	Low	High.
Q4131	Epifix	1 cm^2	N	High	High.
Q4132	Grafix core	1 cm^2	N	High	High.
Q4133	Grafix prime	1 cm^2	N	High	High.
Q4134	HMatrix	1 cm^2	N	High	High.
Q4135	Mediskin	1 cm^2	N	Low	Low.
Q4136	EZderm	1 cm^2	N	Low	Low.
Q4137	Amnioexcel or Biodexcel, 1cm	1 cm^2	N	Low	High.
Q4138	BioDfence DryFlex, 1cm	1 cm^2	N	Low	High.
Q4139	Amniomatrix or Biodmatrix, 1cc	1 cc	N	N/A	N/A.
Q4140	Biodfence 1cm	1 cm^2	N	Low	High.
Q4141	Alloskin ac, 1 cm	1 cm^2	N	Low	Low.
Q4142	Xcm biologic tiss matrix 1cm	1 cm^2	N	Low	Low.
Q4143	Repriza, 1cm	1 cm^2	N	Low	Low.
Q4145	Epifix, 1mg	1 mg	N	N/A	N/A.
Q4146	Tensix, 1cm	1 cm^2	N	Low	Low.
Q4147	Architect ecm px fx 1 sq cm	1 cm^2	N	High	High.
Q4148	Neox 1k, 1cm	1 cm^2	N	High	High.
Q4149	Excellagen, 0.1 cc	0.1 cc	N	N/A	N/A.
Q4150	Allowrap DS or Dry 1 sq cm	1 cm^2	N	N/A	Low.
Q4151	AmnioBand, Guardian 1 sq cm	1 cm^2	N	N/A	Low.
Q4152	Dermapure 1 square cm	1 cm^2	N	N/A	Low.
Q4153	Dermavest 1 square cm	1 cm^2	N	N/A	Low.
Q4154	Biovance 1 square cm	1 cm^2	N	N/A	High.
Q4155	NeoxFlo or ClarixFlo 1 mg	1 mg	N	N/A	N/A.
Q4156	Neox 100 1 square cm	1 cm^2	N	N/A	High.
Q4157	Revitalon 1 square cm	1 cm^2	N	N/A	Low.
Q4158	MariGen 1 square cm	1 cm^2	N	N/A	Low.
Q4159	Affinity 1 square cm	1 cm^2	N	N/A	Low.
Q4160	NuShield 1 square cm	1 cm^2	N	N/A	High.
C9349	Fortaderm, fortaderm antimic	1 cm^2	G	N/A	High.

d. Pass-Through Evaluation Process for Skin Substitutes

At the beginning of the OPPS, skin substitutes were originally evaluated for pass-through status using the medical device pass-through process (65 FR 67839). Since mid-2001, skin substitutes have been evaluated for pass-through payment status through the drug, biological, and radiopharmaceutical pass-through payment process. In 2001, there were two distinct HCPCS codes describing skin substitutes. For the CY 2015 update, there are 61 distinct HCPCS codes describing skin substitutes (not including the not otherwise classified HCPCS code, Q4100), and of these 61 products, 18

products that are listed in Table 35 below have had, currently have, or will have pass-through payment status.

TABLE 35—SKIN SUBSTITUTES THAT HAVE HAD, CURRENTLY HAVE, OR WILL HAVE PASS-THROUGH PAYMENT STATUS

CY 2015 HCPCS code	CY 2015 short descriptor	Pass-through expiration date
C9358	SurgiMend, fetal	12/31/2010
C9360	SurgiMend, neonatal	12/31/2011
C9363	Integra Meshed Bil Wound Mat	12/31/2011
C9349	FortaDerm, FortaDerm Antimic	12/31/2017
Q4101	Apligraf	12/31/2002
Q4104	Integra BMWD	12/31/2006
Q4105	Integra DRT	12/31/2006
Q4106	Dermagraft	03/31/2005
Q4107	Graftjacket	12/31/2006
Q4108	Integra matrix	12/31/2010
Q4110	Primatrix	12/31/2008
Q4121	Theraskin	12/31/2016
Q4122	Dermacell	12/31/2015
Q4124	Oasis tri-layer wound matrix	12/31/2013
Q4127	Talymed	12/31/2015
Q4131	Epifix	12/31/2014
Q4132	Grafix core	12/31/2014
Q4133	Grafix prime	12/31/2014

As discussed earlier, and as we stated in the CY 2015 OPPS/ASC proposed rule (79 FR 40999 through 41001) and in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we packaged all skin substitutes not on pass-through payment status under the policy that packages all drugs and biologicals that function as supplies when used in a surgical procedure (78 FR 74938), because we consider skin substitutes to be a type of surgical supply in the HOPD. The adoption of the policy to package all drugs and biologicals that function as supplies when used in a surgical procedure, followed the packaging policies for implantable biologicals, implantable devices, and more broadly, the policy to package medical and surgical supplies into the related procedure under 42 CFR 419.2(b)(4). Further, as noted in the CY 2014 OPPS/ASC final rule with comment period, we believe these policies represented an example of a broader category of drugs and biologicals that should be packaged in the OPPS, that is, drugs and biologicals that function as supplies in a surgical procedure (78 FR 74930).

Separately, in the CY 2010 OPPS/ASC final rule with comment period, we finalized a policy to evaluate implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) for pass-through payment through the medical device pass-through evaluation process, because implantable biologicals function as implantable devices (74 FR 60473), which have historically been considered supplies in the OPPS (65 FR 18443), and have been evaluated for pass-through payment through the medical device pass-through evaluation process since CY 2010. As noted earlier, the finalized packaging policy in the CY 2014 OPPS/ASC final rule with comment period to package all drugs and biologicals that function as supplies when used in a surgical procedure included skin substitutes as a type of surgical supply, and, notably, the similarities between implantable biologicals and skin substitutes were a key factor in packaging (like we did beginning in 2009 with implantable biologicals) skin substitutes into the associated surgical procedure (78 FR 74932). We also note that many skin substitutes are FDA-approved or cleared as devices, even though skin substitutes have traditionally been treated as biologicals under the OPPS. The similarities between these classes of products (implantable devices, implantable biologicals, and skin substitutes) informed our proposal to similarly treat applications for pass-through payment for skin substitutes using the OPPS device pass-through process, described below.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41000), we proposed that applications for pass-through payment for skin substitutes be evaluated using the medical device pass-through process and payment methodology. As a result of this proposal, we proposed that the last skin substitute pass-through applications evaluated using the drug and biological pass-through payment evaluation process would be those with an application deadline of the first business date in September 2014, and an effective date of January 1, 2015. In light of this proposal, we would change the December 1, 2014 pass-through payment application deadline (for an effective date of April 1, 2015) for both drugs and biologicals and devices to January 15, 2015, in order to provide sufficient time for applicants to adjust to the new policies and procedures in effect as of January 1, 2015. Any applications submitted after the first business date in September 2014, through January 15, 2015, would be evaluated for the April 1, 2015 cycle. We believe that requiring skin substitutes seeking pass-through payment to use the OPPS device pass-through evaluation process is more appropriate because, although skin substitutes have characteristics of both surgical supplies and biologicals, we believe skin substitutes are best characterized as surgical supplies or devices because of their required surgical application and because they share significant clinical similarity with other surgical devices and supplies, including implantable biologicals. Therefore, we stated in the proposed rule that if this proposal is finalized, beginning with applications seeking pass-through payment effective April 1, 2014, new skin substitutes would no longer be eligible to submit biological pass-through applications; rather, such applications for pass-through payment would be evaluated using the medical device pass-through payment evaluation process, for which payment is based on charges reduced to cost from claims. We

refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/* to view the device pass-through payment application requirements and review criteria that would apply to the evaluation of all skin substitute product applications for pass-through payment status beginning on or after January 1, 2015. Those skin substitutes that are approved for pass-through payment status as biologicals effective on or before January 1, 2015, would continue to be paid as pass-through biologicals for the duration of their period of pass-through payment.

We also proposed to revise our regulations at §§ 419.64 and 419.66 to reflect this proposed new policy. Specifically, we proposed to revise § 419.64 by deleting the existing paragraph (a)(4)(iv) text because it is currently outdated and adding new text at paragraph (a)(4)(iv) to exclude skin substitutes from consideration for drug and biological pass-through payment. We proposed to modify the regulation at § 419.66(b)(3) to add that a pass-through device may be applied in or on a wound or other skin lesion, and we proposed to simplify the language that ''whether or not it remains with the patient when the patient is released from the hospital'' to read ''either permanently or temporarily.'' We also proposed to delete the current example in § 419.66(b)(4)(iii) of the regulations regarding the exclusion of materials, for example, biological or synthetic materials, that may be used to replace human skin from device pass-through payment eligibility. We invited public comment on these proposals.

Comment: Several commenters supported CMS' proposal to evaluate skin substitute pass-through applications through the medical device pass-through process and pay for pass-through skin substitutes according to the medical device pass-through payment methodology beginning January 1, 2015. The commenters believed that this policy change will limit instability in the high cost/low cost groups from pass-through skin substitutes with very high ASPs. The commenter stated that instability could occur because manufacturers set ASP and hospitals are relatively insensitive to price for separately paid pass-through skin substitutes. Therefore, the commenter added, a new high priced pass-through skin substitute could gain significant sales and move the high cost/low cost threshold significantly higher from year to year.

Response: We agree with the commenters and appreciate their support.

Comment: Several commenters opposed CMS' proposal to evaluate skin substitute pass-through applications through the medical device pass-through process. Some of these commenters argued that CMS lacks the authority to change the process for evaluating skin substitute pass-through applications. The commenters also believed that biologicals approved by the FDA under section 351 of the PHSA (those approved by the FDA under biologics license applications (BLAs)) cannot be treated as devices for pass-through payment evaluation purposes according to the Social Security Act and Congressional intent. The commenters also claimed that changing the pass-through payment process for skin substitutes will stifle innovation of new wound care products.

Response: We disagree with the commenters' assertion that the agency lacks the authority to change the process for evaluating skin substitutes for pass-through and that biologicals approved by the FDA under section 351 of the PHSA (BLA process) cannot be treated as devices for pass-through payment evaluation purposes according to the Social Security Act and Congressional intent. As we stated in the 2010 OPPS final rule in response to a similar comment on the proposal to change the pass-through evaluation process for implantable biologicals: ''We do not agree with the commenters who asserted that Congress intended biologicals approved under BLAs to be paid under the specific OPPS statutory provisions that apply to SCODs, including the pass-through provisions'' (74 FR 60476). Similarly, Congress did not specify that we must pay for skin substitutes as separately payable biologicals rather than devices or supplies, if they also meet our criteria for payment as a device. We believe that skin substitutes can satisfy the definitions applied under the OPPS of a device or supply and a biological and that, for OPPS payment purposes, it is appropriate for us to consider skin substitutes as devices or supplies under both pass-through and nonpass-through payment policies, and not as separately payable biologicals. For example, beginning in CY 2014, we package the costs of skin substitutes into the costs of the surgical procedures in which they are used, as we do for implantable biologicals and other implantable devices. Therefore, we do not believe that we must pay for skin substitutes under our OPPS payment methodologies for separately payable biologicals, rather than our device payment methodologies.

In addition, for the skin substitute packaging policy, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74933), we stated the following: ''We do not believe that the FDA approval process should exempt products from this packaging proposal or factor into the level of Medicare payment.'' Similarly, regarding our proposal to change the pass-through payment evaluation process and payment methodology for skin substitutes from the drug and biological process to the device process, we also believe that any particular FDA approval process should not exempt such products that appropriately fall under the category of skin substitutes under the OPPS from the application of this pass-through payment proposal or direct which pass-through payment evaluation process must be used.

Notably, none of the current 61 skin substitute products described by distinct HCPCS codes and listed in Table 35 above have been approved by FDA under section 351 of the PHSA. This fact is somewhat counterintuitive, as biologics or biologicals or biological products are most commonly understood to be products approved by the FDA under section 351 of the PHSA. Current skin substitute products' FDA classifications include a variety of Class III medical devices, Class II medical devices, and HCT/Ps under section 361 of the PHSA, which are tissue bank materials not subject to FDA approval requirements. We also note that whether a future wound healing product is described by the OPPS packaged category of products described in 42 CFR 419.2(b)(16) as ''skin substitutes and similar products that aid wound healing'' will depend upon the particular characteristics of the future product. We do not intend for the category of products described as ''skin substitutes and similar products that aid wound healing'' to necessarily include all products with a wound healing indication. However, if a new wound healing product, regardless of FDA approval or clearance type, fits with the ''skin substitutes and similar products that aid wound healing'' category of products, all of the applicable OPPS policies that apply to ''skin substitutes and similar products that aid wound healing'' would also apply to the new wound healing product.

Finally, we do not believe that this policy will stifle innovation of new skin substitutes, as new skin substitutes that can demonstrate a substantial clinical improvement over current wound treatments could receive pass-through

status as a device. In addition, there are currently 61 distinct HCPCS codes for various skin substitutes. Of these 61 products, only 18 (30 percent) have had, currently have, or will have pass-through payment status granted through the drug and biological pass-through payment process. Therefore, pass-through payment does not appear to be necessary for the commercialization of these products, which have (in terms of distinct HCPCS codes describing them) expanded significantly from 2 skin substitutes in CY 2001 to 61 skin substitutes in CY 2015. Furthermore, we have not restricted access to the high cost skin substitute group, and we have only required manufacturers of new skin substitutes to submit pricing information for assignment to the high cost group of skin substitutes. For these reasons, we do not believe that any CMS OPPS payment policies will stifle innovation or impede the development of new skin substitutes.

Comment: One commenter was concerned that the substantial clinical improvement criterion for medical device pass-through places an unduly high burden on new skin substitute products. The commenter believed that this requirement is ''incompatible with skin substitute products, which are not required to submit efficacy data to the Food and Drug Administration.'' This commenter also disagreed with CMS' proposal to not accept any skin substitute applications though the drug and biological pass-through payment process after September 1, 2014, and to move the final pass-through payment deadline for drug and biologicals and devices from December 1, 2014, to January 15, 2015. The commenter requested that additional guidance on substantial clinical improvement be provided specifically for application to skin substitute products, beyond that described in the November 2, 2001, interim final rule with comment period entitled ''Medicare Program—Prospective Payment System for Hospital Outpatient Services: Criteria for Establishing Additional Pass-Through Categories for Medical Devices'' (66 FR 55850).

Response: The comment that FDA does not require submission of efficacy data for skin substitute products is overly simplified. The different skin substitute products that have been identified in Table 35 above are subject to different FDA regulatory requirements (that is, based on review by CBER versus CDRH, regulatory classification and claims).

FDA/CDRH draws a distinction between wound dressing devices intended only to serve as a wound covering versus products intended to promote wound healing. Those devices that are intended to promote wound healing are subject to Premarket Approval (PMA) and require clinical data to support safety and effectiveness of the device. Those devices that are intended to serve as a wound covering are subject to Premarket Notification (510(k)) and require demonstration of substantial equivalence (that is, the device demonstrates that it is as safe and effective as a legally marketed predicate device). Generally, substantial equivalence in safety and effectiveness is demonstrated through comparative bench and animal studies and leveraged with historical clinical effectiveness data for similar devices. The weakness of the evidence for many skin substitute products has been documented in two recent technology assessments by the Agency for Healthcare Research and Quality. However, different pre-market data requirements for skin substitute products regulated by FDA should not excuse these products from the substantial clinical improvement pass-through criterion for device pass-through payment. Pass-through payment status is not intended to be granted to every new product, but only to those that satisfy the pass-through payment requirements. As stated in the CY 2001 OPPS interim final rule: ''We believe 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, the need for additional payments for devices that offer little or no clinical improvement over a previously existing device is less apparent'' (66 FR 55852).

Regarding the requirements for satisfying the substantial clinical improvement criterion, we believe that the list on page 55852 of the CY 2001 OPPS interim final rule suffices. For example, among the items listed is: ''More rapid beneficial resolution of the disease process treated because of the use of the device.'' If a new skin substitute demonstrated improved wound healing compared to existing wound treatments, it could potentially qualify for pass-through as a medical device, assuming that the skin substitute is not described by an expired pass-through payment device category.

Finally, we believe that sufficient notice was provided of this policy change in the CY 2015 OPPS/ASC proposed rule, and that accepting drug and biological applications through the first business date of September 2014 deadline for a January 1, 2015 pass-through payment effective date is a fair application of a policy that takes effect on January 1, 2015. The regular December 1, 2014 application deadline, which is being extended to January 15, 2015 for this cycle, was for pass-through payment applications with an earliest effective date of April 1, 2015, which is well past the effective date of this new policy.

After consideration of the public comments we received, we are finalizing our proposal for applications seeking pass-through payment for skin substitute and similar wound healing products effective beginning April 1, 2015, to apply using the medical device pass-through evaluation process.

e. 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, in the CY 2015 OPPS/ASC proposed rule (79 FR 41001), we proposed 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 2015.

For CY 2015, 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 2013 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 2015 OPPS/ASC final rule with comment period and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the fourth quarter CY 2013 claims data to make the 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 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 $95 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than $95 (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 was displayed in Table 41 of the CY 2015 OPPS/ASC proposed rule (79 FR 41001 through 41002).

We did not receive any public comments on this proposal. Therefore, we are finalizing our CY 2015 proposal, without modification, to continue 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. Table 36 below displays the packaging status of each drug and biological HCPCS code to which the methodology applies for CY 2015.

TABLE 36—HCPCS CODES TO WHICH THE CY 2015 DRUG–SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2015 HCPCS code	CY 2015 long descriptor	CY 2015 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	N
J1441	Injection, filgrastim (g-csf), 480 mcg	N
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
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

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

a. 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 the CY 2015 OPPS/ASC proposed rule (79 FR 41002), we proposed 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).

b. CY 2015 Payment Policy

In the CY 2015 OPPS/ASC proposed rule (79 FR 41003), we proposed to continue our CY 2014 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 proposed 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 proposed 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.

Comment: Commenters supported CMS' proposal to pay for separately payable drugs and biologicals based on the statutory default rate of ASP+6 percent. A few commenters supported CMS' proposal, but recommended that CMS examine ways to compensate hospitals for the unique, higher overhead and handling costs associated with therapeutic radiopharmaceuticals.

Response: We appreciate the commenters' support of our proposal. We continue to believe that ASP+6 percent based on the statutory default is appropriate for hospitals for CY 2015 and that this percentage amount includes payment for acquisition and overhead cost. We see no evidence that an additional overhead adjustment is required for separately payable drugs, biologicals, and therapeutic radiopharmaceuticals for CY 2015.

After consideration of the public comments we received, we are finalizing our proposal, without modification, 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). 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 for CY 2015. In addition, we are finalizing our proposal which states that payment for separately payable drugs and biologicals be included in the budget neutrality adjustments, under the requirements of section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payment of these separately paid drugs and biologicals. We note that separately payable drug and biological payment rates listed in Addenda A and B to this final rule with comment period (available via the Internet on the CMS Web site), which illustrate the final CY 2015 payment of ASP+6 percent for separately payable nonpass-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 October 1, 2014, or WAC, AWP, or mean unit cost from CY 2013 claims data and updated cost report information available for this final rule with comment period. In general, these published payment rates are not reflective of actual January 2015 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2015 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of 2014 (July 1, 2014 through September 30, 2014) are used to set the payment rates that are released for the quarter beginning in January 2015 near the end of December 2014. In addition, payment rates for drugs and biologicals in Addenda A and B to this final rule with comment period for which there was no ASP information available for October 2014 are based on mean unit cost in the available CY 2013 claims data. If ASP information becomes available for payment for the quarter beginning in January 2015, 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 final rule with comment period (reflecting October 2014 ASP data) that do not have ASP information available for the quarter beginning in January 2015. These drugs and biologicals will then be paid based on mean unit cost data derived from CY 2013 hospital claims. Therefore, the payment rates listed in Addenda A and B to this final rule with comment period are not for January 2015 payment purposes and are only illustrative of the CY 2015 OPPS payment methodology using the most recently available information at the time of issuance of this final rule with comment period.

4. Payment Policy for Therapeutic Radiopharmaceuticals

Beginning in CY 2010 and continuing for CY 2014, 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 2015. Therefore, in the CY 2015 OPPS/ASC proposed rule (79 FR 41003), we proposed for CY 2015 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 proposed to rely on CY 2013 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 2015 payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals were included in Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site).

Comment: Several commenters supported CMS' proposal to pay for separately payable therapeutic radiopharmaceuticals under the statutory default payment rate of ASP+6 percent, if ASP data are submitted to CMS.

Response: We appreciate the commenters' support. We continue to believe that providing payment for therapeutic radiopharmaceuticals based on ASP or mean unit cost if ASP information is not available would provide appropriate payment for these products. When ASP data are not available, we believe that paying for therapeutic radiopharmaceuticals using mean unit cost will appropriately pay for the average hospital acquisition and associated handling costs of nonpass-through separately payable therapeutic radiopharmaceuticals. As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60523), although using mean unit cost for payment for therapeutic radiopharmaceuticals when ASP data are not available is not the usual OPPS process (the usual process relies on alternative data sources such as WAC or AWP when ASP information is temporarily unavailable, prior to defaulting to the mean unit cost from hospital claims data), we continue to believe that WAC or AWP is not an appropriate proxy to provide OPPS payment for average therapeutic radiopharmaceutical acquisition cost and associated handling costs when manufacturers are not required to submit ASP data. Payment based on WAC or AWP under the established OPPS methodology for payment of separately payable drugs and biologicals is usually temporary for a calendar quarter until a manufacturer is able to submit the required ASP data in accordance with the quarterly ASP submission timeframes for reporting under section 1847A of the Act. Because ASP reporting for OPPS payment of separately payable therapeutic radiopharmaceuticals is not required, a manufacturer's choice to not submit ASP could result in payment for a separately payable therapeutic radiopharmaceutical based on WAC or AWP for a full year, a result that we believe would be inappropriate.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent. We also are finalizing our proposal to continue to rely on CY 2013 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable. The CY 2015 final rule payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site).

5. 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).

Comment: A few commenters requested that CMS extend payment for HCPCS code Q9969 an additional 3 to 5 years to ensure adequate data are collected and provide a longer ramp up period for more widespread use of non-HEU materials since they are not yet widely available. One commenter believed that the $10 payment is not sufficient and requested that CMS increase the payment rate. This commenter also requested that CMS eliminate the copayment.

Response: 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. We have reassessed this payment for CY 2015 and have not identified any new information that would cause us to modify payment at this time. We do not agree with the commenter's suggestion to eliminate the beneficiary's copayment because section 1833(t)(8) of the Act and §§ 419.41 through 419.45 of the regulations require a beneficiary copayment. We are continuing the policy of providing an additional $10 payment for radioisotopes produced by non-HEU sources for CY 2015. 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.

6. Payment for Blood Clotting Factors

For CY 2014, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee. That is, for CY 2014, 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 2014 updated furnishing fee was $0.192 per unit.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41003), for CY 2015, we proposed 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 was based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending in 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 were 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 proposed 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*.

Comment: Commenters supported CMS' proposal to continue to apply the furnishing fee for blood clotting factors provided in the OPD. The commenters also supported CMS' proposal to pay for separately payable drugs at ASP+6 percent based on the statutory default for CY 2015.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS Web site.

7. Payment for Nonpass-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 2014, 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 nonpass-through drugs and biologicals for the given year.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41004), for CY 2015, we proposed 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 2015 payment methodology for other separately payable nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals, which was proposed to be ASP+6 percent. 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 2015, we are also continuing to package payment for all new nonpass-through policy-packaged products (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) with HCPCS codes but without claims data (those new CY 2015 HCPCS codes that do not crosswalk to predecessor HCPCS codes). This is consistent with the CY 2014 finalized policy packaging proposal of 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 final rule with comment period.

In accordance with the OPPS ASP methodology, in the absence of ASP data, for CY 2015, we proposed 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 proposed 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 proposed 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 2015 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 proposed 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 proposed 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 proposed with new drugs and biologicals, we proposed 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 2015, we proposed to announce any changes to the payment amounts for new drugs and biologicals in this CY 2015 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2015 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 2015 HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals were not available at the time of development of the proposed rule. However, these agents are included in Addendum B to this CY 2015 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site), where they are assigned comment indicator ''NI.'' This comment indicator reflects that their interim final OPPS treatment is open to public comment in this CY 2015 OPPS/ASC final rule with comment period.

There are several nonpass-through drugs and biologicals that were payable in CY 2013 and/or CY 2014 for which we did not have CY 2013 hospital claims data available for the 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 2015, we proposed 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 nonpass-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 one 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 proposed to package items for which we estimated the per day administration cost to be less than or equal to $90 (although, as mentioned in section V.B.2. of this final rule with comment period, we are finalizing a packaging threshold of $95 for CY 2015) and to pay separately for items for which we estimated the per day administration cost to be greater than $90 (with the exception of 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, which we proposed to continue to package regardless of cost) in CY 2015. We also proposed that the CY 2015 payment for separately payable items without CY 2013 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 proposed 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 were displayed in Table 42 of the proposed rule (79 FR 41005).

Finally, there were 35 drugs and biologicals, shown in Table 43 of the proposed rule (79 FR 41005 through 41006), that were payable in CY 2013 but for which we lacked CY 2013 claims data and any other pricing information for the ASP methodology for the CY 2015 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 2015, as we finalized in CY 2014 (78 FR 75031), we proposed to continue to assign status indicator ''E'' to drugs and biologicals that lack CY 2013 claims data and pricing information for the ASP methodology. All drugs and biologicals without CY 2013 hospital claims data or data based on the ASP methodology that were assigned status indicator ''E'' on this basis at the time of the proposed rule for CY 2015 were displayed in Table 43 of the proposed rule (79 FR 41005 through 41006). We also proposed to continue our policy to assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2015 if pricing information becomes available.

We did not receive any specific public comments regarding our proposed payment for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes, but without OPPS hospital claims data. Many commenters supported our proposal to pay for separately payable drugs at ASP+6 percent under the statutory default. However, these comments were not specific to new drugs and biologicals with HCPCS codes but without OPPS claims data.

After consideration of the public comments we received, we are finalizing our CY 2015 proposal without modification, including our proposal to assign drug or biological products status indicator ''K'' and pay for them separately for the remainder of CY 2015 if pricing information becomes available. The final estimated units per day and status indicators for drugs and biologicals without CY 2013 claims data are displayed in Table 37 below.

We did not receive any public comments on our proposal to continue to assign status indicator ''E'' to drugs and biologicals that lack CY 2013 claims data and pricing information for the ASP methodology and, therefore, we are finalizing this proposal without modification. All drugs and biologicals without CY 2013 hospital claims data and without pricing information for the ASP methodology that are assigned status indicator ''E'' on this basis at the time of this final rule with comment period for CY 2015 are displayed in Table 38 below.

TABLE 37—DRUGS AND BIOLOGICALS WITHOUT CY 2013 CLAIMS DATA

CY 2015 HCPCS code	CY 2015 long descriptor	Estimated average number of units per day	CY 2015 SI	CY 2015 APC
90581	Anthrax vaccine, for subcutaneous or intramuscular use	1	K	1422
J0215	Injection, alefacept, 0.5 mg	29	K	1633
J0365	Injection, aprotonin, 10,000 kiu	1	N	1439
J0630	Injection, calcitonin salmon, up to 400 units	2	K	1433
J2670	Injection, tolazoline hcl, up to 25 mg	1	N	1457
J3355	Injection, urofollitropin, 75 iu	2	K	1741
J7196	Injection, antithrombin recombinant, 50 IU	268	K	1332
J7505	Muromonab-cd3, parenteral, 5 mg	1	N	7038
J7513	Daclizumab, parenteral, 25 mg	1	N	1612
J8650	Nabilone, oral, 1 mg	4	K	1424
J9151	Injection, daunorubicin citrate, liposomal formulation, 10 mg	10	K	0821
J9215	Injection, interferon, alfa-n3, (human leukocyte derived), 250,000 iu	1	N	1473
J9300	Injection, gemtuzumab ozogamicin, 5 mg	1	K	9004

TABLE 38—DRUGS AND BIOLOGICALS WITHOUT CY 2013 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

CY 2015 HCPCS code	CY 2015 long descriptor	CY 2015 SI
90296	Diphtheria antitoxin, equine, any route	E
90393	Vaccina immune globulin, human, for intramuscular use	E
90477	Adenovirus vaccine, type 7, live, for oral use	E
90644	Meningococcal conjugate vaccine, serogroups c & y and hemophilus influenza b vaccine (hib-mency), 4 dose schedule, when administered to children 2–15 months of age, for intramuscular use.	E
90681	Rotavirus vaccine, human, attenuated, 2 dose schedule, live, for oral 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
J0364	Injection, apomorphine hydrochloride, 1 mg	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
J1562	Injection, immune globulin (vivaglobin), 100 mg	E
J1620	Injection, gonadorelin hydrochloride, per 100 mcg	E
J1655	Injection, tinzaparin sodium, 1000 iu	E
J1730	Injection, diazoxide, up to 300 mg	E
J1835	Injection, itraconazole, 50 mg	E
J2460	Injection, oxytetracycline hcl, up to 50 mg	E
J2513	Injection, pentastarch, 10% solution, 100 ml	E
J2725	Injection, protirelin, per 250 mcg	E
J2670	Injection, tolazoline hcl, up to 25 mg	E
J2725	Injection, protirelin, per 250 mcg	E
J2940	Injection, somatrem, 1 mg	E
J3305	Injection, trimetrexate glucuronate, per 25 mg	E
J3365	Injection, iv, urokinase, 250,000 i.u. vial	E
J3400	Injection, triflupromazine hcl, up to 20 mg	E
J8562	Fludarabine phosphate, oral, 10 mg	E
J9165	Injection, diethylstilbestrol diphosphate, 250 mg	E
J9212	Injection, interferon alfacon-1, recombinant, 1 microgram	E
J9219	Leuprolide acetate implant, 65 mg	E
Q0174	Thiethylperazine maleate, 10 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an iv anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.	E
Q0515	Injection, sermorelin acetate, 1 microgram	E

VI. 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 2015 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 2015. 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 beginning in CY 2015. The sum of the CY 2015 pass-through estimates for these two groups of device categories equals the total CY 2015 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 the CY 2015 OPPS/ASC proposed rule (79 FR 41007), for CY 2015, we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. We also proposed that, beginning in CY 2015, applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology. We proposed that the last skin substitute pass-through applications evaluated using the drugs and biologicals pass-through evaluation process would be those with an application deadline of September 1, 2014, and an earliest effective date of January 1, 2015. Therefore, in light of this proposal, we proposed to change the December 1, 2014 pass-through application deadline (for an earliest effective date of April 1, 2015) for both drugs and biologicals and devices to January 15, 2015, in order to provide sufficient time for applicants to adjust to the new policies and procedures that will be in effect as of January 1, 2015. We discuss our proposal to change the pass-through evaluation process for skin substitutes and address comments to this proposal and the proposal to change the April 1, 2015 pass-through effective date application deadline in section V.B.2.d. of this final rule with comment period, where we explain that we are finalizing this proposal. Therefore, beginning in CY 2015, we will include an estimate of any skin substitutes eligible for pass-through payment in our estimate of pass-through spending for devices.

We did not receive any public comments on our proposed methodology or proposed estimate for pass-through spending for devices. Therefore, we are finalizing our proposal to base the pass-through estimate for devices on our established methodology, as described above. Moreover, we are finalizing our proposal, beginning in CY 2015 and in future years, to include an estimate of any skin substitutes eligible for pass-through payment 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 reinstated for CY 2015. Because, as we proposed, we will pay for most nonpass-through separately payable drugs and biologicals under the CY 2015 OPPS at ASP+6 percent, as we discuss in section V.B.3. of the proposed rule and this final rule with comment period, which represents the otherwise applicable fee schedule amount associated with most pass-through drugs and biologicals, and because, as we proposed, we will pay for CY 2015 pass-through drugs and biologicals at ASP+6 percent, as we discuss in section V.A. of the proposed rule and this final rule with comment period, our estimate of drug and biological pass-through payment for CY 2015 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 final rule with comment period. In the CY 2015 OPPS/ASC proposed rule (79 FR 41007), we proposed 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 2015. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through status approved prior to CY 2015 is not $0. In section V.A.4. of this final rule with comment period, we discuss our

proposed and finalized 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 proposed 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 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 2015. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, beginning in CY 2015. The sum of the CY 2015 pass-through estimates for these two groups of drugs and biologicals equals the total CY 2015 pass-through spending estimate for drugs and biologicals with pass-through status.

B. Estimate of Pass-Through Spending

In the CY 2015 OPPS/ASC proposed rule (79 FR 41007), we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2015, consistent with section 1833(t)(6)(E)(ii)(II) of the Act, and our OPPS policy from CY 2004 through CY 2014 (78 FR 75034 through 75036).

For the first group of devices for pass-through payment estimation purposes, there is one device category, HCPCS code C1841 (Retinal prosthesis, includes all internal and external components), eligible for pass-through payment as of October 1, 2013, continuing to be eligible for CY 2014, and that will continue to be eligible for pass-through payment for CY 2015. Based on the one device category, HCPCS code C1841, we are finalizing our proposed rule estimate for the first group of devices of $0.5 million.

In estimating our CY 2015 pass-through spending for device categories in the second group, we include: Device categories that we knew at the time of the development of the final rule will be newly eligible for pass-through payment in CY 2015; additional device categories that we estimate could be approved for pass-through status subsequent to the development of the final rule and before January 1, 2015; and contingent projections for new device categories established in the second through fourth quarters of CY 2015. We proposed 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 the proposed rule, the estimate of CY 2015 pass-through spending for this second group of device categories was $10.0 million. We did not receive any public comments regarding our proposed pass-through estimate for devices. We are establishing one new device category subsequent to the publication of the proposed rule, HCPCS code C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components), that will be effective January 1, 2015. We estimate that HCPCS code C2624 will cost $50.5 million in pass-through expenditures in CY 2015. Therefore, for this CY 2015 OPPS/ASC final rule with comment period, the estimate of CY 2015 pass-through spending for this second group of device categories is $60.5 million.

To estimate CY 2015 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 2015, we proposed to utilize 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 2015 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 2015, 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 proposed to include in the CY 2015 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 the proposed rule, using the methodology described above, we calculated a CY 2015 proposed spending estimate for this first group of drugs and biologicals of approximately $2.8 million.

We did not receive any public comments on our proposed methodology for calculating for calculating the spending estimate for the first group of drugs and biologicals.

For this final rule with comment period, using the methodology described above, we calculated a final CY 2015 spending estimate for this first group of drugs and biologicals of approximately $11.7 million.

To estimate proposed CY 2015 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we know are newly eligible, or project will be newly eligible, beginning in CY 2015), in the CY 2015 OPPS/ASC proposed rule (79 FR 41008), we proposed 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 2015 pass-through payment estimate. We also proposed to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2015 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 $2.2 million.

We did not receive any public comments on our proposed methodology for calculating for

calculating the spending estimate for the second group of drugs and nonimplantable biologicals.

For this final rule with comment period, using our finalized methodology for estimating CY 2015 pass-through payments for this second group of drugs, we calculated a spending estimate for this second group of drugs and biologicals of approximately $10.1 million. Our CY 2015 estimate for total pass-through spending for drugs and biologicals (spending for the first group of drugs and biologicals ($11.7 million) plus spending for the second group of drugs and biologicals ($10.1 million)) equals $21.8 million.

In summary, in accordance with the methodology described above in this section, for this final rule with comment period, we estimate that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2015 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2015 will be approximately $82.8 million (approximately $61.0 million for device categories and approximately $21.8 million for drugs and biologicals), which represents 0.15 percent of total projected OPPS payments for CY 2015. Therefore, we estimate that pass-through spending in CY 2015 will not amount to 2.0 percent of total projected OPPS CY 2015 program spending.

VII. OPPS Payment for Hospital Outpatient Visits

A. Payment for Hospital Outpatient Clinic and Emergency Department Visits

Since April 7, 2000, we have instructed hospitals to report facility resources for clinic and 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.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75045), we finalized a new policy which created an 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 new APC 0634. 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.

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.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41008 through 41009), for CY 2015, we proposed 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. We proposed to continue to assign HCPCS code G0463 to APC 0634. We proposed to use CY 2013 claims data to develop the CY 2015 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 currently recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). Finally, as we established in the CY 2014 OPPS/ASC final rule with comment period, there is no longer a policy to recognize a distinction between new and established patient clinic visits.

Comment: Commenters requested that CMS discontinue the single HCPCS G-code for reporting clinic visits and return to a reporting structure that recognizes differences in clinical acuity and resource utilization. The commenters expressed concern that CMS' clinic visit coding proposal creates a payment bias that unfairly penalizes certain providers, such as trauma centers, cancer hospitals, and major teaching hospitals, which provide care for more severely ill Medicare beneficiaries. One commenter urged CMS to carefully review its ratesetting process for HCPCS code G0463 to ensure that claims containing packaged services that are intended to be part of the hospital clinic rates are not being excluded from the payment computations, thereby creating artificially low rates. Another commenter recommended that CMS work with the American Medical Association (AMA) to develop facility-specific CPT codes for E/M clinic visits (with no distinction between new and established patients) and seek input from industry stakeholders to develop descriptions for these new codes that allow for their consistent application by hospital outpatient clinics/facilities.

Response: We believe that the spectrum of hospital resources provided during an outpatient hospital clinic visit is appropriately captured and reflected in the single level payment for clinic visits. We also believe that the single visit code is consistent with a prospective payment system, where payment is based on an average estimated relative cost for the service, although the cost of individual cases may be more or less costly than the average. We believe the proposed payment rate for APC 0634 represents an appropriate payment for clinic visits, as it is based on the geometric mean costs of all visits. Although the cost for any given clinic visit may be higher or lower than the geometric mean cost of APC 0634, the payment remains appropriate to the hospital delivering a variety of clinic visits. The high volume of claims from every level of clinic CPT code that we used for ratesetting for HCPCS code G0463 allows us to have accurate data upon which to develop appropriate payment rates.

With regard to specific concerns for hospitals that treat patients with a more

complex case-mix, we note that the relatively low estimated cost of clinic visits overall would result in much less underpayment or overpayment for hospitals that may serve a population with a more complex case-mix. As we stated in the CY 2015 OPPS/ASC proposed rule (79 FR 41008), we proposed to use CY 2013 claims data to develop the CY 2015 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 currently recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). We note that claims containing packaged services that are intended to be part of the hospital clinic rates are not excluded from payment computations for HCPCS code G0463, consistent with our application of our line-item trim as described in section II.A.2.a. of this final rule with comment period. The line-item trim described in section II.A.2.a. of this final rule with comment period requires the lines to be eligible for payment in both the claims year and the prospective years. Therefore, the lines that would be packaged when modeling clinic visits would not be subject to this trim. For a more detailed discussion of the OPPS data process, we refer readers to section II.A. of this final rule with comment period.

With regard to the potential for facility-specific CPT codes, as we have stated in the past (76 FR 74346), if the AMA were to create facility-specific CPT codes for reporting visits provided in HOPDs (based on internally developed guidelines), we would consider such codes for OPPS use.

After consideration of the public comments we received, we are finalizing our CY 2015 proposal, without modification, to continue to use HCPCS code G0463 (for hospital use only) to represent any and all clinic visits under the OPPS for CY 2015. In addition, for CY 2015 we are finalizing our proposals, without modification, to continue to assign HCPCS code G0463 to APC 0634 and to use CY 2013 claims data to develop the CY 2015 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 currently recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215).

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. In the CY 2015 OPPS/ASC proposed rule, we did not propose any change in ED visit coding. Rather, for CY 2015, we proposed to 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 CY 2015 proposed OPPS payment rates using our established standard process. We stated that we intend to further explore the issues described above related to ED visits, including concerns about excessively costly patients, such as trauma patients. We also stated that we may propose changes to the coding and APC assignments for ED visits in future rulemaking.

Comment: Commenters supported CMS' proposal to continue its current methodology to recognize the existing five CPT codes for Type A ED visits, as well as the five HCPCS codes for Type B ED visits, and to establish the associated CY 2015 OPPS payment rates using its standard process. Commenters commended CMS for proceeding with caution and agreed that additional study is needed on the appropriate payment structure for ED visits. Commenters also expressed their desire to work with CMS on a future policy proposal to create an appropriate payment structure for ED visits. Some commenters stated that one level of hospital ED payment is not appropriate for the various levels of resources required in ED visits, especially at major teaching hospitals, and expressed concern that a single level of ED visit payment would create a payment bias that would unfairly penalize certain providers, such as trauma centers and major teaching hospitals, which provide care for more severely ill Medicare beneficiaries. One commenter requested that CMS continue with its current ED visit payment policy for the foreseeable future and no longer attempt to make future changes to the policy in the coming years. Another commenter recommended that CMS work with the AMA to develop facility-specific CPT codes for Type A ED visits and Type B ED visits and seek input from industry stakeholders to develop descriptions for these new codes that allow for their consistent application by hospital outpatient clinics/facilities.

Response: We appreciate the commenters' support of our proposal to continue the current coding structure for ED visits while we continue to study the most appropriate payment structure for Type A and Type B ED visits. As discussed above, we received multiple comments that a single payment for an ED visit might underrepresent resources required to treat the most complex patients, such as trauma patients. As we have stated before (78 FR 75040), considering this issue requires additional study. As we continue to give additional study to this issue, we continue to welcome stakeholder input on the particular number of visit levels that would not underrepresent resources required to treat the most complex patients, such as trauma patients.

With regard to the potential for facility-specific CPT codes, as we have also stated in the past (76 FR 74346), if the AMA were to create facility-specific CPT codes for reporting visits provided in HOPDs (based on internally developed guidelines), we would consider such codes for OPPS use.

Comment: One commenter recommended, on a short-term basis, that CMS develop a set of three trauma-specific HCPCS codes for all trauma patients, for whom a trauma team is activated.

Response: We appreciate the alternative presented by the commenter. We will take this recommendation into consideration as we continue to study and fully consider the most appropriate payment structure for Type A and Type B ED visits.

After consideration of the public comments we received, we are finalizing our proposals, without modification, to 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 CY 2015 OPPS payment rates using our established standard process. We intend to further explore the issues described above related to ED visits, including concerns about excessively costly patients, such as trauma patients. We note that we may propose changes to the coding and APC assignments for ED visits in the future rulemaking.

B. 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)).

As we discussed in the CY 2015 OPPS/ASC proposed rule (79 FR 41009), compared to the CY 2012 hospital claims data used for the CY 2014 OPPS ratesetting, the CY 2013 hospital claims data used for the CY 2015 OPPS ratesetting again show increases in the geometric mean line item costs as well as the geometric mean line item charges for CPT code 99291, which continue to suggest that hospitals' billing practices for CPT code 99291 have remained the same. Because the CY 2013 claims data do not support any significant change in hospital billing practices for critical care services, we stated in the proposed rule that 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. Therefore, for CY 2015, we proposed 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 proposed 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. We stated that we will continue to monitor the hospital claims data for CPT code 99291 in order to determine whether revisions to this policy are warranted based on changes in hospitals' billing practices.

We did not receive any public comments on this issue. Accordingly, we are finalizing our proposals, without modification, to continue our policy to recognize the existing CPT codes for critical care services and establish a payment rate based on historical claims data, and 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.

VIII. 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 (APC 0172 Level I Partial Hospitalization) and a higher amount for days with 4 or more services

(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 APC per diem payment rates. 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 . . . us[e] data on claims from 1996 and us[e] 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).

B. PHP APC Update for CY 2015

In the CY 2015 OPPS/ASC proposed rule (79 FR 41009 through 41012), for CY 2015, we proposed 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 computed proposed CMHC PHP APC geometric mean per diem costs for Level I (3 services per day) and Level II (4 or more services per day) PHP services using only CY 2013 CMHC claims data and the most recent cost data, and proposed hospital-based PHP APC geometric mean per diem costs for Level I and Level II PHP services using only CY 2013 hospital-based PHP claims data and the most recent cost report data. These proposed geometric mean per diem costs were shown in Table 44 of the CY 2015 OPPS/ASC proposed rule (79 FR 41011). To prevent confusion, we will refer to the per diem information listed in Table 44 of the proposed rule and Tables 39 and 40 of this final rule with comment period as the PHP APC per diem costs or the PHP APC geometric mean per diem costs, and the per diem information listed in Addendum A as the PHP APC per diem payment rates or the PHP APC geometric mean per diem 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 final rule with comment period.

For CY 2015, the proposed geometric mean per diem costs for days with 3 services (Level I) were approximately $97 for CMHCs and approximately $177 for hospital-based PHPs. The proposed geometric mean per diem costs for days with 4 or more services (Level II) were approximately $115 for CMHCs and approximately $190 for hospital-based PHPs.

The CY 2015 proposed geometric mean per diem costs for CMHCs calculated under the proposed CY 2015 methodology using CY 2013 claims data and the most recent cost data remained relatively constant when compared to the CY 2014 final geometric mean per diem costs for CMHCs established in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75050), with geometric mean per diem costs for Level I CMHC PHP services decreasing from approximately $99 to approximately $97 for CY 2015, and geometric mean per diem costs for Level II CMHC PHP services increasing from approximately $112 to approximately $115 for CY 2015.

The CY 2015 proposed geometric mean per diem costs for hospital-based PHPs calculated under the proposed CY 2015 methodology using CY 2013 claims data and the most recent cost report data showed more variation when compared to the CY 2014 final geometric mean per diem costs for hospital-based PHPs, with geometric mean per diem costs for Level I hospital-based PHP services decreasing from approximately $191 to approximately $177 for CY 2015, and geometric mean per diem costs for Level II hospital-based PHP services

decreasing from approximately $214 to approximately $190 for CY 2015.

We understand that having little variation in the PHP per diem payment rates from one year to the next allows providers to more easily plan their fiscal needs. However, we believe that it is important to base the PHP payment rates on the claims and cost reports submitted by each provider type so these rates accurately reflect the cost information for these providers. We recognize that several factors may cause a fluctuation in the 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). We invited public comments on what causes PHP costs to fluctuate from year to year and on these proposals.

The proposed CY 2015 geometric mean per diem costs for the CMHC and hospital-based PHP APCs were shown in Table 44 of the proposed rule. We invited public comments on these proposals.

Comment: Several commenters opposed the proposed CY 2015 PHP APC per diem payment rates and raised concerns about a continued decline in payments for these services. Commenters stated that the proposed per diem payment rates were inadequate to pay providers for furnishing these services, and were below most program costs for providing PHP services. Other commenters suggested that CMS continue to use the CY 2014 payment rates for CY 2015. A few commenters expressed concerns that the 15-percent reduction in payment rates for Level II services in hospitals dropped the payment rates too far below providers' costs. Another commenter asked that CMS provide documentation to support the proposed payment rates for PHP services.

Response: We acknowledge the concerns raised by the commenters who believe that reduced payment rates for CY 2015 will not adequately pay their costs to provide PHP services. However, the per diem payment rates reflect the cost of what each provider type expends to maintain such programs. Therefore, we do not believe that the final payment rates would be inadequate to cover the costs of providing these services.

Based on the final geometric mean per diem costs derived from CY 2013 claims data and the most recent cost data, CMHCs' geometric mean per diem costs increased from CY 2014 to CY 2015 for APC 0172 Level I (3 services per day) from approximately $99 to approximately $100, and for APC 0173 Level II (4 or more services per day) from approximately $112 to approximately $119. These per diem cost increases for CMHC APCs 0172 and 0173 are 0.76 percent and 5.7 percent, respectively. Final hospital-based PHP per diem costs decreased by significantly smaller amounts than the per diem costs that were proposed, but still declined when compared to CY 2014 geometric mean per diem costs. The PHP APC geometric mean per diem costs decreased for hospital-based PHPs from CY 2014 to CY 2015 for APC 0175 Level I (3 services per day) from approximately $191 to approximately $186, and for APC 0176 Level II (4 or more service per day) from approximately $214 to approximately $203. These final hospital-based PHP APC geometric mean per diem cost decreases are 2.6 percent for APC 0175 (instead of the proposed decrease of 7.1 percent) and 5.3 percent for APC 0176 (instead of the proposed decrease of 11.3 percent). We believe that the PHP APC per diem payment rates for both providers accurately reflect the claims and cost data of each provider type. Again, the resulting PHP APC per diem payment rates and the APC payment structures reflect the cost of what providers expend to maintain such programs. At this time, we cannot establish payment rates that do not accurately reflect the current claims and cost data. For these reasons, we are not suspending implementation of the CY 2015 PHP APC per diem payment rates for CMHCs and hospital-based PHPs.

The PHP APC per diem payment rates are directly related to the accuracy of the claims and cost data submitted by providers. Therefore, it is imperative that providers submit accurate claims and cost data in order for the payment rates to accurately reflect the providers' costs.

Regarding the documentation supporting the proposed PHP per diem payment rates, for each calendar year update, we explain how the PHP APC per diem payment rates are calculated in a proposed rule and a final rule. The industry is welcome to comment during the rulemaking process. We also make available to the public the OPPS PHP limited data set (LDS) and the OPPS LDS, which we discussed in the CY 2015 OPPS/ASC proposed rule (79 FR 40931). The OPPS PHP LDS can be used to recreate the PHP cost estimates and, when used in conjunction with the OPPS LDS, can be used to recreate the PHP APC payment rates. Both of these files are available twice a year, once for the proposed rule and again for the final rule. The LDSs are available for purchase under a CMS data use agreement through the CMS Web sites at: *http://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/HospitalOPPSPHPLDS.html* and *http://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/HospitalOPPS.html*.

Comment: A number of commenters noted the difficulty in planning and budgeting when payment rates for these services fluctuate and asked that CMS establish consistent and stable payments. Several commenters stated that they are committed to working with CMS to better understand and stabilize the payment rates for the PHP benefit, and to determine the factors driving the fluctuation in rates. One commenter asserted that the wide variability in PHP APC payment rates from year-to-year does not allow quality providers to plan for and to maintain services in a predictable way. Another commenter believed that the erratic payment rate structure could diminish access to care because providers may be unable to forecast statistical and financial parameters based on the proposed PHP APC payment rates.

In response to our solicitation for public comments in the proposed rule on what the industry believed was causing the fluctuation in payment rates, a few commenters stated that other types of hospitals (rehabilitation, long-term acute care, and inpatient psychiatric facilities) are now providing PHP-like services, and questioned whether the cost structure of these facilities could be distorting PHP APC payment rates. Another commenter stated that as providers move away from PHPs and toward other mental health care options, the sample size used in calculating payment rates is smaller. The commenter further stated that volumes of services in a few areas could take on greater influence in the calculations and affect costs, creating instability in the PHP APC payment rates and difficulty in planning.

A few commenters mentioned that their PHPs had not experienced significant operational or clinical protocol changes, and no changes in the personnel delivering the mix of services that would support a reduction in the

geometric mean per diem costs. Several commenters stated that almost one-third of the proposed PHP APC payment rate reduction could be explained by the budget neutrality adjustment, which disproportionately affects PHPs, and which, for CY 2015, may have led to payment rates that are less than the geometric mean per diem costs.

A few commenters cited a study that they had a contractor conduct to investigate the fluctuations. The commenters stated that the study results did not suggest that the tiered payments, the use of a geometric mean versus a median methodology, the different payments by site of service, or provider-driver factors, such as service-mix or patient-mix, were the source of the problem. The commenters noted that the study found a dramatic decrease in the total volume of PHP services provided, but an increase in hospital-based PHP days, particularly for Level II services. The commenters believed that this shift to providing more hospital-based PHP services has partially offset the decline in CMHC PHP days and may have caused PHP costs to fluctuate. The commenters suggested several areas for potential future study, including the shift of services from CMHCs to hospital-based PHPs, a different of mix of providers within the hospital category, other types of hospitals newly offering PHP services, volume, and the size of hospitals and of PHPs.

Response: We acknowledge the difficulties in planning and budgeting that can occur when payments fluctuate, or when payment rates decline. However, we are continuing to pay for PHP services based on provider data. We also believe that changes in payment rates from one year to the next are appropriate in a payment system that is annually updated to more accurately estimate the cost of a service upon which the relative payment weights are based. We continue to believe that payment rates for PHP services have fluctuated from year to year based on a variety of factors, including direct changes to the PHP APC per diem payment rate, and changes to the OPPS. Over the past several years, we have made changes to the OPPS methodology for calculating PHP APC per diem payment rates to more accurately align the payments with costs. The changes have included establishing two PHP APC payment tiers, establishing separate APCs and associated per diem payment rates for CMHCs and hospital-based providers based on each provider's costs, and basing payments on the geometric mean costs rather than on median costs.

In addition, the OPPS is a budget neutral payment system and, as a result, changes in the relative payment weights associated with certain services may affect those of other services in the payment system. Furthermore, provider-driven changes, such as a provider's decision to change its mix of services or to change its charges and clinical practice for some services, may cause fluctuations in the per diem payment rates. We provided a detailed discussion of possible reasons for the fluctuation in the rates in the CY 2015 OPPS/ASC proposed rule (79 FR 41012) and in section VIII.B. of this final rule with comment period.

We appreciate the commenters' providing possible reasons for fluctuations or declines in the payment rates. While several providers noted that their operations have not changed to support a decline in payments, we reiterate that our payment rates are based upon claims and cost data submitted to us by providers and, therefore, reflect the cost of what providers expend to maintain such programs. We also acknowledge the variables raised by the commenters that could cause the payment rate fluctuations and the study that several commenters had commissioned to look into PHP payments. We are unable to comment directly on the study results because we are not certain of the detailed methods used for this study. However, we appreciate the areas of potential future study suggested by commenters, and will take them into consideration in future analyses.

Comment: Many commenters stated that the methodology for calculating payment rates was ''flawed and illogical'' and asked CMS to reexamine the methodology to determine why payment rates are declining. The commenters suggested that CMS consider other methods for paying for PHP services, such as removing PHP services from APC group assignments and creating PHPs under an independent payment status, such as is done under the home health benefit. The commenters suggested that CMS establish a base payment rate for PHP services at a higher level than the current mean cost, and annually adjust the base rate by an inflation factor.

A few commenters supported the two-tiered payment methodology. However, the commenters suggested using only hospital-based data, which was implemented in CY 2009. Some commenters disagreed with CMS paying PHPs differently by site of service. One commenter disputed CMS' assertion that CMHCs generally provide fewer PHP services in a day. The commenter stated that claims information indicates that CMHCs submit a greater percentage of their claims for 4 or more services per day. The commenter added that CMS does not collect wage data on CMHCs in its costs reports. Several commenters did not support continued use of the CY 2014 policy, which uses the geometric mean per diem costs to calculate PHP payment rates.

Many commenters suggested other alternatives to the current payment system, such as developing oversight strategies for poorly performing CMHCs if their performance suggests a high risk of fraud, and allowing top performing CMHCs to admit patients into intensive outpatient programs similarly structured as PHPs. One commenter noted that some hospital-based providers are moving away from PHPs and providing programs that are structured similarly to a PHP, but are not Medicare-certified PHPs (that is, providing several individual mental health services in a day that would be similar to a PHP, but providers are not enrolled as a PHP). The commenter stated that the programs similar to PHPs would require fewer services and be subject to fewer regulatory requirements (for example, no certification or recertification, no physical examination requirement, and no minimum attendance mandate), and yet have similar payment rates as those established for PHPs. The commenter suggested that CMS require that these programs bill for furnishing these services under the mental health services composite APC under the OPPS, with payment aligned with how commercial insurers pay for these services. The commenter also suggested that CMS consider policy levers to ease regulatory requirements for administering PHPs.

Response: The OPPS successfully pays for outpatient services provided, such as and including partial hospitalization services, and we disagree that the system is flawed and illogical. This system bases payment on the geometric mean costs of providing the service or services using provider data from claims and cost reports. As discussed above, we believe this system provides appropriate payment for partial hospitalization services based on provider costs.

Sections 1833(t)(2) and 1833(t)(9) of the Act set forth the requirements for establishing and adjusting the OPPS payment rates, including the PHP payment rates. As such, we are directed to pay for these services under the OPPS (which uses APCs) and may not remove these PHP services from the OPPS and pay for them separately (such as by establishing a base rate and annually

adjusting it for inflation). The estimated costs of the PHP APCs are based on the most updated cost and claims data. The OPPS conversion factor used to calculate payments for those PHP APCs is updated by a market basket each year. While we continuously examine ways in which the data process could be improved, we also welcome and appreciate public comment with regard to potential improvements. Similarly, we appreciate the meaningful comments that stakeholders provided regarding ways that the cost modeling process could be more accurate or methods to extract more appropriate data from the claims available for OPPS cost modeling. For a more detailed discussion of the OPPS ratesetting process, including PHP payments, we refer readers to the CY 2015 OPPS Final Rule 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 link for ''Hospital Outpatient Regulations and Notices'', then on the link to the CY 2015 OPPS final rule, and then on the CY2015 OPPS Claims Accounting document.

With respect to the commenters' request to return to the two-tiered payment methodology calculated using only hospital-based data that was implemented in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68693), we refer commenters to the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). Because the cost of providing PHP services differs significantly by site of service, in CY 2011, we implemented differing PHP payment rates for hospital-based PHPs and CMHCs. 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 blend of CMHC and hospital data. We calculate the PHP APC per diem payment rates based on the data provided for each type of provider in order to pay for services. The resulting PHP APC per diem payment rates reflect the cost of what providers expend to maintain such programs based on data provided by these types of providers, which we believe is an improvement over the two-tiered payment methodology calculated using only hospital-based data.

In regard to the commenters' concerns regarding the use of geometric mean rather than the median, in the CY 2013 OPPS/ASC final rule with comment period, we established the geometric mean rather than the median as the measure upon which to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (77 FR 68406 to 68412). The CY 2015 PHP APC per diem payment rates are based on geometric mean costs. While a few commenters disagreed with our use of geometric mean costs, we believe that the use of geometric mean costs rather than median costs represents an improvement to our cost estimation process. As we stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68409), we believe that including outlier observations in developing the relative payment weights and capturing the full range of service costs lead to more accurate relative payment weights. In addition to better incorporating those cost values that surround the median and, therefore, describing a broader range of cost patterns, basing the relative payment weight on geometric mean costs also may promote better stability in the payment system by making OPPS payments more reflective of the range of costs associated with providing services. Further, applying the geometric mean to the PHP APCs helps ensure that the relativity of the OPPS payment weights is properly aligned. We do not believe that paying for some services based on median costs, while using geometric mean costs for other services is appropriate or equitable.

We believe that paying providers using the four PHP APC per diem payment rates based on the methodologies described above supports continued access to the PHP benefit, while also providing appropriate payment based on the unique cost structures of CMHCs and hospital-based PHPs. We also believe that each of these policies enables us to continue our responsible stewardship of the Medicare Trust Fund by more accurately matching payments with costs. For a full discussion of each of these policies implemented in prior rulemaking, including details on the rationales, we refer readers to the above-mentioned final rules with comment period, which are available on the CMS OPPS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.*

In response to the commenters' concerns regarding CMS' statement that CMHCs provide fewer services in a day, as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050), we are calculating the payment rates for PHP services based on the claims and cost data submitted by providers. The updated data used for calculating payments for this CY 2015 OPPS/ASC final rule with comment period indicate that CMHCs do indeed have a greater percentage of PHP days with 4 or more services, compared to hospital-based PHPs (94.6 percent of days compared to 88.3 percent of days, respectively). However, in spite of their providing a greater percentage of days with 4 or more services, our updated cost data continue to show that CMHC costs per day are lower than those of hospital-based PHPs.

In response to the question about wage data, CMHCs are required to include wage data for their staff on their cost reports, with certain exceptions. We direct readers to Medicare's cost reporting instructions for CMHCs that are available online in the Provider Reimbursement Manual, Part 2, Chapter 18 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*.

With respect to the suggestion that CMS develop oversight strategies for poor performing CMHCs with conduct that suggests potential fraud, we already have oversight strategies in place for providers that operate in a questionable manner. For example, MACs perform medical reviews of certain PHP claims, and PHP providers with claims that present ongoing concerns may have their claims placed on prepayment review. In some cases, CMHC and hospital-based PHP payments may be suspended or a CMHC's or hospital's billing privileges may be revoked. Our Office of Financial Management (OFM) has Recovery Audit Contractors (RACs), which regularly identify and collect overpayments from Medicare providers. Additionally, the Center for Program Integrity (CPI) and Zone Program Integrity Contractors (ZPICs) investigate potential fraud, waste, and abuse across the Medicare program, including potential concerns within CMHCs. Finally, the Office of Inspector General (OIG) and other law enforcement agencies continue in their efforts to address fraud and abuse throughout the Medicare program, including questionable billing for partial hospitalization services.

With respect to the commenters' request to allow top performing CMHCs to admit beneficiaries who require partial hospitalization services into outpatient programs that are structured similarly to PHPs, Medicare covers and

pays for reasonable and necessary PHP services provided by hospitals and CMHCs under the OPPS. While some private insurers and some State Medicaid programs recognize other types of intensive outpatient mental health programs as a distinct benefit like PHP services, the Medicare program does not. However, hospitals may provide and bill for individual services that make up various other mental health programs.

Because all Medicare outpatient mental health services are capped at the hospital-based Level II PHP per diem payment rate, from a payment standpoint, it does not matter how many of these individual services are billed to Medicare because payment will never exceed the hospital-based Level II PHP per diem payment rate. However, CMHCs may only be paid for partial hospitalization services under the OPPS.

We are constantly monitoring the OPPS in search of potential refinements that would improve the accuracy and stability of the payment system. We are unclear about the policy changes that the commenters suggested that we make regarding easing the regulatory requirements for administering PHPs. Some of the PHP requirements are set forth in the statute. For example, physician certification and recertification requirements for PHP services are set forth in section 1835(a)(2)(F) of the Act and would require Congressional legislation to change. However, if providers have suggestions for specific policy changes to improve PHP operations while safeguarding access to PHP services and paying accurately for these services, we welcome those suggestions during rulemaking or through other dialogue with the industry.

Comment: Many commenters described the key role that PHPs play in the continuum of care for patients with mental health issues. A number of commenters stated that if CMS moved forward with the proposed payment rates, much-needed PHP programs would struggle to remain financially viable. Multiple commenters believed that additional reductions in payments for CY 2015 would limit the ability of hospitals and CMHCs to provide these vital psychiatric services, reducing capacity or leading to closures, especially in rural areas, and thereby reducing access to care for Medicare patients. Several commenters noted that, as access to PHP services decreases, the decreases could lead to patients not receiving any services or to patients receiving services that are not appropriate for their needs; to use of more expensive inpatient psychiatric services; or to use of already stressed emergency departments. One commenter believed that CMS was concerned about the potential for hospital-based PHP closures, but not about CMHC closures.

Response: In response to commenters' concern about reduced PHP payment rates leading to decreased capacity and PHP closures, thereby reducing access to care and further eroding the viability of the safety net system, we emphasize again that the resulting PHP APC per diem payment rates for CY 2015 reflect the costs of what providers expend to maintain PHP programs. Therefore, it continues to be unclear to us why reduced PHP payment rates would lead to reduced capacity or program or business closures. As noted previously, the final CY 2015 per diem costs increased for CMHCs compared to CY 2014, and decreased less than proposed for hospital-based PHPs. As we stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74350), the closure of PHPs may be due to any number of reasons, such as poor business management or marketing decisions, competition, oversaturation of certain geographic areas, and Federal and State fraud and abuse efforts, among others. It does not directly follow that closure could be due to reduced per diem payment rates alone, especially when these per diem payment rates reflect the costs of PHP providers as stated in claims and cost data.

In response to the commenters' concerns that further reduction in the CMHC and hospital-based PHP APC per diem payment amounts could further erode the viability of the safety net system and make it more difficult for patients to receive needed mental health services, we take such concerns seriously for both CMHCs and hospital-based PHPs. We will continue to monitor facility closings and openings for both rural and urban areas to make sure that access issues do not exist. We also remain steadfast in our concern regarding access to care for all beneficiaries, while also providing appropriate payments for such care.

A PHP is not the only program in which a Medicare beneficiary is able to receive needed mental health care. Access to other forms of mental health services is also available. Although not equivalent to a PHP, Medicare provides payment for outpatient mental health services in addition to PHP services. Many beneficiaries in need of mental health treatment receive other outpatient services generally from hospital programs that are available nationwide.

Comment: Many commenters suggested that future payment rates be tied to quality criteria. One commenter recommended a payment system that rewards individual providers for outstanding quality and outcomes while keeping costs under control, and suggested that CMS use value-based purchasing rather than ''antiquated cost reimbursement-based purchasing.'' One commenter suggested that CMS conduct an analysis to determine what quality PHP care entails in terms of costs and staffing, rather than basing payment rates on reported costs.

Response: We responded to a similar public comment in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68410 through 68411) and refer readers to a summary of that comment and our response. Sections 1833(t)(2) and 1833(t)(9) of the Act set forth the requirements for establishing and adjusting OPPS rates, which include PHP rates. Section 1833(t)(17) of the Act authorizes the Hospital OQR Program, which applies a payment reduction to subsection (d) hospitals that fail to meet program requirements. In the CY 2015 OPPS/ASC proposed rule (79 FR 41040), we considered future inclusion of, and requested comments on, the following quality measures addressing PHP issues that would apply in the hospital outpatient setting: (1) 30-Day Readmissions; (2) Group Therapy; and (3) No Individual Therapy. We refer readers to section XIII. of this final rule with comment period for a more detailed discussion of PHP measures considered for inclusion in the Hospital OQR Program in future years. The Hospital OQR Program does not apply to CMHCs. Further, currently, there is no statutory language explicitly authorizing a value-based purchasing program for PHPs. With respect to the suggestion of conducting an analysis to determine what quality PHP care entails in terms of costs and staffing, we will take the suggestion into consideration in future analyses.

We do not consider the OPPS, the system under which PHPs are paid, to be ''antiquated.'' Rather, we find the OPPS to be a robust system, which aligns payments with provider costs. As noted previously, we regularly monitor the OPPS and, in recent years, have made changes to further improve the system's ability to pay accurately for services provided.

Comment: Many commenters noted that they provide services to Medicare beneficiaries which they cannot bill for on their claims. The services cited by the commenters included, for example: Assisting patients in finding appropriate housing; accessing other health care

services; obtaining medications; working through issues with family members; accessing transportation to medical and other appointments; assisting with information and appointments with Social Security; answering Medicare questions; accessing food banks and food stamps; obtaining eye and dental services; and integrating highly volatile and anxious patients into the milieu without upsetting the environment. Commenters stated that, currently, there is no way to show through the billing process that these events take place because there are no billing codes that capture these activities.

Response: Section 1861(ff) of the Act and 42 CFR 410.43 describe the items and services included in partial hospitalization services. As set forth in these sections, partial hospitalization services generally consist of a variety of group, individual, and family psychotherapy sessions, supplemented with occupational therapy, the services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients, drugs and biologicals furnished for therapeutic purposes that cannot be self-administered, diagnostic services, education and training, and certain activity therapies designed to stabilize an acute episode of mental illness. Section 1861(ff)(2)(I) of the Act explicitly excludes meals and transportation from the items and services included in partial hospitalization services. The PHP APC per diem payment rate is the bundled payment for partial hospitalization services. Only the items and services specifically identified in the statute and regulations are considered partial hospitalization services. All other items and services are not paid as part of partial hospitalization services.

Comment: A number of commenters asked that CMS have a dialogue with the PHP industry, and that the public comments on the proposed rule be directly addressed by CMS in an open forum where ideas could be cooperatively shared.

Response: We maintain positive working relationships with various industry leaders representing both CMHCs and hospital-based PHP providers with whom we have consistently met over the years to discuss industry concerns and ideas. These relationships have provided significant and valuable input regarding PHP ratesetting. We also hold Hospital Outpatient Open Door Forum calls monthly, in which all individuals are welcome to participate and/or submit questions regarding specific issues, including questions related to PHPs. Furthermore, we initiate rulemaking annually, through which we receive public comments on proposals set forth in a proposed rule, and we respond to those comments in a final rule. All individuals are provided an opportunity to comment, and we give consideration to each comment that we receive. Given the relationships that we have established with various industry leaders and the various means for us to receive comments and recommendations, we believe that we receive adequate input regarding PHP ratesetting and take that input into consideration when establishing the PHP per diem payment amounts. We continue to welcome any input and information that the industry is willing to provide.

Comment: Several commenters requested a better understanding of the Program for Evaluating Payment Patterns Electronic Report (PEPPER), the areas of risk it has identified, how the PEPPER fits into fraud and abuse efforts, and how the PEPPER fits into the benefit in general, and indicated that this information might be helpful to providers. The commenters expressed concern regarding various areas of risk cited by the PEPPER, including ''No individual therapy.'' The commenter stated that although most providers furnish individual therapy, it is often not documented or billed as it is not included in the local coverage determinations (LCDs).

Response: The PEPPER is a data report that contains statistics for each PHP area identified nationally to be at risk for improper payment (referred to in the report as ''target areas''). Each PEPPER contains a single PHP provider's claims data statistics, obtained from claims submitted to the MAC for these target areas. PEPPER does not identify the presence of improper payments, but it can be used by the provider as a guide for auditing and monitoring efforts. A provider can use the PEPPER to compare its claims data over time to identify areas of potential concern and to identify changes in billing practices. When a provider is sent a PEPPER, the report includes a user's guide, which describes the PEPPER and the target areas, among other things, and provides contact information for additional questions or information. Additional information on the PEPPER, including training and resources, is available at the PEPPER Web site at: *http://pepperresources.org/.*

Regarding ''individual therapy,'' which is one area of risk that the PEPPER is assessing, individual therapy is a partial hospitalization service. For a review of the partial hospitalization services, we refer readers to section 1861(ff)(2)(A) of the Act and our regulations at 42 CFR 410.43(a)(4)(i). We expect that providers would furnish individual therapy services as one of the services provided within a PHP.

Comment: One commenter noted that new Medicare conditions of participation (CoPs) are about to become effective for CMHCs, and stated that most CMHCs are unaware of them. One commenter noted that complying with the new CoPs would increase its costs. The commenter also stated that, under a provision of the Affordable Care Act that became effective October 1, 2014, providers need to be aware that a CMHC must provide at least 40 percent of its items and services to individuals who are not eligible for benefits under Medicare.

Response: The Conditions of Participation for Community Mental Health Centers final rule (78 FR 64604, October 29, 2013) established, for the first time, CoPs that CMHCs must meet in order to participate in the Medicare program. The CMHC CoPs are codified in 42 CFR Part 485, Subpart J, and became effective on October 29, 2014. Prior to the issuance of this final rule, on June 17, 2011, CMS issued a proposed rule (76 FR 35684) outlining the CoPs for Medicare-certified CMHCs. The proposed rule was open to public comment until August 16, 2011. Also, CMS issued press releases and fact sheets on the CoPs. CMS also has been working with trade organizations and the States to inform providers about the CoPs and the implementation date. Therefore, we believe that all CMHCs should be aware of these new requirements. More information on the CoPs for CMHCs can be found at 42 CFR Part 485, and through the link to the final rule at: *http://www.gpo.gov/fdsys/pkg/FR-2013-10-29/pdf/2013-24056.pdf.* The proposed rule can be accessed through the following link on the Web site found at: *http://www.gpo.gov/fdsys/pkg/FR-2011-06-17/pdf/2011-14673.pdf.* The final rule fact sheets can be accessed through the following link to the Web site found at: *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2013-Fact-sheets-items/2013-10-28.html.* The proposed rule press release can be accessed through the following link to the Web site found at: *http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2011-Press-releases-items/2011-06-16.html.* We believe that the cost associated with the CoPs is a reasonable and necessary business expense to

ensure the health and safety of all CMHC clients. In addition, effective October 29, 2014, under 42 CFR 485.918(b)(1)(v), pursuant to section 1861(ff)(3)(B) of the Act, a CMHC must provide at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Social Security Act, as measured by the total number of CMHC clients treated by the CMHC for whom services are not paid by Medicare, divided by the total number of clients treated by the CMHC in the applicable timeframe. Under this requirement, a newly enrolling or revalidating CMHC must submit to CMS a certification statement provided by an independent entity (such as an accounting technician). The document must indicate that (1) the entity has reviewed the CMHC's client care data, and (2) the CMHC meets the applicable 40 percent requirement. (We refer readers to 78 FR 64620). CMS has issued a change request that instructs MACs on the processing of such CMHC certifications. This requirement implements the provision of the Affordable Care Act noted by the commenter. For more detailed information, we refer readers to the Conditions of Participation for Community Mental Health Centers final rule (78 FR 64604).

Comment: A number of commenters noted the complexities of abiding by the LCDs on PHPs and believed that such LCDs are making it difficult for hospital-based PHP providers to continue to provide PHP services. Some commenters questioned whether the LCDs should be clarified or updated.

Response: LCDs issued by MACs specify under what clinical circumstances an item or service is considered to be reasonable and necessary. They are administrative and educational tools to assist providers in submitting correct claims for payment. The MACs publish LCDs to provide guidance to the public and medical community within their jurisdictions. The MACs develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. LCDs must be consistent with the statutory requirements for the Medicare program and with Medicare regulations and guidance. More information about LCDs can be found in the CMS Program Integrity Manual (Internet only manual) 100–08, Chapter 13, available at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf.*

Providers with questions about LCDs should contact their MAC for clarification or assistance. Inquiries of a clinical nature, such as the rationale behind coverage or noncoverage of certain items or services, are handled within the Medical Review (MR) department under the MAC responsible for the development of the LCD.

Comment: One commenter recommended that the annual payment update for PHP APCs reflect the market basket update that is applied to all other OPPS APCs.

Response: The PHP APC payment rates are based on the OPPS conversion factor, to which the market basket update is applied. Therefore, the market basket update is applied to the PHP APC payment rates. The OPPS conversion factor is discussed in further detail in section II.B. of this final rule with comment period.

Comment: One commenter stated that physicians are billing inpatient codes rather than PHP codes. The commenter believed that the change in physician reporting may have altered what facilities reported, which would have reduced the number of facility fees reported, and skewed the APC data downward. The commenter recommended that CMS conduct an analysis of the frequency and type of CPT codes that have been submitted for PHP over the last 3 years.

Response: As stated in section 1861(ff) of the Act and 42 CFR 410.43, payment for partial hospitalization services generally represents the provider's overhead costs, support staff, some drugs and the services of some nurses, clinical social workers, and occupational therapists, whose professional services are considered to be partial hospitalization services for which payment is made to the provider. Physician services that meet the requirements of 42 CFR 415.102(a) are separately covered and not paid as part of partial hospitalization services. Therefore, we do not use physician claims in developing the PHP APC geometric mean per diem costs and it is unclear to us how physician billing would impact PHP APC payment rates.

Regarding the recommendation that CMS conduct an analysis of the frequency and type of CPT codes that have been submitted for PHP services over the last 3 years, we will take the suggestion under consideration for future rulemaking, as we strengthen the PHP payment structure.

In summary, after consideration of the public comments we received, we are finalizing our CY 2015 proposal, without modification, to update the four PHP APC per diem costs based on geometric mean cost levels calculated using the most recent claims and cost data for each provider type. The updated PHP APCs geometric mean per diem costs for PHP services that we are finalizing for CY 2015 are shown in Table 39 and 40 below. As noted earlier in this section, we refer readers to Addendum A to this final rule with comment for the final PHP APC payment rates.

TABLE 39—CY 2015 GEOMETRIC MEAN PER DIEM COSTS FOR CMHC PHP SERVICES

APC	Group title	Geometric mean per diem costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$100.15
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	118.54

TABLE 40—CY 2015 GEOMETRIC MEAN PER DIEM COSTS FOR HOSPITAL-BASED PHP SERVICES

APC	Group title	Geometric mean per diem costs
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	$185.87
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	203.01

C. 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 the CY 2015 OPPS/ASC proposed rule (79 FR 41012), we proposed to continue designating 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 2015, excluding outlier payments. CMHCs are projected to receive 0.03 percent of total OPPS payments in CY 2015, excluding outlier payments. Therefore, we proposed to designate 0.47 percent of the estimated 1.0 percent outlier target amount for CMHCs, and establish a threshold to achieve that level of outlier payments. Based on our simulations of CMHC payments for CY 2015, in the CY 2015 OPPS/ASC proposed rule, we proposed to continue to set the threshold for CY 2015 at 3.40 times the highest CMHC PHP APC payment rate (that is, APC 0173 (Level II Partial Hospitalization)) (79 FR 41012). We stated that 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 proposed to continue to apply the same outlier payment percentage that applies to hospitals. Therefore, for CY 2015, we proposed to continue to pay 50 percent of CMHC per diem costs over the threshold. In section II.G. of the CY 2015 OPPS/ASC proposed rule (79 FR 41012), for the hospital outpatient outlier payment policy, we proposed 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 did not propose to set a dollar threshold for CMHC outlier payments.

In summary, in the CY 2015 OPPS/ASC proposed rule, we proposed to establish that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment rate for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. We invited public comments on these proposals.

We did not receive any public comments regarding our proposed outlier policy. Therefore, we are finalizing our CY 2015 proposal to set a separate outlier threshold for CMHCs. As discussed in section II.G. of this final rule with comment period, using more recent data for this final rule with comment period, we set the target for hospital outpatient outlier payments at 1.00 percent of total estimated OPPS payments. We allocated a portion of the 1.00 percent, an amount equal to 0.65 percent of outlier payments, or 0.0065 percent of total estimated OPPS payments, to CMHCs for PHP outlier payments. For CY 2015, as proposed, we are setting the CMHC outlier threshold at 3.40 multiplied by the APC 0173 payment rate and the CY 2015 outlier percentage applicable to costs in excess of the threshold at 50 percent. In other words, if a CMHC's cost for partial hospitalization services paid under either APC 0172 or APC 0173 exceeds 3.40 times the payment rate for APC 0173, the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate.

IX. Procedures That Will 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 list) and, therefore, will not be paid by Medicare under the OPPS; and on the criteria that we use to review the inpatient list each year to determine whether or not any procedures should be removed from the list.

B. Changes to the Inpatient List

In the CY 2015 OPPS/ASC proposed rule (79 FR 41012 through 41013), for the CY 2015 OPPS, we proposed 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 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 did not identify any procedures that potentially could be removed from the inpatient list for CY 2015. Therefore, we proposed to not remove any procedures from the inpatient list for CY 2015.

After our annual review of APCs and code assignments as required by section 1833(t)(9) of the Act and further clinical review performed by CMS medical officers, we proposed to add CPT code 22222 (Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic) to the CY 2015 inpatient list.

The complete list of codes that we proposed to be paid by Medicare in CY 2015 only as inpatient procedures was

included as Addendum E to the proposed rule (which is available via the Internet on the CMS Web site).

Comment: Several commenters supported CMS' proposal to add CPT code 22222 to the inpatient list.

Response: We appreciate the commenters' support.

Comment: Several commenters requested that CMS remove CPT codes 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); 43771 (Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only); 43772 (Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only); 43773 (Laparoscopy, surgical, gastric restrictive procedure; removal and revision of adjustable gastric restrictive device component only); 43774 (Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components); 54411 (Removal and replacement of a multi-component inflatable penile prosthesis through an infected field at the same operative session); and 54417 (Removal and replacement of a non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session) from the CY 2015 inpatient list based on their own experience, specialty society recommendation, or designation of a procedure as safe in the outpatient setting under one of the many clinical guidelines available.

Response: We reevaluated data on CPT codes 0312T, 43771, 43772, 43773, 43774, 54411, and 54417 using recent utilization data and further clinical review performed by CMS' medical advisors. As a result of the reevaluation, we have determined that these procedures can be safely performed only in the inpatient setting. We are not removing them from the inpatient list for CY 2015.

Comment: Some commenters requested that CPT code 63044 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace) be removed from the inpatient list.

Response: We reevaluated data on CPT code 63044 using recent utilization data and further clinical review performed by CMS medical advisors. As a result of the reevaluation, we agree with the commenters that this procedure can be safely performed in the outpatient setting. In addition, as a result of our reevaluation, we believe that CPT code 63043 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace) can be safely performed in the outpatient setting. Therefore, we are removing CPT codes 63043 and 63044 from the inpatient list. Because CPT codes 63043 and 63044 are add-on codes, they are being assigned status indicator ''N'' for CY 2015.

Comment: Other commenters urged CMS to continue reviewing its inpatient only policy in light of ongoing changes in delivery systems and procedural safety and technological advances.

Response: We agree with the commenters and will continue to review the inpatient only policy.

After consideration of the public comments we received, we are finalizing our proposals for the inpatient only list, with modifications. We are removing CPT codes 63043 and 63044 from the inpatient list and adding CPT code 22222 (Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic) to the CY 2015 inpatient list.

The complete list of codes that will be paid by Medicare in CY 2015 only as inpatient procedures is included as Addendum E to this final rule with comment period (which is available via the Internet on the CMS Web site.

X. Nonrecurring Policy Changes: Collecting Data on Services Furnished in Off-Campus Provider-Based Departments of Hospitals

As we discussed in the CY 2014 OPPS/ASC proposed rule and final rule with comment period (78 FR 43626 and 78 FR 75061) and in the CY 2014 Medicare Physician Fee Schedule (MPFS) proposed rule and final rule with comment period (78 FR 43301 and 78 FR 74427), in recent years, the research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resultant increase in the delivery of physicians' services in a hospital setting. When a Medicare beneficiary receives outpatient services in a hospital, the total payment amount for outpatient services made by Medicare is generally higher than the total payment amount made by Medicare when a physician furnishes those same services in a freestanding clinic or in a physicians' office.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41013), we stated that we continue to seek a better understanding of how the growing trend toward hospital acquisition of physicians' offices and subsequent treatment of those locations as off-campus provider-based departments (PBDs) of hospitals affects payments under the MPFS and the OPPS, as well as beneficiary cost-sharing obligations. We also noted that MedPAC continues to question the appropriateness of increased Medicare payment and beneficiary cost-sharing when physicians' offices become hospital outpatient departments and to recommend that Medicare pay selected hospital outpatient services at MPFS rates (MedPAC March 2012 and June 2013 *Report to Congress*). In order to understand how this trend is affecting Medicare, we need information on the extent to which this shift is occurring. To that end, during the CY 2014 OPPS/ASC rulemaking cycle, we sought public comment regarding the best method for collecting information and data that would allow us to analyze the frequency, type, and payment for physicians' and outpatient hospital services furnished in off-campus PBDs of hospitals (78 FR 75061 through 75062 and 78 FR 74427 through 74428). In response to our solicitation, we received many detailed public comments. However, the commenters did not present a consensus opinion regarding whether this data collection was advisable or which data collection method would be preferable. Based on our analysis of the public comments we received, we proposed for the CY 2015 OPPS/ASC proposed rule that the most efficient and equitable means of gathering this important information across two different payment systems would be to create a HCPCS modifier to be reported with every code for physicians' services and outpatient hospital services furnished in an off-campus PBD of a hospital on both the CMS–1500 claim form for physicians' services and the UB–04 form (CMS Form 1450) for hospital outpatient services. We noted that a main provider may treat an off-campus facility as provider-based if certain requirements in 42 CFR 413.65 are satisfied, and we define a ''campus'' at 42 CFR 413.65(a)(2) to be the physical area immediately adjacent to the provider's main buildings, other areas and

structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.

Section 220(a)(1) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) added a new subparagraph (M) under section 1848(c)(2) of the Act that granted CMS the authority to engage in data collection to support valuation of services paid under the MPFS. In the CY 2015 OPPS/ASC proposed rule, we indicated that we are seeking more information on the frequency and type of services furnished in PBDs under this authority to improve the accuracy of MPFS practice expense payments for services furnished in off-campus PBDs. We discussed this issue in more detail in the CY 2015 MPFS proposed rule (79 FR 40333). In that discussion, we noted our concerns that our current MPFS practice expense methodology primarily distinguishes between the resources involved in furnishing services in two sites of service: the nonfacility setting and the facility setting. As more physician practices become hospital-based and are treated as off-campus PBDs, we believe it is important to develop an understanding of which practice expense costs typically are incurred by the physicians and practitioners in the setting, which are incurred by the hospital, and whether the facility and nonfacility site-of-service differentials adequately account for the typical resource costs, given these new ownership arrangements.

To understand how this trend is affecting Medicare, including the accuracy of payments made through the MPFS, we stated in the proposed rule that we need to develop data to assess the extent to which this shift toward hospital-based physician practices is occurring. Therefore, in the CY 2015 OPPS/ASC proposed rule (79 FR 41013), we proposed to collect information on the type and frequency of physicians' services and outpatient hospital services furnished in off-campus PBDs beginning January 1, 2015, in accordance with our authority under section 1848(c)(2)(M) of the Act (as added by section 220(a) of Pub. L. 113–93). As noted above, we proposed to create a HCPCS modifier that is to be reported with every code for physicians' services and outpatient hospital services furnished in an off-campus PBD of a hospital. Under the proposal, the modifier would be reported on both the CMS–1500 claim form for physicians' services and the UB–04 form (CMS Form 1450) for hospital outpatient services. In the proposed rule (79 FR 41013), we sought additional public comments on whether or not the use of a modifier code is the best mechanism for collecting this service-level data in the hospital outpatient department.

Comment: Many commenters agreed on the need to collect information on the frequency, type, and payment of services furnished in off-campus PBDs of hospitals. However, several commenters expressed concern that the HCPCS modifier would create additional administrative burden for providers. Many of these commenters stated that the new modifier would require significant changes to hospitals' billing systems, including a separate chargemaster for outpatient off-campus PBDs and training for staff on how to use the new modifier. Many of these commenters suggested that CMS should re-propose a detailed data collection methodology, test it with providers, make adjustments, and allow additional time for implementation. One commenter suggested that CMS withdraw the current proposal and ask the Advisory Panel on Hospital Outpatient Payment (HOP Panel) to develop a proposal for data collection.

Response: While we understand the commenters' concerns about the additional administrative burden of reporting a new HCPCS modifier, we have weighed the burden of reporting the modifier for each service against the benefit of having data that will allow us to obtain and assess accurate information on the type and frequency of physicians' services and outpatient hospital services furnished in off-campus PBDs. We do not believe that the modifier is excessively burdensome for providers to report. This is especially the case because, under current rules, when billing for services, providers must know where services are performed in order to accurately complete value code 78 of an outpatient claim or the service location portion of a professional claim. However, as discussed later in this section, we agree that a place of service (POS) code on the professional claim allows for the same type of data collection as a modifier on the hospital claim and would be less burdensome than the modifier for practitioner billing. We discuss the timeframe for implementation later in this section. With respect to bringing this proposal to the HOP Panel, we note that such a proposal is outside the scope of the HOP Panel, which is generally charged with advising Medicare on the clinical integrity of APCs and their associate relative payment weights. The proposed modifier is for collecting data and, as structured, does not affect APCs and their associated relative payment weights. Therefore, it would not be appropriate to solicit HOP Panel discussion or recommendations on this proposal on data collection.

Comment: Some commenters who were concerned about the administrative burden of the new HCPCS modifier suggested several alternative methods for CMS to collect data on services furnished in off-campus PBDs. Several of these commenters recommended that CMS consider the establishment of a new POS code for professional claims, or for both professional claims and hospital claims, because they believed this approach would be less administratively burdensome than attaching a modifier to each service reported on the claim that was furnished in an off-campus PBD. Some commenters preferred identifying services furnished in off-campus PBDs on the Medicare cost report (CMS–2552–10). Some commenters suggested using provider numbers and addresses to identify off-campus PBDs, or changing the provider enrollment process to be able to track these data. Other commenters suggested creating a new bill type to track outpatient hospital services furnished in off-campus PBDs.

Commenters generally recommended that CMS choose the least administratively burdensome approach that would ensure accurate data collection, but did not necessarily agree on what approach would optimally achieve that result. Some commenters believed that a HCPCS modifier would more clearly identify specific services furnished at off-campus PBDs, and would provide better information about the type and level of care furnished. Some commenters believed that a HCPCS modifier would be the least administratively burdensome approach because hospitals and physicians already report a number of claims-based modifiers. Other commenters argued that additional modifiers would increase administrative burden because this approach would increase the modifiers that would need to be considered when billing.

Response: With respect to creating a new POS code to obtain data on services furnished in off-campus PBDs of a hospital, we note that POS codes are only reported on professional claims and are not included on hospital claims. Therefore, a POS code could not be easily implemented for hospital claims. However, POS codes are already required to be reported on every professional claim and POS 22 is currently used to report when physicians' services are furnished in an

outpatient hospital department. (More information on existing POS codes is available on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html*.)

Although we considered proposing a new POS code for professional claims to collect data on services furnished in the off-campus PBD setting, we ultimately did not do so, in part because we were aware that previous Government Accountability Office and Office of the Inspector General reports (October 2004, A–05–04–0025; January 2005, A–06–04–00046; July 2010, A–01–09–00503; September 2011, A–01–10–00516) have noted frequent inaccuracies in the reporting of POS codes. In addition, at the time the proposed rule was developed, we had concerns that using a POS code to report this information might not give us the reliable data we are looking to collect, especially if such data were to be crosswalked with hospital claims for the same service, because the hospital claim would have a modifier, not a POS code. However, we have been persuaded by public comments suggesting that use of a POS code would be less administratively burdensome on professional claims than use of a modifier. Specifically, because a POS code is already required on every professional claim, we believe that creating a new POS code to distinguish outpatient hospital services that are furnished on-campus versus off-campus would require less staff training and education than would use of a modifier on the professional claim. In addition, professional claims only have space for four modifiers. While a very small percentage of professional claims have four modifiers, required use of an additional modifier for every professional claim could lead to more occurrences where there would not be space for all applicable modifiers. Unlike hospital claims, we note that a new professional claim is required whenever the place of service changes. That is, even if the same practitioner treats the same patient on the same day in the office and hospital, the services furnished in the office setting must be submitted on one claim with the POS 11 (Office) code, while those furnished in the outpatient hospital department would be submitted on a separate claim with the POS 22 (Outpatient Hospital) code (we note that the POS 22 code will be changing under the final policy). Likewise, if a new POS code were to be created for an off-campus PBD setting, a separate claim for services furnished in that setting would be required relative to a claim for services furnished on the main campus by the same practitioner to the same patient on the same day. Based on public comments and after further consultation with Medicare billing experts, we believe that the use of the POS code on professional claims would be no less accurate than the use of a modifier on professional claims in identifying services furnished in off-campus PBDs. In addition, we believe that the POS code would be less administratively burdensome for practitioners billing using the professional claim because a POS code is already required for every professional claim.

With respect to adding new fields to existing claim forms or creating a new bill type, we do not believe that this data collection warrants these measures. We believe that those changes would create greater administrative burden than a HCPCS modifier or POS code, especially because providers are already accustomed to using modifiers and POS codes. Revisions to the claim form to add new fields or an additional bill type would create significant administrative burden to revise claims processing systems and educate providers, which we believe is not necessary, given the availability of a modifier and POS codes. Although providers may not be familiar with this new modifier or any new POS code; because these types of codes already exist generally for hospital and professional claims, providers and suppliers should already have an understanding of these types of codes and how to apply them. Finally, we do not believe that expansions to the claim form or use of a new bill type would provide us with detailed information on exactly which services were furnished in an off-campus PBD versus those furnished on the main campus when those services are furnished on the same day.

We also do not believe that we could accurately determine which services are furnished at off-campus PBDs using currently available national provider identifier (NPI) and facility address data. Hospitals are required to report the 9-digit zip code indicating where a service was furnished for purposes of paying properly for physician and anesthesia services paid under the MPFS when that zip code differs from the master address for the hospital on file in CMS claims systems (Pub. 100–04, Transmittal 1681, February 13, 2009). However, the billing zip code for the hospital main campus could be broad enough to incorporate on and off-campus PBDs. Further, a zip code reported in value code 78 does not allow CMS to distinguish between services furnished in different locations on the same date. Therefore, we do not believe that a comparison of the zip code captured in value code 78 and the main campus zip code is sufficiently precise.

Finally, while we considered the suggestion that CMS use currently reported Medicare hospital cost report (CMS–2552–10) data to identify services furnished at off-campus PBDs, we note that although aggregate data on services furnished in different settings must be reported through the appropriate cost center, we would not be able to obtain the service-specific level of detail that we would be able to obtain from claims data.

We will take under consideration the suggestion that CMS create a way for hospitals to report their acquisition of off-campus PBDs through the enrollment process, although this information, as currently reported, like many of the suggestions above, would not allow us to know exactly which services are furnished in off-campus PBDs and which services are furnished on the hospital's main campus when a hospital provides both on the same day.

Comment: Commenters noted that the proposed modifier would not allow CMS to know the precise location of the off-campus PBDs for billed services or when services are furnished at different off-campus PBD locations in the same day.

Response: We agree that neither the proposed modifier nor a POS code provides precise information on the specific location of each off-campus PBD for each furnished service. However, we believe having information on the type and frequency of services furnished at all off-campus locations will assist CMS in better understanding the distribution of services between on-campus locations and off-campus locations.

Comment: MedPAC believed there may be some value in collecting data on services furnished in off-campus PBDs to validate the accuracy of site-of-service reporting when the physician's office is off-campus but bills as an outpatient department. MedPAC indicated that any data collection effort should not prevent the development of policies to align payment rates across settings. MedPAC encouraged CMS to seek legislative authority to set equal payment rates across settings for evaluation and management office visits and other select services.

Response: We thank MedPAC for its support of our data collection efforts to better inform the frequency and types of services that are being furnished in off-campus PBDs.

Comment: Many commenters suggested that providers would not be able to accurately apply the new modifier by the January 1, 2015 implementation timeline and recommended a 1-year delay before providers would be required to apply the modifier to services furnished at off-campus PBDs. Some commenters requested only a 6-month delay in implementation. Commenters indicated that significant revisions to internal billing processes would require additional time to implement.

Response: Although we believe that the customary January 1st effective date that applies to most policies adopted in the final rules with comment period for both the MPFS and the OPPS would provide sufficient lead time, we understand the commenters' concerns with the proposed timeline for implementation, given that the new reporting requirements may require changes to billing systems as well as education and training for staff. Accordingly, although we are finalizing our proposal to create a HCPCS modifier for hospital services furnished in an off-campus PBD setting, we are adopting a voluntary reporting period of the new HCPCS modifier for 1 year. That is, reporting the new HCPCS modifier for services furnished at an off-campus PBD will not be mandatory until January 1, 2016, in order to allow providers time to make systems changes, test these changes, and train staff on use of the new modifier before reporting is required. We welcome early reporting of the modifier and believe a full year of preparation should provide hospitals with sufficient time to modify their systems for accurate reporting. With respect to the POS code for professional claims, we will request two new POS codes to replace POS code 22 (Hospital Outpatient) through the POS Workgroup and expect that it will take some time for these new codes to be established. Once the new POS codes are ready and integrated into CMS claims systems, practitioners would be required to use them, as applicable. More information on the availability of the new POS codes will be forthcoming in subregulatory guidance. However, we do not expect the new POS codes to be available prior to July 1, 2015. There will be no voluntary reporting period of the POS codes for applicable professional claims because each professional claim requires a POS code in order to be accepted by Medicare. However, we do not view this to be problematic because we intend to give prior notice on the POS coding changes and, as many of the commenters noted, because practitioners are already accustomed to using a POS code on every claim they submit.

Comment: Many commenters expressed concern that this data collection would eventually lead to equalizing payment for similar services furnished in the nonfacility setting and the off-campus PBD setting. Several commenters noted that the trend of hospitals acquiring physician practices is due to efforts to better integrate care delivery and suggested that CMS weigh the benefits of care integration when deciding payment changes. Some commenters suggested that CMS use these data to equalize payment for similar services between these two settings. These commenters suggested that there is little difference in costs and care between the two settings that would warrant the difference in payment. Several of these commenters highlighted beneficiary cost-sharing as one reason for site-neutral payment, noting that the total payment amount for outpatient services is generally higher than the total payment amount for those same services when furnished in a physician's office.

Response: We appreciate these comments. At this time, we are only finalizing a data collection in this final rule with comment period. We did not propose and, therefore, are not finalizing any adjustment to payments furnished in the off-campus PBD setting.

Comment: One commenter noted that the CMS proposal would not provide additional information on how a physician practice billed prior to becoming an off-campus PBD, which would be important for analyzing the impact of this trend.

Response: We agree that understanding physician billing patterns prior to becoming an off-campus PBD is important in analyzing the impact of this trend, and we will continue to evaluate ways to analyze claims data to gather this information. We believe that collecting data using the additional modifier and POS code finalized in this final rule with comment period will be an important tool in furthering this analysis.

Comment: Some commenters suggested that the term ''off-campus'' be better defined. Commenters asked how billing would occur for hospitals with multiple campuses because the CMS definition of campus references main buildings and does not include remote locations. The commenters maintained that remote locations are not the same as off-campus departments and that remote campuses furnish both inpatient and outpatient hospital services, in contrast to individual hospital departments. The commenters argued that these types of locations are not ones that were formerly a physician office practice, and furnish completely different types of services than a physician office. One commenter also asked whether the modifier is intended to cover services furnished in freestanding emergency departments.

Response: For purposes of the modifier and the POS codes we are finalizing in this final rule with comment period, we define ''campus'' using the definition at 42 CFR 413.65(a)(2) to be the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus. Our intent is to capture outpatient services furnished off of the hospital's main campus and off of any other hospital campuses. The term ''remote location of a hospital'' is defined at 42 CFR 413.65(a)(2). Under these regulations, a ''remote location'' includes a hospital campus other than the main hospital campus. Specifically, a remote location is ''a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider. . . .'' Therefore, we agree with the commenter that remote locations of the hospital should not be required to report the modifier nor should practitioners be required to report the off-campus POS code in these settings. This term ''remote location'' does not include ''satellite'' locations of a hospital, but because a satellite facility is one that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital, we also are not requiring satellite facilities to report the modifier or the POS codes. Satellite facilities are described in the regulations at 42 CFR 412.22(h). Accordingly, reporting of the modifier and POS codes would be required for outpatient services furnished in PBDs beyond 250 yards from the main campus of the hospital, excluding services furnished in a remote location or satellite facility of the hospital.

We also appreciate the comment on emergency departments. We do not intend for hospitals to report the new modifier for services furnished in an emergency department that is provider-

based to a hospital. We note that there is already a POS code for the emergency department, POS 23 (emergency room-hospital), and this code would continue to be used for emergency department services. That is, the new off-campus PBD code that will be created for purposes of this data collection would not apply to hospital emergency department services. Hospitals that have questions about which departments are considered to be ''off-campus PBDs'' should review additional guidance that CMS releases on this policy and work with the appropriate CMS regional office if individual, specific questions remain.

Comment: Several commenters asked for clarification on when to report the modifier for services furnished both on-campus and off-campus on the same day. The commenters provided several scenarios of visits and diagnostic services furnished on the same day.

Response: The location where the service is actually furnished would dictate the use of the modifier, regardless of where the order for services initiated. We expect the modifier and the POS code for off-campus PBDs to be reported in locations in which the hospital expends resources to furnish the service in an off-campus PBD setting. For example, hospitals would not report the modifier for a diagnostic test that is ordered by a practitioner who is located in an off-campus PBD when the service is actually furnished on the main campus of the hospital. This issue does not impact use of the POS codes because practitioners submit a different claim for each POS where they furnish services for a specific beneficiary.

Comment: A few commenters asked for clarification on whether their entity constitutes a PBD.

Response: PBDs are departments of the hospital that meet the criteria specified in regulations at 42 CFR 413.65. Questions about PBDs may be directed to the appropriate CMS regional office.

Comment: One commenter recommended that CMS publish the data it acquires through adoption of this modifier.

Response: Data collected through the new HCPCS modifier would be part of the Medicare Limited Data Set and would be available to the public for purchase along with the remainder of the Limited Data Set. Similarly, professional claims data with revised POS coding would be available as a standard analytic file for purchase.

In summary, after consideration of the public comments received, we are finalizing our proposal with modifications. For hospital claims, we are creating a HCPCS modifier that is to be reported with every code for outpatient hospital services furnished in an off-campus PBD of a hospital. This code will not be required to be reported for remote locations of a hospital defined at 42 CFR 412.65, satellite facilities of a hospital defined at 42 CFR 412.22(h), or for services furnished in an emergency department. This 2-digit modifier will be added to the HCPCS annual file as of January 1, 2015, with the label ''PO,'' the short descriptor ''Serv/proc off-campus pbd,'' and the long descriptor ''Services, procedures and/or surgeries furnished at off-campus provider-based outpatient departments.'' Reporting of this new modifier will be voluntary for 1 year (CY 2015), with reporting required beginning on January 1, 2016. Additional instruction and provider education will be forthcoming in subregulatory guidance.

For professional claims, instead of finalizing a HCPCS modifier, in response to public comments, we will be deleting current POS code 22 (outpatient hospital department) and establishing two new POS codes—one to identify outpatient services furnished in on-campus, remote, or satellite locations of a hospital, and one to identify services furnished in an off-campus PBD hospital setting. We will maintain the separate POS code 23 (Emergency room-hospital) to identify services furnished in an emergency department of the hospital. These new POS codes will be required to be reported as soon as they become available. However, advanced notice of the availability of these codes will be shared publicly as soon as practicable.

XI. CY 2015 OPPS Payment Status and Comment Indicators

A. CY 2015 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 CY 2015 payment status indicators and their definitions is displayed in Addendum D1 to this final rule with comment period, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The CY 2015 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this final rule with comment period, which are available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The changes to CY 2015 payment status indicators and their definitions are discussed in detail below.

We note that, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74869 through 74888), for CY 2014, we created a new status indicator ''J1'' to identify HCPCS codes that are paid under a comprehensive APC. However, because we delayed implementation of the new comprehensive APC policy until CY 2015, we also delayed the effective date of payment status indicator ''J1'' to CY 2015. A claim with payment status indicator ''J1'' will trigger a comprehensive APC payment for the claim. We refer readers to section II.A.2.e. of this final rule with comment period for a discussion of implementation of the new comprehensive APC policy.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41014), for CY 2015, we proposed to delete payment status indicator ''X'' and to assign ancillary services that are currently assigned payment status indicator ''X'' to either payment status indicator ''Q1'' or ''S.'' We also proposed to revise the definition of payment status indicator ''Q1'' by removing payment status indicator ''X'' from the packaging criteria, so that codes assigned payment status indicator ''Q1'' would be designated as STV-packaged, rather than STVX-packaged, because payment status indicator ''X'' was proposed for deletion. These proposed changes, the public comments we received and our responses, and our finalized policies are discussed in section II.A.3.c.(1) of this final rule with comment period. Section II.A.3.c.(1) of this final rule with comment period discusses the ancillary services packaging policy. The ancillary services packaging policy is the policy that makes maintaining status indicator ''X'' no longer necessary. After consideration of the public comments that we received and that are discussed in section II.A.3.c.(1) of this final rule with comment period, we are finalizing, without modification, our CY 2015 proposal to delete payment status indicator ''X'' and to assign ancillary services that are currently assigned payment status indicator ''X'' to either payment status indicator ''Q1'' or ''S.''

In addition, for CY 2015, we proposed to clarify the definition of payment status indicator ''E'' to state that

payment status indicator ''E'' applies to items, codes, and services in any of the following cases:

- For which pricing is not available;
- Not covered by any Medicare outpatient benefit category;
- Statutorily excluded by Medicare; or
- Not reasonable and necessary.

Regarding items ''for which pricing is not available,'' this applies to drugs and biologicals assigned a HCPCS code but with no available pricing information (for example, WAC).

In reviewing the OPPS status indicators and Addendum D1 for CY 2015, we noticed that there are a few drugs or biologicals that are currently assigned payment status indicator ''A,'' indicating payment under a non-OPPS fee schedule. These drugs or biologicals are administered infrequently in conjunction with emergency dialysis for patients with ESRD, but when administered in the HOPD, they are paid under the standard OPPS drug payment methodology for drugs and biologicals, that is, at ASP+6 percent unless they are packaged. (We refer readers to section V. of this final rule with comment period for additional discussion of these drugs and their status indicators.) We proposed to change the status indicators for these drugs or biologicals for CY 2015 by removing the phrase ''EPO for ESRD Patients'' from the list of examples for status indicator ''A.'' In addition, we proposed to clarify the definition of payment status indicator ''A'' by adding the phrase ''separately payable'' to nonimplantable prosthetic and orthotic devices.

We did not receive any public comments regarding our proposed change and clarifications of the definitions of payment status indicators ''E'' and ''A.'' Therefore, we are finalizing our clarification and proposed policies, without modifications, for CY 2015.

B. CY 2015 Comment Indicator Definitions

In the CY 2015 OPPS/ASC proposed rule (79 FR 41014), for the CY 2015 OPPS, we proposed to use the same two comment indicators that are in effect for the CY 2014 OPPS.

- ''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.

We proposed to use the ''CH'' comment indicator in the CY 2015 OPPS/ASC proposed rule (79 FR 41014) to indicate HCPCS codes for which the status indicator or APC assignment, or both, are proposed for change in CY 2015 compared to their assignment as of June 30, 2014. We believed that using the ''CH'' indicator in the proposed rule would facilitate the public's review of the changes that we proposed for CY 2015. We proposed to use the ''CH'' comment indicator in the CY 2015 OPPS/ASC final rule with comment period to indicate HCPCS codes for which the status indicator or APC assignment, or both, would change in CY 2015 compared to their assignment as of December 31, 2014. 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 2015 OPPS/ASC final rule with comment period.

In addition, we proposed that any existing HCPCS codes with substantial revisions to the code descriptors for CY 2015 compared to the CY 2014 descriptors would be labeled with comment indicator ''NI'' in Addendum B to the CY 2015 OPPS/ASC final rule with comment period. However, in order to receive the comment indicator ''NI,'' the CY 2015 revision to the code descriptor (compared to the CY 2014 descriptor) must be significant such that the new code descriptor describes a new service or procedure for which the OPPS treatment may change. We use comment indicator ''NI'' to indicate that these HCPCS codes will be open for comment as part of the CY 2015 OPPS/ASC final rule with comment period. In the CY 2015 OPPS/ASC proposed rule, we stated that, like all codes labeled with comment indicator ''NI,'' we would respond to public comments and finalize their OPPS treatment in the CY 2016 OPPS/ASC final rule with comment period.

In accordance with our usual practice, we proposed that CPT and Level II HCPCS codes that are new for CY 2015 also would be labeled with comment indicator ''NI'' in Addendum B to the CY 2015 OPPS/ASC final rule with comment period.

We did not receive any public comments on the proposed use of comment indicators for CY 2015.

We believe that the CY 2014 definitions of the OPPS comment indicators continue to be appropriate for CY 2015. Therefore, we are continuing to use those definitions without modification for CY 2015. Only HCPCS codes with comment indicator ''NI'' in this CY 2015 OPPS/ASC final rule with comment period are subject to comment. HCPCS codes that do not appear with comment indicator ''NI'' in this CY 2015 OPPS/ASC final rule with comment period will not be open to public comment, unless we specifically request additional comments elsewhere in this final rule with comment period.

The definitions of the OPPS comment indicators for CY 2015 are listed in Addendum D2 to this final rule with comment period, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

XII. 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), and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75064 through 75090).

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, 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. These covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment (72 FR 42495). 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.B. of this final rule with comment period, 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 Level II codes to the public or recognizes the release of new 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. Thus, these quarterly updates are to implement newly created 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 Category I CPT codes, except vaccine codes, are released only once a year and, therefore, are implemented only through the January quarterly update. New 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 the process used to update the 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 procedures, and procedures for which there is revised coding, 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. Treatment of New Codes

1. Process for Recognizing New 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 products, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule to evaluate each year all new 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 (72 FR 42533 through 42535). In addition, we identify new codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system.

We have separated our discussion below into two sections based on whether we proposed to solicit public comments in the CY 2015 OPPS/ASC proposed rule (and respond to those comments in this CY 2015 OPPS/ASC final rule with comment period) or whether we are soliciting public comments in this CY 2015 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2016 OPPS/ASC final rule with comment period).

We note that we sought public comment in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75067) on the new Category I and Category III CPT and Level II HCPCS codes that were effective January 1, 2014. We also sought public comment in the CY 2014 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2013. These new codes, with an effective date of October 1, 2013, or January 1, 2014, were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2014 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 2014 OPPS/ASC final rule with comment period. In the proposed rule, we stated that we will respond to public comments and finalize the treatment of these codes under the ASC payment system in this CY 2015 OPPS/ASC final rule with comment period.

2. Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April 2014 and July 2014 for Which We Solicited Public Comments in the CY 2015 OPPS/ASC Proposed Rule

In the April 2014 and July 2014 CRs, we made effective for April 1, 2014 and July 1, 2014, respectively, a total of seven new Level II HCPCS codes and four new Category III CPT codes that describe ASC covered surgical procedures and covered ancillary services that were not addressed in the

CY 2014 OPPS/ASC final rule with comment period.

In the April 2014 ASC quarterly update (Transmittal 2927, CR 8675, dated April 10, 2014), we added two new surgical Level II HCPCS codes and one new drug and biological Level II HCPCS code to the list of covered surgical procedures and covered ancillary services, respectively. Table 45 of the CY 2015 OPPS/ASC proposed rule (79 FR 41016) listed the new Level II HCPCS codes that were implemented April 1, 2014, along with their proposed payment indicators for CY 2015.

In the July 2014 quarterly update (Transmittal 2970, CR 8786, dated May 23, 2014), we added one new brachytherapy Level II HCPCS code and three new drug and biological Level II HCPCS codes to the list of covered ancillary services. Table 46 of the CY 2015 OPPS/ASC proposed rule (79 FR 41016 through 41017) listed the new Level II HCPCS codes that were implemented July 1, 2014 along with their proposed payment indicators and proposed ASC payment rates for CY 2015.

Through the July 2014 quarterly update CR, we also implemented ASC payment for four new Category III CPT codes as one ASC covered surgical procedure and three covered ancillary services, effective July 1, 2014. These codes were listed in Table 47 of the CY 2015 OPPS/ASC proposed rule (79 FR 41017), along with their proposed payment indicators and proposed payment rates for CY 2015.

The HCPCS codes listed in Table 45 of the CY 2015 OPPS/ASC proposed rule (79 FR 41016) were included in Addenda AA or BB to the proposed rule (which are available via the Internet on the CMS Web site). Because the payment rates associated with the new Level II HCPCS codes and Category III CPT codes that became effective July 1, 2014 (listed in Table 46 and Table 47 of the proposed rule (79 FR 41016 through 41017)) were not available to us in time for incorporation into the Addenda to the OPPS/ASC proposed rule, our policy is to include these HCPCS codes and their proposed payment indicators and payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. These codes and their final payment indicators and rates are included in the appropriate Addendum to this CY 2015 OPPS/ASC final rule with comment period. Therefore, the codes implemented by the July 2014 ASC quarterly update CR and their proposed CY 2015 payment indicators and rates that were displayed in Table 46 and Table 47 of the proposed rule were not included in Addenda AA or BB to the proposed rule (which are available via the Internet on the CMS Web site). The final list of ASC covered surgical procedures and covered ancillary services and the associated payment weights and payment indicators are included in Addenda AA or BB to this CY 2015 OPPS/ASC final rule with comment period, consistent with our annual update policy.

We invited public comment 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 2014 and July 2014 through the quarterly update CRs, as listed in Tables 45, 46, and 47 of the CY 2015 OPPS/ASC proposed rule (79 FR 41016 through 41017). We proposed to finalize their payment indicators and their payment rates in this CY 2015 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding these proposed ASC payment indicators. Therefore, we are adopting as final for CY 2015 the ASC payment indicators for the ASC covered surgical procedures and covered ancillary services described by the new Level II HCPCS codes implemented in April 2014 and July 2014 through the quarterly update CRs as shown below, in Tables 41 and 42, respectively.

For the new Category III CPT codes implemented in July 2014 through the quarterly update CR, as shown below in Table 43, we are not finalizing the ''Z2'' payment indicator that we proposed for CPT codes 0348T, 0349T, and 0350T. For CY 2015, these codes will be conditionally packaged under the OPPS when provided with a significant procedure (status indicator ''Q1''). With the exception of device removal procedures (as discussed in section XII.D.1.b. of this final rule with comment period), HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator ''N1'') under the ASC payment system. Therefore, we are changing the final CY 2015 ASC payment indicator for CPT codes 0348T, 0349T, and 350T from ''Z2'' to ''N1.'' We are adopting as final the payment indicator proposed for CPT code 0356T.

These new HCPCS and CPT codes also are displayed in Addenda AA and BB to this final rule with comment period (which are available via the Internet on the CMS Web site). We note that after publication of the CY 2015 OPPS/ASC proposed rule, the CMS HCPCS Workgroup created permanent HCPCS J-codes for CY 2015 to replace certain temporary HCPCS C-codes and Q-codes made effective for CY 2014. These permanent CY 2015 HCPCS J-codes are listed alongside the temporary CY 2014 HCPCS C-codes and Q-codes in Tables 41 and 42 below. We also note that the CMS HCPCS Workgroup created a long descriptor for J1781 that is slightly different from the long descriptor listed for HCPCS code C9134 in the CY 2015 OPPS/ASC proposed rule.

TABLE 41—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2014

CY 2014 HCPCS code	CY 2015 HCPCS code	CY 2015 long descriptor	Final CY 2015 payment indicator
C9739	C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants	G2
C9740	C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants	G2
C9021	J9301	Injection, obinutuzumab, 10 mg	K2

G2 = Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight.
K2 = Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate.

TABLE 42—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2014

CY 2014 HCPCS code	CY 2015 HCPCS code	CY 2015 long descriptor	Final CY 2015 payment indicator
C2644	C2644	Brachytherapy source, cesium-131 chloride solution, per millicurie	H2
C9022	J1322	Injection, elosulfase alfa, 1mg	K2
C9134	J7181	Injection, Factor XIII A-subunit, (recombinant), per iu	K2
Q9970 *	J1439	Injection, ferric carboxymaltose, 1 mg	K2

* HCPCS code Q9970 replaced HCPCS code C9441 effective July 1, 2014.
H2 = Brachytherapy source paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate.
K2 = Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate.

TABLE 43—NEW CATEGORY III CPT CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2014

CY 2014 CPT code	CY 2015 CPT code	CY 2015 long descriptor	Final CY 2015 payment indicator
0348T		Radiologic examination, radiostereometric analysis (RSA); spine, (includes, cervical, thoracic and lumbosacral, when performed).	N1
0349T		Radiologic examination, radiostereometric analysis (RSA); upper extremity(ies), (includes shoulder, elbow and wrist, when performed).	N1
0350T		Radiologic examination, radiostereometric analysis (RSA); lower extremity(ies), (includes hip, proximal femur, knee and ankle, when performed).	N1
0356T		Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each.	R2

N1 = Packaged service/item; no separate payment made.
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.

3. Process for New Level II HCPCS Codes and Category I and Category III CPT Codes for Which We Are Soliciting Public Comments in This CY 2015 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Category I and Category III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January ASC quarterly update CRs. In the past, we also have released new Level II HCPCS codes that are effective October 1 through the October ASC quarterly update CRs and incorporated these new codes in the final rule with comment period updating the ASC payment system 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.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41017), we proposed to continue this process for CY 2015. Specifically, for CY 2015, we proposed to include in Addenda AA and BB to the CY 2015 OPPS/ASC final rule with comment period any new Category I and III CPT codes effective January 1, 2015, that would be incorporated in the January 2015 ASC quarterly update CR and any new Level II HCPCS codes, effective October 1, 2014 or January 1, 2015, that would be released by CMS in its October 2014 and January 2015 ASC quarterly update CRs. We stated that these codes would be flagged with comment indicator ''NI'' in Addenda AA and BB to this CY 2015 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim payment status. We also stated that their payment indicators and payment rates, if applicable, would be open to public comment in this CY 2015 OPPS/ASC final rule with comment period and would be finalized in the CY 2016 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding this proposed process. Therefore, for CY 2015, we are finalizing our proposal, without modification, to continue our established process for recognizing and soliciting public comments on new Level II HCPCS codes and Category I and III CPT codes that become effective on October 1, 2014, or January 1, 2015, as described above.

C. Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Additions to the List of ASC Covered Surgical Procedures

In the CY 2015 OPPS/ASC proposed rule (79 FR 41017 through 41018), we proposed to update the list of ASC covered surgical procedures by adding 10 procedures to the list for CY 2015. These 10 procedures were among those excluded from the ASC list for CY 2014 because we believed they did not meet the definition of a covered surgical procedure based on our expectation that they would be expected to pose a significant risk to beneficiary safety when performed in an ASC, or would be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. We conducted a review of all 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. We determined that these 10 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 and, therefore, we proposed to include them on the list of ASC covered surgical procedures for CY 2015.

The 10 procedures that we proposed to add to the ASC list of covered surgical procedures, including their HCPCS code long descriptors and proposed CY 2015 payment indicators, were displayed in Table 48 of the CY 2015 OPPS/ASC proposed rule (79 FR 41018).

Comment: Several commenters supported adding the 10 procedures to the CY 2015 covered surgical procedures list for ASCs.

Response: We thank the commenters for their support. As indicated later in this section, we are finalizing our proposal to add these procedure codes to the ASC list, in addition to two other procedure codes recommended by commenters.

Comment: Some commenters stated that the APC relative weight for APC 0208 is too low for the cervical and lumbar fusion procedures (as described by HCPCS codes 22551, 22554, and 22612) proposed to be added to the list of ASC covered surgical procedures, and they urged CMS to reassign these three procedures codes to another APC with a higher relative weight.

Response: As discussed in detail in section II.A.2.e. of this final rule with comment period, we agree with the commenters, and we are reassigning CPT codes 22551, 22554, and 22612 to APC 0425 for CY 2015 because the geometric mean costs of these codes are more similar to the geometric mean cost of APC 0425, which has a higher geometric mean cost than APC 0208.

Comment: Some commenters stated that, in order to perform the procedures proposed to be added to the ASC list of covered surgical procedures, additional procedure codes needed to be added to the list because some of the proposed additions to the list could not be furnished without procedures described by additional codes. Other codes were requested to be added because they represent procedures that are commonly furnished in conjunction with procedures described by the codes that were proposed to be added. Commenters stated that without adding the additional codes for procedures that must be performed in conjunction with or are often performed along with the proposed added procedures, these types of cases will continue to not be furnished in the ASC setting. Commenters stated that some of the procedures described by these codes were covered by other carriers and could be safely performed in the ASC setting for Medicare patients. Some commenters believed that, because Medicare makes facility payments for unlisted CPT codes under the OPPS, CMS should provide ASCs with the same flexibility to use unlisted CPT codes to report procedures. The list of codes that commenters requested to be added in addition to those that were proposed to be added is shown in Table 44 below.

TABLE 44—PROCEDURES REQUESTED FOR ADDITION TO THE CY 2015 LIST OF ASC COVERED SURGICAL PROCEDURES

CY 2015 CPT/ HCPCS codes	CY 2015 short descriptor
19307	Mast mod rad.
20930***	Sp bone algrft morsel add-on.
20931***	Sp bone algrft struct add-on.
20936*	Sp bone agrft local add-on.
20937*	Sp bone agrft morsel add-on.
20938*	Sp bone agrft struct add-on.
22526	Idet single level.
22527	Idet 1 or more levels.
22532*	Lat thorax spine fusion.
22533*	Lat lumbar spine fusion.
22534*	Lat thor/lumb addl seg.
22552*	Addl neck spine fusion.
22558*	Lumbar spine fusion.
22585*	Additional spinal fusion.
22610*	Thorax spine fusion.
22633*	Lumbar spine fusion combined.
22830*	Exploration of spinal fusion.
22840*	Insert spine fixation device.
22842*	Insert spine fixation device.
22845*	Insert spine fixation device.
22846*	Insert spine fixation device.
22849*	Reinsert spinal fixation.
22850*	Remove spine fixation device.
22851	Apply spine prosth device.
22855*	Remove spine fixation device.
22856	Cerv artific diskectomy.
23470	Reconstruct shoulder joint.
28805	Amputation thru metatarsal.
31600	Incision of windpipe.
32551	Insertion of chest tube.
33244	Remove eltrd transven.
35471	Repair arterial blockage.
35903	Excision graft extremity.
37191	Ins endovas vena cava filtr.
37193	Rem endovas vena cava filter.
39400	Mediastinoscopy incl biopsy.
43280	Laparoscopy fundoplasty.
43281	Lap paraesophag hern repair.
43770	Lap place gastr adj device.
44180	Lap enterolysis.
44970	Laparoscopy appendectomy.
54332	Revise penis/urethra.
54336	Revise penis/urethra.
54535	Extensive testis surgery.
54650	Orchiopexy (fowler-stephens).
57120	Closure of vagina.
57282	Colpopexy extraperitoneal.
57283	Colpopexy intraperitoneal.
57310	Repair urethrovaginal lesion.
57425	Laparoscopy surg colpopexy.
58260	Vaginal hysterectomy.
58262	Vag hyst including t/o.
58543	Lsh uterus above 250 g.
58544	Lsh w/t/o uterus above 250 g.
58553	Laparo-vag hyst complex.
58554	Laparo-vag hyst w/t/o compl.
58573	Tlh w/t/o uterus over 250 g.
60252	Removal of thyroid.
60260	Repeat thyroid surgery.
60271	Removal of thyroid.
63011	Remove spine lamina 1/2 scrl.
63012	Remove lamina/facets lumbar.
63015	Remove spine lamina >2 crvcl.
63016	Remove spine lamina >2 thrc.
63017	Remove spine lamina >2 lmbr.
63035	Spinal disk surgery add-on.
63040	Laminotomy single cervical.
63046	Remove spine lamina 1 thrc.
63048	Remove spinal lamina add-on.
63057	Decompress spine cord add-on.
63064	Decompress spinal cord thrc.
63075	Neck spine disk surgery.
63076	Neck spine disk surgery.
77002****	Needle localization by xray.
L-codes**	(L codes for implants—plates and screws, peek or bone, putty—HCPCS not specified).

* CPT codes on the OPPS inpatient list for CY 2015.

** HCPCS codes for prosthetics or prosthetic supplies.

*** CPT codes already on the ASC list of covered surgical procedures.

**** CPT code already on the ASC list of covered ancillary services.

Response: We examined all of the codes that commenters requested for addition to the ASC list of covered surgical procedures. Of the 75 codes requested for addition to the ASC list, we did not review the 19 procedures that are reported by CPT codes that are on the OPPS inpatient list (identified with one asterisk in Table 44), or the unspecified non-surgical HCPCS L-codes (identified with two asterisks in Table 44) because these codes are not eligible for addition to the ASC list of covered surgical procedures, consistent with our final policy which is discussed in detail in the August 2, 2007 final rule (72 FR 42476 through 42486; 42 CFR 416.166). In addition, we did not review the 2 procedures reported by CPT codes that are already on the ASC list of covered surgical procedures (identified with three asterisks in Table 44), or the 1 procedure reported by a CPT code that is on the ASC list of covered ancillary

services (identified with four asterisks in Table 44).

With respect to the remaining procedures described by the 52 codes in Table 44 that commenters requested be added to the list of ASC covered surgical procedures, we do not agree that any of the procedures described by these codes should be added to the list because they do not meet our criteria for inclusion on this list. Under 42 CFR 416.2 and 416.166, 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 would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. The criteria used under the revised ASC payment system to identify procedures that would be expected to pose a significant safety risk when performed in an ASC include, but are not limited to, those procedures that: Generally result in extensive blood loss; require major or prolonged invasion of body cavities; directly involve major blood vessels; are generally emergent or life threatening in nature; commonly require systemic thrombolytic therapy; are designated as requiring inpatient care under § 419.22(n); can only be reported using a CPT unlisted surgical procedure code; or are otherwise excluded under § 411.15 (we refer readers to § 416.166). Procedures that do not meet the criteria set forth in 42 CFR 416.166 would not be added to the list of ASC covered surgical procedures.

Although the commenters asserted that some of the procedures they were requesting for addition to the list are as safe as procedures already on the list, based on our review of the procedures listed in Table 44, we found that all of the remaining procedures described by the 52 codes either would be expected to pose a threat to beneficiary safety or would require active medical monitoring and care of the beneficiary at midnight following the procedure. Specifically, we found that prevailing medical practice called for inpatient hospital stays for beneficiaries undergoing many of the procedures and that some of the procedures directly involve major blood vessels and/or may result in extensive blood loss. Therefore, we are not including any of the procedures suggested by commenters on the list of ASC covered surgical procedures for CY 2015.

Regarding the comment about unlisted codes being noncovered in the ASC, we have a longstanding ASC policy that all unlisted codes are noncovered in the ASC because we are unable to determine (due to the nondescript nature of unlisted codes) if a procedure that would be reported with an unlisted code 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. We continue to believe it would not be appropriate to provide ASC payment for unlisted CPT codes in the surgical range, even if payment may be provided under the OPPS. ASCs do not possess the breadth and intensity of services that hospitals must maintain to care for patients of higher acuity, and we would have no way of knowing what specific procedures reported by unlisted CPT codes were provided to patients in order to ensure that they are safe for ASC performance.

After consideration of the public comments we received, we are finalizing the addition of the 10 HCPCS codes that we proposed to the list of ASC covered surgical procedures for CY 2015. As addressed in section XII.C.1.e. of this final rule with comment period, we also are adding CPT code 63044 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace) to the ASC list of covered surgical procedures for CY 2015. This code was removed from the OPPS inpatient-only list in response to comments and, after review of the procedure described by this code, we believe that the procedure could be safely performed in an ASC and would not require active medical monitoring and care of the beneficiary at midnight following the procedure. The procedure codes, descriptors, and payment indicators for these 11 new covered surgical procedures for CY 2015 are displayed in Table 45 below.

TABLE 45—ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2015

CY 2015 HCPCS code	CY 2015 long descriptor	Final CY 2015 ASC payment indicator
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below c2.	J8
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below c2.	J8
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed).	J8
22614	Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (list separately in addition to code for primary procedure).	N1
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical.	G2
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar.	G2
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar.	G2
63044	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (list separately in addition to code for primary procedure).	N1
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; cervical.	G2
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar.	G2

TABLE 45—ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2015—Continued

CY 2015 HCPCS code	CY 2015 long descriptor	Final CY 2015 ASC payment indicator
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (eg, far lateral herniated intervertebral disc).	G2

b. 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 surgical procedures eligible for payment in ASCs, each year we identify surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that our medical advisors 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) Changes for CY 2015 to Covered Surgical Procedures Designated as Office-Based

In developing the CY 2015 OPPS/ASC proposed rule, we followed our policy to annually review and update the 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 2013 volume and utilization data and the clinical characteristics for all surgical procedures that are assigned payment indicator ''G2'' (Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in CY 2014, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2,'' ''P3,'' or ''R2'' in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75071 through 75075).

Our review of the CY 2013 volume and utilization data resulted in our identification of two covered surgical procedures, CPT codes 10022 and 19296 that we believe meet the criteria for designation as office-based. The data indicate these procedures are performed more than 50 percent of the time in physicians' offices and our medical advisors believe the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The two CPT codes we proposed to permanently designate as office-based were listed in Table 49 of the CY 2015 OPPS/ASC proposed rule (79 FR 41019).

We invited public comment on this proposal.

Comment: One commenter stated that CPT code 10022 was performed only 51 percent of the time in the office setting and recommended that it temporarily be designated as office-based rather than permanently.

Response: As stated in the proposed rule and above, we designate new procedure codes as temporarily office-based in situations where we have little to no utilization data on these procedures and our Medical Officers have determined these procedures are clinically similar to other procedures that are permanently office-based. For CPT code 10022, we have enough volume and utilization data from CY 2013 to indicate that CPT code 10022 is performed more than 50 percent of the time in physicians' offices and our medical advisors believe this service is of a level of complexity consistent with other procedures performed routinely in physicians' offices. Therefore, we believe that this code should be designated as permanently office-based.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to designate the procedures described by CPT codes 10022 and 19296 as permanently office-based for CY 2015, as set forth in Table 46 below.

TABLE 46—ASC COVERED SURGICAL PROCEDURES NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2015

CY 2015 CPT code	CY 2015 long descriptor	CY 2014 ASC payment indicator	Proposed CY 2015 ASC payment indicator*	Final CY 2015 ASC payment indicator*
10022	Fine needle aspiration; with imaging guidance	G2	P3	P3

TABLE 46—ASC COVERED SURGICAL PROCEDURES NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2015—Continued

CY 2015 CPT code	CY 2015 Long descriptor	CY 2014 ASC payment indicator	Proposed CY 2015 ASC payment indicator*	Final CY 2015 ASC payment indicator*
19296	Placement of radiotherapy afterloading expandable catheter (single or multi-channel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy.	G2	P2	P2

* Final payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates effective January 1, 2015. We note that these payment indicators do not include the effect of the negative update to the MPFS payment rates effective April 1, 2015 under current law. Updates to the ASC rates and payment indicators effective April l, 2015 will be included in the April 2015 quarterly ASC addenda posted on the CMS Web site. For a discussion of the MPFS rates, we refer readers to the CY 2015 MPFS final rule with comment period.

We also reviewed CY 2013 volume and utilization data and other information for the 8 procedures finalized for temporary office-based status in Tables 52 and 53 in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75074 through 75075). Among these eight procedures, there were very few claims data or no claims data for six 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 (eg, abscess, hematoma, seroma, lymphocele, cyst), soft tissue (eg, extremity, abdominal wall, neck), percutaneous); CPT code 64617 (Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed); 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 (eg, retinopathy of prematurity), photocoagulation or cryotherapy). Consequently, we proposed to maintain their temporary office-based designations for CY 2015.

We proposed that one procedure that has a temporary office-based designation for CY 2014, CPT code 0226T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed), be packaged under the OPPS for CY 2015. Our policy is to package covered surgical procedures under the ASC payment system if these procedures are packaged under the OPPS. Consequently, we proposed to package, and assign payment indicator ''N1'' to, this covered surgical procedure code in CY 2015.

HCPCS code 0124T (Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication)) was finalized for temporary office-based status in the CY 2014 OPPS/ASC final rule with comment period. However, this code was deleted effective December 31, 2013.

The proposed CY 2015 payment indicator designations for the 7 remaining procedures that were temporarily designated as office-based in CY 2014 were displayed in Table 50 of the CY 2015 OPPS/ASC proposed rule (79 FR 41019). The procedures for which the proposed office-based designations for CY 2015 are temporary also were indicated by asterisks in Addendum AA to the proposed rule (which is available via the Internet on the CMS Web site).

We invited public comment on these proposals.

Comment: One commenter stated that because CPT code 10030 is new for CY 2014, it should not be designated as temporarily office-based at this time.

Response: As stated in the 2014 OPPS/ASC final rule with comment period (78 FR 75074 through 75075), after reviewing the clinical characteristics, utilization, and volume of related codes, we determined that the procedures described by CPT code 10030 would be predominantly performed in physicians' offices. However, because we had no utilization data for CPT code 10030, we made the office-based designation temporary rather than permanent for CY 2014. As discussed above, we continue to have no claims data for this procedure so we are continuing to designate the procedures described by CPT code 10030 as temporarily office-based. We will reevaluate CPT code 10030 in next year's rulemaking.

After consideration of the public comment we received, for CY 2015 we are finalizing our proposal without modification to designate six procedures listed in Table 47 below as temporarily office-based. HCPCS code 0226T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed) was included in our proposal for CY 2015. However, this code will be deleted effective December 31, 2014.

TABLE 47—CY 2015 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2014 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2015 CPT code	CY 2015 long descriptor	CY 2014 ASC payment indicator	CY 2015 ASC payment indicator**
0099T	Implantation of intrastromal corneal ring segments	R2*	R2*
0226T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed.	R2*	D5

TABLE 47—CY 2015 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2014 OPPS/ASC FINAL RULE WITH COMMENT PERIOD—Continued

CY 2015 CPT code	CY 2015 long descriptor	CY 2014 ASC payment indicator	CY 2015 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 (eg, abscess, hematoma, seroma, lymphocele, cyst), soft tissue (eg, extremity abdominal wall, neck), percutaneous.	P2*	P2*
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, 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 (eg, retinopathy of prematurity), photocoagulation or cryotherapy.	R2*	R2*

* If designation is temporary.

** Final payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates effective January 1, 2015. We note that these payment indicators do not include the effect of the negative update to the MPFS payment rates effective April 1, 2015 under current law. Updates to the ASC rates and payment indicators effective April 1, 2015 will be included in the April 2015 quarterly ASC addenda posted on the CMS Web site. For a discussion of the MPFS rates, we refer readers to the CY 2015 MPFS final rule with comment period.

c. ASC Covered Surgical Procedures To Be Designated as Device-Intensive

(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.

(2) Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2015

As we discuss in section II.A.2.e of the CY 2015 OPPS/ASC proposed rule (79 FR 40940 through 40953), for CY 2015, we proposed to implement 28 comprehensive APCs created to replace the current device-dependent APCs and a few nondevice-dependent APCs under the OPPS, which would eliminate all device-dependent APCs for CY 2015. We proposed to define a comprehensive APC as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Because a comprehensive APC would treat all individually reported codes as representing components of the comprehensive service, our OPPS proposal is to make a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service and all adjunctive services provided to support the delivery of the primary service.

Unlike the OPPS claims processing system that can be configured to make a single payment for the encounter-based comprehensive service whenever a HCPCS code that is assigned to a comprehensive APC appears on the claim, the ASC claims processing system does not allow for this type of conditional packaging. Therefore, we proposed that all separately paid covered ancillary services that are provided integral to covered surgical procedures that would map to comprehensive APCs would 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. The OPPS relative payment weights for the comprehensive APCs would include costs for ancillary services; therefore, we could duplicate payment if we based the ASC payment rate on the OPPS relative payment weights for the comprehensive APCs. Therefore, to avoid this issue, we proposed that the ASC payment rates for these comprehensive APCs would be based on the CY 2015 OPPS relative payments weights that have 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 proposed to use 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.

Payment rates for ASC device-intensive procedures are based on a modified payment methodology to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures. Device-intensive procedures are currently 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 proposed to implement the comprehensive APC policy and, therefore, eliminate device-dependent APCs under the OPPS in CY 2015, we need to define ASC device-intensive procedures for CY 2015. We proposed to define ASC device-intensive procedures as those procedures that are assigned to any APC (not only an APC formerly designated device-dependent) with a device offset percentage greater than 40 percent based on the standard OPPS APC ratesetting methodology. We believe that our proposal to lower the offset threshold from greater than 50 percent to greater than 40 percent better aligns with the OPPS device credit policy finalized for CY 2014 (78 FR 75006 and 75007) that applies to procedures with a significant device offset amount, which is defined as exceeding 40 percent of the APC cost. Because the ASC device-intensive methodology is applied to procedures with significant device costs, we believe that the definition of ''significant'' with regard to device-intensive procedures should match that used under the OPPS to determine ''significant'' device costs for the device credit policy. We

proposed changes to § 416.171(b)(2) to reflect this proposal.

We also proposed 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 2013 OPPS claims and cost report data available for the final rule with comment period.

The ASC covered surgical procedures that we proposed to designate as device-intensive and that would be subject to the device-intensive procedure payment methodology for CY 2015 were listed in Table 51 of the proposed rule (79 FR 41021 through 41023). The CPT code, the CPT code short descriptor, the proposed CY 2015 ASC payment indicator (PI), the proposed CY 2015 OPPS APC assignment, the proposed CY 2015 OPPS APC device offset percentage, and an indication if the full credit/partial credit (FB/FC) device adjustment policy would apply also were listed in Table 51. All of these procedures were included in Addendum AA to the proposed rule (which is available via the Internet on the CMS Web site).

We invited public comment on these proposals.

Comment: Some commenters supported the proposal to change the device offset threshold from 50 percent to 40 percent, citing that the proposal allowed for greater flexibility in allowing clinical considerations to determine site-of-care decisions and would likely lead to a migration of services from HOPDs to ASCs. However, some commenters urged CMS to monitor volume and to explore the implications of the expansion of this policy. Other commenters requested that CMS adopt additional changes to the device-intensive policy to encourage migration of services to ASCs from other settings. Some commenters recommended that the device offset percentage be lowered to 30 percent. Some commenters expressed the same views as CMS received in prior rulemaking—that the ASC device offset percentages should be based on a percentage of the total unadjusted ASC cost for a service rather than a percentage of the HOPD, or that the device offset be applied to all procedures for which CMS can establish a device cost regardless of the percentage of the total cost that the device represents. These commenters suggested that these alternatives would result in savings to the Medicare program. Some commenters also expressed the same views as CMS received in prior rulemakings—that CMS should not adjust the device portion of the ASC payment for device-intensive procedures by the wage index.

Response: In the August 2, 2007 final rule (72 FR 42503 through 42508), we established a modified payment methodology for calculating ASC payment rates for device-intensive procedures under the ASC payment system. We defined device-intensive procedures as those procedures that are assigned to device-dependent APCs under the OPPS with device costs of greater than 50 percent of the APC cost under the OPPS (that is, the device offset percentage is greater than 50 percent). In the CY 2015 OPPS/ASC proposed rule (79 FR 41020), we proposed to define ASC device-intensive procedures 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. In that proposed rule, we stated that we believe that lowering the offset threshold from greater than 50 percent to greater than 40 percent better aligns with the OPPS device credit policy finalized for CY 2014 (78 FR 75006 through 75007) that applies to procedures with a significant device offset amount, which is defined as exceeding 40 percent of the APC cost. Because the ASC device-intensive methodology is applied to procedures with significant device costs, we believe that the definition of ''significant'' with regard to device-intensive procedures should match that used under the OPPS to determine ''significant'' device costs for the device credit policy. We do not believe that it should be lowered to 30 percent, because the intent of the policy change is to align significant device cost percentage in the OPPS with the device-intensive procedures in the ASC payment system.

We do not agree with the commenters that the device-intensive methodology should be applied to all procedures where a device offset could be established. Nor do we agree with the commenters who suggested using a threshold to determine device-intensive procedures that is based on the ASC payment rate instead of the OPPS payment rate. Under 42 CFR 416.167 and 416.171, most ASC payment rates are based on the OPPS relative payment weights, and our ASC policy is to be consistent with the OPPS. ''Device intensive'' identifies those procedures assigned to APCs with significant device costs and applies to services that are performed both in the HOPD and ASC. Procedures are not device intensive in one setting and not in another—they either have significant associated device costs or they do not, based on the purpose of the surgical procedure. Accordingly, we believe that the device-intensive methodology for ASCs should align with the device-intensive policies for OPPS.

We also continue to believe it would not be appropriate to vary the portion of the national payment that is wage-adjusted for different services, such as applying the wage index only to the service portion of the ASC payment for device-intensive procedures, as the commenters requested. As indicated above, our ASC policy is to be consistent with the OPPS because ASC payment rates are based on the OPPS relative payment weights. Therefore, we apply the ASC geographic wage adjustment to the entire ASC payment rate for device-intensive procedures. We also refer readers to our responses to similar comments in the CY 2009, CY 2010, CY 2011, CY 2012, CY 2013, and CY 2014 OPPS/ASC final rules with comment period (73 FR 68735; 74 FR 60608 through 60609; 75 FR 72039; 76 FR 74409; 77 FR 68449; and 78 FR 75076, respectively). We respond to the commenters' request to monitor volume and to explore the implications of this policy in the next response.

Comment: Some commenters supported the lowering of the device offset percentage to 40 percent, but stated that this policy, if finalized, would make device-intensive procedures more attractive to ASCs. Commenters suggested that CMS monitor its data to determine whether the policy results in significant increases in volume of these services and that CMS explore the implications of further expanding the list of device-intensive procedures.

Response: We will continue to monitor our data to ensure that our payment policies do not have the unintended consequence of inappropriately encouraging shifts in site of service.

Comment: One commenter expressed appreciation that CMS designated HCPCS code 0334T (Sacroiliac joint stabilization for arthrodesis, percutaneous or minimally invasive (indirect visualization), includes obtaining and applying autograft or allograft (structural or morselized), when performed, includes image guidance when performed (eg, CT or fluoroscopic)) as device-intensive, but expressed concern that the device offset percentage was too low, thereby resulting in an undervalued ASC payment. The commenter stated that

Medicare patients otherwise eligible for this treatment in the ASC would be denied access due to the low ASC payment. The commenter suggested that CMS consider HCPCS-specific device offsets rather than at the APC level. Alternatively, the commenter suggested that CMS add ''device offset similarity'' (that is, identifying and grouping procedure codes based on the similarity of their respective device offsets) as an additional criterion (in addition to clinical and cost similarity) in APC assignment. Another commenter stated that ASC payment for transprostatic implant procedures (as described by HCPCS codes C9739 and C9740) was too low because these procedures were not designated as device-intensive in the ASC setting, and it is unlikely that any transprostatic implant procedures would be conducted in the ASC setting for a Medicare patient.

Response: In the August 2, 2007 ASC final rule (72 FR 42504), we finalized our policy to apply the OPPS device offset percentage to the OPPS national unadjusted payment to acquire 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. The device offset percentage represents a weighted average for all of the procedures assigned to the APC. It is not uncommon that, within an APC, there will be a range of device costs associated with the various procedures assigned to the APC. The device offset for the APC represents a weighted average for all of the procedures assigned to the APC, and the device offset percentage is our best estimate of the amount of device cost included in an APC payment under the OPPS.

We did not propose calculating offsets at the HCPCS level or introducing a new criterion for APC code assignments. These would be significant changes to our longstanding policy of calculating offsets at the APC level, discussed above, and we believe our current policy allows for appropriate payment. Moreover, under 42 CFR 416.167 and 416.171, ASC covered surgical procedures are classified using OPPS APC groups described in 42 CFR 419.31. Under our policy, we cannot assign a CPT code to a different APC for the ASC setting.

We believe that APC 0425 is an appropriate APC assignment for CPT code 0334T based on clinical and resource similarity to other procedures assigned to APC 0425 and have calculated the device offset for this procedure according to our longstanding policy discussed above. We believe that payment for this code is appropriate.

With respect to the comment about ASC payment for transprostatic implant procedures being too low because the procedures do not currently qualify for a device-intensive offset adjustment, as addressed in section III.C.3.e. of this final rule with comment period, for CY 2015, we are maintaining our APC assignments for HCPCS codes C9739 and C9740 to APCs 0162 and 1564, respectively. As discussed in section III.C.3.e. of this final rule with comment period, the APC assignments for HCPCS codes C9739 and C9740 are initial APC assignments until we obtain claims data for these two codes for the CY 2016 OPPS update. We will reevaluate whether these codes qualify for a device-intensive adjustment based on their APC assignments for CY 2016 in next year's rulemaking cycle.

As indicated in section II.A.2.e. of this final rule with comment period, after consideration of the public comments we received regarding the proposed OPPS comprehensive APC policy, we are finalizing our proposal to implement the comprehensive APC policy for CY 2015, with some minor modifications. With respect to modifications to the comprehensive APC policy that affect the ASC payment policy, we note that the finalized comprehensive APC policy includes all device-dependent APCs, except for APCs 0427, 0622, and 0652, which will become standard APCs because we are discontinuing the device-dependent APC policy. This modification does not affect any of our proposals with respect to the finalized comprehensive APCs or the definition of device-intensive.

Given the final OPPS comprehensive APC policy and after consideration of the public comments we received, we are finalizing our proposal that all separately paid covered ancillary services that are provided integral to covered surgical procedures that would map to comprehensive APCs will 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. Further, the ASC payment rates for these comprehensive APCs will be based on the CY 2015 OPPS relative payments weights that have 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) and use 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. We also will define ASC device-intensive procedures 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 and codify this policy in the regulations at 42 CFR 416.171(b)(2). Finally, we will update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with our final modified definition of device-intensive procedures, reflecting the final APC assignments of procedures and APC device offset percentages based on the CY 2013 OPPS claims and cost report data available for this final rule with comment period.

We are designating the ASC covered surgical procedures displayed in Table 48 below as device-intensive and subject to the device-intensive procedure payment methodology for CY 2015. The CPT code, the CPT code short descriptor, the final CY 2015 ASC payment indicator (PI), the final CY 2014 OPPS APC assignment, the final CY 2015 OPPS APC device offset percentage, and an indication if the full credit/partial credit (FB/FC) device adjustment policy will apply, also are listed in Table 48 below. All of these procedures are included in Addendum AA to this final rule with comment period (which is available via the Internet on the CMS Web site).

d. 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.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41021 through 41023), we proposed to update the list of ASC covered device-intensive procedures, based on the revised device-intensive definition proposed above, that would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2015. Table 51 of the proposed rule (79 FR 41021 through 41023) displays the ASC covered device-intensive procedures that we proposed would be subject to the no cost/full credit or partial credit device adjustment policy for CY 2015. Specifically, when a procedure that is listed in Table 51 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 proposed to reduce the payment for implantation procedures listed in Table 51 of the CY 2015 OPPS/ASC proposed rule (79 FR 41021 through 41023) 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 51 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.

We currently apply the ''FB/FC'' modifier policy to device-intensive procedures that involve devices that would be amenable to removal and replacement in a device recall or warranty situation. We proposed to apply the ''FB/FC'' modifier policy to all device-intensive procedures beginning in CY 2015 because, in addition to receiving devices at no cost/full credit or partial credit due to a device recall or warranty situation, ASCs also may receive devices at no cost/full credit or partial credit due to being part of an investigational device trial. 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 proposed to apply our FB/FC policy to all device-intensive procedures.

We invited public comment on these proposals.

We did not receive any comments on this proposal. Therefore, we are finalizing our proposals without modification. Specifically, we will apply our FB/FC policy to all device-intensive procedures beginning in CY 2015. The device-intensive procedures for CY 2015 are listed in Table 48 below. For CY 2015, we will reduce the payment for the procedures listed in Table 48 below by the full device offset amount if a device is furnished without cost or with full credit. ASCs must append the HCPCS modifier ''FB'' to the HCPCS code for a surgical procedure listed in Table 48 below when the device is furnished without cost or with full credit. In addition, for CY 2015, we will reduce the payment for the procedures listed in Table 48 below by one-half of the device offset amount if a device is provided with partial credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the device cost. The ASC must append the HCPCS ''FC'' modifier to the HCPCS code for a surgical procedure listed in Table 48 below when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device.

TABLE 48—ASC COVERED SURGICAL PROCEDURES DESIGNATED AS DEVICE-INTENSIVE FOR CY 2015, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WILL APPLY

HCPCS code	Short descriptor	Final CY 2015 ASC PI	Final CY 2015 OPPS APC	Final CY 2015 device offset percentage	Final FB/FC policy will apply
19298	Place breast rad tube/caths	J8	0648	0.4408	Yes.
19325	Enlarge breast with implant	J8	0648	0.4408	Yes.
19342	Delayed breast prosthesis	J8	0648	0.4408	Yes.
19357	Breast reconstruction	J8	0648	0.4408	Yes.
22551	Neck spine fuse&remov bel c2	J8	0425	0.5565	Yes.
22554	Neck spine fusion	J8	0425	0.5565	Yes.
22612	Lumbar spine fusion	J8	0425	0.5565	Yes.
23515	Treat clavicle fracture	J8	0064	0.4319	Yes.
23585	Treat scapula fracture	J8	0064	0.4319	Yes.
23615	Treat humerus fracture	J8	0064	0.4319	Yes.
23616	Treat humerus fracture	J8	0064	0.4319	Yes.
23630	Treat humerus fracture	J8	0064	0.4319	Yes.
23670	Treat dislocation/fracture	J8	0064	0.4319	Yes.
24361	Reconstruct elbow joint	J8	0425	0.5565	Yes.
24363	Replace elbow joint	J8	0425	0.5565	Yes.
24365	Reconstruct head of radius	J8	0425	0.5565	Yes.
24366	Reconstruct head of radius	J8	0425	0.5565	Yes.
24370	Revise reconst elbow joint	J8	0425	0.5565	Yes.
24371	Revise reconst elbow joint	J8	0425	0.5565	Yes.
24435	Repair humerus with graft	J8	0425	0.5565	Yes.
24498	Reinforce humerus	J8	0425	0.5565	Yes.
24515	Treat humerus fracture	J8	0064	0.4319	Yes.
24516	Treat humerus fracture	J8	0064	0.4319	Yes.
24545	Treat humerus fracture	J8	0064	0.4319	Yes.
24546	Treat humerus fracture	J8	0064	0.4319	Yes.
24575	Treat humerus fracture	J8	0064	0.4319	Yes.
24579	Treat humerus fracture	J8	0064	0.4319	Yes.
24586	Treat elbow fracture	J8	0064	0.4319	Yes.
24587	Treat elbow fracture	J8	0064	0.4319	Yes.
24615	Treat elbow dislocation	J8	0064	0.4319	Yes.
24635	Treat elbow fracture	J8	0064	0.4319	Yes.
24666	Treat radius fracture	J8	0064	0.4319	Yes.
25441	Reconstruct wrist joint	J8	0425	0.5565	Yes.
25442	Reconstruct wrist joint	J8	0425	0.5565	Yes.
25444	Reconstruct wrist joint	J8	0425	0.5565	Yes.
25446	Wrist replacement	J8	0425	0.5565	Yes.
25574	Treat fracture radius & ulna	J8	0064	0.4319	Yes.
25575	Treat fracture radius/ulna	J8	0064	0.4319	Yes.
25607	Treat fx rad extra-articul	J8	0064	0.4319	Yes.
25608	Treat fx rad intra-articul	J8	0064	0.4319	Yes.
25609	Treat fx radial 3+ frag	J8	0064	0.4319	Yes.
26686	Treat hand dislocation	J8	0064	0.4319	Yes.
27279	Arthrodesis sacroiliac joint	J8	0425	0.5565	Yes.
27415	Osteochondral knee allograft	J8	0425	0.5565	Yes.
27428	Reconstruction knee	J8	0425	0.5565	Yes.
27438	Revise kneecap with implant	J8	0425	0.5565	Yes.
27440	Revision of knee joint	J8	0425	0.5565	Yes.
27442	Revision of knee joint	J8	0425	0.5565	Yes.
27443	Revision of knee joint	J8	0425	0.5565	Yes.
27446	Revision of knee joint	J8	0425	0.5565	Yes.
27745	Reinforce tibia	J8	0425	0.5565	Yes.
27759	Treatment of tibia fracture	J8	0064	0.4319	Yes.
27823	Treatment of ankle fracture	J8	0064	0.4319	Yes.
27827	Treat lower leg fracture	J8	0064	0.4319	Yes.
27828	Treat lower leg fracture	J8	0064	0.4319	Yes.
28415	Treat heel fracture	J8	0064	0.4319	Yes.
28715	Fusion of foot bones	J8	0425	0.5565	Yes.
33206	Insert heart pm atrial	J8	0089	0.6972	Yes.
33207	Insert heart pm ventricular	J8	0089	0.6972	Yes.
33208	Insrt heart pm atrial & vent	J8	0089	0.6972	Yes.
33210	Insert electrd/pm cath sngl	J8	0090	0.6858	Yes.
33211	Insert card electrodes dual	J8	0090	0.6858	Yes.
33212	Insert pulse gen sngl lead	J8	0090	0.6858	Yes.
33213	Insert pulse gen dual leads	J8	0089	0.6972	Yes.
33214	Upgrade of pacemaker system	J8	0089	0.6972	Yes.
33216	Insert 1 electrode pm-defib	J8	0090	0.6858	Yes.
33217	Insert 2 electrode pm-defib	J8	0090	0.6858	Yes.
33221	Insert pulse gen mult leads	J8	0655	0.7495	Yes.

TABLE 48—ASC COVERED SURGICAL PROCEDURES DESIGNATED AS DEVICE-INTENSIVE FOR CY 2015, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WILL APPLY—Continued

HCPCS code	Short descriptor	Final CY 2015 ASC PI	Final CY 2015 OPPS APC	Final CY 2015 device offset percentage	Final FB/FC policy will apply
33224	Insert pacing lead & connect	J8	0089	0.6972	Yes.
33227	Remove&replace pm gen singl	J8	0090	0.6858	Yes.
33228	Remv&replc pm gen dual lead	J8	0089	0.6972	Yes.
33229	Remv&replc pm gen mult leads	J8	0655	0.7495	Yes.
33230	Insrt pulse gen w/dual leads	J8	0107	0.7851	Yes.
33231	Insrt pulse gen w/mult leads	J8	0108	0.8114	Yes.
33233	Removal of pm generator	J8	0090	0.6858	Yes.
33240	Insrt pulse gen w/singl lead	J8	0107	0.7851	Yes.
33249	Nsert pace-defib w/lead	J8	0108	0.8114	Yes.
33262	Remv&replc cvd gen sing lead	J8	0107	0.7851	Yes.
33263	Remv&replc cvd gen dual lead	J8	0107	0.7851	Yes.
33264	Remv&replc cvd gen mult lead	J8	0108	0.8114	Yes.
33270	Ins/rep subq defibrillator	J8	0108	0.8114	Yes.
33271	Insj subq impltbl dfb elctrd	J8	0090	0.6858	Yes.
33282	Implant pat-active ht record	J8	0090	0.6858	Yes.
37221	Iliac revasc w/stent	J8	0229	0.5036	Yes.
37225	Fem/popl revas w/ather	J8	0229	0.5036	Yes.
37226	Fem/popl revasc w/stent	J8	0229	0.5036	Yes.
37227	Fem/popl revasc stnt & ather	J8	0319	0.5911	Yes.
37228	Tib/per revasc w/tla	J8	0229	0.5036	Yes.
37229	Tib/per revasc w/ather	J8	0319	0.5911	Yes.
37230	Tib/per revasc w/stent	J8	0319	0.5911	Yes.
37231	Tib/per revasc stent & ather	J8	0319	0.5911	Yes.
37236	Open/perq place stent 1st	J8	0229	0.5036	Yes.
37238	Open/perq place stent same	J8	0229	0.5036	Yes.
53440	Male sling procedure	J8	0385	0.5902	Yes.
53444	Insert tandem cuff	J8	0385	0.5902	Yes.
53445	Insert uro/ves nck sphincter	J8	0386	0.6988	Yes.
53447	Remove/replace ur sphincter	J8	0386	0.6988	Yes.
54400	Insert semi-rigid prosthesis	J8	0385	0.5902	Yes.
54401	Insert self-contd prosthesis	J8	0386	0.6988	Yes.
54405	Insert multi-comp penis pros	J8	0386	0.6988	Yes.
54410	Remove/replace penis prosth	J8	0386	0.6988	Yes.
54416	Remv/repl penis contain pros	J8	0386	0.6988	Yes.
55873	Cryoablate prostate	J8	0385	0.5902	Yes.
61885	Insrt/redo neurostim 1 array	J8	0039	0.8616	Yes.
61886	Implant neurostim arrays	J8	0318	0.8688	Yes.
61888	Revise/remove neuroreceiver	J8	0061	0.5625	Yes.
62361	Implant spine infusion pump	J8	0227	0.8062	Yes.
62362	Implant spine infusion pump	J8	0227	0.8062	Yes.
63650	Implant neuroelectrodes	J8	0061	0.5625	Yes.
63655	Implant neuroelectrodes	J8	0039	0.8616	Yes.
63663	Revise spine eltrd perq aray	J8	0061	0.5625	Yes.
63664	Revise spine eltrd plate	J8	0061	0.5625	Yes.
63685	Insrt/redo spine n generator	J8	0318	0.8688	Yes.
64553	Implant neuroelectrodes	J8	0061	0.5625	Yes.
64555	Implant neuroelectrodes	J8	0061	0.5625	Yes.
64561	Implant neuroelectrodes	J8	0061	0.5625	Yes.
64565	Implant neuroelectrodes	J8	0061	0.5625	Yes.
64568	Inc for vagus n elect impl	J8	0318	0.8688	Yes.
64569	Revise/repl vagus n eltrd	J8	0061	0.5625	Yes.
64575	Implant neuroelectrodes	J8	0061	0.5625	Yes.
64580	Implant neuroelectrodes	J8	0039	0.8616	Yes.
64581	Implant neuroelectrodes	J8	0061	0.5625	Yes.
64590	Insrt/redo pn/gastr stimul	J8	0039	0.8616	Yes.
65770	Revise cornea with implant	J8	0293	0.6611	Yes.
69714	Implant temple bone w/stimul	J8	0425	0.5565	Yes.
69715	Temple bne implnt w/stimulat	J8	0425	0.5565	Yes.
69718	Revise temple bone implant	J8	0425	0.5565	Yes.
69930	Implant cochlear device	J8	0259	0.8283	Yes.
0238T	Trluml perip athrc iliac art	J8	0319	0.5911	Yes.
0282T	Periph field stimul trial	J8	0061	0.5625	Yes.
0283T	Periph field stimul perm	J8	0318	0.8688	Yes.
0302T	Icar ischm mntrng sys compl	J8	0089	0.6972	Yes.
0303T	Icar ischm mntrng sys eltrd	J8	0090	0.6858	Yes.
0304T	Icar ischm mntrng sys device	J8	0090	0.6858	Yes.
0308T	Insj ocular telescope prosth	J8	0351	0.9066	Yes.
0316T	Replc vagus nerve pls gen	J8	0039	0.8616	Yes.

TABLE 48—ASC COVERED SURGICAL PROCEDURES DESIGNATED AS DEVICE-INTENSIVE FOR CY 2015, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WILL APPLY—Continued

HCPCS code	Short descriptor	Final CY 2015 ASC PI	Final CY 2015 OPPS APC	Final CY 2015 device offset percentage	Final FB/FC policy will apply
0387T	Leadless c pm ins/rpl ventr	J8	0319	0.5911	Yes.

e. ASC Treatment of Surgical Procedures Removed From the OPPS Inpatient List for CY 2015

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. In the CY 2015 OPPS/ASC proposed rule (79 FR 41023), we stated there are no procedures proposed for removal from the OPPS inpatient list for CY 2015, so we did not propose any procedures for possible inclusion on the ASC list of covered surgical procedures.

Comment: Some commenters recommended that, if a surgical procedure was removed from the inpatient list, it be made eligible for payment in the ASC setting.

Response: As 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-only list for possible inclusion on the ASC list of covered surgical procedures. We review these procedures and include them on the ASC list of covered surgical procedures only if the surgical procedure 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.

Although there were no procedures proposed for removal from the OPPS inpatient list for CY 2015, we are removing CPT code 63043 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace) and CPT code 63044 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace) from the inpatient-only list in response to a public comment. We refer readers to section IX.B. of this final rule with comment period for our discussion of the CY 2015 inpatient-only list. As discussed previously, because these procedures were removed from the OPPS inpatient-only list, we review them to determine whether they should be included on the list of ASC covered surgical procedures. We believe that the procedure described by CPT code 63044 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 including the procedure described by CPT code 63044 on the list of ASC covered surgical procedures and list the procedure code, descriptor, and payment indicator for this new covered surgical procedure in Table 45 of section XII.C.1.a. of this final rule with comment period. However, we do not believe that the procedure described by CPT code 63043 should be added to the ASC list because we believe that the beneficiary would generally require active medical monitoring and care at midnight following the procedure, so we are not adding it to the list of ASC covered surgical procedures.

2. Covered Ancillary Services

Consistent with the established ASC payment system policy, we proposed to update the ASC list of covered ancillary services to reflect the proposed payment status for the services under the CY 2015 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 2015. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2014 may be proposed for packaged status under the CY 2015 OPPS and, therefore, also under the ASC payment system for CY 2015.

To maintain consistency with the OPPS, we proposed that these services also would be packaged under the ASC payment system for CY 2015. Comment indicator ''CH,'' discussed in section XII.F. of the CY 2015 OPPS/ASC proposed rule (79 FR 41028), is used in Addendum BB to the proposed rule (which is available via the Internet on the CMS Web site) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2015.

Except for the Level II HCPCS codes and Level III CPT codes listed in Table 46 and Table 47 of the proposed rule (79 FR 41016 through 41017), all ASC covered ancillary services and their proposed payment indicators for CY 2015 were included in Addendum BB to the proposed rule (which is available via the Internet on the CMS Web site).

We invited public comment on this proposal.

Comment: Commenters were concerned that, because ASC payment rates are already substantially lower than HOPD rates, packaging these ancillary services codes would not provide adequate payment for all of the procedures being performed, and would result in cases shifting from the ASC to the more expensive HOPD setting. The commenters noted that this was particularly problematic because there are 244 ancillary and surgical codes that are separately payable as procedures in CY 2014 under the OPPS but are proposed to be packaged and no longer separately payable in CY 2015 under the OPPS. The commenters noted that Medicare currently pay ASCs approximately 55 percent of the hospital rate for the same service and expressed concern that packaging the payment for the secondary services will lower the ASC payment even further and discourage the movement of volume to ASCs. Commenters recommended that CMS work to ensure that any packaging policies are not structured to

disproportionately impact the already lower cost provider.

Response: We discuss the OPPS ancillary services packaging policy for CY 2015 in section II.A.3.c.(1) of this final rule with comment period. Of the 21 APCs proposed for conditional packaging under this policy, 17 of the 21 contain services that are not ASC services. Therefore, for the most part, this packaging policy does not apply to the ASC. The four remaining APCs contain primarily minor imaging services, such as a chest X-ray. Most of these diagnostic tests are not typically performed in the ASC; instead, they are performed pre-operatively before the patient has surgery at the ASC. Therefore, we do not believe that ASCs will be adversely impacted by the OPPS ancillary services packaging policy in CY 2015. In addition, to the extent that any of the packaged covered ancillary services are performed with covered surgical procedures, the relative weights of the surgical procedures will reflect the additional cost of the packaged ancillary service. We typically consider the potential effect of OPPS payment policy changes, including new packaging policies, on ASC payments, and we will continue to do so in the future.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS. All CY 2015 ASC covered ancillary services and their final payment indicators are included in Addendum BB to this final rule with comment period (which is available via the Internet on the CMS Web site).

D. ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. 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, the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year is used 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 2014 OPPS/ASC final rule with comment period (78 FR 75064 through 75090), we updated the CY 2013 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2,'' ''G2,'' and ''J8'' using CY 2012 data, consistent with the CY 2014 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2014 OPPS device offset percentages.

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 2015 MPFS proposed rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2014 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 2014 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 2014 payment rate for the procedure according to the final policy of the revised ASC payment system (§ 416.171(d)).

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2015

In the CY 2015 OPPS/ASC proposed rule (79 FR 41024), we proposed to update ASC payment rates for CY 2015 using the established rate calculation methodologies under § 416.171 and using our proposed modified definition of device-intensive procedures, as discussed above. Because the proposed OPPS relative payment weights were based on geometric mean costs for CY 2015, the ASC system used geometric means to determine proposed relative payment weights under the ASC standard methodology. We proposed to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2.''

We proposed 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 proposed modified definition of device-intensive procedures, as discussed above. Therefore, we proposed 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 2015 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 2015 MPFS nonfacility PE RVU-based amount or the proposed CY 2015 ASC payment amount calculated according to the ASC standard ratesetting methodology.

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 CY 2014. For CY 2015, we proposed to continue this policy for the device removal procedures for these same reasons.

We invited public comment on these proposals. We did not receive any public comments on these proposals. Therefore, we are finalizing our proposed policies without modification to calculate the CY 2015 payment rates for ASC covered surgical procedures according to our established methodologies using the modified definition of device-intensive procedures. For those covered surgical procedures where the payment rate is the lower of the final rates under the ASC standard ratesetting methodology and the MPFS final rates, the final payment indicators and rates set forth in this rule are based on a comparison using the MPFS rates effective January 1, 2015. These payment rates and indicators do not include the effect of the negative update to the MPFS payment rates effective April 1, 2015 under current law. Updates to these rates and payment indicators effective April l, 2015 will be included in the April 2015 quarterly ASC addenda posted on the CMS Web site. For a discussion of the MPFS rates, we refer readers to the CY 2015 MPFS final rule with comment period.

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 did not propose any changes to our policies or the categories of services for CY 2015. We identify the specific services with a double asterisk in Addenda AA and BB to this final rule with comment period (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. ASCs use the corresponding HCPCS Level II G-code (G0448) for proper reporting when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service. When not performed on the same day as the service described by CPT code 33225, ASC payment for the service described by CPT code 33249 is based on APC 0108 using the device-intensive methodology. When not performed on the same day as the service described by CPT code 33249, ASC payment for the service described by CPT code 33225 is based on APC 0655 using the device-intensive methodology. For a complete discussion of our policy regarding payment for CRT–D services in ASCs, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74427 through 74428).

In the CY 2015 OPPS/ASC proposed rule (79 FR 41025), for CY 2015, we proposed 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. Consequently, we also proposed that CPT code 33249 would continue to be assigned to APC 0108 and payment for CPT code 33225 would be packaged into the payment for the primary covered surgical procedure (for example, CPT code 33249) under the ASC payment system for CY 2015. Because we proposed to package CPT code 33225 packaged under the ASC payment system and, therefore, it would not receive separate payment, it would no longer be necessary that ASCs use the HCPCS Level II G-code (G0448) for proper reporting when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service.

We invited public comment on these proposals.

We did not receive any public comments on these proposals. Further, we are finalizing 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. Therefore, we are finalizing our proposals under the ASC payment system without modification. Specifically, 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).

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. 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. 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). In the CY 2015 OPPS/ASC proposed rule (79 FR 41025), we did not propose any changes to our current policy regarding ASC payment for LDR prostate brachytherapy services for CY 2015.

2. 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. This modification to the ASC payment methodology for ancillary services was finalized in response to a comment on the CY 2011 OPPS/ASC proposed rule that suggested it is inappropriate to use the MPFS-based payment methodology for nuclear medicine procedures because the associated diagnostic radiopharmaceutical, although packaged under the ASC payment system, is separately paid under the MPFS (42 CFR 416.171(d)(1)). We set the payment indicator to ''Z2'' for these nuclear medicine procedures in the ASC setting so that payment for these procedures would be based on the OPPS relative payment weight rather than the MPFS nonfacility PE RVU-based amount to ensure that the ASC will be compensated for the cost associated with the diagnostic radiopharmaceuticals.

In addition, because the same issue exists for radiology procedures that use contrast agents (the contrast agent is packaged under the ASC payment system but is separately paid under the MPFS), we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430) 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. Currently, the one device that is eligible for pass-through payment in the OPPS is described by HCPCS code C1841 (Retinal prosthesis, includes all internal and external components). The payment amount for HCPCS code C1841 under the ASC payment system is 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 note that the cost for the new pass-through device would not be included in the APC weight because historical claims are used to establish the OPPS relative weights). 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. There are no other device costs included in the APC for the surgical procedure associated with HCPCS code C1841. Therefore, payment for the associated surgical procedure is made according to the standard methodology and no device offset is applied. HCPCS code C1841 was approved for pass-through payment effective October 1, 2013, and will continue to be eligible for pass-through payment in CY 2015.

b. Payment for Covered Ancillary Services for CY 2015

In the CY 2015 OPPS/ASC proposed rule (79 FR 41026 through 41027), for CY 2015, we proposed 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 2015 OPPS and ASC payment rates. We also proposed to continue to set the CY 2015 ASC payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the proposed OPPS payment rates for CY 2015.

Consistent with established ASC payment policy (72 FR 42497), we proposed that the proposed CY 2015 payment for separately payable covered radiology services be based on a comparison of the proposed CY 2015 MPFS nonfacility PE RVU-based amounts (we refer readers to the CY 2015 MPFS proposed rule) and the proposed CY 2015 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 proposed 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 the proposed rule 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 proposed to pay based on the ASC standard ratesetting methodology are assigned payment indicator ''Z2'' (proposed revised definition, as discussed below: 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'' (proposed revised definition, as discussed below: 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 proposed to continue this modification to the payment methodology in CY 2015 and, therefore, set the payment indicator to ''Z2'' for 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 proposed to continue this modification to the payment methodology in CY 2015 and, therefore, proposed to assign the payment indicator ''Z2'' to radiology services that use contrast agents.

Covered ancillary services are items and services that are integral to a covered surgical procedure performed in an ASC for which separate payment may be made under the ASC payment system (42 CFR 416.2). Covered ancillary services include, among other categories of items and services, certain radiology services, including diagnostic imaging services, for which separate payment is allowed under the OPPS when these services are necessary for the successful completion of a surgical procedure and are performed in the ASC immediately preceding, during, or immediately following the covered surgical procedure, as evidenced by the service being provided on the same day as a covered surgical procedure (42 CFR 416.164(b)(5)). Currently, there are certain nonimaging diagnostic tests for which payment is not made under Medicare Part B when provided in an ASC setting although these tests are paid under the OPPS. Therefore, we believe that certain nonimaging diagnostic tests for which separate payment is allowed under the OPPS should be considered covered ancillary services and separately paid when these tests are required for the successful performance of the surgery and are performed in the ASC on the same day as a covered surgical procedure.

Therefore, we proposed that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS be covered ancillary services when they are integral to an ASC covered surgical procedure. We believe that adopting such a payment policy is reasonable and appropriate to ensure access to these tests in ASCs and is consistent with the OPPS. We proposed 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.

We proposed 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 because this would ensure appropriate and equitable payment for these diagnostic tests provided integral to covered surgical procedures and not provide a payment incentive for migration of the tests from physician offices to ASCs. Further, we believe these diagnostic tests are similar to the covered ancillary services that are radiology services, and this is the payment methodology we use for those services. We proposed that the diagnostic tests for which the proposed payment is based on the ASC standard ratesetting methodology be assigned to payment indicator ''Z2'' (proposed revised definition: 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'' (proposed revised definition: Radiology *or diagnostic* service paid separately when provided integral to a surgical

procedure on ASC list; payment based on MPFS nonfacility PE RVUs). We proposed changes to the definitions for payment indicators ''Z2'' and ''Z3,'' as detailed in section XII.F.2. of this final rule with comment period, and proposed changes to § 416.164(a)(11) and (b)(5) as well as § 416.171(b)(1) to reflect these proposals.

We have 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 proposed to add this code to the list of ASC covered ancillary services and proposed 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 would expect the procedure described by CPT code 91035 to be integral to the endoscopic attachment of the electrode to the esophageal mucosa.

Most covered ancillary services and their proposed payment indicators were listed in Addendum BB to the proposed rule (which is available via the Internet on the CMS Web site).

We invited public comment on these proposals.

Comment: Several commenters supported CMS' proposals to expand the scope of ASC covered ancillary services to include certain diagnostic tests and to add CPT code 91035 to the list of ASC covered ancillary services and allow separate payment for this code when the test is integral to an ASC covered surgical procedure. However, these commenters expressed concern regarding the proposed ASC payment for CPT code 91035 and requested that CMS reassign the code to a higher-paying APC.

Response: We thank the commenters for their support for our proposal. Payment for CPT 91035 is addressed in section III.C.2. of this final rule with comment period. Briefly, the ASC payment is dependent upon the APC assignment for this service. Based on our analysis of the latest hospital outpatient claims data used for this final rule with comment period, we believe that CPT code 91035 is appropriately assigned to APC 0361. Our claims data show a geometric mean cost of approximately $466 for CPT code 91035 based on 1,272 single claims (out of 5,099 total claims), and a geometric mean cost of approximately $341 for APC 0361. Further, the geometric mean cost of APC 0142 is approximately $884, which is almost twice the geometric mean cost of CPT code 91035. Also, assignment of 91035 to APC 0142 would create a 2 times violation in APC 0142, because the geometric mean cost of the highest cost significant procedure in APC 0142 (CPT code 44361, with a geometric mean cost of $1,019) is 2.2 times the geometric mean cost of 91035. Therefore, APC 0142 would not be appropriate for 91035 and we are finalizing our CY 2015 proposal to continue to assign CPT code 91035 to APC 0361.

After consideration of the public comments we received, we are finalizing these proposals without modification: to expand the scope of ASC-covered ancillary services to include certain diagnostic tests for which separate payment is allowed under the OPPS when provided integral to covered ASC surgical procedures; to pay for these diagnostic 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; and to revise §§ 416.164(a)(11) and (b)(5) as well as § 416.171(b)(1) to reflect these finalized policies. We also are revising the regulation text at § 416.171(d) to reflect that payment for these tests will be at the lower of the MPFS nonfacility PE RVU-based amount or the rate calculated according to the ASC standard ratesetting methodology, as discussed above and in the CY 2015 OPPS/ASC proposed rule (79 FR 41027). For those covered ancillary services where the payment rate is the lower of the final rates under the ASC standard ratesetting methodology and the MPFS final rates, the final payment indicators and rates set forth in this rule are based on a comparison using the MPFS rates effective January 1, 2015. These payment rates and indicators do not include the effect of the negative update to the MPFS payment rates effective April 1, 2015 under current law. Updates to these rates and payment indicators effective April l, 2015 will be included in the April 2015 quarterly ASC addenda posted on the CMS Web site. For a discussion of the MPFS rates, we refer readers to the CY 2015 MPFS final rule with comment period.

E. New Technology Intraocular Lenses (NTIOLs)

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of new technology intraocular lenses (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 Public Law 103–432 and our regulations at § 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, we 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.
  - The date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class would be set 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 2015

We did not receive any requests for review to establish a new NTIOL class for CY 2015 by March 3, 2014, the due date published in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75085).

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 did not propose to revise the payment adjustment amount for CY 2015.

4. Announcement of CY 2015 Deadline for Submitting Requests for CMS Review of Applications for a New Class of NTIOLs

In accordance with 42 CFR 416.185(a) of our regulations, CMS announces that in order to be considered for payment effective beginning in CY 2016, requests for review of applications for a new class of new technology IOLs must be received at CMS by 5 p.m. EST, on March 2, 2015. Send requests to ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. To be considered, requests for NTIOL reviews must include the information requested on the CMS Web site at: *http://www.cms.gov/ASC Payment/downloads/NTIOLprocess.pdf*.

F. 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). We indicated that in the CY 2015 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 2014 OPPS/ASC final rule with comment period.

The ''CH'' comment indicator was used in Addenda AA and BB to the 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 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. ASC Payment and Comment Indicators

In the CY 2015 OPPS/ASC proposed rule (79 FR 41028), we did not propose any changes to the definitions of the ASC comment indicators for CY 2015. In order to incorporate changes associated with our proposal for CY 2015, as detailed in section XII.D.2.b. of the proposed rule, that certain diagnostic tests qualify as covered ancillary services when provided integral to an ASC covered surgical procedure, we proposed to revise the definitions for payment indicators ''Z2'' and ''Z3'' to add the words ''or diagnostic'' after ''Radiology'' so that the proposed definition for payment indicator ''Z2'' would be ''Radiology *or diagnostic* service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight,'' and the proposed definition for payment indicator ''Z3'' would be ''Radiology *or diagnostic* service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS nonfacility PE RVUs.'' We refer readers to Addenda DD1 and DD2 to the proposed rule (which are available via the Internet on the CMS Web site) for the complete list of ASC payment and comment indicators for the CY 2015 update.

We did not receive any public comments regarding our proposals to change the definitions of ''Z2'' and ''Z3''. Therefore, we are finalizing our proposal to revise the definitions for payment indicators ''Z2'' and ''Z3'' to add the words ''or diagnostic'' after ''Radiology'' so that the revised definition for payment indicator ''Z2'' will be ''Radiology *or diagnostic* service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight,'' and the revised definition for payment indicator ''Z3'' will be ''Radiology *or diagnostic* service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS nonfacility PE RVUs.''

G. Calculation of the ASC Conversion Factor and the 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 and 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.b. of the proposed rule), 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. In other words, 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.

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.

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*.) The pre-floor and pre-reclassified IPPS hospital wage indexes for FY 2014 do not reflect OMB's new area delineations and, because the ASC wage indexes are the pre-floor and pre-reclassified IPPS hospital wage indexes, the CY 2014 ASC wage indexes do not reflect the OMB changes. As discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28054 through 28068), we proposed to use the new CBSAs delineations issued by OMB in OMB Bulletin 13–01 for the IPPS hospital wage index beginning in FY 2015. Therefore, because the ASC wage indexes are the pre-floor and pre-reclassified IPPS hospital wage indexes, the proposed CY 2015 ASC wage indexes reflected the new OMB delineations. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49950 through 49957), we finalized our proposal to use these new OMB delineations for the IPPS hospital wage index. Therefore, the final ASC wage indexes, which are the pre-floor and pre-reclassified IPPS hospital wage indexes, will reflect the new OMB delineations. As discussed in section XII.G.2.b. of the CY 2015 OPPS/ASC proposed rule (79 FR 41030), we proposed a transition to these new OMB delineations for ASCs in certain situations for CY 2015.

We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital whose wage index data would 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). In other situations, where there are no IPPS hospitals located in a relevant labor market area, we will continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2015 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). In the CY 2015 OPPS/ASC proposed rule (79 FR 41029 through 41030), consistent with our established policy, we proposed to scale the CY 2015 relative payment weights for ASCs according to the following method. Holding ASC utilization and the mix of services constant from CY 2013, we proposed to compare the total payment using the CY 2014 ASC

relative payment weights with the total payment using the CY 2015 relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2014 and CY 2015. We proposed to use the ratio of CY 2014 to CY 2015 total payment (the weight scaler) to scale the ASC relative payment weights for CY 2015. The proposed CY 2015 ASC scaler was 0.9142 and scaling would apply to the ASC relative payment weights of the covered surgical procedures and covered ancillary radiology 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. For this final rule with comment period, we used CY 2013 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 2013 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2013 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 the 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. Transition Period to New OMB Delineations for ASC Wage Index

As discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28054 through 28055), we proposed to use the new CBSA delineations issued by OMB in OMB Bulletin 13–01 dated February 28, 2013 for the IPPS hospital wage index. Therefore, because the ASC wage indexes are the pre-floor and pre-reclassified IPPS hospital wage indexes, the proposed CY 2015 ASC wage indexes reflected the new OMB delineations. While we believe that instituting the latest OMB labor market area delineations would create a more accurate and up-to-date wage index system, we also recognize that implementing the new OMB delineations may cause some short-term instability in ASC payments. Therefore, we proposed a transition to the new OMB delineations similar to what we proposed for the IPPS for FY 2015 (79 FR 28062) and the OPPS as described in section II.C of the proposed rule. Specifically, for ASCs, we proposed a 1-year blended wage index for all ASCs that would experience any decrease in their actual wage index exclusively due to the implementation of the new OMB delineations. For ASCs where the CY 2015 ASC wage index with the CY 2015 CBSAs would be lower than with the CY 2014 CBSAs, we proposed that the CY 2015 ASC wage index would be 50 percent of the ASC wage index based on the CY 2014 CBSA and 50 percent of the ASC wage index based on the new CY 2015 CBSA. We believe a 1-year 50/50 blended wage index would mitigate the short-term instability and negative payment impacts due to the proposed implementation of the new OMB delineations, providing ASCs that would be negatively impacted by the new OMB delineations with a transition period during which they may adjust to their new geographic CBSA. We believe that a longer transition period would reduce the accuracy of the overall labor market area wage index system.

Comment: Some commenters objected to CMS continuing to use the pre-floor and pre-reclassified IPPS hospital wage indexes for the labor portion of ASC costs. These commenters stated that ASCs and hospitals compete in the same local markets and provide many of the same services and require similar staff. Commenters stated that the different wage index for hospitals than for ASCs increases the gap between the OPPS and ASC payment rates.

Response: 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. We have responded to similar comments in the past and believe our prior rationale for using unadjusted wage indexes is still a sound one. 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. We did not propose to change our use of the pre-floor, pre-reclassified IPPS wage indexes for the ASC wage index. Therefore, in addition to the reasons stated above, we will continue to apply the pre-floor, pre-reclassified IPPS hospital wage indexes for the labor portion of ASC costs. We refer readers to our responses to similar comments in the CY 2010, CY 2011, CY 2012, CY 2013, and CY 2014 OPPS/ASC final rules with comment period (74 FR 60625; 75 FR 72059; 76 FR 74446; 77 FR 68463; and 78 FR 75086, respectively).

Comment: Commenters supported CMS' proposal to phase in reductions to the ASC wage indexes that occur as a result of the new OMB labor market delineations.

Response: We appreciate the commenters' support and, as stated below, we are finalizing this policy as proposed.

After consideration of the public comments we received, we are finalizing our proposal to apply a 1-year blended wage index for all ASCs that would experience any decrease in their actual wage index exclusively due to the implementation of the new OMB delineations. Specifically, for ASCs where the CY 2015 ASC wage index with the CY 2015 CBSAs is lower than with the CY 2014 CBSAs, we will calculate the CY 2015 ASC wage index such that it will be 50 percent of the ASC wage index based on the CY 2014 CBSA and 50 percent of the ASC wage index based on the new CY 2015 CBSA.

c. 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. In the CY 2015 OPPS/ASC proposed rule (79 FR 41030 through 41031), consistent with our final ASC payment policy, for the CY 2015 ASC payment system, we proposed 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 2015, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2013 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2015 ASC wage indexes. Specifically, holding CY 2013 ASC utilization and service-mix and the proposed CY 2015 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2014 ASC wage indexes and the total adjusted payment using the proposed CY 2015 ASC wage indexes (which reflect the new OMB delineations and would include any applicable transition period). 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 2014 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2015 ASC wage indexes and applied the resulting ratio of 0.9983 (the proposed CY 2015 ASC wage index budget neutrality adjustment) to the CY 2014 ASC conversion factor to calculate the proposed CY 2015 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.'' The statute, therefore, 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 illustrative examples of how the MFP adjustment is applied to the ASC payment system.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41031), based on IHS Global Insight's (IGI's) 2014 first quarter forecast with historical data through 2013 fourth quarter, for the 12-month period ending with the midpoint of CY 2015, the CPI–U update was projected to be 1.7 percent. Also, based on IGI's 2014 first quarter forecast, the MFP adjustment for the period ending with the midpoint of CY 2015 was projected to be 0.5 percent. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of CMS' market baskets as well as the CPI–U and MFP. 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). 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 proposed to reduce the CPI–U update of 1.7 percent by the MFP adjustment of 0.5 percentage point, resulting in an MFP-adjusted CPI–U update factor of 1.2 percent for ASCs meeting the quality reporting requirements. Therefore, we proposed to apply a 1.2 percent MFP-adjusted CPI–U update factor to the CY 2014 ASC conversion factor for ASCs meeting the quality reporting requirements. We proposed 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 0.5 percentage point MFP reduction. Therefore, we proposed to apply a −0.8 percent quality reporting/MFP-adjusted CPI–U update factor to the CY 2014 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also proposed that if more recent data are subsequently available (for example, a more recent estimate of the CY 2015 CPI–U update and MFP adjustment), we would use such data, if appropriate, to determine the CY 2015 ASC update for the final rule with comment period.

For CY 2015, we also proposed to adjust the CY 2014 ASC conversion factor ($43.471) by the proposed wage index budget neutrality factor of 0.9983 in addition to the MFP-adjusted update factor of 1.2 percent discussed above, which results in a proposed CY 2015 ASC conversion factor of $43.918 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we proposed to adjust the CY 2014 ASC conversion factor ($43.471) by the proposed wage index budget neutrality factor of 0.9983 in addition to the quality reporting/MFP-adjusted update factor of −0.8 percent discussed above, which results in a proposed CY 2015 ASC conversion factor of $43.050.

We invited public comment on these proposals.

Comment: Some commenters stated that CMS should replace the CPI–U as the update mechanism for ASC payments with the hospital market basket. Commenters stated that the CPI–U measures inflation in a basket of consumer goods atypical of what ASCs purchase. In addition, the commenters stated that the Affordable Care Act requires CMS to reduce the update by a measure of productivity gains, which inappropriately subjects ASCs to two productivity adjustments: improvements reflected in the price of consumer purchased goods and the additional statutorily required reduction. While the commenters maintained that the hospital market basket would be the most appropriate update for ASCs, they suggested that there are various alternatives within the CPI–U that CMS could explore that more accurately reflect the economic climate in the ASC environment. For instance, CMS could use subsets of the CPI–U (medical care, medical care services, and outpatient services) that are consistent with the services being provided in the ASC setting.

MedPAC commented that, in the CY 2013 rulemaking, CMS requested public comment on the feasibility of ASC cost information to determine whether CPI–U or another type of update factor would be more appropriate, but that CMS did not propose to begin collecting ASC cost data. MedPAC acknowledged that there may be a burden associated with requiring ASCs to submit cost reports, but recommended that CMS collect some sort of ASC cost data, such as through surveys.

Response: As we have stated in response to similar comments in the past (for example, 77 FR 68465; 78 FR 75088 through 75089), we continue to believe that, while commenters argue that the items included in the CPI–U index may not adequately measure inflation for the goods and services provided by ASCs, the hospital market basket does not align with the cost structures of ASCs. Hospitals provide a much wider range of services, such as room and board and emergency services, and the costs associated with providing these services are not part of the ASC cost structure. Therefore, at this time, we do not believe that it is appropriate to use the hospital market basket for the ASC annual update.

We recognize that the CPI–U is an output price index that accounts for productivity. However, section 1833(i)(2)(D)(v) of the Act requires the agency to reduce the annual update factor by the MFP adjustment. For the reasons stated above, we do not believe that the hospital market basket appropriately reflects the cost structures of ASCs, and because we do not have cost data on ASCs, we are continuing to use the CPI–U which we believe provides a reasonable approximation of the price increases facing ASCs. We will continue to explore the feasibility of collecting ASC cost data. However, based on our past experience, we do not believe that collecting such data through surveys would be productive. We appreciate the commenter's suggestion to adjust the CPI–U, such as by using subsets of services within the CPI–U, for productivity and will take this suggestion into consideration if we propose changes to the ASC update factor in the future.

After consideration of the public comments we received, we are applying our established methodology for determining the final CY 2015 ASC conversion factor. Using more complete CY 2013 data for this final rule with comment period than were available for the proposed rule, we calculated a wage index budget neutrality adjustment of 0.9998. Based on IGI's 2014 third quarter forecast, the CPI–U for the 12-month period ending with the midpoint of CY 2015 is now projected to be 1.9 percent, while the MFP adjustment (as discussed and finalized in the CY 2012 MPFS final rule with comment period (76 FR 73300 through 73301)) is 0.5 percent, resulting in an MFP-adjusted CPI–U update factor of 1.4 percent for ASCs that meet the quality reporting requirements. The final ASC conversion factor of $44.071, for ASCs that meet the quality reporting requirements, is the product of the CY 2014 conversion factor of $43.471 multiplied by the wage index budget neutrality adjustment of 0.9998 and the MFP-adjusted CPI–U payment update of 1.4 percent. For ASCs that do not meet the quality reporting requirements, we are reducing the CPI–U update of 1.9 percent by 2.0 percentage points and then we are applying the 0.5 percentage point MFP reduction, resulting in a -0.6 percent quality reporting/MFP-adjusted CPI–U update factor. The final ASC conversion factor of $43.202 for ASCs that do not meet the quality reporting requirements is the product of the CY 2014 conversion factor of $43.471 multiplied by the wage index budget neutrality adjustment of 0.9998 and the quality reporting/MFP-adjusted CPI–U payment update of −0.6 percent.

3. Display of CY 2015 ASC Payment Rates

Addenda AA and BB to this CY 2015 OPPS/ASC final rule with comment period (which are available via the Internet on the CMS Web site) display the final updated ASC payment rates for CY 2015 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 final rates under the ASC standard ratesetting methodology and the MPFS final rates, the final payment indicators and rates set forth in this rule are based on a comparison using the MPFS rates effective January 1, 2015. These payment rates and indicators do not include the effect of the negative update to the MPFS payment rates effective April 1, 2015 under current law. Updates to these rates and payment indicators effective April l, 2015 will be included in the April 2015 quarterly ASC addenda posted on the CMS Web site. For a discussion of the MPFS rates, we refer readers to the CY 2015 MPFS final rule with comment period. The 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 CY 2015 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''Subject to Multiple

Procedure Discounting'' indicates that the surgical procedure will 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 2015. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that the payment indicator assignment is an interim assignment that is open to comment in the final rule with comment period.

The values displayed in the column titled ''CY 2015 Payment Weight'' are the relative payment weights for each of the listed services for CY 2015. The payment weights for all covered surgical procedures and covered ancillary services whose 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 CY 2015 payment rate displayed in the ''CY 2015 Payment Rate'' column, each ASC payment weight in the ''CY 2015 Payment Weight'' column was multiplied by the CY 2015 conversion factor of $44.071. The 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.H.2.b. of this final rule with comment period).

In Addendum BB, there are no relative payment weights displayed in the ''CY 2015 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''CY 2015 Payment'' column displays the CY 2015 national unadjusted ASC payment rates for all items and services. The CY 2015 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 October 2014.

Addendum E provides the HCPCS codes and short descriptors for surgical procedures that are to be excluded from payment in ASCs for FY 2015.

We did not receive any public comments regarding the continuation of our policy to provide CY 2015 ASC payment information as detailed in Addenda AA and BB. Therefore, Addenda AA and BB to this final rule with comment period (which are available via the Internet on the CMS Web site) display the updated ASC payment rates for CY 2015 for covered surgical procedures and covered ancillary services, respectively, and provide additional information related to the CY 2015 rates.

XIII. Hospital Outpatient Quality Reporting Program Updates

A. Background

1. Overview

CMS seeks to promote higher quality and more efficient health care 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 (LTCHQR) Program;
- PPS-exempt cancer hospitals, under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;
- Ambulatory surgical centers, under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program;
- Inpatient psychiatric facilities, under the Inpatient Psychiatric 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 two value-based purchasing programs, the Hospital Value-Based Purchasing (Hospital 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 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 our 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.

3. Measure Updates and Data Publication

a. 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.*

Many of the quality measures used in Medicare and Medicaid reporting programs are endorsed by the National Quality Forum (NQF). We note that not all of the measures adopted by the Hospital OQR Program are NQF-endorsed, nor is NQF endorsement a program requirement (section 1833(t)(17)(C)(i) of the Act). As part of its regular maintenance process for endorsed performance measures, the NQF requires measure stewards (owners/developers) to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes with the NQF on an annual basis. The NQF solicits information from measure stewards for annual reviews, and it reviews measures for continued endorsement in a specific 3-year cycle.

We note that the NQF's annual or triennial maintenance processes for endorsed measures may result in the NQF requiring updates to measures in order to maintain endorsement status. Other non-NQF measures may undergo maintenance changes as well. We believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates into the measure specifications for measures that we have adopted for the Hospital OQR Program so that these measure specifications remain current. We also recognize that some changes to measures are substantive in nature and might not be appropriate for adoption using a subregulatory process.

Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68469 through 68470), we finalized our proposal to follow the same process for updating Hospital OQR Program measures that we adopted for the Hospital IQR Program measures, including the subregulatory process for making updates to the adopted measures (77 FR 53504 through 53505). This process 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).

b. Public Display of Quality Measures

We refer readers to the CY 2014 OPPS/ASC proposed rule (78 FR 43645) for a discussion of our policy for the publication of Hospital OQR Program data on the *Hospital Compare* Web site and noninteractive CMS Web sites.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41033), we did not propose any changes to our policies on the public display of quality measures.

Comment: One commenter urged CMS to continue to keep stakeholders such as physicians, hospitals, measure developers, and patient groups engaged in public reporting to ensure that accurate and beneficial reporting is performed. This commenter encouraged CMS to establish streamlined policies and procedures for partnering with nongovernmental entities that have an interest in posting data through ongoing communication with these stakeholders, including the rulemaking process.

Response: We interpret the commenter's suggestion to ''. . . establish streamlined policies and procedures for partnering with nongovernmental entities that have an interest in posting data . . .'' to mean that we should establish streamlined policies and procedures to partner with physicians, hospitals, measure developers, and patient groups that wish to be involved in our quality data reporting efforts. To the extent feasible and practical, we work with as many stakeholders as possible to ensure data are accurately reported and displayed on *Hospital Compare* and other CMS Web sites. In the future, we will continue working with stakeholders to consolidate and streamline reporting.

B. Process for Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471), we finalized a policy that once a quality measure is adopted for the Hospital OQR Program, it is retained for use in subsequent years unless otherwise specified.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41033), we did not propose any changes to the process for retaining measures previously adopted.

C. Removal of Quality Measures From the Hospital OQR Program Measure Set

1. Considerations in Removing Quality Measures From the Hospital OQR Program

In the FY 2010 IPPS/LTCH PPS final rule, 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.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185), we finalized a set of criteria for determining whether to remove measures from the Hospital IQR Program. These criteria are: (1) Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures); (2) performance or improvement on a measure does not result in better patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) 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 such as patient harm. These criteria were suggested through public comment on proposals for the Hospital IQR Program, and we determined that these criteria are also applicable in evaluating the Hospital OQR Program quality measures for removal.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473), we finalized our proposal to apply these measure removal criteria in the Hospital OQR Program as well. In addition to the Hospital IQR Program's criteria, we consider eliminating measure redundancy and incorporating the views of the Measure Applications Partnership (MAP) when evaluating measures for removal.

2. Criteria for Removal of ''Topped-Out'' Measures

In the CY 2015 OPPS/ASC proposed rule (79 FR 41033 through 41034), we proposed to refine the criteria for determining when a measure is ''topped-out.'' We had previously finalized that a measure is ''topped-out'' when measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures) (77 FR 68472). We do not believe that measuring hospital performance on ''topped-out'' measures provides meaningful information on the quality of care provided by hospitals. We further believe that quality measures, once ''topped-out,'' represent care standards that have been widely adopted by hospitals. We believe such measures should be considered for removal from the Hospital OQR Program because their associated reporting burden may outweigh the value of the quality information they provide.

In order to determine ''topped-out'' status, we proposed to apply the following two criteria, the first of which was previously adopted by the Hospital VBP Program for certain measures in the Hospital Inpatient VBP Program final rule (76 FR 26510). The second criterion is a modified version of what was previously adopted by the Hospital VBP Program in the above mentioned final rule (76 FR 26510), with the change from the ''less than'' operator (<) to the ''less than or equal to'' operator (≤). Specifically, we proposed that a measure under the Hospital OQR Program is ''topped-out'' when it meets both of the following criteria:

- Statistically indistinguishable performance at the 75th and 90th percentiles; and
- A truncated coefficient of variation less than or equal to 0.10.

To identify if a measure has statistically indistinguishable performance at the 75th and 90th percentiles, we would determine whether the difference between the 75th and 90th percentiles for a measure is within two times the standard error of the full dataset. The coefficient of variation (CV) is a descriptive statistic that expresses the standard deviation as a percentage of the sample mean; this provides a statistic that is independent of the units of observation. Applied to this analysis, a large CV would indicate a broad distribution of individual hospital scores, with large and presumably meaningful differences between hospitals in relative performance. A small CV would indicate that the distribution of individual hospital scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions among individual hospitals' measure performance. The truncated CV excludes observations with rates below the 5th percentile and above the 95th percentile. We adopted the second of these ''topped-out'' criteria for the Hospital VBP Program (79 FR 50055). Both criteria were adopted for the Hospital IQR Program (79 FR 50204) and are being adopted for the ASCQR Program (section XIV.A.3. of this final rule with comment period).

We invited public comment on this proposal.

Comment: Many commenters supported CMS' proposed criteria for identifying ''topped-out'' measures. Some commenters recommended that CMS proceed cautiously, expressing concern that removal of measures could disrupt hospitals' quality improvement efforts. Some commenters believed there is value in collecting data on some topped-out measures, regardless of national performance scores. Other commenters urged CMS to assess the topped-out measures individually and in a broader context before removing them.

Response: We agree that, in some cases, measures that are quantitatively ''topped-out'' may still be appropriate if, for example, the specified care topic is important to providers and/or beneficiaries or if some classes or some hospitals may still have room for improvement with the measure. We recognize that some measures may not be appropriate for the topped-out analysis, including measures of outcomes for which small numbers are desired (for example, hospital-acquired infection and patient safety oriented measures). We note that ''topped-out'' status is only one of many factors we consider in removing measures. We consider the removal of each topped-out measure on a case-by-case basis, as appropriate, and determine whether a clinical or other quality improvement need for the measure justifies the retention of a topped-out measure that otherwise meets our criteria. We refer readers to III.C.1. of this final rule with comment period, ''Considerations in Removing Quality Measures from the Hospital OQR Program,'' for a discussion of the different factors we consider in removing measures.

Comment: Many commenters urged CMS to continue monitoring performance on ''topped-out'' measures to ensure that high performance continues and that quality gains are sustained.

Response: We expect hospitals to always follow appropriate standards-of-care and clinical guidelines regardless of whether a quality measure exists. We believe that HOPDs are committed to providing quality care to patients and we do not have any indication that HOPDs will stop doing so when measures are removed. We currently monitor the performance of removed measures to ensure that performance does not decline significantly and will continue to do so. However, we must balance the costs of continued monitoring of a successful measure with high levels of performance with the adoption of other measures where there are opportunities for improvement in clinical quality.

At this time, we believe the two finalized topped-out criteria will ensure the detection of potential topped-out measures that have high performance with little variability. However, we will consider the need for refinement and, if we determine changes may be necessary, we will propose such changes in future rulemaking.

After consideration of the public comments we received, we are finalizing the ''topped-out'' criteria as proposed. Specifically, we are finalizing a policy that a measure under the Hospital OQR Program is ''topped-out'' when it meets both of the following criteria: (1) Statistically indistinguishable performance at the 75th and 90th percentiles; and (2) a truncated coefficient of variation less than or equal to 0.10. To identify if a measure has statistically indistinguishable performance at the 75th and 90th percentiles, we will determine whether the difference between the 75th and 90th percentiles for a measure is within two times the standard error of the full dataset. However, consistent with our discussion above at XIII.C.1. of this final rule with comment period, ''Considerations in Removing Quality Measures from the Hospital OQR Program,'' we evaluate different factors in considering the removal of measures. We will assess the benefits of retaining a measure on a case-by-case basis before proposing to remove a measure from the Hospital OQR Program.

3. Removal of Measures From the Hospital OQR Program for the CY 2017 Payment Determination and Subsequent Years

In the CY 2015 OPPS/ASC proposed rule (79 FR 41034), we proposed to remove three measures for the CY 2017 payment determination and subsequent years: OP–4, OP–6, and OP–7. Based on our analysis of Hospital OQR Program

chart-abstracted measure data for January 1, 2013–June 30, 2013 (Q1–Q2) encounters, the following measures met both: (1) The previously finalized criteria for being ''topped-out''; that is, measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (77 FR 68472); and (2) the two criteria we finalized in section XIII.C.2. of this final rule with comment period for determining ''topped-out'' status. These measures are:

- OP–4: Aspirin at Arrival (NQF # 0286);
- OP–6: Timing of Antibiotic Prophylaxis; and
- OP–7: Prophylactic Antibiotic Selection for Surgical Patients (NQF # 0528).

Therefore, we proposed to remove these three measures from the Hospital OQR Program beginning with the CY 2017 payment determination.

We believed that removal was appropriate as there appeared little room for improvement for these measures, all of which address standards of clinical care. In addition, by removing these measures, we hoped to alleviate the maintenance costs and administrative burden to hospitals associated with retaining them. Should we determine that hospital adherence to these practices has unacceptably declined, we stated that we would re-propose these measures in future rulemaking. In addition, we would comply with any requirements imposed by the Paperwork Reduction Act before reinstituting these measures. We noted that we removed three measures under the Hospital IQR Program similar to these measures; the similar measures were AMI–1, SCIP–Inf–1, and SCIP–Inf–2, respectively. We note that we retained SCIP–Inf–1 and SCIP–Inf–2 as voluntarily reported electronic clinical quality measures in the Hospital IQR Program (79 FR 50208).

We invited public comment on these proposals.

Comment: Many commenters supported the proposal to remove OP–4, OP–6, and OP–7, noting that the removal would reduce administrative burden on hospitals. Some commenters specifically supported the removal of these measures to align with the Hospital IQR Program. One commenter recommended the removal of the three proposed topped-out measures effective January 2015, to reduce administrative burden for hospitals.

Response: We thank the commenters for their support. We continue to look for ways to minimize burden as we pursue the quality objectives of the Hospital OQR Program. We agree that quality of care measures should be aligned across our quality reporting and value-based purchasing programs to the extent possible. The patient encounter period for the CY 2017 payment determination is January 1, 2015 through December 31, 2015. Thus, for patient encounters beginning January 1, 2015, hospitals would not be required to submit data on any measures that we are finalizing for removal as discussed below.

Comment: Some commenters inquired about the criteria for resuming data collection for measures that are removed from the Hospital OQR Program. One commenter recommended that CMS establish a process, similar to the one used by NQF, to place a measure in ''reserve status'' for some time after the measure is determined to be ''topped-out'' to ensure no ''backsliding'' has occurred. Another commenter suggested that CMS consider sampling hospitals on their performance on these removed measures to ensure continued high performance on these measures.

Response: We thank the commenters for their suggestions to monitor topped-out measures for continued high performance and we understand their concerns of backsliding. Should we determine that hospital adherence to these practices has unacceptably declined; we would propose to reinstate the measure in future rulemaking to resume data collection. We expect hospitals to always follow appropriate standards-of-care and clinical guidelines in exercising positive interventions, regardless of whether a measure is removed.

Comment: Some commenters urged CMS to retain OP–4 for voluntary reporting. Some commenters opposed the removal of OP–4, noting that this measure provides incentives for better care and improves patient outcomes, and the data help Medicare beneficiaries make informed choices about their health care options. One commenter recommended that CMS not remove OP–4 until there are at least 2 years of continued high performance data.

Response: We agree with the commenters that OP–4 should be retained. Upon further analysis, we have found that, although technically ''topped-out,'' the rate distributions for OP–4 indicate that hospitals with a small number of cases have lower rates. Because performance for OP–4 is still low in some hospitals, and there is substantial evidence indicating that aspirin at arrival is associated with better patient outcomes, we are not finalizing our proposal to remove OP–4.

Comment: Some commenters opposed the removal of OP–6 and OP–7, noting that the removal of these measures may cause unnecessary harm to surgical patients. One commenter recommended that CMS not remove OP–6 and OP–7 until there are at least 2 years of continued high performance data.

Response: We thank the commenters for expressing their concerns. Our proposed criteria for topped-out measures did not include a timeframe for sustained statistical performance; however, we will take this suggestion into consideration for future rulemaking. Based on our topped-out analysis, both OP–6 and OP–7 are ''topped-out'' across hospitals, and we do not believe that removal of these two measures would cause unnecessary harm to surgical patients because our data show that hospital performance on OP–6 and OP–7 is high and unvarying, indicating that HOPDs have been in compliance with OP–6 in exercising the correct timing as well as with OP–7 in administering the appropriate antibiotic for surgical patients. In addition, unlike OP–4, we did not see indications in the measure distributions for OP–6 and OP–7 that imply outlier hospitals with a small number of cases have statistically significantly lower rates. Therefore, this leads us to believe that removal of these two measures would not cause unnecessary harm to surgical patients. Because our data indicate that hospital performance on OP–6 and OP–7 is high and unvarying, we believe the costs associated with the maintenance of our administrative systems and the costs to hospitals to continue reporting outweigh the benefits of retaining of these measures in the Hospital OQR Program. We expect hospitals to follow appropriate standards-of-care and clinical guidelines in exercising positive interventions, regardless of whether a measure is removed. Therefore, as noted below, we are finalizing our proposal to remove the OP–6 and OP–7 measures and will continue to monitor clinical trends and repropose these measures if we see the performance gap widening.

Comment: One commenter noted that, beginning with CY 2015 reporting, hospitals will be required to report a new element (Rectal Culture-Guided Antibiotic) for OP–7. The commenter requested clarification because CMS proposed to remove this measure.

Response: We clarify that, as stated above, we are removing OP–7 from the Hospital OQR Program beginning with the CY 2017 payment determination. The patient encounter period for the CY 2017 payment determination is January 1, 2015 through December 31, 2015. Therefore, beginning with CY 2015

patient encounters, hospitals are not required to submit Rectal Culture-Guided Antibiotic data or other data for OP–7.

After consideration of the public comments we received and for the reasons we discussed above, we are finalizing our proposal to remove OP–6 and OP–7 from the Hospital OQR Program as proposed. However, we are not finalizing our proposal to remove OP–4 and are retaining that measure in the Hospital OQR Program for reasons discussed above. Hospitals are to report data on OP–4 as previously required. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (FR 72 66865), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68482), and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75111 through 75112) for more information about OP–4 and the data submission requirements. Set out in the table below are the measures we are removing for the CY 2017 payment determination and subsequent years.

HOSPITAL OQR PROGRAM MEASURES REMOVED FOR THE CY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF #	Measure
N/A	OP–6: Timing of Prophylactic Antibiotics
0528	OP–7: Prophylactic Antibiotic Selection for Surgical Patients

D. Quality Measures Previously Adopted for the CY 2016 Payment Determination and Subsequent Years

As previously discussed, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471), we finalized a policy that, beginning CY 2013, when we adopt measures for the Hospital OQR Program, these measures are automatically adopted for all subsequent years' payment determinations, unless we propose to remove, suspend, or replace the measures. The table below lists 27 measures that we adopted for the CY 2016 payment determination and subsequent years under the Hospital OQR Program.

HOSPITAL OQR PROGRAM MEASURE SET PREVIOUSLY ADOPTED FOR THE CY 2016 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
0286	OP–4: Aspirin at Arrival
0289	OP–5: Median Time to ECG
N/A	OP–6: Timing of Prophylactic Antibiotics **
528	OP–7: Prophylactic Antibiotic Selection for Surgical Patients **
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: 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 ***

* OP–26: Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228889963089&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D1r_OP26MIF_v+6+0b.pdf&blobcol=urldata&blobtable=MungoBlobs.*

** Measures removed beginning with the CY 2017 payment determination, as set forth in section XIII.D.3.b. of this final rule with comment period.

*** Measure collected voluntarily, as set forth in section XIII.D.3.b. of this final rule with comment period.

**** Name has been updated to correspond with NQF-endorsed name.

Comment: Some commenters expressed views on previously adopted Hospital OQR Program measures. Some commenters were supportive of previously adopted measures, and some commenters recommended changing measure specifications for some measures. Several commenters asked CMS to consider removing previously

adopted measures from the Hospital OQR Program, specifically, OP–9, OP–10, OP–14, OP–15, OP–20, OP–22, and OP–25, because these measures are no longer NQF-endorsed, are not recommended by the MAP, or are deemed unsuitable for public reporting.

Response: Because we did not propose to remove OP–9, OP–10, OP–14, OP–15, OP–20, OP–22, or OP–25 from the Hospital OQR Program, change their measure specifications, or discuss the related MAP recommendations in the CY 2015 OPPS/ASC proposed rule, these comments are beyond the scope of the proposed rule. Therefore, we are not changing the status of any of the measures referred to by commenters. However, we will take into consideration commenters' concerns regarding these measures for future rulemaking.

Regarding removal of measures from the Hospital OQR Program based upon NQF endorsement, we focus on measures appropriate to the specific provider category that reflect the level of care and the most important areas of service and measures for that provider category. Section 1833(t)(17)(C)(i) of the Act requires the Secretary to ''develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and 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.'' This provision does not require that the measures we adopt for the Hospital OQR Program be endorsed by any particular entity, and we believe that consensus among affected parties can be achieved by means other than endorsement by a national consensus building entity, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment.

At this time, we continue to believe there is value in collecting and reporting these measures, but we can consider removal in future rulemaking. We thank the commenters for the measure suggestions and will share them with measure stewards.

1. Data Submission Requirements for OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF # 0431) Reported via NHSN for the CY 2017 Payment Determination and Subsequent Years

The Influenza Vaccination Coverage among Healthcare Personnel (HCP) (NQF # 0431) was finalized for the Hospital OQR Program in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75099). We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75116 through 75117) for a discussion of the previously finalized data submission requirements for this measure. This measure was previously finalized for the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51631). In the CY 2015 OPPS/ASC proposed rule (79 FR 41035), we made two clarifications: (1) correcting the previously stated submission deadline; and (2) clarifying that hospitals should report the Influenza Vaccination Coverage among HCP (NQF # 0431) measure by CMS Certification Number (CCN) rather than separately reporting for both the inpatient and outpatient setting.

a. Clarification of Submission Deadline and Data Submitted

We noted that there was a typographical error in our discussion in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75116 through 75117), and we proposed to remedy that error in the proposed rule. Specifically, we stated that the deadline for hospitals to submit NHSN hospital-acquired infection (HAI) measure collection data would be ''May 15, 2015, with respect to the October 1, 2015 through March 31, 2015 encounter period'' (78 FR 75117). In the CY 2015 OPPS/ASC proposed rule, we clarified that the beginning of the encounter period should be ''October 1, 2014'' instead of ''October 1, 2015.'' In addition, we clarified that the data to be submitted are more specifically referred to as ''Healthcare Personnel (HCP) Influenza Vaccination summary reporting data'' instead of ''HAI measure collection data.''

Comment: Commenters supported the CMS clarification of the reporting deadline for OP–27 because this deadline will align the reporting for both inpatient and outpatient settings.

Response: We thank commenters for their support. We agree that measures should be aligned across our quality reporting and value-based purchasing programs to the extent possible.

As stated above, we are clarifying that the beginning of the encounter period is October 1, 2014, and that the data to be submitted are ''Healthcare Personnel Influenza Vaccination summary reporting data'' instead of ''HAI measure collection data.''

b. Clarification on Reporting by CMS Certification Number (CCN)

We received public comment about the burden of separately collecting HCP influenza vaccination status for both the hospital inpatient and outpatient settings (78 FR 75098). We believe that reporting a single vaccination count for each health care facility enrolled in NHSN will be less burdensome to facilities. Therefore, in response to these concerns, we collaborated with CDC and clarified in an Operational Guidance document that, beginning with the 2014–2015 influenza season (CY 2014 reporting period and CY 2016 payment determination), facilities will report data to NHSN by enrolled facility (also known as OrgID). CDC will then translate and submit the data to CMS on behalf of the facilities by CCN.[1] The CDC also has produced an Operational Guidance document regarding reporting for this measure, which can be found at: *http://www.cdc.gov/nhsn/PDFs/HCP/Operational-Guidance-ACH–HCP-Flu.pdf*.

Reporting data in this way will allow health care facilities with multiple care settings to simplify data collection and submit a single count applicable across the inpatient and outpatient settings. We will then publicly report the percentage of HCP who received an influenza vaccination per CCN. This single count per CCN will inform the public of the percentage of vaccinated HCP at a particular healthcare facility, which would still provide meaningful data and help to improve the quality of care. Specific details on data submission for this measure can be found at: *http://www.cdc.gov/nhsn/acute-care-hospital/hcp-vaccination/* and at: *http://www.cdc.gov/nhsn/acute-care-hospital/index.html*. This clarification was also noted in the FY 2015 IPPS/LTCH PPS final rule for the Hospital IQR Program (79 FR 50217).

Comment: Many commenters supported CMS' guidance allowing hospitals to report OP–27 for both the inpatient and outpatient settings using one single count because it provides a clearer picture of vaccination rates, reduces provider burden, and aligns the inpatient and outpatient settings. Some commenters, however, requested further clarification on this guidance because the Hospital IQR Program clarified in the FY 2015 IPPS/LTCH PPS final rule that hospitals ''should report a single count per enrolled facility, and not CCN'' and that facilities should ''collect

[1] We erroneously referred to ''CNN'' in the CY 2015 OPPS/ASC proposed rule (79 FR 41035). We have corrected that reference in this final rule with comment period to ''CCN.''

and submit a single vaccination count for each health care facility enrolled in NHSN by facility OrgID.''

Response: We thank commenters for their support of the guidance issued. Consistent with the Hospital IQR Program in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217), for OP–27, hospitals should report a single count per enrolled facility (by OrgID), and not per CCN. We require facilities to collect and submit a single vaccination count for each health care facility enrolled in NHSN by facility OrgID.

Comment: One commenter was concerned that viewers of *Hospital Compare* will not understand that the measure entails data in both hospital inpatient and outpatient settings. The commenter believed this would create confusion among consumers and misinform their decision-making.

Response: We thank the commenter for its concern. However, we do not agree that reporting a single vaccination count for each enrolled health care facility will cause confusion. We believe that it will be easier for consumers to understand the influenza vaccination rate of a hospital as a whole when we combine data for both the inpatient and outpatient settings, and we believe the measure is important enough for it to be implemented in both the inpatient and outpatient settings.

As stated above, we clarify that, consistent with the Hospital IQR Program and CDC Operational Guidance, hospitals should report to NHSN a single count per enrolled facility by the facility OrgID.

2. Delayed Data Collection for OP–29 and OP–30

In the CY 2014 OPPS/ASC final rule with comment period, we adopted OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF # 0558) (78 FR 75102) and OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF # 0659) (78 FR 75102), both chart-abstracted measures, and proposed that aggregate data would be collected via an online Web-based tool (the QualityNet Web site) beginning with the CY 2016 payment determination. We finalized that, for the CY 2016 payment determination, hospitals would be required to submit aggregate-level encounter data between July 1, 2015 and November 1, 2015 for data collected during January 1, 2014 through December 31, 2014 (78 FR 75114).

On December 31, 2013, we issued guidance stating that we would delay the implementation of OP–29 and OP–30 for 3 months for the CY 2016 payment determination, changing the encounter period from January 1, 2014 through December 31, 2014 to April 1, 2014 through December 31, 2014 (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772854917*). The data submission window for data collected from April 1, 2014 through December 31, 2014 is still July 1, 2015 through November 1, 2015. The data submission windows and the encounter periods for subsequent years remain as previously finalized (78 FR 75114); hospitals are to submit Web-based data between July 1 and November 1 of the year prior to a payment determination with respect to the encounter period of January 1 to December 31 of 2 years prior to a payment determination year.

Comment: Several commenters noted their support for efforts to limit the overuse of colonoscopies, but expressed concern that OP–29 and OP–30 are burdensome because they are chart-abstracted measures, have not been specified or tested at the facility level, and are measures of physician quality rather than facility quality. Another commenter stated that these measures are not yet meaningful due to low sample sizes and the lack of specifications detailed with algorithms for the measures.

Response: We have previously responded to the commenters' concerns that the measure is not specified or tested at the facility level and is a measure of physician quality rather than facility quality. We refer readers to our responses in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75099 through75103) where we finalized these measures. We continue to believe the measures are suitable for HOPDs based on the reasons we discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75100 through 75102). In addition, we understand the commenters' concerns regarding the administrative effort associated with chart-abstraction. We will continue to examine options for less burdensome reporting mechanisms for these and other program measures in the future.

Comment: Many commenters supported CMS' delayed collection of OP–29 and OP–30, but requested specific rationale for the delay.

Response: Based on feedback from stakeholders, we believed it would be too burdensome to require hospitals to implement OP–29 and OP–30 by January 1, 2014 since these measures could require coordination with other physicians (78 FR 75113). Consequently, we delayed the data collection period until April 1, 2014. We believe that this 3-month period was sufficient to allow hospitals to put the necessary mechanisms in place to collect these data.

3. OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery

In the CY 2014 OPPS/ASC final rule with comment period, we adopted OP–31 Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF # 1536) for the CY 2016 payment determination and subsequent years (78 FR 75103). This measure assesses the rate of patients 18 years and older (with a diagnosis of uncomplicated cataract) in a sample who had improvement in visual function achieved within 90 days following cataract surgery based on completing both a pre-operative and post-operative visual function survey.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41036), we: (1) Corrected our response to public comments, (2) noted our decision to delay data collection for the CY 2016 payment determination, and (3) proposed voluntary data collection for the CY 2017 payment determination and subsequent years for OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF # 1536).

a. Correction of Response to Public Comments

In the CY 2014 OPPS/ASC final rule with comment period, we stated, in response to commenters concerned that the proposed chart-abstracted measures had not been field-tested, that ''all three measures that we are finalizing . . . were field-tested in the HOPD facility setting by the measure stewards. These three measures are: (1) Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF # 0658); (2) Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF # 0659); and (3) [OP–31] Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF # 1536)'' (78 FR 75099 through 75100).

We inadvertently misstated that the OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF # 1536) had been field-tested in the HOPD

setting, and we are clarifying here that this measure has not been field-tested in that setting. However, we note that, in considering and selecting this measure, we took into account other principles or factors, including: NQS goals, type of measure, HHS Strategic Plan and Initiatives, NQF endorsement, MAP support, stakeholder input, alignment with quality goals and settings, relevance, utility, and burden. More information about these principles can be found in the CY 2014 OPPS/ASC proposed rule and final rule with comment period (78 FR 43643 through 43644) and in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68467 through 68468).

b. Delayed Data Collection for OP–31 and Exclusion From the CY 2016 Payment Determination Measure Set

Since our adoption of this measure, we have come to believe that it can be operationally difficult for hospitals to collect and report this measure. Specifically, we are concerned that the results of the survey used to assess the pre-operative and post-operative visual function of the patient may not be shared across clinicians, making it difficult for hospitals to have knowledge of the visual function of the patient before and after surgery.

We also are concerned about the use of inconsistent surveys to assess visual function; the measure specifications allow for the use of any validated survey and results may be inconsistent should clinicians use different surveys. Therefore, on December 31, 2013, we issued guidance stating that we would delay the implementation of OP–31 by 3 months from January 1, 2014 to April 1, 2014 for the CY 2016 payment determination (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772854917*). Because of continuing concerns, on April 2, 2014, we issued additional guidance stating that we would further delay the implementation of the measure from April 1, 2014 to January 1, 2015 for the CY 2016 payment determination (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228721506778*). In the CY 2015 OPPS/ASC proposed rule (79 FR 41036), we proposed to exclude OP–31 Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF # 1536) from the CY 2016 payment determination measure set. We proposed not to subject hospitals to a payment reduction with respect to this measure for the CY 2016 payment determination.

We invited comment on this proposal.

Comment: Many commenters commended CMS' recognition of the associated operational issues and the proposal to exclude OP–31 from the CY 2016 payment measure determination set. Other commenters disagreed; they stated that complications following cataract surgery are not acceptable, and they strongly believed that OP–31 tracks patient-centered clinical outcomes and improves care coordination among providers.

Response: We agree that complications following cataract surgery are not acceptable. While OP–31 does not address complications following cataract surgery, it does address improvement in visual function following cataract surgery and tracks an important patient-centered clinical outcome. Based on stakeholder feedback, we believe this measure should be excluded from the CY 2016 payment determination because there are a low number of hospitals ready to operationalize this measure for the CY 2016 payment determination. As noted below, we believe that by the CY 2017 payment determination, many more hospitals will be operationally able to collect the data necessary for this measure and may choose to do so.

After consideration of the public comments we received, we are finalizing our proposal to exclude OP–31 from the CY 2016 payment determination measure set as proposed. Therefore, we will not subject hospitals to a payment reduction with respect to OP–31 for the CY 2016 payment determination.

c. Voluntary Collection of Data for OP–31 for the CY 2017 Payment Determination and Subsequent Years

We continue to believe that OP–31 promotes accountability for Medicare beneficiaries, improve coordination of services, reduce fragmented care, encouraged redesigned care processes for high quality and efficient service delivery, and incentivize higher value care (78 FR 75099). Furthermore, we believe that HOPDs should be partners in care with physicians and other clinicians, and this measure provides an opportunity to do so. Therefore, we are continuing to include this measure in the Hospital OQR Program measure set. However, in the CY 2015 OPPS/ASC proposed rule (79 FR 41036), we proposed that hospitals have the option to voluntarily collect and submit OP–31 data for the CY 2015 encounter period/CY 2017 payment determination and subsequent years. In addition, we proposed to not subject hospitals to a payment reduction with respect to this measure during the period of voluntary reporting. For hospitals that choose to submit data voluntarily, we would request that they submit such data using the means and timelines finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75113). Data submitted voluntarily will be publicly reported as discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 43645) and final rule with comment period (78 FR 75092).

We invited public comment on this proposal.

Comment: Many commenters requested that CMS remove the measure from the program entirely, rather than delaying implementation and allowing voluntary reporting. The commenters repeated similar concerns expressed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75099 through 75103), where this measure was finalized, regarding associated burden, suitability for the Hospital OQR Program versus the PQRS, program alignment of this measure, non-standardization of collected information, NQF endorsement, MAP recommendations, and coordination challenges faced by facilities.

Response: We do not agree that we should remove the measure entirely, because we believe OP–31 addresses an area of care that is not adequately addressed in our current measure set and is an important area of care coordination between performing physicians, practitioners that assess visual function, and HOPDs where procedures are performed. We previously addressed the above concerns in our responses the CY 2014 OPPS/ASC final rule with comment period where we finalized this measure and refer readers to that final rule with comment period (78 FR 75099 through 75103) for a discussion of these issues.

Comment: Commenters opposed to voluntary reporting of OP–31 were concerned that incomplete display of data is confusing and not meaningful to consumers and is hard to validate. Furthermore, commenters feared that the display of data from some hospitals but not others would lead some patients to conclude that some hospitals are more committed to improving cataract surgery.

Response: We appreciate the commenters' concerns, but we do not agree that voluntary data reporting will result in data that are confusing, are not meaningful, or cause patients to conclude that some hospitals are more committed to improving cataract surgery. There are many situations

where hospitals do not submit information to the Hospital OQR Program due to lack of cases or low case volume. Where quality information is submitted, we make this information publicly available as statutorily required, and we state when it is not available. Furthermore, reporting of measure data by some hospitals and not others under voluntary reporting would not affect the validity of data reported for this Web-based measure any more so than a required measure where not all hospitals had cases. We note that at this time, we do not validate aggregate data submitted to CMS using an online tool, so difficulty to validate this information is not a program issue. We refer readers to section XIII.H.3 of this final rule with comment period where we discuss our validation procedures.

We understand some facilities are capable of reporting data for this measure at this time, and we believe those facilities should report if they are operationally able to do so. We believe voluntary reporting is beneficial for HOPDs because all HOPDs, both participating and not participating in voluntary reporting, can use the reported data to gauge their own performance and identify improvement efforts. By retaining the measure but allowing voluntary reporting, we can continue to monitor the data submitted to assess further enhancement of the measure as necessary.

Comment: Commenters expressed support for patient-reported outcome measures like OP–31 and recommended additional outcome measures for cataract procedures, such as Complications within 30 Days Following Cataract Surgery Requiring Additional Procedures (NQF #0564) and Better Visual Acuity Within 90 Days Following Cataract Surgery (NQF #0565).

Response: We thank the commenters for the support and their input regarding patient-reported outcome measures. We may consider these suggestions for future measure selection.

Comment: One commenter suggested that CMS allow voluntary reporting for all newly adopted measures, given the inconvenience and burden associated with preparing to report a measure that later may become suspended or for which we delay implementation.

Response: We thank the commenter for the suggestion. We understand that hospitals may have been inconvenienced by this measure, but disagree that all newly adopted measures should be voluntarily reported. We have retained the vast majority of measures adopted for the Hospital OQR Program.

After consideration of the public comments we received, we are finalizing our proposal that hospitals have the option to voluntarily collect and submit OP–31 data for the CY 2015 encounter period/CY 2017 payment determination and subsequent years as proposed. For hospitals that choose to submit data, we request that they submit such data using the means and timelines finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75113 through 75115). We will not subject hospitals to a payment reduction with respect to this measure during the period of voluntary reporting. However, data submitted voluntarily will be publicly reported.

E. New Quality Measure for the CY 2018 Payment Determination and Subsequent Years

In the CY 2015 OPPS/ASC proposed rule (79 FR 41036 through 41039), we proposed to adopt one new claims-based measure into the Hospital OQR Program for the CY 2017 payment determination and subsequent years: OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. Colonoscopy is one of the most frequently performed procedures in the outpatient setting in the United States.[2] The most recent data available indicate that, in 2002 alone, physicians performed an estimated 14 million colonoscopies in the United States.[3] Colonoscopies are associated with a range of well-described and potentially preventable adverse events that can lead to hospital visits, repeat procedures, or surgical intervention for treatment, including colonic perforation, gastrointestinal (GI) bleeding, and cardiopulmonary events such as hypoxia, aspiration pneumonia, and cardiac arrhythmias. While hospital visits are generally unexpected after outpatient colonoscopy, the literature suggests that the majority of these visits occur within the first 7 days.[4 5 6] Reported hospital visit rates after outpatient colonoscopy range from 0.8 to 1.0 percent at 7 to 14 days post procedure, and from 2.4 to 3.8 percent at 30 days post procedure.[7 8 9] Some adverse events such as bleeding occur after the 7th day, but based on input from clinical experts, public comment, and empirical analyses, we concluded that unplanned hospital visits within 7 days is the optimal outcome to ensure capture of procedure-related adverse events and to minimize capture of hospital visits unrelated to the procedure. This measure provides the opportunity for providers to improve quality of care and to lower the rates of adverse events leading to hospital visits after outpatient colonoscopy; this measure will encourage providers to achieve the outcome rates of the best performers.

We believe it is important to reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care. Therefore, we proposed to include OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, which is based on paid Medicare FFS claims, in the Hospital OQR Program for the CY 2017 payment determination and subsequent years. We expect that the measure would promote improvement in patient care over time because transparency in publicly reporting measure scores will make patient unplanned hospital visits (emergency department visits, observation stays, and inpatient admissions) following colonoscopies more visible to providers and patients and encourage providers to incorporate quality improvement activities in order to reduce these visits. Providers are often unaware of complications following colonoscopy for which patients visit the hospital.[10] This risk-standardized quality measure will address this information gap and

[2] Russo A, Elixhauser A, Steiner C, Wier L. Hospital-Based Ambulatory Surgery, 2007: Statistical Brief #86. *Healthcare Cost and Utilization Project (HCUP) Statistical Briefs.* Rockville (MD) 2006.

[3] Seeff LC, Richards TB, Shapiro JA, et al. How many endoscopies are performed for colorectal cancer screening? Results from CDC's survey of endoscopic capacity. *Gastroenterology.* Dec 2004; 127(6):1670–1677.

[4] Rathgaber SW., Wick TM. Colonoscopy completion and complication rates in a community gastroenterology practice. *Gastrointest Endosc.* 2006; 64:556–62.

[5] Rabeneck L, Saskin R, Paszat LF. Onset and clinical course of bleeding and perforation after outpatient colonoscopy: A population-based study. *Gastrointest Endosc.* 2011; 73:520–3.

[6] Ko CW, Riffle S, Michael L, et al. Serious complications within 30 days of screening and surveillance colonoscopy are uncommon. *Clin Gastroenterol Hepatol.* 2010; 8:166–73.

[7] Ko CW, Riffle S, Shapiro JA, et al. Incidence of minor complications and time lost from normal activities after screening or surveillance colonoscopy. *Gastrointest Endosc.* Apr 2007; 65(4):648–656.

[8] Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med.* Oct 25 2010; 170(19):1752–1757.

[9] Chukmaitov AS, Menachemi N, Brown SL, Saunders C, Tang A, Brooks R. Is there a relationship between physician and facility volumes of ambulatory procedures and patient outcomes? *J Ambul Care Manage.* Oct–Dec 2008; 31(4):354–369.

[10] Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med.* Oct 25 2010; 170(19):1752–1757.

promote quality improvement by providing feedback to facilities and physicians, as well as transparency for patients on the rates and variation across facilities in unplanned hospital visits after colonoscopy.

The outcome measured in the OP–32 measure is all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure. The measure score, also referred to as the facility-level risk-standardized hospital visit rate, is derived from the calculation of the ratio of the numerator to the denominator multiplied by the crude rate. The numerator is the number of predicted (meaning adjusted actual) hospital visits, which is the number of unplanned hospital visits within 7 days of colonoscopy that the facility is predicted to have based on its case-mix. The denominator is the number of expected hospital visits, which is the number of unplanned hospital visits the facility is expected to have based on the nation's performance with the facility's case-mix. The crude rate is the national unadjusted number of patients who had a hospital visit post-colonoscopy among all patients who had a colonoscopy.

Based on discussions with clinical and technical panel experts, the measure excludes colonoscopies for patients undergoing concomitant high-risk upper GI endoscopy because these patients are at a higher risk for hospital visits than patients undergoing a typical colonoscopy, and patients with a history of inflammatory bowel disease (IBD) or diverticulitis in the year preceding the colonoscopy because we likely could not fully characterize and adjust for their pre-procedure risk of needing a post-procedure hospital visit or identify whether these admissions are planned or unplanned. The measure also excludes procedures for patients who lack continuous enrollment in Medicare FFS Parts A and B in the 1 month after the procedure to ensure all patients have complete data available for outcome assessment. The statistical risk adjustment model includes 15 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within 7 days following colonoscopy. Additional methodology details and information obtained from public comments for measure development are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under ''Hospital Outpatient Colonoscopy.''

Section 1890A(a)(2) of the Act outlines the pre-rulemaking process established under section 1890A of the Act, which requires the Secretary to make available to the public by December 1 of each year a list of quality and efficiency measures that the Secretary is considering. This measure was included on a publicly available document titled ''MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs'' on the NQF Web site at: *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report_2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx* (formerly referred to as the ''List of Measures Under Consideration'') in compliance with section 1890A(a)(2) of the Act. (We note that at the time the measure was listed on the ''MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs,'' it was named ''High-Acuity Care Visits after Outpatient Colonoscopy Procedure.'')

The MAP, which represents stakeholder groups, conditionally supported the measure, ''noting the need to provide outcome information to inform consumer decisions and drive quality improvement.'' The MAP further stated that ''[t]his measure addresses an important quality and safety issue with incidence of these events ranging from 10 to 22 per 1,000 after risk adjustment.'' However, the MAP also ''recognized the need for the measure to be further developed and gain NQF endorsement. The MAP expects the endorsement process to resolve questions of the reliability and validity of the measure as well as with the accuracy of the algorithm for attributing claims data in light of possible effects of the Medicare 3-day payment window policy.'' 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.

We believe we have addressed the concerns raised by the MAP to the extent possible. The measure is well-defined and precisely specified for consistent implementation within and between organizations that will allow for comparability. Reliability testing demonstrated the measure data elements produced were repeatable; that is, the same results were produced a high proportion of the time when assessed in the same population in the same time period. Validity testing demonstrated that the measure data elements produce measure scores that correctly reflect the quality of care provided and that adequately identify differences in quality. In order to ensure the accuracy of the algorithm for attributing claims data and the comprehensive capture of HOPD colonoscopies potentially affected by the policy, we identified physician claims for colonoscopy in the HOPD setting from the Medicare Part B Standard Analytical Files (SAF) with an inpatient admission within 3 days and lacking a corresponding HOPD facility claim. We then attribute the colonoscopies identified as affected by this policy to the appropriate HOPD facility using the facility provider ID from the inpatient claim.

Section 1833(t)(17)(C)(i) of the Act 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 the MAP, which represents stakeholder groups, reviewed, conditionally supported the measure, and stated that it ''would provide valuable outcome information to inform consumer decision and drive quality improvement.'' Further, the measure was subject to public comment during the MAP and measure development processes, with some public commenters agreeing with the MAP's conclusions on the measure (MAP Report, January 2014, p. 184 *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report_2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*). We also note that the measure was submitted to NQF for endorsement on February 21, 2014.

Currently, there are no publicly available quality of care reports for providers or facilities that conduct outpatient colonoscopies. Thus, adoption of this measure provides an opportunity to enhance the information available to patients choosing among providers who offer this elective procedure. We believe this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to providers and patients all unplanned hospital visits following the procedure. Further, providing outcome rates to providers will make visible to clinicians meaningful quality differences and encourage improvement. Although this measure is not NQF-endorsed, it is currently undergoing the endorsement process, as noted above. Therefore, we believe the

statutory requirement for included measures to have, to the extent feasible and practicable, been set forth by a national consensus-building entity has been met.

We invited public comment on the proposal to include OP–32 in the Hospital OQR Program for the CY 2017 payment determination and subsequent years.

Comment: Several commenters supported the adoption of OP–32, stating that it will provide patients with important information about the quality of colonoscopy care furnished in outpatient settings. Some commenters noted that CMS has appropriately considered the MAP's input in adopting this measure and that the measure's adoption is a good first step in the continued evolution of the Hospital OQR Program.

Response: We thank commenters for their support and acknowledgement that the measure is appropriate for the Hospital OQR Program. We agree that measuring quality of care associated with colonoscopy procedures is an important clinical care area to assess for HOPDs.

Comment: Many commenters urged CMS not to adopt OP–32 until it is NQF-endorsed. Several of these commenters also noted that the MAP supported this measure on condition of NQF-endorsement, and stated that the NQF process would resolve a number of questions about the reliability, validity and feasibility of this measure. The commenters requested that, in general, CMS only include measures in the Hospital OQR Program that have been NQF-endorsed in order to avoid subsequent suspension or removal of these measures.

Response: We note that not all of the measures adopted by the Hospital OQR Program are NQF-endorsed, and as we stated in our earlier discussion in this final rule with comment period, NQF endorsement is not a program requirement, as consensus among affected parties can be reached through means other than NQF endorsement. Under section 1833(t)(17)(C)(i) of the Act, the Secretary must develop measures that reflect consensus among affected parties and, to the extent feasible and practicable, must include measures set forth by one or more national consensus building entities.

Whenever possible, we strive to adopt NQF-endorsed measures because these measures will meet these requirements. However, we believe the requirements that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance and use of the measure, and through public comments. Further, it may not be feasible or practicable to adopt an NQF-endorsed measure, such as when an NQF-endorsed measure does not exist. Section 1833(t)(17)(C)(i) of the Act does not require that each measure we adopt for the OQR Program be endorsed by a national consensus building entity, or by the NQF specifically. As discussed below, we believe the measure as developed exhibits sufficient levels of reliability, validity, and feasibility to be adopted for the Hospital OQR Program. We have also submitted this measure to the NQF for endorsement.

Comment: A few commenters noted that the measure is currently being reviewed by the NQF All-Cause Admissions and Readmissions Standing Committee. Commenters were disappointed that the Committee's minutes indicated there were no discussions of consideration of key elements of the measure's construction and testing.

Response: We thank the commenters for sharing their concerns. We believe the NQF process is rigorous and transparent. We understand the NQF All-Cause Admissions and Readmissions Standing Committee applies the four NQF criteria for measure endorsement [11] and votes on each criterion. In addition, our understanding is that the measure was discussed in detail by NQF working groups prior to the measure discussion at the All-Cause Admissions and Readmissions Standing Committee (*http://www.qualityforum.org/ProjectMaterials.aspx?projectID=73619*).

NQF also seeks public comments on measures before endorsement. *http://www.qualityforum.org/comments_By_Project.aspx?projectID=110&ActivityID=762#p=3.* (This link requires users to log in to the NQF Web site.) For questions related to NQF internal procedures, we suggest contacting the NQF directly at *http://www.qualityforum.org/About_NQF/Contact_NQF.aspx.*

Comment: Many commenters did not support CMS' proposal to finalize OP–32, stating that complications from colonoscopies are rare and hospitals already take steps to ensure colonoscopies are conducted in such a way so as to eliminate preventable complications. Some commenters specifically noted that the literature indicates the measured incidence rate is less than 2 percent, and does not rise to the level of importance needed for a national quality measurement program.

Response: Given the widespread use of colonoscopy for colorectal cancer screening in the outpatient setting, we consider measuring the quality of this high volume procedure to be a priority. We agree that the incidence of colonoscopy complications is relatively low. However, serious adverse events, such as perforation of the bowel and bleeding, may occur following colonoscopies. We view OP–32 as a critical outcome measure for which the goal is to drive toward and sustain zero harm. In addition, some literature suggests that many facilities performing colonoscopies are unaware of patients accessing hospital-based care with adverse events because patients return to different facilities, including other hospitals and emergency departments, and would not return to the same outpatient facility. For example, one study showed that physicians were unaware of nearly 75 percent of hospital admissions for adverse events following colonoscopy.[12] While most colonoscopies are performed without subsequent complication, we note that, among Medicare patients aged 65 and older, 1.6 percent of outpatient colonoscopies resulted in an unplanned hospital visit within 7 days.[13] This is based on a 20-percent sample of nationwide Medicare FFS patients. If we were to use full national data (that is, a 100 percent sample), we estimate 1.7 million colonoscopies would have been performed among Medicare FFS patients and nearly 27,000 unplanned hospitals visits would have occurred within 7 days of colonoscopy. These findings suggest that adverse events are not as rare or inconsequential as many believed and that quality measurement for colonoscopy procedures in the hospital outpatient setting is important.

Comment: Many commenters expressed concern that OP–32 includes hospital visits unrelated to colonoscopy (counted in the numerator). Some commenters questioned why the measure uses an all-cause categorization versus only admissions attributable to colonoscopies. One commenter suggested that all high-risk colonoscopies (such as patients with multiple biopsies, patients with

[11] Available at: *http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx.*

[12] Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. Arch Intern Med. Oct 25 2010; 170(19): 1752–1757.

[13] 2010 Medicare 20 percent fee-for-service sample. Based on an analysis of 20 percent sample of Medicare FFS data from 2010 during measure development. The 20 percent sample included 332,391 outpatient colonoscopies meeting the measure inclusion and exclusion criteria, and 1.6 percent of these colonoscopies were followed by an unplanned hospital visit. This equates to 5,331 unplanned hospital visits in the 20 percent sample.

inflammatory bowel disease, and diverticulitis) should be excluded from the measure. Commenters recommended that OP–32 should be limited to low-risk surveillance and screening colonoscopies as well as nontherapeutic colonoscopies for Medicare patients. One commenter appreciated that OP–32 includes a mechanism for excluding hospital visits for certain ''planned'' procedures, but encouraged CMS to expand that list to also include bone fractures and behavioral health disorders.

Response: We clarify that this measure is purposely designed to use a broad outcome of hospital visits following surgery rather than a narrow set of easily identifiable complications. From a patient and health care system perspective, the goal of this measure is to encourage and inform provider efforts to minimize all potential acute complications, not just those narrowly related to procedural technique. This is important as the literature [14 15 16 17 18] suggests that hospital visits following colonoscopy occur due to a range of adverse events relating to the bowel preparation, anesthesia, the colonoscopy procedure itself, and follow-up care. These adverse events include a range of symptoms and signs such as abdominal pain, bloating, dizziness and collapse, electrolyte disturbances, and cardiorespiratory symptoms (from sedation use) in addition to other complications, such as bleeding and bowel perforation, that are directly related to procedural techniques. The broad outcome of unplanned hospital visits captures all of these potential acute complications of colonoscopy.

As to the suggestion of expanding the list to include bone fractures and behavioral health disorders, we note that inpatient admissions for bone fracture and behavioral health disorders (such as depression and anxiety) are typically acute and are not generally considered as ''planned'' admissions. We do not expect planned admissions for these conditions within the first 7-days following colonoscopy. Furthermore, we have adapted the planned readmission algorithms developed by CMS independent of OP–32. This algorithm has been validated against medical record (chart-extracted) data to ensure it only removes planned admissions.

Our goal for including the measure is to encourage providers to be mindful of reducing post-colonoscopy admission caused by prior colonoscopy procedures performed at a HOPD. For example, patients may be at higher risk of falls post-colonoscopy secondary to dehydration following the bowel preparation for the procedure, and there may be opportunities for providers to minimize this risk. Furthermore, we removed planned admissions from the measure outcome by adapting CMS' Planned Readmission Algorithm version 3.0.[19 20] This algorithm removes nonacute admissions for scheduled procedures (for example, total hip replacement) and other types of care always considered planned (for example, rehabilitation or maintenance chemotherapy) from the outcome because these admissions do not reflect differences in colonoscopy quality of care.

Comment: One commenter noted that CMS stated that the statistical risk adjustment model includes 15 clinically relevant risk- adjustment variables (such as number of polyps removed) that are strongly associated with risk of hospital visits within seven days following colonoscopy and certain patients receiving colonoscopies that would be more likely to have a subsequent visit were excluded. The commenter stated that CMS did not report the variation between hospitals in the application for NQF-endorsement. The commenter raised the possibility of no statistically significant difference between a hospital's risk-adjusted visit rate and the national average. The commenter believed this scenario would make it impossible to identify poor performers and good performers for this measure. Without this type of differentiation, the commenter did not understand how this measure will be actionable for care improvement. The commenter suggested that CMS conduct a root cause analysis for specific related readmission after colonoscopy or test of the variation of the measure between hospital providers. The commenter also suggested that The Joint Commission's guidelines and relevant Conditions of Participation standards would enhance care improvement efforts.

Response: We thank the commenter for their suggestions to enhance improvement efforts for colonoscopy. We clarify that, in the application for NQF endorsement, we noted that the measure, following risk-adjustment, is able to detect statistically significant variation (good and poor performers) between outpatient facilities by demonstrating measure score variation using the 2010 Healthcare Cost and Utilization Project (HCUP) data from four States (California, New York, Nebraska, and Florida). Using a very conservative bootstrapping (sampling with replacement) statistical technique, we constructed 95 percent interval estimates (similar to confidence intervals) around the facility measure score and used the estimates to place facilities into three performance categories: worse than expected; no different than expected; and better than expected. Based on this analysis, we identified 5 outlier facilities among a total of 992 ASCs and HOPDs. This analysis included only about one-tenth of all outpatient facilities in the United States, and typically we see greater variation between facilities when 100 percent of nationwide facilities are included for actual measure implementation and reporting due to increased precision related to greater sample size.

We disagree with the notion that there is a possibility of no statistically significant difference between a hospital's risk-adjusted visit rate and the national average. Our analysis shows statistically significant facility variation. Some facilities have a hospital visit rate that is higher than the expected national average rate and this is statistically significant. Also, we only tested provider variation using data from 4 States. We expect greater variation and more outliers using nationwide data.

We are committed to filling the performance gaps in colonoscopy performed in the outpatient setting. Therefore, we believe this measure is appropriate for the outpatient setting. However, in response to comments, to allow sufficient time to conduct further analysis of this measure, we are finalizing this measure beginning with the CY 2018 payment determination, rather than the CY 2017 payment determination as proposed. We plan to perform a dry run of the measure in

[14] Day LW, Kwon A, Inadomi JM, et al. Adverse events in older patients undergoing colonoscopy: a systematic review and meta-analysis. 2011; 74:885–96.

[15] Ko CW, Dominitz JA. Complications of colonoscopy: Magnitude and management. Gastrointest Endosc Clin N Am 2010;20:659–71.

[16] ASGE Standards of Practice Committee, Fisher DA, Maple JT, et al. Complications of colonoscopy. Gastrointest Endosc 2011;74:745–52.

[17] Baudet JS, Diaz-Bethencourt D, Aviles J, et al. Minor adverse events of colonoscopy on ambulatory patients: The impact of moderate sedation. Eur J Gastroenterol Hepatol 2009; 21:656–61.

[18] Ko CW, Riffle S, Shapiro JA, et al. Incidence of minor complications and time lost from normal activities after screening or surveillance colonoscopy. 2007; 65:648–56.

[19] Horwitz L, Grady J, Dorsey K, Zhang W, Keenan M, Keshawarz A, Cohen D, Ngo C, Okai M, Nwosu C, Lin Z, Bhat K, Krumholz H, Bernheim S. 2014 Measures Updates and Specifications Report: Hospital-Wide All-Cause Unplanned Readmission—Version 3.0. 2014: Centers for Medicare & Medicaid Services, 2014.

[20] Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

2015. From our perspective, a dry run is a preliminary analysis of data in which HOPDs may review their measure results, and ask questions about and become familiar with the measure methodology. Dry runs will include 3 to 4 years of paid Medicare FFS claims. We will use the most recent complete claims samples (usually 6 to 9 months prior to the start date) for dry runs. For example, if the dry run begins in March 2015, the most recent data available may be July 2011 to June 2014 (assuming we use 3 years of data). Because we use paid Medicare FFS claims, HOPDs will not need to submit any additional data for the dry run. General information about dry run as well as confidential reports will be made available for hospitals to review on their accounts at *https://www.qualitynet.org*. The dry run will generate confidential reports at the patient level, indicating whether the patient had a hospital visit, the type of visit (admission, emergency department visit, or observational stay), the admitting facility, and the principal discharge diagnosis. Further, the dry run will enable HOPDs to see the measure score reports and have the opportunity to receive individual patient data and information contained within individual patient records. In addition, we will continue to generate these reports for HOPDs after we implement the measure beginning with the CY 2018 payment determination. HOPDs can use the information to identify performance gaps and develop quality improvement strategies.

Dry run results are not linked to public reporting, payment determinations, or reliability testing. We expect the dry run to take approximately one month to conduct, during which facilities will be provided the confidential report and the opportunity to review their performance and provide feedback to us. The measure will have no payment impact until the CY 2018 payment determination and subsequent years. Public display of data will occur on or after December 1, 2017, but there will be no public display of the dry run data.

We agree that adhering to The Joint Commission's guidelines and relevant Conditions of Participation standards could enhance care improvement efforts and hospitals' rates on this measure, and we encourage hospitals to follow these guidelines and standards. We also believe that issuing reports to hospitals, such as those that we will provide during the dry-run, would help hospitals to identify the root cause (practices and conditions) that could cause hospital visits after colonoscopy.

Comment: Many commenters expressed concern that OP–32 is not sufficiently reliable to be included in the Hospital OQR Program; specifically, the measure developer has indicated that the measure is only ''fairly'' reliable, with an interclass correlation coefficient (ICC) of 0.335. These commenters contended that ''fair'' reliability is not sufficient for publicly reported quality metrics since such information could misinform the public, and urged CMS to conduct an analysis on the measure's reliability to understand the amount of data required to achieve ''good'' reliability. Several commenters argued that ''good'' reliability should result in an ICC of at least 0.60. Other commenters believed that reliability will improve with several years' worth of data. Another commenter requested that data from this measure be withheld from public reporting until concerns about its reliability and validity can be thoroughly assessed.

Response: We disagree with commenters and believe that OP–32 is sufficiently reliable to be included in the Hospital OQR Program. The ICC value submitted in the initial NQF application (0.335) was calculated using a split sample of data from 2 years. We randomly split the patient cohort at each hospital into two equal halves, calculated the measure using each half, and then calculated the agreement between these two (the 'test' and the 'retest'). After submitting the measure to NQF for endorsement review, we conducted additional calculations of the reliability testing score, this time using the Spearman-Brown prophecy formula. The Spearman-Brown prophecy formula is an accepted statistical method which estimates the ICC if the sample were increased. Therefore, it allows us to estimate what the reliability score would be if all observations were used for public reporting rather than using a split sample. Our Spearman-Brown prophecy formula calculations resulted in a higher ICC of 0.43.

The NQF considers the ICC values ranging from 0.21 to 0.40 as ''fair'' reliability and values ranging from 0.41 to 0.60 as ''moderate'' reliability. Therefore, the ICC values of 0.335 and 0.43 are interpreted as ''fair'' and ''moderate'' reliability, respectively. These ICC values are also in line with other NQF-endorsed outcome measures used in other CMS programs. For example, in the Hospital Readmissions Reduction Program, the Inpatient Acute Myocardial Infarction (AMI) 30-day Risk Standardized Readmission measure (NQF #0505) (76 FR 51667) has an ICC of 0.369, and the Pneumonia (PN) 30-day Risk Standardized Readmission measure (NQF #0506), also in the Hospital Readmissions Reduction Program (76 FR 51667), has an ICC of 0.406. Both measures are NQF-endorsed.

Regarding the concerns that the public may be misinformed and that we should withhold public reporting until the measure's reliability and validity is addressed, as stated above, we believe the reliability of the measure is sufficiently reliable for inclusion in the Hospital OQR Program and do not agree that the public may be misinformed or that we should withhold public reporting. In addition to our calculations above, reliability testing previously conducted by the measure steward demonstrated the measure data elements produced were repeatable; that is, the same results were produced a high proportion of the time when assessed in the same population in the same time period. Also, validity testing by the measure steward demonstrated that the measure data elements produce measure scores that correctly reflect the quality of care provided and that adequately identify differences in quality.

As the commenters suggested, the measure reliability may be further improved by using several years' worth of data; however, we must balance the reliability of the measure with the timeliness of the measure. As discussed, at this time, we believe that 1 year of data appropriately balances these competing interests for payment determination purposes, but we will continue to assess this belief during the dry run. Also, we will consider conducting additional reliability assessments of the measure using an extended data period.

Moreover, we believe it is important to include this measure in the program because colonoscopy is a high volume, common procedure performed at outpatient facilities and is frequently performed on relatively healthy patients to screen for colorectal cancer (CRC). Given the widespread use of colonoscopy, understanding and minimizing procedure-related adverse events is a high priority. These adverse events, such as abdominal pain, bleeding, and intestinal perforation, can result in unanticipated hospital visits post procedure. Physicians performing colonoscopies are often unaware that patients seek acute care at hospitals following the procedure and the associated adverse events are potentially preventable. We strongly believe that the measure would promote improvement in patient care over time because transparency in publicly

reporting measure scores would make patient unplanned hospital visits (emergency department visits, observation stays, and inpatient admissions) following colonoscopies more visible to HOPDs and patients and incentivize HOPDs to incorporate quality improvement activities in order to reduce these visits.

Finally, we believe this measure should be included in the program because currently, this risk-standardized colonoscopy quality measure is the only measure available that would address this information gap and promote quality improvement by providing feedback to facilities and physicians, as well as transparency for patients on the rates and variation across facilities in unplanned hospital visits after colonoscopy. There are no publicly available quality of care reports for HOPDs that conduct outpatient colonoscopies. Therefore, adoption of this measure provides an opportunity to enhance the information available to patients choosing among HOPDs that offer this elective procedure. We believe this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to HOPDs and patients all unplanned hospital visits following the procedure. In addition, providing outcome rates to HOPDs would make visible to clinicians meaningful quality differences and incentivize improvement.

In response to comments, however, to allow sufficient time to conduct further analysis of this measure, we are finalizing this measure beginning with the CY 2018 payment determination, rather than the CY 2017 payment determination as proposed. We plan to perform a dry run (a preliminary analysis) of the measure in 2015. We refer readers to our discussion of the dry run above, in response to a previous comment.

With national implementation of a dry run of this measure, we will also review the appropriate cutoff volume for facilities, if necessary, in reporting the measure score. We require a minimum volume (cutoff volume) of colonoscopies per facility to be able to calculate a reliable measure score for the facility. We have yet to determine the minimum volume per facility (that is, the cutoff colonoscopy volume). Because we used a Medicare 20 percent sample to develop the measure, we could not estimate this cutoff during measure development. However, testing during the measure dry-run with 100 percent of the sample per facility will help us to determine the appropriate cutoff volume of colonoscopies per facility. HOPDs will be notified via the QualityNet Web site of the cutoff volume of colonscopies per facility.

While some HOPDs perform too few colonoscopies for us to calculate a measure score, and we would not publicly report their data, these facilities would remain in the measure cohort. Typically, for public reporting of hospital measures on the *Hospital Compare* Web site, the measure score is reported as ''Number of cases too small'' for hospitals with fewer cases than the cutoff. We will use the same protocol when the measure is publicly reported for the Hospital OQR Program, and will report a measure score as ''Number of cases too small'' for HOPDs with fewer cases than the cutoff on the QualityNet Web site.

Comment: Many commenters were concerned that HOPDs may not have actionable information generated from OP–32. Specifically, commenters were concerned that claims would not accurately capture the data of patients who had initial colonoscopy at a facility but had a subsequent hospital visit at a different facility. Several of these commenters questioned whether this measure will benefit facilities or patients if each facility only receives a report with an aggregate number of claims based on historical data. Commenters requested that CMS clarify its plan to report detailed patient-level data confidentially to facilities that indicate whether the patient had a hospital visit, the type of visit (admission, emergency department visit, and observational stay), the admitting facility, and the principal discharge diagnosis. These reports would enable facilities to understand their performance and take steps where remediation is needed. One commenter also recommended that CMS allow at least a two-quarter black-out period so that hospitals have ample time to review and request corrections to their data.

Response: We do not believe that claims data will be difficult to capture at a facility different from where the colonoscopy was performed. Hospitals are responsible for accurately populating claims, regardless of where the patient had the procedure done.

In addition, due to commenters' concerns, we intend to conduct a dry run (discussed in detail above) and provide detailed facility specific information containing confidential patient-level data to all HOPDs. The dry run will generate confidential reports at the patient level, indicating whether the patient had a hospital visit, the type of visit (admission, emergency department visit, or observational stay), the admitting facility, and the principal discharge diagnosis. Further, it will enable HOPDs to see the measure score reports and have the opportunity to receive individual patient data and information contained within individual patient records. In addition, we will continue to generate these reports for HOPDs after we implement the measure beginning with the CY 2018 payment determination. HOPDs can use the information to identify performance gaps and develop quality improvement strategies. As we previously stated, dry runs have no payment impact and are not linked to public reporting. The main purpose of the dry run is to provide opportunities for hospitals to review their measure results and ask questions about measure methodology.

Comment: A few commenters stated that the measure methodology should include risk adjustment for socioeconomic factors so the results are accurate and reflect differences in socioeconomic burden and racial composition of patients across hospitals. Commenters were concerned that without proper risk adjustment, a hospital that serves a disproportionate share of low-income patients with confounding socioeconomic factors may have more unplanned visits following outpatient procedures. Commenters stated that the measure score can be skewed by factors such as race, homelessness, cultural and linguistic barriers, and low literacy. Commenters also stated that the readmissions of low-income patients with confounding socioeconomic factors are caused by factors beyond the control of the hospital and, therefore, do not reflect the quality of care being provided. Several commenters recommended that, after the NQF has reviewed OP–32, CMS consider submitting this measure as part of the socioeconomic status (SES) trial period created by the NQF Board of Directors.

Response: We do not believe that the measure is biased for low-income patients with confounding socioeconomic factors. When developing the measure, we tested how the measure score varied among outpatient facilities with varying proportion of low SES patients. Using patient dual eligibility status as an indicator of low SES, we noted that the median measure score, and the measure score distribution, was similar among facilities with many low SES patients compared to facilities with a few low SES patients. Based on our testing as well as input from the measure developer and the national technical expert panel, we concluded that facilities with a high proportion of low

SES patients were not biased by this measure and that the measure score was unaffected by SES status. These findings were presented to the NQF All-Cause Admissions and Readmissions Measures Standing Committee on May 6, 2014.[21]

Also, we thank the commenters for the suggestions to submit the measure as part of the SES trial period, which is a trial for a defined period that would assess the impact and implications of risk adjusting relevant quality measures for sociodemographic factors and was a recommendation of the Consensus Standards Approval Committee following its review of the NQF Expert Panel's report Risk Adjustment for Socioeconomic Status and Other Sociodemographic Factors. (*http://www.qualityforum.org/Press_Releases/2014/NQF_Board_Approves_Trial_Risk_Adjustment.aspx*). We will take this suggestion into consideration in future years.

Comment: One commenter requested clarification of how the measure numerator and denominator for OP–32 are calculated.

Response: The measure score is the ratio of predicted hospital visits (numerator) over the expected hospital visits (denominator) multiplied by the crude national rate. The measure score numerator is the predicted rate, which is the number of unplanned hospital visits the facility is predicted to have within 7 days of colonoscopy, and it accounts for the observed unplanned hospital visit rate, the number of colonoscopies performed at the facility, and the facility's case mix. This is sometimes referred to as the ''adjusted actual rate.''

The measure score denominator is the expected rate, which is the number of unplanned hospital visits the facility is expected to have based on the nation's performance with that facility's case and mix. It is the sum of all patients' expected probabilities of a hospital visit, given their risk factors and the risk of readmission at an average facility. The contribution of each risk factor (for example, age) to the patient's risk of a hospital admission is calculated based on all of the patients in the measure cohort. The crude national rate is the average rate of hospital visits following colonoscopy observed in the entire measure cohort. We also refer readers to the measure discussion above and measure specifications (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=75057)* for a more detailed discussion of how the numerator and denominator are calculated.

Comment: Commenters believed that the Medicare 3-day window payment policy for hospitals does not allow HOPDs to generate a claim when there is an inpatient admission during the 3-day window payment policy, that is, during the 3 days subsequent to the colonoscopy. Commenters stated that HOPDs may be advantaged with systematic undercounting of hospital visits while ASCs get a full count of all hospital visits within 7 days subsequent to outpatient colonoscopy. Commenters did not believe the methodological solution proposed by the measure developer, using physician claims with an HOPD Place of Service (POS) code, is adequate due to the high error rates in POS coding on physician claims. Commenters were concerned that these challenges would make comparisons of HOPD and ASC data impossible, and significantly reduce the validity of the measure in the HOPD setting.

Response: We agree that the ability to detect meaningful variation is an important indication of the value of a measure. We have shown facility variation in unplanned hospital visits following colonoscopy in both nationwide Medicare data from HOPDs and also in the 2010 Healthcare Cost and Utilization Project (HCUP) data. We have also shown facility variation in unplanned hospital visits among ASCs alone using HCUP data from California. ASCs are unaffected by the 3-day payment window policy.[22] We are confident that the variation shown is a reflection of facility variation in quality and not as a result of any issues to do with the 3-day window payment policy. We are aware of the impact of the 3-day window payment policy and will ensure HOPD colonoscopies affected by the 3-day window payment policy are included in the measure cohort and outcome to the fullest extent possible. Based on our internal testing with claims data, we believe our current algorithm is appropriate and accurate. However, since we always strive for improvement, we will evaluate the colonoscopy measure dry run data and work with HOPDs and ASCs to further review and refine the algorithm if necessary.

We clarify that HOPD colonoscopy claims for calculation of the measure are identified using both the physician and the facility claims. We did not intend to imply that colonoscopies performed in HOPDs are solely identified from physician claims. For both ASCs and HOPDs, the measure first identifies colonoscopy claims using both the physician claim and the corresponding facility claim to ensure that each colonoscopy claim is attributed to the appropriate facility. As a second step, the measure matches (1) physician claims that contain HOPD as the POS that do not have a matching facility claim with (2) inpatient claims to identify potential HOPD colonoscopies that have a subsequent inpatient admission within the measure's timeframe of interest. This second step identifies HOPD colonoscopy claims affected by the 3-day window payment policy.

An OIG review (*http://oig.hhs.gov/oas/reports/region10/11000516.pdf*), concluded that, based on a sample of 2009 claims, inaccuracies in physician POS coding often occur where a procedure occurs at a HOPD or ASC and a facility claim exists, yet the physician claimed a nonfacility POS. By matching both facility and physician colonoscopy claims for any given patient, we ensure that we accurately identify colonoscopy claims to the fullest extent possible and attribute the colonoscopy to the appropriate provider including HOPD colonoscopies affected by the 3-day window payment policy.

We also have taken steps to educate providers about the appropriate POS coding and actively audit providers to improve the accuracy of POS coding. Beginning in 2012, we also introduced the ''PD'' modifier to indicate physician claims affected by the 3-day window payment policy.

Regarding the comment concerning challenges in comparing HOPD and ASC data, the measure includes colonoscopies from all outpatient settings to ensure that the expected hospital visit rate for any facility is estimated using the full national experience of colonoscopy patients. We appreciate the concern that there are structural differences in claims across HOPD and ASC settings. However, the measure links claims across multiple settings to identify outpatient colonoscopy claims, comorbidities for risk-adjustment, and patient outcomes. Linking patient claims across multiple settings largely mitigates the impact of potential difference in coding practice among settings and allows comparisons of colonoscopy quality across settings.

Comment: One commenter was concerned that the low occurrence rate may make the measure unreportable.

Response: On *Hospital Compare,* we report measure rates, but may refrain from publishing numerator and/or

[21] Available at: *http://www.qualityforum.org/All-Cause_Admissions_and_Readmissions_Measures.aspx.*

[22] Center for Medicare and Medicaid Services, ''Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy,'' National Quality Form Measure Submission Form, 20.

denominator data if either are less than 11. Consistent with the CMS Policy for Privacy Act Implementation & Breach Notification, 2007, CMS statistical, aggregate or summarized information created as a result of analysis conducted using identifiable CMS data obtained under CMS-approved projects/studies may only be disclosed if the data are not individual-specific and the data are aggregated to a level where no data cells contain 10 or fewer individuals *https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/SystemLifecycleFramework/downloads/privacypolicy.pdf.*

Comment: Many commenters expressed concern that, if finalized, the OP–32 measure's data collection period would begin July 1, 2014, several months before adoption of the measure is finalized. These commenters requested that CMS delay the beginning of the data submission period until at least 30 days after the rule is finalized.

Response: After consideration of the public comments we received, we are not finalizing our proposal to use paid Medicare FFS claims from a 12-month period from July 1 of the year 3 years before the payment determination year to June 30 of the following year. We will not use administrative claims data for services that occur prior to January 1, 2015. Instead, after the dry run, we will use paid Medicare FFS claims from a 12-month period from January 1 to December 31 of the year 2 years before a payment determination year. Specifically, since we are finalizing this measure beginning with the CY 2018 payment determination, and we will start with paid Medicare FFS claims from January 1, 2016 to December 31, 2016.

Comment: Some commenters suggested that CMS consider developing additional outcomes measures specific to colonoscopies, such as a measure of whether colonoscopy patients remain cancer free.

Response: We appreciate the commenters' suggestions and will take them into consideration for future measure selection.

We continue to believe that quality of care measurement in the clinical area of outpatient colonoscopy is an important gap area with ample room for improvement and that this measure has sufficient reliability and validity for use in the Hospital OQR Program. Therefore, after consideration of the public comments we received, we are finalizing our proposal to adopt the OP–32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure for the Hospital OQR Program. However, to allow HOPDs sufficient time to review their measure data from the dry run and utilize the confidential facility reports with patient-level associated hospital event information, we are finalizing to make this measure required beginning with the CY 2018 payment determination and subsequent years, instead of the CY 2017 payment determination and subsequent years as proposed.

We plan to perform a dry run of the measure in 2015. Also, with national implementation of a dry run of this measure, we will also review the appropriate cutoff volume for facilities, if necessary, in reporting the measure score. We refer readers to our discussion of the dry run and the cutoff volume above, in responses to previous comments.

The finalized measure set for the Hospital OQR Program CY 2017 payment determination and subsequent years, which includes previously finalized measures, is listed below.

FINALIZED HOSPITAL OQR PROGRAM MEASURE SET 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: 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.**

*OP–26: Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228889963089&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D1r_OP26MIF_v+6+0b.pdf&blobcol=urldata&blobtable=MungoBlobs.*

** Measure voluntarily collected as set forth in section XIII.D.3.b. of this final rule with comment period.

*** Name has been updated to correspond with NQF-endorsed name.

The finalized measure set for the Hospital OQR Program CY 2018 payment determination and subsequent years, which includes previously finalized measures, and which includes the newly adopted measure, OP–32, is listed below.

FINALIZED HOSPITAL OQR PROGRAM MEASURE SET 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: 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. **
N/A	OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. ****

* OP–26: Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228889963089&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D1r_OP26MIF_v+6+0b.pdf&blobcol=urldata&blobtable=MungoBlobs.*

** Measure voluntarily collected as set forth in section XIII.D.3.b. of this final rule with comment period.

*** Name has been updated to correspond with NQF-endorsed name.

**** New measure finalized for the CY 2018 payment determination and subsequent years.

F. Possible Hospital OQR Program Measures and Topics for Future Consideration

The current measure set for the Hospital OQR Program includes measures that assess processes 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 (1) electronic clinical quality measures; (2) partial hospitalization measures; (3) behavioral health measures; and (4) other measures that align with the National Quality Strategy and the CMS Quality Strategy domains.

1. Electronic Clinical Quality Measures

HHS believes all patients, their families, and their health care 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. (HHS August 2013 Statement, ''Principles and Strategy for Accelerating Health Information Exchange'' (*http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf*). The Department is committed to accelerating health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health information technology (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.*

These initiatives are designed to encourage HIE among health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs as well as those who are not eligible for those programs, and are designed to improve care delivery and coordination across the entire care continuum. For example, the Transition of Care Measure #2 in Stage 2 of the Medicare and Medicaid EHR Incentive Programs (77 FR 54017 through 54020) requires HIE to share summary records for more than 10 percent of care transitions.

We anticipate that as EHR technology evolves and more 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 submitting data for the Hospital OQR Program electronically would significantly reduce the administrative burden associated with reporting chart-abstracted measures. We recognize that considerable work needs to be done by measure owners and health IT developers and implementers to make this possible with respect to the clinical quality measures targeted for electronic specifications (e-specifications). This work includes completing e-specifications for measures, pilot testing, reliability and validity testing, and implementing such specifications in certified EHR technology to capture and calculate the results.

We received the following comments on these future measures.

Comment: Many commenters supported CMS' efforts to establish electronic clinical quality measures after validation and testing, but expressed concerns and offered suggestions. One commenter specifically noted the importance of health information exchanges in disseminating infection prevention and control information across the care continuum. Some commenters encouraged CMS to obtain input from ONC and hospital staff, for the purpose of ensuring the maturity of e-specifications and the ability of certified EHRs to support valid, feasible, and reliable electronic clinical quality measures for implementation in different programs. Some commenters urged CMS to proceed in a phased approach to implementing electronic clinical quality measures.

Response: We agree that health information exchanges are critical in quality care improvement, including infection prevention and control. To the greatest extent feasible, we strive to work with ONC and stakeholders, including hospital staff, to develop and specify electronic clinical quality measures before their adoption. If we decide to propose electronic clinical quality measures in the future, we will consider a phased approach.

Comment: One commenter stated that it is premature to expand the measure set to include electronic clinical quality measures at this time because tremendous work in developing or defining e-specifications, pilot testing, and validity and reliability testing is still needed.

Response: We recognize that much work needs to be done before the adoption of electronic clinical quality measures. However, we also believe that implementation of electronic clinical quality measures will ultimately reduce provider burden and facilitate care coordination and patient engagement. We will weigh and balance these concerns when we propose to adopt electronic clinical quality measures in the future.

Comment: One commenter stated that the additional time needed to develop electronic clinical quality measures will allow hospitals to optimize their EHRs and develop information sharing networks.

Response: We thank the commenter for raising this concern. We believe, to the extent feasible, it is important to ensure that hospitals are ready to implement EHRs and will continue to work with them as we implement electronic clinical quality measures.

We thank the commenters for their views and will consider them as we develop and implement future electronic clinical quality measures.

2. Partial Hospitalization Program Measures

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the hospital outpatient setting. Therefore, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75106), we stated that, through future rulemaking, we intended to propose new measures that help us further our goal of achieving better health care and improved health for Medicare beneficiaries who receive health care in hospital outpatient settings, such as partial hospitalization programs (PHPs) that are part of HOPDs.

Partial hospitalization is an intensive outpatient program of psychiatric services provided to patients as an alternative to inpatient psychiatric care for individuals who have acute mental illness. The PHP was designed to assist individuals with acute psychiatric illness in managing debilitating symptoms and prevent the need for hospitalization or rehospitalization. Behavioral health treatments and services have improved and evolved through medication advances, recovery-based therapy, and evidenced-based interventions, including peer supports. PHP services have had the opportunity to evolve to provide individuals with a unique setting that can contribute to maintaining social and community connectivity while focusing on sustained recovery to prevent initial hospitalization during a given episode and subsequent rehospitalization. Currently, the Hospital OQR Program has not adopted measures applicable to PHPs.

Although we believe that the PHP is an important program offering an alternative to inpatient stays, we note that PHP utilization has been declining.[23] Therefore, as we consider implementing PHP measures in future years, we invited public comment regarding the utility of including measures for this care setting in the Hospital OQR Program.

We specifically requested public comment on three PHP measures we submitted to the MAP for consideration as part of the ''MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs'' (*http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx* (formerly referred to as the ''List of Measures Under Consideration'')):

- 30-Day Readmission;
- Group Therapy; and
- No Individual Therapy.

These measures are included in the Program for Evaluating Payment Patterns Electronic Reports (PEPPERs) developed under the Comprehensive Error Rate Testing (CERT) Program. Further information on these claims-based measures that provide indicators of quality of care can be found at *http://www.pepperresources.org/LinkClick.aspx?fileticket=stK9uUmQWlM%3d&tabid=148*.

We also requested public input on other possible quality measures for partial hospitalization services for inclusion in the Hospital OQR Program in future years.

Comment: Some commenters supported CMS' consideration of PHP measures, noting that these measures will encourage hospitals to monitor their performance over time and identify opportunities for quality improvement.

Response: We thank the commenters for their support. We agree that PHPs are an important alternative to inpatient stays and there may be value in collecting and reporting this data.

Comment: Many commenters did not support PHP quality metrics in the Hospital OQR Program, stating that there are significant differences between outpatient and PHP treatment services,

[23] *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Leung_PHP_PPS_2010.pdf.*

structure, and supervision, as well as other concerns. Commenters recommended that CMS adopt PHP measures that have been NQF-endorsed and are MAP-recommended, noting that the three PHP measures mentioned in the proposed rule were not recommended by the MAP because they were not well-defined or required additional evidence relating to their value. Commenters suggested that CMS address the MAP's concerns before proposing these measures for use in the Hospital OQR Program.

Response: We disagree that PHP measures are not appropriate for the Hospital OQR Program based on differences between outpatient and PHP treatment services, structure, and supervision. Because PHP services are provided by HOPDs, are an important alternative to inpatient stays, and are utilized by Medicare beneficiaries, we believe that there may be value in collecting and reporting quality measure data for these services. However, at this time, we are not proposing any PHP measures for the Hospital OQR Program. The PHP measures on which we invited comment have not been recommended by the MAP. The MAP stated that it needed further information on the 30-Day Readmission measure and recommended that the No Individual Therapy and Group Therapy measures be submitted for NQF endorsement before they are adopted by the Hospital OQR Program (*http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*).

If we do consider proposing PHP measures in the future, to the extent feasible, we intend to propose to adopt measures which are NQF-endorsed and have been MAP-recommended. Before adopting a measure, we try to address stakeholder concerns, including the differences in the outpatient and PHP settings. Finally, if we choose to propose the three measures discussed in the proposed rule, we will consider the comments of the MAP and address them to the extent feasible. We note, however, that not all of the measures adopted by the Hospital OQR Program are NQF-endorsed, nor is NQF endorsement a program requirement (section 1833(t)(17)(C)(i) of the Act).

Comment: Some commenters believed that using PHP measures in the Hospital OQR Program would constitute a duplication of efforts because the measures are already included in PEPPER. Other commenters also viewed PEPPER measures as auditing tools rather than quality measures.

Response: We will consider the commenters' viewpoint if we propose to adopt the PEPPER measures in future rulemaking. We note that these measures, while addressing areas of payment concern, also address areas of quality of care concern and that the PEPPER measures are not publicly reported at the facility level.

Comment: Commenters expressed concerns about the 30-day readmissions measure because this patient population tends to be readmitted for behavioral conditions due to social issues for which hospitals have little control. Commenters stated that PHP patients' clinical needs evolve over time, that readmissions are often needed to stabilize patients, and that measuring facilities on readmission rates could cause unintended consequences. Commenters further stated that the readmission measure is not sufficiently risk-adjusted.

Response: We thank the commenters for raising these concerns. We will consider these concerns if we propose to adopt the 30-day readmission PEPPER measure for the Hospital OQR Program in future rulemaking.

Comment: Some commenters stated that CMS should better understand the challenges facing PHP and readmissions before imposing PHP quality measures because quality measures could further destabilize the PHP rate and threaten access to this service.

Response: We understand that utilization of PHP services has been decreasing and that many challenges may be unique to the PHP setting. We will consider these issues before proposing to adopt any PHP measures in future rulemaking.

Comment: One commenter recommended that CMS include the 60+ Days of Service measure in the PHP measure suite as well as assessments of intensive outpatient programs that treat individuals with substance use disorders.

Response: We thank the commenter for the recommendation and will consider this measure if we propose to adopt PHP measures in future rulemaking. We note that Medicare does not cover intensive outpatient program (IOP) services, and this could affect the usefulness of the recommended measure for the Hospital OQR Program.

Comment: Some commenters encouraged CMS to develop specific PHP measures such as: (1) Requiring PHPs to identify a specific appointment within 14 days; (2) requiring continuing care information be provided directly to the follow-up provider; and (3) establishing Quality Service Criteria for use in judging performance, including criteria relating to access, treatment intensity, discharge planning, and continuity of care.

Response: We appreciate the commenters' suggestions. We support coordination of care efforts and will consider developing these types of measures for the Hospital OQR Program.

Comment: One commenter argued that the Group Therapy measure should only be adopted as a percentage rating of group therapy as a comparison to all interventions billed. The commenter also noted that both group therapy and individual psychotherapy are needed for optimal success.

Response: We thank the commenter for sharing its views. We are unclear what the commenter means by ''a percentage rating of group therapy'' and so cannot respond at this time. However, we welcome clarification and will consider all of the commenter's concerns if we propose to adopt PHP measures in future rulemaking.

Comment: One commenter voiced support for our efforts in working toward electronic quality of care measures in the PHP setting of care.

Response: We note that we did not specifically discuss electronic quality-of-care measures for the PHP setting in the proposed rule. However, we are working diligently to implement electronic measures across the quality reporting programs, and we may consider electronic clinical quality measures for the PHP setting in the future.

We thank the commenters for their views and will consider them as we develop future policies.

3. Behavioral Health Measures

In addition to PHP measures, we are considering other measures specific to behavioral health in the outpatient setting, including measures addressing depression and alcohol abuse. Major depression is a leading cause of disability in the United States, complicates the treatment of other serious illnesses, and is associated with an increased risk of suicide. Major depression is a common mental health condition, affecting 6 to 9 percent of those over 55 years of age.[24] Along with other serious mental health conditions, it has a higher Medicare inpatient readmission rate than all other conditions with the exception of heart failure.[25] Alcohol use disorders are the

[24] O'Connor E, Whitlock E, Beil T, et al. Screening for depression in adult patients in primary care settings: a systematic evidence review. Annals of Internal Medicine 2009 December 1:151(11):793–803.

[25] Stephen F. Jencks, M.D., M.P.H., Mark V. Williams, M.D., and Eric A. Coleman, M.D., M.P.H.

most prevalent type of addictive disorder in individuals ages 65 and over.[26] Roughly 6 percent of the elderly are considered to be heavy users of alcohol.[27] Alcohol abuse is often associated with depression and contributes to the etiology of serious medical conditions, including liver disease and coronary heart disease. Because of the prevalence of depression and alcohol abuse and their impact on the Medicare population, we believe that we should consider measures in these and other behavioral health areas for use in future Hospital OQR Program payment determination years. Therefore, we invited public comment on measures applicable to these areas that would be suitable for the Hospital OQR Program.

Comment: Many commenters supported CMS' efforts to develop and implement quality measurement tools related to alcohol abuse and depression because of the prevalence of these conditions within the Medicare population and the need to improve care coordination for these conditions. Commenters encouraged CMS to incorporate measures that address the following principles: (1) The patient's readiness for treatment; (2) the treatment will address mental health issues in conjunction with the alcohol abuse; and (3) the patient's willingness to participate in an alcohol abuse program without the need for coerced efforts.

Response: We thank commenters for their support, and we will consider these principles if we choose to propose to adopt behavioral health measures in the future.

Comment: One commenter suggested adopting a measure that evaluates screening for psychological/physical or sexual trauma, arguing that trauma informed care is critical to successful recovery and better engagement and retention in ambulatory care.

Response: We agree that this clinical topic is important, and we will consider adopting a measure screening for trauma in the future.

Comment: Some commenters argued that behavioral health measures are more suited to the IPFQR Program.

Response: We disagree with this view. We believe all care settings should seek to improve the behavioral health outcomes of their patients.

Comment: One commenter recommended that CMS work with the NQF to develop appropriate measures related to beneficiary wellness concerns. The commenter noted that behavioral health quality measures are used in the nursing home and home health care settings, and that these measures should be reviewed to determine if they are applicable to the outpatient setting. The commenter believed that any measures used should be claims-based and not generated by chart abstraction to minimize administrative burden.

Response: We interpret ''beneficiary wellness concerns'' to mean measures of behavioral health. We endeavor to adopt measures that are NQF-endorsed and believe it is critical to work with stakeholders to develop measures. However, we note that not all of the measures adopted by the Hospital OQR Program are NQF-endorsed, nor is NQF endorsement a program requirement (section 1833(t)(17)(C)(i) of the Act) as consensus among affected parties can be reflected through means other than NQF endorsement. In addition, to the extent feasible, we believe it is important to align measures across all our quality reporting programs, and we will look to other settings for measures of behavioral health. Finally, we will continue to examine options for less burdensome reporting mechanisms for these and other program measures in the future; this includes claims-based and electronically submitted data.

Comment: Some commenters recommended that behavioral health quality measures not be considered at this time for the Hospital OQR Program, arguing that additional research and education needs to be done to develop helpful behavioral measures.

Response: We will continue to research appropriate measures and work with stakeholders as we consider behavioral health measures for the Hospital OQR Program in the future.

Comment: One commenter urged CMS to work with its behavioral health Technical Experts Panel (TEP) and the MAP to identify and bring forward behavioral health measures that are suitable for this population and for consideration by all stakeholders.

Response: We convene TEPs, groups of stakeholders and experts, to provide technical input on the development, selection, and maintenance of measures. Convening TEPs is one important step in the measure development or reevaluation process to ensure transparency and it provides an opportunity to receive multi-stakeholders input early in the process. We refer readers to *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TechnicalExpertPanels.html* for more information on TEPs. We believe it is important to work with stakeholders as we develop and adopt behavioral health measures. We will leverage both TEPs and the MAP as we consider future measures.

Comment: One commenter recommended that CMS incorporate standardized behavioral health measures that are currently in widespread use, such as the National Center for Quality Assurance's behavioral health measures.

Response: We thank the commenter for its recommendation, and we will consider these measures for future rulemaking.

Comment: Some commenters supported CMS' efforts to identify depression and depression-related issues in the Medicare population. The commenters believed that an identification tool should be used for any new patient encounter and recommended that every Medicare provider should be required to use a depression screening tool at any initial patient screening/encounter. Some commenters, however, noted that depression screening in the ambulatory setting is nearly universal, and, therefore, such a measure may be ''topped-out'' even before adoption.

Response: We thank commenters for their support. We interpret the commenters' suggestions to mean that we should include measures that encourage providers to screen patients to identify depression. We will consider depression screening measures in the future.

We thank the commenters for their views on behavioral health measures in the outpatient setting and will consider them as we develop future policies.

4. National Quality Strategy and CMS Quality Strategy Measure Domains

In considering future Hospital OQR Program measures, we are focusing on the following National Quality Strategy 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. We believe measures in these areas will promote better care and align measures across multiple CMS quality programs, in particular, the Hospital OQR, Hospital IQR, and ASCQR Programs.

Rehospitalizations among Patients in the Medicare Fee-for-Service Program. N Engl J Med 2009;360:1418–28.

[26] Stephen Ross. Alcohol Use Disorders in the Elderly. Psychiatry Weekly (no date) Available at: *http://www.psychweekly.com/aspx/article/ArticleDetail.aspx?articleid=19.*

[27] AL Mirand and JW Welte. Alcohol consumption among the elderly in a general population, Erie County, New York. Am J Public Health. 1996 July; 86(7): 978–984.

We received the following comments on these future measures.

Comment: Many commenters supported the Hospital OQR Program's effort to align future measures with the NQS priorities and CMS quality strategy, noting that doing so will make the Hospital OQR Program more consistent with the Hospital IQR Program. Commenters urged CMS to further align our measures with other quality reporting programs. One commenter stated that CMS should respond to all MAP recommendations as part of any proposed rule so that stakeholders may gain a better understanding of our decisions, particularly when a MAP recommendation is not being followed.

Response: We thank the commenters for their support. To the extent practicable, we strive to align measures across our quality reporting programs. We also appreciate the feedback of the MAP and work to address its concerns before adopting measures in the Hospital OQR Program. As we stated above, to the extent feasible, we strive to state and address the MAP concerns when adopting a measure.

Comment: Some commenters recommended that CMS introduce measures to track and monitor radiation dose exposure and contrast dose exposure, including organ-specific radiation exposure based on patient weight and contrast administration, and a meaningful tracking mechanism for patient longitudinal exposure. One commenter noted that the PQRS program has included some similar measures giving radiologists an incentive to track patient exposure. In addition, the commenter noted that The Joint Commission, the FDA, and the EPA have all issued guidance recommending that exposure to radiation through medical devices be minimized.

Response: We thank the commenters for their recommendations, and we may consider these types of measures in future years.

Comment: One commenter urged CMS to require hospitals to comply with all manufacturing standards for imaging equipment to facilitate patient safety and promote the overall quality of patient care in hospitals. The commenter also recommended a measure tracking the demonstrated reduction in suboptimal or nondiagnostic echocardiograms and the resulting improvements in diagnosis and reductions in costs to Medicare and beneficiaries.

Response: We thank the commenter for its recommendation, and we may consider these types of measures in future years.

Comment: One commenter encouraged the implementation of a CAHPS survey used to encourage patient experience improvement across the ambulatory surgery sector. The commenter urged CMS to continue to analyze and address the role of the survey and discuss the comparative roles of surveys across other care settings and quality reporting programs. Another commenter encouraged CMS to involve consumers and purchasers in refinement of the CAHPS survey for the outpatient setting.

Response: We thank the commenters for these suggestions. We intend to include such survey measures for the outpatient setting on our December 1, 2014 Measures under Consideration (MUC) List for MAP review. We currently use patient experience-of-care surveys in a variety of health care settings. For example, both the ESRD QIP and the Hospital IQR Program use patient experience-of-care surveys, the In-center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), respectively. We agree that, to the extent feasible, survey instruments should be aligned and coordinated across settings. The developmental process of CAHPS and patient experience-of-care surveys involves several opportunities for input from patients, patient advocates, and stakeholders from the HOPD and ASC industry, including professional associations, clinicians, accreditation organizations, and the government. These opportunities include serving on the TEP, responding to the **Federal Register** notice requesting measures, topics, or public domain questionnaires, and providing comment on the survey through the OMB clearance process.

Comment: One commenter recommended that CMS target high volume procedures that may be unnecessary at the composite, individual hospital, and physician levels, including those that are part of the Choosing Wisely campaign.

Response: We thank the commenter for its recommendation, and we may consider these types of measures in future years.

Comment: One commenter requested that CMS risk-adjust measures of clinical outcomes for SES in order to avoid disadvantaging hospitals, particularly safety-net hospitals that are evaluated on these outcomes.

Response: We thank the commenter for this feedback. We addressed the topic of risk adjustment with respect to the Hospital IQR and Hospital Readmissions Reduction Programs in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50219 and 50026 through 50027), and we believe the same approach would apply to risk adjustment for Hospital OQR Program measures because the Hospital OQR Program outcome measures are risk-adjusted, and this approach aligns with outcome measures methodology used in other programs across settings. The purpose of risk adjustment when comparing outcome rates for two different outpatient facilities is to statistically compensate (or adjust) for risk factor differences in the two facilities so that the outcome rates can be compared legitimately despite the differences in risk factors.

We appreciate the commenters' suggestions on the importance of addressing SES in the Hospital OQR Program. We continue to consider and evaluate stakeholder concerns regarding the impact of patients' SES on Hospital OQR measures.

Comment: Many commenters urged CMS to adopt only NQF-endorsed measures for its quality reporting and pay-for-performance programs, arguing that the consensus-based process validates quality measures' rigor and ensures that the measures have been are reliable and have been carefully tested, validated, and scrutinized. Commenters also commended CMS for considering the MAP's input in selecting measures, particularly because the MAP considers NQF endorsement, measures' feasibility of implementation, stakeholder input, and validity.

Response: We thank commenters for their support for the MAP process. To the extent feasible, we seek to adopt measures that have been NQF-endorsed. However, we also note that consensus among affected parties can be reflected through means other than NQF endorsement. We also refer readers to our discussion above in section XIII.E. of this final rule with comment period in response to a similar comment.

Comment: Commenters suggested that CMS consider adopting measures of HAIs, such as SSI, CLABSI, CAUTI, MRSA, and *C. difficile,* or infection control process measures, such as MRSA colonization at admission or hand hygiene adherence, use of barrier precautions, or other process measures. Commenters noted that infections such as MRSA and *C. difficile* are a significant source of morbidity and mortality. One commenter encouraged CMS to develop composite measures of common surgical infections; another commenter requested that CMS adopt

measures that have aligned data elements with the CDC's NHSN.

Response: We agree that it is important to minimize infection events that present significant health risks to patients. We also believe that infection prevention measures provide information critical to quality improvement efforts. We note that several measures that focus on these infections are already included in the Hospital IQR Program (79 FR 50202) and are aligned with the CDC's NHSN. We will consider including these types of measures for the outpatient setting in the Hospital OQR Program and aligning them with other quality reporting programs, such as the Hospital IQR Program, to the extent feasible in future years.

Comment: One commenter suggested that CMS consider measures of adverse outcomes from high-volume procedures such as cataract removals, other eye procedures, endoscopies, musculoskeletal procedures, and colonoscopies.

Response: We thank the commenter for its suggestion and may consider these types of measures in future years.

We thank the commenters for their views and will consider them as we develop future policies.

G. Payment Reduction for Hospitals That Fail To Meet the Hospital Outpatient Quality Reporting (OQR) Program Requirements for the CY 2015 Payment Update

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, required 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): ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' or ''U.'' We note that we are finalizing our proposal to delete status indicator ''X''' as described in sections II.A.3. and X. of this final rule with comment period. We also note that we are finalizing our proposal to develop status indicator ''J1'' as part of our comprehensive APC policy, effective for CY 2015, discussed in section II.A.2.e. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910) and sections II.A.2.e. of the CY 2015 OPPS/ASC proposed rule and this final rule with comment period. 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 final rule with comment period.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2015

In the CY 2015 OPPS/ASC proposed rule (79 FR 41017), we proposed 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 2015 annual payment update factor. For the CY 2015 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of $72.692 by the proposed full conversion factor of $74.176. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2015 OPPS, we proposed to apply the reporting ratio, when applicable, to all HCPCS codes to which we have assigned status indicators ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' and ''U'' (other than new technology APCs to which we have assigned status indicators ''S'' and ''T''). We note that we are finalizing our proposal to delete status indicator ''X'' as described in sections II.A.3. and X. of the proposed rule and this final rule with comment period. We note that we are finalizing our proposal to develop status indicator ''J1'' as part of our CY 2015 comprehensive APC policy, discussed in sections II.A.2.e. of the CY 2015 OPPS/ASC proposed rule and this final rule with comment period and to apply the reporting ratio to the comprehensive APCs. We proposed to continue to exclude services paid under New Technology APCs. We proposed 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 proposed 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 proposed 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 did not receive public comments on our proposal. Therefore, we are finalizing our proposal to apply the Hospital OQR Program reduction in the manner described above. We also are finalizing our proposal, with modification, to reflect the CY 2015 OPPS status indicators to which the adjustment would apply. For the CY 2015 OPPS, the final reporting ratio is 0.980, calculated by dividing the final reduced conversion factor of $72.661 by the final full conversion factor of $74.144.

As a result, for the CY 2015 OPPS, we are applying a reporting ratio of 0.980 to the national unadjusted payments, minimum unadjusted copayments, and national unadjusted copayments for all applicable services for those hospitals failing to meet the Hospital OQR Program reporting requirements. This reporting ratio applies to HCPCS codes assigned status indicators ''J1,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''U,'' or ''V,'' excluding services paid under New Technology APCs. 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 will continue to apply. We continue to calculate OPPS outlier eligibility and outlier payment based on the reduced rates for those hospitals that fail to meet the reporting requirements.

H. Requirements for Reporting Hospital OQR Program Data for the CY 2017 Payment Determination and Subsequent Years

1. Administrative Requirements for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109) for a discussion of the Hospital OQR Program procedural requirements for the CY 2015 payment determination and subsequent years. In that final rule with comment period, we codified these procedural requirements at 42 CFR 419.46(a).

2. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

a. General Procedural Requirements

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75110 through 75111) for a discussion of Hospital OQR Program general procedural requirements. In that final rule with comment period, we finalized our proposal to codify these general procedural requirements at 42 CFR 419.46(c).

In the CY 2015 OPPS/ASC proposed rule (79 FR 41042), we proposed to correct a typographical error in 42 CFR 419.46(c). This section states, ''Except as provided in paragraph (d) of this section, hospitals that participate in the Hospital OQR Program must submit to CMS data on measures selected under section 1833(17)(C) of the Act . . .'' We proposed to correct the erroneous reference of ''section 1833(17)(C)'' to ''section 1833(t)(17)(C).''

We invited public comment on this proposal.

We did not receive any public comments on this proposal. Therefore, we are finalizing the typographical correction as proposed.

b. Requirements for Chart-Abstracted Measures Where Data Are Submitted Directly to CMS for the CY 2017 Payment Determination and Subsequent Years

The following chart-abstracted measures finalized previously and retained in the Hospital OQR Program require data to be submitted for the CY 2017 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# 286)
- 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–22: ED—Left Without Being Seen;
- 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);
- 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 refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form and manner for data submission of these measures.

As we noted in the CY 2015 OPPS/ASC proposed rule (79 FR 41042), we neither proposed new chart-abstracted measures where patient-level data is submitted directly to CMS nor proposed new requirements for data submission for chart-abstracted measures.

c. Claims-Based Measure Data Requirements for the CY 2017 and CY 2018 Payment Determination and Subsequent Years

We proposed one additional claims-based measure for the CY 2017 payment determination and subsequent years, OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (79 FR 41036 through 41039). However, as discussed in section XIII.E. of this final rule with comment period, we are finalizing this measure for the CY 2018 payment determination and subsequent years instead of the CY 2017 payment determination and subsequent years as proposed. As discussed in section XIII.E. of this final rule with comment period, we will use claims data from January 1, 2016–December 31, 2016 to calculate OP–32 for the CY 2018 payment determination in order to use the most recently available data. Therefore, we are finalizing that to calculate OP–32, we will use claims data from January 1—December 31 of the calendar year 2 years prior to the payment determination year (for example, for the CY 2018 payment determination, we will use data from January 1, 2016—December 31, 2016).

Therefore, there will be a total of seven claims-based measures for the CY 2017 payment determination and subsequent years:

- 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;
- 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–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.

For the CY 2018 payment determination and subsequent years, there will be a total of eight 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;
- 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);
- OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache; and
- OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75111 through 75112) for a discussion of the claims-based measure data submission requirements for the CY 2015 payment determination and subsequent years.

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 68481, 78 FR 75111). As we noted in the CY 2015 OPPS/ASC proposed rule (79 FR 41042), 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; however, hospitals are still required to submit data as previously finalized (76 FR 74456).

Comment: One commenter supported the proposed deferral of the public reporting of OP–15. The commenter appreciated CMS' concerns regarding inappropriate use of brain CT imaging and the need for an established clinical guideline to address this issue. However, the commenter did not believe older adults or adults on anticoagulant medications should be included in OP–15, and noted that current research suggests headaches are a potential contraindication. The commenter also expressed concern that claims are not detailed enough to capture the clinical indications needed for appropriate exclusions. As a result, the commenter was concerned that this measure may discourage clinically appropriate brain CTs for higher-risk older populations. The commenter believed that CMS should focus its efforts on other CT measures, particularly after trauma or suspected pulmonary embolism. Another commenter asked CMS to remove OP–15 from the measure set.

Response: Given stakeholder concerns, including those of this commenter, we continue to evaluate whether OP–15 needs to be refined before being publicly reported. We continue to believe, for the reasons stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74456), that the measure has value, and we will continue to collect data with regard to this measure. However, we will also continue to defer public reporting until we have resolved these concerns. Because the measure is claims-based, this deferral does not affect data submission requirements for the Hospital OQR Program (that is, HOPDs do not submit data for claims-based measures other than the actual FFS claims), and an HOPD's payment determination will not be affected based on OP–15 while public reporting is deferred.

d. Data Submission Requirements for Measure Data Submitted via the CMS Web-Based Tool for the CY 2017 Payment Determination and Subsequent Years

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 Web-based tool on a CMS Web site (the QualityNet Web site) for the CY 2016 payment determination and subsequent years.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41042), we did not propose any changes to the data submission requirements for data submitted via the CMS Web-based tool.

e. Population and Sampling Data Requirements for the CY 2017 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. In the CY 2015 OPPS/ASC proposed rule (79 FR 41042), we did not propose any changes to this policy.

f. Review and Corrections Period for Chart-Abstracted Measures

Under the Hospital OQR Program, hospitals submit chart-abstracted data to CMS on a quarterly basis. These data are typically due 4 months after the quarter has ended, unless we grant an extension or exception, as further described in section XIII.J. of this final rule with comment period. We refer readers to the CY 2014 OPPS/ASC final rule with comment period for a discussion of our previously finalized policies regarding submissions deadlines for chart-abstracted measures (78 FR 68482). Hospitals may begin submitting data on the first discharge day of any reporting quarter and can modify this data up until the close of the submission period (or 4 months after the quarter has ended). For example, if a hospital enters data on January 2, it could continue to review, correct, and change these data until August 1, the first quarter submission deadline. We generally provide rates for the measures that have been submitted for chart-abstracted, patient-level data 24 to 48 hours following submission. Hospitals are encouraged to submit data early in the submission schedule so that they can identify errors and resubmit data before the quarterly submission deadline.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41042 through 41043), we proposed to formalize this 4-month period as the review and corrections period for chart-abstracted data for the Hospital OQR Program. During this review and corrections period, hospitals can enter, review, and correct data submitted directly to CMS. However, after the submission deadline, hospitals would not be allowed to change these data. We believe that 4 months is sufficient time for hospitals to perform these activities.

We invited public comment on this proposal.

Comment: Many commenters did not support CMS' proposal to have the data submission period run concurrently with the review and corrections period, stating that CMS allows a separate time period for review and corrections for nearly all of CMS' other quality reporting programs. Commenters specifically stated that, with the proliferation of quality measures in each of CMS' quality reporting programs, hospitals need all of the time currently afforded to capture and report data accurately. Commenters recommended that CMS provide at least 30 days immediately after the submission deadline to allow hospitals to review and correct their data.

Response: We disagree with the commenters who believed that our other quality reporting programs have a separate review and corrections period. Providers may review their data during the submission period, but are not afforded time after this period to correct their data. We note that our proposed review and corrections period is consistent with the informal review and corrections period of other quality reporting programs, including the Hospital IQR Program.

As stated in the proposed rule (79 FR 41042–41043), hospitals typically have 4 months to submit, review, and correct their chart-abstracted data, and we merely proposed to formalize this time period as the review and corrections period. We believe that 4 months is adequate because hospitals have been using this period of time to submit, view, and correct their chart-abstracted data for the life of the program. We strongly encourage hospitals to submit their data as early as possible so they can take full advantage of the time needed for review and correction. In addition, the length of time for data submission for chart-abstracted data that is validated affects the timeliness of the validation process; additional time would further lengthen the time from when care is rendered to when data can be made publicly available.

After consideration of the public comments we received, and consistent with our policy in other quality reporting programs, we are finalizing the 4 months review and corrections period as proposed. We strongly encourage hospitals to submit their data to CMS as early as possible to have the maximum time to review and correct their data.

3. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2017 Payment Determination and Subsequent Years

a. Background

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487) for a discussion of finalized policies regarding our validation requirements. We codified these policies at 42 CFR 419.46(e). In the CY 2015 OPPS/ASC proposed rule (79 FR 41043 through 41044), we proposed three changes to our validation procedures: (1) We proposed to change the eligibility requirements for hospitals selected for validation so that a hospital would be eligible if it submits at least one case to the Hospital OQR Program Clinical Data Warehouse during the quarter containing the most recently available data; (2) we proposed to give hospitals the option to either submit paper copies of patient charts or securely transmit electronic versions of medical information for validation; and (3) we proposed that a hospital must identify the medical record staff responsible for submission of records under the Hospital OQR Program to the designated CMS contractor.

b. Selection of Hospitals for Data Validation of Chart-Abstracted Measures for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2012 and CY 2013 OPPS/ASC final rules with comment period (76 FR 74484 through 74485 and 77 FR 68484 through 68485) for a discussion of finalized policies regarding our sampling methodology, including sample size, eligibility for validation selection, and encounter minimums for patient-level data for measures where data is obtained from chart abstraction and submitted directly to CMS from selected hospitals.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41043), we proposed one change to this process. Previously, to be eligible for random selection for validation, a hospital must have been coded as ''open'' in the CASPER system at the time of selection and must have submitted at least 10 encounters to the Clinical Data Warehouse during the data collection period for the applicable payment determination (76 FR 74484). We proposed that, beginning with the CY 2015 encounter period for the CY 2017 payment determination and subsequent years, a hospital will be eligible for validation if it submits at least one case to the Hospital OQR Program Clinical Data Warehouse during the quarter containing the most recently available data. The quarter containing the most recently available data will be defined based on when the random sample is drawn. For example, if we draw a sample in December 2014, the most recent data available would be that from the second quarter of 2014, which ends June 2014, because the submission deadline for second quarter data would be November 1, 2014 (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1205442125082*; 78 FR 68482). As another example, if a sample is drawn in October 2014, the most recent available data would be from quarter one, which ended in March 2014, because data must have been submitted by August 1, 2014. We believe this change is necessary because it increases the probability that selected hospitals

have current data in the Clinical Data Warehouse to be validated. Previously, hospitals that did not have data from the current year available could still be selected for validation.

We invited public comment on this proposal.

Comment: Many commenters supported CMS' proposal to allow a hospital to be eligible for validation if it submits at least one case to the Hospital OQR Program Clinical Data Warehouse during the quarter with the most recently available data. One commenter, however, recommended that CMS change the number of cases for a facility to be eligible for validation from at least 1 case to at least 12 cases because up to 12 records are required per hospital per quarter for validation. Commenters also urged CMS to evaluate the appropriateness of hospital selection based on this narrower criterion and to propose refinements, if necessary, in the future.

Response: We thank commenters for their support. We agree with the suggestion that a hospital should only be eligible for random selection for validation if it submits at least 12 cases to the Hospital OQR Program Clinical Data Warehouse during the quarter with the most recently available data. As the commenter noted, currently, when a hospital is selected for validation, we request up to 12 cases per quarter per hospital. We stated our rationale for requesting up to 12 cases per quarter in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74486), where we explained that we attempt to balance burden to hospitals with data accuracy. Accordingly, we recognize that allowing a hospital to be eligible for random selection for validation if it is ''open'' or requiring only one case in the quarter containing the most recently available data may not allow us an adequate number of records to ensure data submitted by the hospital is valid and are modifying our proposal accordingly to align with our validation procedures and goals.

After consideration of the public comments we received, and for the reasons stated above, we are finalizing our proposal with a modification that, beginning with the CY 2015 encounter period for the CY 2017 payment determination and subsequent years, a hospital will be eligible for random selection for validation if it submits at least 12 cases, instead of just 1 as proposed, to the Hospital OQR Program Clinical Data Warehouse during the quarter containing the most recently available data. The quarter containing the most recently available data will be defined based on when the random sample is drawn.

c. Targeting Criteria for Data Validation Selection for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68485 through 68486) for a discussion of our targeting criteria. In the CY 2015 OPPS/ASC proposed rule (79 FR 41043), we did not propose any changes to these policies.

d. Methodology for Encounter Selection for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486) for a discussion of our methodology for encounter selection. In the CY 2015 OPPS/ASC proposed rule (79 FR 41043), we did not propose any changes to this policy.

e. Medical Record Documentation Requests for Validation and Validation Score Calculation for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486 through 68487) for a discussion of our previously finalized procedures for requesting medical record documentation for validation and validation score calculation. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118), we codified these procedures at 42 CFR 419.46(e)(1) and (e)(2). In the CY 2015 OPPS/ASC proposed rule (79 FR 41043 through 41044), we proposed two changes to these policies for the CY 2017 payment determination and subsequent years: (1) We proposed to give hospitals the option to either submit paper copies of patient charts or securely transmit electronic versions of medical information for validation; and (2) we proposed that a hospital must identify the medical record staff responsible for submission of records under the Hospital OQR Program to the designated CMS contractor.

For records stored electronically, hospitals expend additional resources printing records onto paper that may be more efficiently transmitted electronically. In addition, the length of paper charts has been increasing, and the paper used to submit these records has an environmental impact. Therefore, we proposed to give hospitals the option to either submit copies of paper patient charts or securely transmit electronic versions of medical information, which has the potential to significantly reduce administrative burden, cost, and environmental impact. We have already finalized a similar policy for the Hospital IQR Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50834 through 50836) that allows hospitals for the Hospital IQR Program to submit electronic records through the mail on a CD, DVD, or flash drive. In addition, in the FY 2015 IPPS/LTCH PPS final rule for the Hospital IQR Program (79 FR 50269), we finalized our proposal to also allow hospitals to submit patient charts using a Secure File Transfer Portal on the QualityNet Web site.

The current Hospital OQR Program regulation at § 419.46(e)(1) states: ''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 . . . .'' We proposed that this requirement may be met by employing either of the following options for the CY 2017 payment determination and subsequent years: (1) A hospital may submit paper medical records, the form in which we have historically requested them; or (2) a hospital may securely transmit electronic versions of medical information.

For the CY 2017 payment determination and subsequent years, we proposed that hospitals that chose to securely transmit electronic versions of medical information should either: (1) Download or copy the digital image (that is, PDF) of the patient chart onto CD, DVD, or flash drive and ship the electronic media following instructions specified on the QualityNet Web site; or (2) securely submit digital images (PDFs) of patient charts using a Secure File Transfer Portal on the QualityNet Web site. The Secure File Transfer Portal would allow hospitals to transfer files through either a Web-based portal or directly from a client application using a secure file transfer protocol. The system provides a mechanism for securely exchanging documents containing sensitive information such as Protected Health Information (PHI) or Personally Identifiable Information (PII). Detailed instructions on how to use this system are available in the Secure File Transfer 1.0 User Manual available on QualityNet at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228773343598*.

In addition, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486 through 68487), we stated that our validation contractor would request medical documentation from each hospital selected for validation via certified mail or other trackable method.

This request would be sent to ''the hospital's medical record staff identified by the hospital for the submission of records under the Hospital IQR Program (that is, the hospital's medical records staff identified by the hospital to the State QIO)'' (77 FR 68487). Quality Improvement Organizations (QIOs) are CMS contractors required by the Act (section 1152 through 1154) tasked with, among other responsibilities, assisting hospitals with quality improvement activities. Due to the evolution of the structure of the QIO program, beginning with CY 2015 for the CY 2017 payment determination and subsequent years, we proposed that a hospital must identify the medical record staff responsible for submission of records under the Hospital OQR Program to the designated CMS contractor; this CMS contractor may be a contractor other than the State QIO.

Finally, we noted that a typographical error exists in our validation language in § 419.46(e). This section states, ''CMS may validate one or more measures selected under section 1833(17)(C) of the Act . . . .'' ''[S]ection 1833(17)(C)'' should instead state ''section 1833(t)(17)(C).'' We proposed to make this change in the regulation text.

We invited public comment on these proposals.

Comment: Commenters supported CMS' proposal to offer hospitals the option to submit, for validation purposes, either paper copies of patient charts or to securely transmit electronic versions of medical information using either electronic media (for example, CD, DVD, flash drive) or PDFs submitted using the Secure File Transfer Portal on the QualityNet Web site. Commenters noted that the prevalence of electronic medical records lends itself well to electronic submission of records.

Response: We thank commenters for their support and we agree with their comments.

Comment: Commenters supported CMS' proposal to require hospitals to identify the medical record staff responsible for submitting validation records for the Hospital OQR Program, but requested that CMS make every effort to work with State hospital associations to ensure that the correct individuals have been identified through this new process. Commenters also requested that CMS require contractors to update their lists quarterly to ensure that information is kept current.

Response: We thank commenters for their support. We will consider commenters' concerns when instructing our contractors to keep validation contacts up-to-date, and, to the extent feasible, we will attempt to work with state hospital associations.

After consideration of the public comments we received, we are finalizing our proposals: (1) To give hospitals the option to either submit: (a) Paper copies of patient charts; or (b) electronic versions of medical information by: (i) Downloading or copying the digital image (that is, PDF) of the patient chart onto encrypted CD, DVD, or flash drive and shipping the encrypted electronic media following instructions specified on the QualityNet Web site; or (ii) securely submitting PDFs of patient charts using a Secure File Transfer Portal on the QualityNet Web site; (2) that hospitals must identify the medical record staff responsible for submission of records under the Hospital OQR Program to the designated CMS contractor as proposed; and (3) to correct our typographical error in regulation text to read ''section 1833(t)(17)(C)'' as proposed.

I. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2017 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.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41044), we did not propose any changes to the reconsideration and appeals procedures.

J. Extension or Exception Process for the CY 2017 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), and 42 CFR 419.46(d) for a complete discussion of our extraordinary circumstances extension or waiver process under the Hospital OQR Program. In the CY 2015 OPPS/ASC proposed rule (79 FR 41044), we did not propose any substantive changes to these policies or the processes.

However, in the future, we will refer to the process as the Extraordinary Circumstances Extensions or Exemptions process, instead of the Extraordinary Circumstances Extensions or Waiver process. We are in the process of revising the Extraordinary Circumstances/Disaster Extension or Waiver Request form (CMS–10432), approved under OMB control number 0938–1171. We are updating the forms and instructions so that a hospital or facility may apply for an extension for all applicable quality reporting programs at one time.

In addition, we proposed to make a conforming change from the phrase ''extension or waiver'' to the phrase ''extension or exemption'' in 42 CFR 419.46(d).

We proposed to revise the language in 42 CFR 419.46(d) at 79 FR 41081 (July 14, 2014) to state that CMS may grant an extension or exception 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 exception as follows:

- *Upon request by the hospital.* Specific requirements for submission of a request for an extension or exception are available on the QualityNet Web site.
- *At the discretion of CMS.* CMS may grant exceptions or extensions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

We invited comments on this proposal.

Comment: Commenters supported CMS' decision to update the forms and instructions for the extension or exception process so that a hospital may apply for an extension for all applicable quality programs at one time.

Response: We thank commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to change the phrase ''extension or waiver'' to the phrase ''extension or exemption'' at 42 CFR 419.46(d) as proposed.

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 final rule with comment period 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 74493) 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.

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.

2. Policy for Removal of Quality Measures From the ASCQR Program

We previously adopted a policy to retain measures from the previous year's ASCQR Program measure set for subsequent years' measure sets except when they are removed, suspended, or replaced as indicated (76 FR 74504; 77 FR 68494 through 68495; 78 FR 75122). In the CY 2015 OPPS/ASC proposed rule (79 FR 41045), we proposed a process for removing adopted measures.

In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43863 through 43865), we finalized a process for immediate retirement (a term we later changed to ''removal'') of RHQDAPU Program (now referred to as the Hospital IQR Program) measures based on evidence that the continued use of the measure as specified raised patient safety concerns. We stated that we believe immediate retirement of quality measures should occur when the clinical evidence suggests that continued collection of the data may result in harm to patients. For example, we removed the AMI–6: Beta Blocker at Arrival measure from the Hospital IQR Program because it encouraged care that raised potential safety concerns according to newly published research suggesting that beta-blockers could increase mortality risks for certain patient populations (74 FR 43863). Under such circumstances, we may not be able to wait until the annual rulemaking cycle or until we have had the opportunity to obtain input from the public to retire a measure because of the need to discourage potentially harmful practices, which may result from continued collection of the measure.

In these situations, we would promptly retire the measure and notify hospitals and the public of the retirement of the measure and the reasons for its retirement through the usual communication channels. Further, we would confirm the retirement of the measure that was the subject of immediate retirement in the next program rulemaking. Finally, we stated that, in other circumstances where we do not believe that continued use of a measure raises specific safety concerns, we intend to use the rulemaking process to retire the measure. For the same reasons stated for the Hospital IQR Program, we believe that this process also would be appropriate for the ASCQR Program. Therefore, in the CY 2015 OPPS/ASC proposed rule (79 FR 41045), we proposed to adopt this same removal process for the ASCQR Program. Under this process, we would immediately remove an ASCQR Program measure based on evidence that the continued use of the measure as specified raised patient safety concerns. In these situations, we would promptly remove the measure and notify ASCs and the public of the removal of the measure and the reasons for its removal through the ASCQR Program ListServe and the ASCQR Program QualityNet Web site at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772879650*. Further, we would confirm the removal of the measure that was the subject of immediate removal in the next OPPS/ASC rulemaking.

For situations where we do not believe the continued use of a measure raises specific safety concerns, we proposed to use the regular rulemaking process to remove a measure to allow for public comment. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53505 through 53506), we listed the criteria we have used to determine whether to remove measures from the Hospital IQR Program. These criteria are: (1) Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures); (2) availability of alternative measures with a stronger relationship to patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (5) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. These criteria were suggested through public comment on proposals for the Hospital IQR Program, and we agreed that these criteria should be considered in evaluating the Hospital IQR Program quality measures for removal (75 FR 53506). We believe that these criteria also are applicable in evaluating ASCQR Program quality measures for removal because we have found them useful for evaluating measures in the Hospital IQR Program and our other quality reporting programs, which share similar goals to the ASCQR Program. Accordingly, we proposed to adopt these measure removal criteria for the ASCQR Program.

We invited public comment on these proposals.

Comment: Many commenters supported CMS' proposed measure removal policy and commended CMS for fostering an aligned approach for measures removal criteria across our quality reporting and value-based purchasing programs.

Response: We thank the commenters for their support. We agree that for consistency, an approach to removing measures should be aligned across our quality reporting and value-based purchasing programs to the extent possible.

Comment: One commenter supported CMS' proposal to immediately remove measures that raise public safety concerns. The commenter recommended that CMS notify ASCs by mail and also post notification on the CMS Web site on the ASCQR Web page under the ''Announcements'' heading, in addition to communication through the ASCQR Program ListServe and the QualityNet Web site.

Response: We thank the commenter for supporting our proposal and the suggestions for notifying ASCs. Past experience indicates that the current notification process using the QualityNet Web site and the ASCQR Program ListServe is a fast, efficient, and effective means of publicly communicating information about the ASCQR Program, and using this process would be consistent with how other ASCQR Program information is provided. Therefore, we are not including these additional modes of communication with ASCs for purposes of ASCQR Program notices at this time.

Comment: One commenter believed that proposed measure removal criteria (2) (availability of alternative measures

with a stronger relationship to patient outcomes) and (6) (the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic) are duplicative, and that criterion (2) should read as ''performance or improvement on a measure does not result in better patient outcomes.'' The commenter also suggested that criterion (3) (a measure does not align with current clinical guidelines or practice) and criterion (7) (collection or public reporting of a measure leads to negative unintended consequences other than patient harm) should be applied to all measures, but the remaining criteria should be applied more selectively on a measure-by-measure basis.

Response: We thank the commenter for these recommendations. We disagree with the commenter that criterion (2) and criterion (6) are the same and that criterion (2) should be reworded as suggested. Criterion (2) applies when there is more than one alternative measure with a stronger relationship to patient outcomes that is available, and criterion (6) applies where there is only one measure that is strongly and specifically associated with desired patient outcomes for the particular topic that is available. For criterion (2), there may be different alternative measures available that meet this criterion to different degrees. The suggestion to rephrase criterion (2) to read ''performance or improvement on a measure does not result in better patient outcomes'' would change the meaning of criterion (2).

As we discuss earlier, the measure removal criteria have been developed through public comment on proposals for the Hospital IQR Program. We believe that these criteria also are applicable in evaluating the ASCQR Program quality measures for removal, because we have found them useful for evaluating measures in the Hospital IQR Program as well as other quality reporting programs, which share similar goals to the ASCQR Program. We note that we did not propose any changes to criterion (2) in the CY 2015 OPPS/ASC proposed rule. Further, based on our experience with the Hospital IQR Program, we believe criterion (2) is appropriate and do not believe that additional refinement is necessary. Therefore, we are not revising this criterion. We thank the commenters for their views and will take them into consideration as we continuously assess these criteria.

With respect to the commenter's suggestion that criteria (3) and (7) apply to all measures but the remaining criteria be applied more selectively on a case-by-case basis, we disagree with respect to selective application of the criteria. We intend for all the criteria, including criteria (3) and (7), to apply to all measures to the extent possible. In any given situation, we will focus only on removal criteria that are relevant to a particular set of circumstances. If more than one of the measure removal criteria appears to be relevant, we intend to take a balanced approach in assessing the value of each of the different criteria in a given situation before removing any measure.

After consideration of the public comments we received, we are finalizing our proposal without modification on the measure removal process and criteria. Specifically, we will immediately remove an ASCQR Program measure based on evidence that the continued use of the measure as specified raises patient safety concerns. In these situations, we will promptly remove the measure and notify ASCs and the public of the removal of the measure and the reasons for its removal through the ASCQR Program ListServe and the ASCQR Program QualityNet Web site. Further, we will confirm the removal of the measure that was the subject of immediate removal in the next OPPS/ASC rulemaking.

For situations where we do not believe the continued use of a measure raises specific safety concerns, we will use the regular rulemaking process to remove a measure to allow for public comment. In these situations, we will use the following criteria to determine whether to remove the measures 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.

3. Criteria for Removal of ''Topped-Out'' Measures

In the CY 2015 OPPS/ASC proposed rule (79 FR 41045 through 41046), we proposed to define criteria for when we would consider a measure to be ''topped-out.'' A measure is ''topped-out'' when measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures). We do not believe that measuring ASC performance on ''topped-out'' measures provides meaningful information on the quality of care provided by ASCs. We further believe that quality measures, once ''topped-out,'' represent care standards that have been widely adopted by ASCs. We believe such measures should be considered for removal from the ASCQR Program because their associated reporting burden may outweigh the value of the quality information they provide.

Specifically, we proposed that a measure under the ASCQR Program is ''topped-out'' when it meets both of the following criteria:

- Statistically indistinguishable performance at the 75th and 90th percentiles; and
- A truncated coefficient of variation less than or equal to 0.10.

To identify if a measure has statistically indistinguishable performance at the 75th and 90th percentiles, we would determine whether the difference between the 75th and 90th percentiles for an ASC's measure is within two times the standard error of the full dataset. The coefficient of variation (CV) is a descriptive statistic that expresses the standard deviation as a percentage of the sample mean; this provides a statistic that is independent of the units of observation. Applied to this analysis, a large CV would indicate a broad distribution of individual ASC scores, with large and presumably meaningful differences between ASCs in relative performance. A small CV would indicate that the distribution of individual facility scores is clustered tightly around the mean value, indicating that it is not useful to draw distinctions among individual ASCs on measure performance. The truncated CV excludes observations whose rates are below the 5th percentile and above the 95th percentile; this avoids undue effects of the highest and lowest outlier values, which, if included, can inappropriately widen the dispersion of the distribution. These same criteria for when we would consider a measure to be ''topped-out'' have been adopted in the Hospital VBP Program (79 FR 50055), the Hospital IQR Program (79 FR 50204), and the Hospital OQR Program (section XIII.C.2 of this final rule with comment period).

We invited public comment on this proposal.

Comment: Many commenters supported CMS' proposed ''topped-out'' criteria for measure removal and the alignment of these criteria across the Hospital IQR and Hospital VBP Programs. One commenter suggested that CMS refine the first criterion to ensure that measures exhibit sufficient lack of variability before they are removed. Several commenters suggested that CMS have a mechanism in place to identify a significant decline in adherence rates after a measure has been removed.

Response: We thank the commenters for their support of the proposed topped-out criteria. We expect ASCs to always follow appropriate standards-of-care and clinical guidelines, regardless of whether a quality measure exists. We believe that ASCs are committed to providing quality care to patients, and we do not have any indication that ASCs will stop doing so when measures are removed.

While it is possible that removing a measure could result in reduced performance, we have guarded against this possibility by setting topped-out criteria that evidence very high, unvarying levels of performance. Further, we intend to continue to work with quality measurement stakeholders to ensure that performance does not decline significantly after removing a measure. However, we must balance the costs of continued monitoring of a successful measure with high levels of performance with the adoption of other measures where there are opportunities for improvement in clinical quality.

Regarding the suggestion to further refine the first criterion, which refers to determining that a measure exhibits sufficient lack of variability before removal, we proposed topped-out criteria that evidence very high, unvarying levels of performance and, at this time, do not believe additional refinement that would make the criteria more stringent is necessary. However, we will consider the need for refinement and, if we determine changes may be necessary, we will propose such changes in future rulemaking. In addition, we will not use our topped-out criteria exclusively when evaluating the retention or removal of a measure; a measure that meets our topped-out criteria could be retained for other program reasons as discussed below.

Comment: One commenter cautioned against removing measures solely based on the proposed ''topped out'' criteria, and was concerned that these criteria might lead to the removal of valuable program measures. The commenter cited the example of patient safety measures and surgical site infection rates, which are intended to drive toward and sustain zero harm. The commenter believed that these types of measures could have performance scores that meet the topped out criteria over time. However, the commenter believed they would have enduring value to consumers and providers. Some commenters urged CMS to assess ''topped-out'' measures individually, that is, case-by-case, and in a broader context before removing them from the ASCQR Program.

Response: We agree that some measures that are quantitatively ''topped-out'' may still be appropriate for other reasons. Therefore, as we do for the Hospital IQR Program and the Hospital VBP Program, and consistent with our discussion above in section XIV.B.3. of this final rule with comment period, we will evaluate several factors in considering the removal of measures for the ASCQR Program. We will assess the benefits of retaining a measure on a case-by-case basis before proposing to remove a measure from a quality data reporting program and will not remove a measure solely on the basis of meeting any specific criterion.

Comment: One commenter requested clarification whether ASC–5: Prophylactic IV antibiotic timing is topped-out because this measure is topped-out in the HOPD setting.

Response: We thank the commenter for this request. In response, we have reviewed data collected under the ASCQR Program. Our analysis indicated that performance for the prophylactic IV antibiotic timing measure is relatively high. However, because we continue to have some facilities with completeness of reporting issues and data have been collected for a relatively short time, we do not believe we have sufficient data to support a topped out analysis for the purposes of measure removal for the ASCQR Program at this time. Furthermore, we believe that a prophylactic antibiotic timing measure remains relevant clinically or for quality improvement purposes under the ASCQR Program.

After consideration of the public comments we received, we are finalizing the proposed ''topped-out'' criteria. Specifically, we are finalizing a policy that a measure under the ASCQR Program is ''topped-out'' when it meets both of the following criteria: (1) Statistically indistinguishable performance at the 75th and 90th percentiles; and (2) a truncated coefficient of variation less than or equal to 0.10. To identify if a measure has statistically indistinguishable performance at the 75th and 90th percentiles, we will determine whether the difference between the 75th and 90th percentiles for an ASC's measure is within two times the standard error of the full dataset.

As we do for the Hospital IQR Program and the Hospital VBP Program, and consistent with our discussion above in section XIV.B.3. of this final rule with comment period, we will evaluate several factors in considering the removal of measures for the ASCQR Program. We will assess the benefits of retaining a measure on a case-by-case basis before proposing to remove a measure from the ASCQR Program and will not remove a measure solely on the basis of meeting any specific criterion.

4. 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 beginning with the CY 2014 payment determination. In the CY 2012 OPPS/ASC final rule with comment period, we adopted five claims-based measures for the CY 2014 payment determination and subsequent years, two measures with data submission via an online Web page for the CY 2015 payment determination and subsequent years, and one process of care, healthcare-associated infection measure for CY 2016 payment determination and subsequent years (76 FR 74496 to 74511). In the CY 2014 OPPS/ASC final rule with comment period, we adopted three chart-abstracted measures for the CY 2016 payment determination and subsequent years (78 FR 75124 to 75130).

The quality measures that we previously adopted are listed in the chart below.

ASC PROGRAM MEASURE SET PREVIOUSLY ADOPTED FOR THE CY 2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC #	NQF #	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	Hospital Transfer/Admission.
ASC–5	0264	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.*

* Measure voluntarily collected as set forth in section XIV.E.3.c. of this final rule with comment period.

The comments we received on these previously adopted measures and our responses are set forth below.

Comment: Some commenters asked CMS to remove some previously adopted measures for ASCs, because they believed these measures were either inappropriate or too burdensome for ASCs.

Response: We thank the commenters for their suggestions. At this time, we are not removing any of the measures suggested by commenters. We did not propose to remove any measures from the ASCQR Program in the CY 2015 OPPS/ASC proposed rule. Further, there is no evidence that continued use of the measures as specified raises patient safety concerns that would require immediate removal of the measures based on the process we are finalizing in this final rule with comment period. However, we will take these suggestions into consideration in future years using the measure removal criteria we are adopting in this final rule with comment period.

5. New ASCQR Program Quality Measure for the CY 2018 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124) for a detailed discussion of our approach to ASCQR measure selection. In the CY 2015 OPPS/ASC proposed rule (79 FR 41046 through 41048), we proposed to adopt one new claims-based measure into the ASCQR Program for the CY 2017 payment determination and subsequent years: ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

Colonoscopy is the most commonly performed ambulatory surgery in the United States.[28] The most recent data available indicate that, in 2002 alone, physicians performed an estimated 14 million colonoscopies in the United States.[29] Colonoscopies are associated with a range of well-described and potentially preventable adverse events that can lead to hospital visits, repeat procedures, or surgical intervention for treatment, including colonic perforation, gastrointestinal (GI) bleeding, and cardiopulmonary events such as hypoxia, aspiration pneumonia, and cardiac arrhythmias. While hospital visits are generally unexpected after outpatient colonoscopy, the literature suggests that the majority of these visits occur within the first 7 days.[30] [31] [32] Reported hospital visit rates after outpatient colonoscopy range from 0.8 to 1.0 percent at 7 to 14 days post procedure, and from 2.4 to 3.8 percent at 30 days post procedure.[33] [34] [35] Some adverse events such as bleeding occur after day 7, but based on input from clinical experts, public comment, and empirical analyses, we concluded that unplanned hospital visits within 7 days is the optimal outcome to ensure capture of procedure-related adverse events and to minimize capture of hospital visits unrelated to the procedure. This measure provides the opportunity for ASCs to improve quality of care and to lower the rates of adverse events leading to hospital visits after outpatient colonoscopy; this would encourage ASCs to achieve the outcome rates of the best performers.

We believe it is important to reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care. Therefore, we proposed to include the ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure, which is calculated from paid Medicare FFS claims, in the ASCQR Program for the CY 2017 payment determination and subsequent years. We expect the measure would promote improvement in patient care over time because transparency in publicly reporting

[28] Russo A, Elixhauser A, Steiner C, Wier L. Hospital-Based Ambulatory Surgery, 2007: Statistical Brief #86. *Healthcare Cost and Utilization Project (HCUP) Statistical Briefs.* Rockville (MD) 2006.

[29] Seeff LC, Richards TB, Shapiro JA, et al. How many endoscopies are performed for colorectal cancer screening? Results from CDC's survey of endoscopic capacity. *Gastroenterology.* Dec 2004; 127(6):1670–1677.

[30] Rathgaber SW., Wick TM. Colonoscopy completion and complication rates in a community gastroenterology practice. *Gastrointest Endosc.* 2006; 64:556–62.

[31] Rabeneck L, Saskin R, Paszat LF. Onset and clinical course of bleeding and perforation after outpatient colonoscopy: a population-based study. *Gastrointest Endosc.* 2011; 73:520–3.

[32] Ko CW, Riffle S, Michael L, et al. Serious complications within 30 days of screening and surveillance colonoscopy are uncommon. *Clin Gastroenterol Hepatol.* 2010; 8:166–73.

[33] Ko CW, Riffle S, Shapiro JA, et al. Incidence of minor complications and time lost from normal activities after screening or surveillance colonoscopy. *Gastrointest Endosc.* Apr 2007;65 (4):648–656.

[34] Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med.* Oct 25 2010; 170(19):1752–1757.

[35] Chukmaitov AS, Menachemi N, Brown SL, Saunders C, Tang A, Brooks R. Is there a relationship between physician and facility volumes of ambulatory procedures and patient outcomes? *J Ambul Care Manage.* Oct–Dec 2008; 31(4):354–369.

measure scores would make patient unplanned hospital visits (emergency department visits, observation stays, and inpatient admissions) following colonoscopies more visible to ASCs and patients and incentivize ASCs to incorporate quality improvement activities in order to reduce these visits. ASCs are often unaware of complications following colonoscopy for which patients visit the hospital.[36] This risk-standardized quality measure would address this information gap and promote quality improvement by providing feedback to facilities and physicians, as well as transparency for patients on the rates and variation across facilities in unplanned hospital visits after colonoscopy.

The outcome measured in the ASC–12 measure is all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure. The measure score, also referred to as the facility-level risk-standardized hospital visit rate, is derived from the calculation of the ratio of the numerator to the denominator multiplied by the crude rate. The numerator is the number of predicted (meaning adjusted actual) hospital visits, which is the number of unplanned hospital visits within 7 days of colonoscopy that the facility is predicted to have based on its case-mix. The denominator is the number of expected hospital visits, which is the number of unplanned hospital visits the facility is expected to have based on the nation's performance with the facility's case-mix. The crude rate is the national unadjusted number of patients who had a hospital visit post-colonoscopy among all patients who had a colonoscopy.

Based on discussions with clinical and technical panel experts, the measure excludes colonoscopies for patients undergoing concomitant high-risk upper GI endoscopy because these patients are at a higher risk for hospital visits than patients undergoing a typical colonoscopy, and patients with a history of inflammatory bowel disease (IBD) or diverticulitis in the year preceding the colonoscopy because we likely could not fully characterize and adjust for their pre-procedure risk of needing a post-procedure hospital visit or identify whether these admissions are planned or unplanned. The measure also excludes procedures for patients who lack continuous enrollment in Medicare FFS Parts A and B in the first month after the procedure to ensure all patients included in the analysis have complete data available for outcome assessment. The statistical risk adjustment model includes 15 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within 7 days following a colonoscopy. Additional methodology details and information obtained from public comment for measure development are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital QualityInits/Measure-Methodology.html.*

Section 1890A of the Act requires the Secretary to establish a pre-rulemaking process with respect to the selection of certain categories of quality and efficiency measures. Under section 1890A(a)(2) of the Act, the Secretary must make available to the public by December 1 of each year a list of quality and efficiency measures that the Secretary is considering for the Medicare program. The measure that we proposed was reviewed by the MAP and was included on a publicly available document entitled ''MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs'' (formerly referred to as the ''List of Measures Under Consideration'') on the NQF Web site at: *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx* (''MAP Report''). We note that, at the time the measure was listed on the ''MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs,'' it was named ''High-Acuity Care Visits after Outpatient Colonoscopy Procedure.'' The MAP conditionally supported this measure for the ASCQR Program.

The MAP Report stated that the measure ''[s]hould be submitted for and receive NQF endorsement; Measure is promising but needs further development'' (p. 187). Further, the MAP Report stated that the measure ''would provide valuable outcome information to inform consumer decision and drive quality improvement'' and that the ''NQF endorsement process would resolve questions about the reliability and validity of the measure.'' The MAP also stated that NQF endorsement would resolve questions about ''the feasibility of the algorithm for attributing claims data in light of possible effects of the Medicare three-day payment window'' (p. 187, MAP Report). However, this concern with Medicare Part A hospital payments relates to the Hospital OQR Program and not the ASCQR Program. 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 ASCQR Program.

We believe we have addressed the concerns raised by the MAP to the greatest extent possible. The measure was submitted to NQF for endorsement on February 21, 2014. The measure is well-defined and precisely specified for consistent implementation within and between organizations that will allow for comparability. Reliability testing demonstrated the measure data elements produced were repeatable; that is, the same results were produced a high proportion of the time when assessed in the same population in the same time period. Validity testing demonstrated that the measure data elements produce measure scores that correctly reflect the quality of care provided and that adequately identify differences in quality.

Currently, there are no publicly available quality of care reports for ASCs that conduct outpatient colonoscopies. Therefore, adoption of this measure provides an opportunity to enhance the information available to patients choosing among ASCs that offer this elective procedure. We believe this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to ASCs and patients all unplanned hospital visits following the procedure. In addition, providing outcome rates to ASCs would make visible to clinicians meaningful quality differences and incentivize improvement.

Sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, when read together, require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74465 and 74505), we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus through public comment. We believe this proposed measure meets these statutory

[36] Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med.* Oct 25 2010; 170(19):1752–1757.

requirements. We believe that this measure is appropriate for the measurement of quality of care furnished by ASCs because this procedure is commonly performed in ASCs and, as discussed above, can signify important issues in the care being provided in ASCs. We also believe this measure reflects consensus among affected parties because the MAP, which represents stakeholder groups, reviewed and conditionally supported the measure, and stated that it ''would provide valuable outcome information to inform consumer decision and drive quality improvement.'' Further, the measure was subject to public comment during the MAP and measure development processes, with some public commenters agreeing with the MAP's conclusions on the measure (p. 187, MAP Report, January 2014; *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*).

As discussed above, the statute also requires the Secretary, except as the Secretary may otherwise provide, to include measures set forth by one or more national consensus building entities to the extent feasible and practicable. This measure is not NQF-endorsed; however, as noted above, this measure is currently undergoing the NQF endorsement process. We note that sections 1833(i)(7)(B) and (t)(17) of the Act do not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, under section 1833(i)(7)(B) of the Act, section 1833(t)(17)(C)(i) of the Act, which contains this requirement, applies to the ASCQR Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt nonendorsed measures.

In summary, we proposed to adopt one new measure for the ASCQR Program for the CY 2017 payment determination and subsequent years.

ASC #	NQF #	Proposed ASCQR measure for the CY 2017 payment determination and subsequent years.
ASC–12	Pending	Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

We invited public comment on our proposal to include ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy in the ASCQR Program beginning with the CY 2017 payment determination.

Comment: Several commenters agreed that the ASC–12 measure addresses an important area to monitor for quality improvement, given the number of colonoscopy procedures performed annually in ASCs.

Response: We thank the commenters for their support. We agree that the quality of care associated with colonoscopy procedures is an important clinical care area to assess quality of care for ASCs.

Comment: Many commenters urged CMS not to adopt ASC–12 until it is NQF-endorsed. Several of these commenters also noted that the MAP supported this measure on condition of NQF-endorsement, noting that the NQF process would resolve a number of questions about the reliability, validity and feasibility of this measure. These commenters requested that, in general, CMS only include measures in the ASCQR Program that have been NQF-endorsed in order to avoid later suspending or removing these measures.

Response: We appreciate the commenters' concerns. Under sections 1833(i)(7)(B) and (t)(17)(C)(i) of the Act, except as the Secretary may otherwise provide, the Secretary must develop measures that reflect consensus among affected parties and, to the extent feasible and practicable, must include measures set forth by a national consensus building entity. Whenever possible, we strive to adopt NQF-endorsed measures because these measures will meet these requirements. However, we believe the requirements that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance and use of the measure, and through public comments.

Further, it may not be feasible or practicable to adopt an NQF-endorsed measure, such as when an NQF-endorsed measure does not exist. Section 1833(t)(17)(C)(i) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or by the NQF specifically. Moreover, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the ASCQR Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt measures that do not reflect consensus among affected parties and that are not endorsed by a national consensus building entity. Therefore, not all of the measures adopted for the ASCQR Program are required to be NQF-endorsed.

As discussed below, we believe the measure as developed exhibits sufficient levels of reliability, validity, and feasibility to be adopted for the ASCQR Program. As noted above, we also have submitted this measure to NQF for endorsement.

Comment: Many commenters did not support CMS' proposal to finalize ASC–12 because complications from colonoscopies are very rare and ASCs already take steps to ensure colonoscopies are conducted to eliminate preventable complications. Many commenters noted that the literature on the measure indicates the incidence of complications following colonoscopy is less than 2 percent. These commenters suggested that this low incidence meant that the measure should not be included in the ASCQR Program as it may be topped out or that the quality concern addressed by the measure does not rise to the level of importance needed for a national quality measurement program.

Response: Given the widespread use of colonoscopy for colorectal cancer screening in the outpatient setting, we consider colonoscopy a high volume procedure and measuring the quality of care associated with colonoscopies a high priority for us. We commend ASCs that are already taking steps to ensure colonoscopies are conducted to eliminate preventable complications. While we agree that the incidence of colonoscopy complications is relatively low, serious adverse events, such as perforation of the bowel and bleeding, may occur following colonoscopies. We view this measure as a critical outcome measure where the goal is to drive toward and sustain zero harm.

In addition, some literature suggests that many facilities performing colonoscopies are unaware of patients accessing hospital-based care with adverse events because patients return to different facilities, including hospitals and emergency departments, and would not return to the ASC

facility. For example, one study showed that physicians were unaware of nearly 75 percent of hospital admissions for adverse events following colonoscopy.[37] While most colonoscopies are performed without subsequent complication, we note that, in our analysis of Medicare FFS data, this measure showed that among Medicare patients aged ≥65, 1.6 percent of outpatient colonoscopies resulted in an unplanned hospital visit within 7 days.[38] This estimate is based on a 20 percent sample of nationwide Medicare fee-for-service patients. If we were to use full national data (that is, a 100 percent sample), we estimate 1.7 million colonoscopies would have been performed among Medicare FFS patients and nearly 27,000 unplanned hospitals visits would have occurred within 7-days of the procedure. These findings suggest adverse events are not as rare or inconsequential as many believed and that quality measurement for colonoscopy procedures in the outpatient setting is important.

We agree with the commenters' statement that the low incidence rate may suggest that the measure is topped-out, but in addition to the reasons for adopting this measure discussed above, we believe that a low incidence rate does not conclusively determine whether a measure has reached topped-out status. After the measure has been implemented, over time, we will assess it again for topped-out status using the two topped-out criteria we are finalizing in section XIV.B.3. of this final rule with comment period.

Comment: Many commenters expressed concern that ASC–12 is not sufficiently reliable to be included in the ASCQR Program, specifically, that the measure developer has indicated that the measure is only ''fairly'' reliable, with an interclass correlation coefficient (ICC) of 0.335. These commenters contended that ''fair'' reliability is not sufficient for publicly reported quality metrics because such information could misinform the public, and urged CMS to conduct an analysis on the measure's reliability to understand the amount of data required to achieve ''good'' reliability. Several commenters argued that ''good'' reliability should result in an ICC of at least 0.60. Other commenters believed that reliability will improve with several years' worth of data. Another commenter requested that data from this measure be withheld from public reporting until concerns about its reliability and validity can be thoroughly assessed.

Response: We disagree with commenters and believe that ASC–12 is sufficiently reliable to be included in the ASCQR Program. The ICC value submitted in the initial NQF application (0.335) was calculated using a split sample of data from 2 years. We randomly split the patient cohort at each hospital into two equal halves, calculated the measure using each half, and then calculated the agreement between these two (the 'test' and the 'retest'). After submitting the measure to NQF for endorsement review, we conducted additional calculations of the reliability testing score, this time using the Spearman-Brown prophecy formula. The Spearman-Brown prophecy formula is an accepted statistical method which estimates the ICC if the sample were increased. Therefore, it allows us to estimate what the reliability score would be if all observations were used for public reporting rather than using a split sample. Our Spearman-Brown prophecy formula calculations resulted in a higher ICC of 0.43.

The NQF considers the ICC values ranging from 0.21 to 0.40 as ''fair'' reliability and values ranging from 0.41 to 0.60 as ''moderate'' reliability. Therefore, the ICC values of 0.335 and 0.43 are interpreted as ''fair'' and ''moderate'' reliability, respectively. These ICC values are also in line with other NQF-endorsed outcome measures used in other CMS programs. For example, in the Hospital Readmissions Reduction Program (76 FR 51667), the Inpatient Acute Myocardial Infarction (AMI) 30-day Risk Standardized Readmission measure (NQF #0505) has an ICC of 0.369 and the Pneumonia (PN) 30-day Risk Standardized Readmission measure (NQF #0506) has an ICC of 0.406. Both measures are NQF-endorsed. We consider the reliability of 0.335, as noted in the proposed rule, acceptable for the ASCQR Program.

Regarding the concerns that we should withhold public reporting until the measure's reliability and validity is addressed, as stated above, we believe the reliability of the measure is sufficiently reliable for inclusion in the ASCQR Program and do not agree that the public may be misinformed or that we should withhold public reporting. In addition to our calculations above, reliability testing previously conducted by the measure steward demonstrated the measure data elements produced were repeatable; that is, the same results were produced a high proportion of the time when assessed in the same population in the same time period. Also, validity testing by the measure steward demonstrated that the measure data elements produce measure scores that correctly reflect the quality of care provided and that adequately identify differences in quality.

As the commenters suggested, the measure reliability may be further improved by using several years' worth of data; however, we must balance the reliability of the measure with the timeliness of the measure. As discussed, at this time, we believe that 1 year of data appropriately balances these competing interests for payment determination purposes, but we will continue to assess this belief during the dry run we discuss below. Also, we will consider conducting additional reliability assessments of the measure using an extended data period.

Moreover, we believe it is important to include this measure in the program because colonoscopy is a high volume, common procedure performed at outpatient facilities and is frequently performed on relatively healthy patients to screen for colorectal cancer. Given the widespread use of colonoscopy, understanding and minimizing procedure-related adverse events is a high priority. These adverse events, such as abdominal pain, bleeding, and intestinal perforation, can result in unanticipated hospital visits post procedure. Physicians performing colonoscopies are often unaware that patients seek acute care at hospitals following the procedure and the associated adverse events are potentially preventable. We strongly believe that the measure would promote improvement in patient care over time because transparency in publicly reporting measure scores would make patient unplanned hospital visits (emergency department visits, observation stays, and inpatient admissions) following colonoscopies more visible to ASCs and patients and incentivize ASCs to incorporate quality improvement activities in order to reduce these visits.

Finally, we believe this measure should be included in the program because currently this risk-standardized quality measure is the only measure available that would address this information gap and promote quality improvement by providing feedback to facilities and physicians, as well as transparency for patients on the rates

[37] Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med.* Oct 25 2010;170(19):1752–1757.

[38] 2010 Medicare 20 percent fee-for-service sample. Based on an analysis of 20 percent sample of Medicare FFS data from 2010 during measure development. The 20 percent sample included 332,391 outpatient colonoscopies meeting the measure inclusion and exclusion criteria, and 1.6 percent of these colonoscopies were followed by an unplanned hospital visit. This equates to 5,331 unplanned hospital visits in the 20 percent sample.

and variation across facilities in unplanned hospital visits after colonoscopy. There are no publicly available quality of care reports for ASCs that conduct outpatient colonoscopies. Therefore, adoption of this measure provides an opportunity to enhance the information available to patients choosing among ASCs that offer this elective procedure. We believe this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to ASCs and patients all unplanned hospital visits following the procedure. In addition, providing outcome rates to ASCs would make visible to clinicians meaningful quality differences and incentivize improvement.

In response to comments, however, to allow sufficient time to conduct further analysis of this measure, we are finalizing the adoption of this measure beginning with the CY 2018 payment determination, rather than beginning with the CY 2017 payment determination as proposed. We plan to perform a dry run of the measure in 2015. From our perspective, a dry run is a preliminary analysis of data in which ASCs may review their measure results, and ask questions about and become familiar with the measure methodology. Dry runs will include three to four years of paid Medicare FFS claims. We will use the most recent complete claims samples (usually 6 to 9 months prior to the start date) for dry runs. For example, if the dry run begins in March 2015, the most recent data available may be July 2011 to June 2014 (assuming 3 years of data). Because we use paid Medicare FFS claims, ASCs will not need to submit any data for the dry run. The general information on the dry run as well as the confidential dry run reports will be available for ASCs to review on their accounts at *https://www.qualitynet.org*. The dry run will generate confidential reports at the patient level, indicating whether the patient had a hospital visit, the type of visit (admission, emergency department visit, or observational stay), the admitting facility, and the principal discharge diagnosis. Further, the dry run will enable ASCs to see the measure score reports and have the opportunity to receive individual patient data and information contained within individual patient records. ASCs can use the information to identify performance gaps and develop quality improvement strategies. Dry run results are not linked to public reporting or payment determinations. We expect the dry run to take approximately 1 month to conduct once data are obtained, after which facilities will be provided the confidential report and the opportunity to review their performance and provide feedback to us.

In addition, we will continue to generate these reports for ASCs after we implement the measure beginning with the CY 2018 payment determination. The measure will have no payment impact until the CY 2018 payment determination and subsequent years. Public display of measure data will occur on or after December 1, 2017, but there will be no public display of the dry run data.

With national implementation of a dry run of this measure, we also will review the appropriate cutoff volume for facilities, if necessary, in reporting the measure score. We require a minimum volume (cutoff volume) of colonoscopies per facility to be able to calculate a reliable measure score. We have yet to determine the minimum volume per facility (that is, the cutoff colonoscopy volume). Because we used a Medicare 20-percent sample to develop the measure, we could not estimate this cutoff during measure development. However, testing during the measure dry-run with 100 percent of the sample per facility will help us to determine the appropriate cutoff volume of colonoscopies per facility. ASCs will be notified via the QualityNet Web site of the cutoff volume of colonoscopies per facility, if any.

While some ASCs perform too few colonoscopies for us to calculate a measure score and we would not publicly report their data, these facilities would remain in the measure cohort. Typically, for public reporting of hospital measures on the CMS Web site *Hospital Compare,* the measure score is reported as ''Number of cases too small'' for hospitals with fewer cases than the cutoff. We will use the same protocol when the measure is publicly reported for the ASCQR Program, and will report a measure score as ''Number of cases too small'' for ASCs with fewer cases than the cutoff on the QualityNet Web site.

Comment: Several commenters pointed out that, from the perspective of using claims as a data source for this measure, the codes for ASCs are services rendered-driven, while the codes for HOPDs are diagnosis-driven. Commenters were concerned that the coded information and the associated risk-adjustment for this measure may not be able to capture the sensitivity and specificity of the clinical care following an outpatient colonoscopy. Given the difference in coding practices and claims architecture between HOPDs and ASCs, commenters recommended further testing for a fair performance comparison between HOPDs and ASCs. One commenter inquired if CMS plans to field test this measure prior to implementation. Commenters contended that the measure must be systematically assessed to assure the measure results are attributable to differences in quality alone. The commenters suggested that the measure score should be directly validated against outpatient medical records and measure results across settings must be assessed to ensure that any comparisons are valid.

Response: We thank the commenters for expressing their concerns regarding possible effects of coding practices and claims architecture on the data available through administrative claims in capturing the sensitivity and specificity of the clinical care following an outpatient colonoscopy. The measure is designed, however, to mitigate any differences in coding practices across HOPDs and ASCs. For example, to capture comorbidities for risk adjustment, the measure uses claims across care settings, including physician outpatient claims, so differences in claims submitted during the procedure are not likely to affect the comorbidities assigned to the patient. In addition, the outcome counts hospital visits regardless of whether they are billed as admissions, emergency room visits, or observations stays; therefore, if there are differences between colonoscopies done at ASCs and HOPDs in the type of hospital visit a patient with complications incurs (for example, whether observation stays or ED visits are used), the measure will be insensitive to these differences.

We recognize that the claims architecture differs for HOPDs and ASCs because the two facility types utilize different bill forms and have different payment systems. However, we do not agree that our measure specifications do not account for differences in claims architecture and necessary billing codes in discerning hospital events following colonoscopy. The measure includes colonoscopies from all outpatient settings to ensure that the expected hospital visit rate for any facility is estimated using the full national experience of colonoscopy patients. Specifically, we include all outpatient colonoscopies to make sure that: (1) The effects that risk factors exert on the outcome are estimated based on colonoscopies performed among all outpatient settings; and (2) the national average rate of hospital visits following colonoscopy is calculated based on all outpatient colonoscopies. Our approach

includes all outpatient claims, including HOPD, ASC, and physician claims. To identify all outpatient colonoscopy claims, including claims affected by the Medicare 3-day payment window policy, the measure specifications link claims across multiple care settings (outpatient and inpatient). Furthermore, the measure specifications link claims across multiple care settings to derive comorbidity data to ensure the patient comorbidities are captured to the fullest extent possible for risk-adjustment and to identify patient outcomes.

Linking patient claims across multiple settings largely mitigates the impact of potential difference in coding practice among settings and allows comparisons of colonoscopy quality across settings. For example, potential variation in the coding of comorbidities in the index colonoscopy claim may occur based on the setting. However, we derive comorbidities for risk adjustment from all inpatient and outpatient claims in the preceding 12 months. By using all claims in the preceding year, we capture patient comorbidities to the fullest extent possible and mitigate the impact of potential coding differences between settings that would occur if we used the index colonoscopy claim alone.

Further, similar approaches to deriving comorbidities from claims data are used for other risk-adjusted outcome measures. The measure developer has validated the accuracy of this approach on multiple occasions for prior measures developed for the inpatient setting. For example, in the Hospital Readmissions Reduction Program (76 FR 51667), the Inpatient Acute Myocardial Infarction (AMI) 30-day Risk Standardized Readmission measure (NQF #0505) has an ICC of 0.369, and the Pneumonia (PN) 30-day Risk Standardized Readmission measure (NQF #0506) has an ICC of 0.406. Both measures are NQF-endorsed.

Regarding the suggestion that the measure score should be directly validated against outpatient medical records, at this time, we believe that it would be overly burdensome to validate the reported data, because of the limited experience that ASCs have with reporting quality data to CMS coupled with the low incidence of cases for this measure. In addition, as stated in section XIV.D.6. of this final rule with comment period, 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 Medicare Administrative Contractors).

We appreciate commenters' concerns regarding factors that may impact HOPDs and ASCs. In response to comments, to allow sufficient time to conduct further analysis of this measure, we are finalizing the adoption of this measure beginning with the CY 2018 payment determination, rather than beginning with the CY 2017 payment determination as proposed.

In addition, we plan to perform a dry run (a preliminary analysis) of the measure in 2015. We refer readers to our discussion of the dry run above, in response to a previous comment.

Comment: Several commenters disagreed with the statement in the proposed rule (79 FR 41047) that the ASC–12 measure is ''well-defined and precisely specified for consistent implementation within and between organizations that will allow for comparability.'' These commenters raised the issue that the Medicare payment window policy that applies to hospitals will result in under-detection of hospital events for colonoscopies performed by HOPDs; the 3-day (or 1-day) payment window applies to outpatient services furnished by hospitals and hospitals that are wholly owned or wholly operated Part B entities. Hospitals are required to bundle the technical component of all outpatient diagnostic services and related nondiagnostic services (for example, therapeutic) with the claim for an inpatient stay when services are furnished to a Medicare beneficiary in the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1-day) preceding an inpatient admission in compliance with section 1886 of the Act. Commenters expressed their concern that as a result of this payment policy, HOPDs may have systematic undercounting of hospital visits while ASCs get a full count of all hospital visits within 7 days subsequent to outpatient colonoscopy. Commenters did not believe the methodological solution proposed by the measure developer, using physician claims with an HOPD Place of Service (POS) code indicating the colonoscopy was performed at an HOPD, is adequate due to the high error rates in POS coding on physician claims. Commenters were concerned that these challenges would make comparison of HOPD and ASC data impossible, and significantly reduce the validity of the measure in the HOPD setting.

Response: We disagree with the commenters, and we continue to believe this measure is ''well-defined and precisely specified for consistent implementation within and between organizations that will allow for comparability,'' as we stated in the CY 2015 OPPS/ASC proposed rule (79 FR 41047).

We agree that the ability to detect meaningful variation is an important indication of the value of a measure. As the commenter has correctly noted, we have shown facility variation in unplanned hospital visits following colonoscopy in both nationwide Medicare data from HOPDs and also in the 2010 Healthcare Cost and Utilization Project (HCUP) data. We have also shown facility variation in unplanned hospital visits among ASCs alone using HCUP data from California.[39] The observed average hospital visit rate and the variation in unplanned hospital visit rates among ASCs, which are unaffected by the 3-day payment window policy, were very similar to HOPDs suggesting that the measure performs equally well in both settings. Accordingly, we are confident that the variation shown is a reflection of facility variation in quality and not as a result of any issues to do with the 3-day payment window policy.

Based on our internal testing with claims data, we believe our current algorithm is appropriate and accurate. However, since we always strive for improvement, we will evaluate the colonoscopy measure dry run data and work with HOPDs and ASCs to further review and refine the algorithm if necessary.

Regarding POS billing, the OIG has found billing errors incorrectly assigning the service site for both HOPDs and ASC-related claims on physician claims where there were matching HOPD or ASC claims and that the percentage of incorrectly billed claims was significantly higher for ASC-related claims.[40] Many physicians' services can be furnished either in a facility setting such as an HOPD or ASC, or in a non-facility setting such as a physician's office, urgent care center or independent clinic. For these services, Medicare has two different payment rates under the physician fee schedule (PFS). The PFS facility rate is generally lower to reflect the fact that certain resources are supplied by the facility, and Medicare makes a separate payment to the facility under another payment system. By matching both facility and physician colonoscopy claims for any given patient, the current measure methodology ensures that colonoscopy claims are identified to the fullest extent

[39] Center for Medicare and Medicaid Services, ''Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy,'' National Quality Form Measure Submission Form, 20.

[40] OIG, Physician services processed by Medicare Part B Contractors during Calendar Year 2009, September 2011, A–01–10–00516.

possible and attribute the colonoscopy to the appropriate provider when billing is affected by the 3-day window payment policy.

We clarify that HOPD claims for colonoscopy procedures for calculation of the measure are identified using both physician and facility claims. We did not intend to imply that HOPD colonoscopy claims are identified solely from physician claims. For both ASCs and HOPDs, the measure first identifies colonoscopy claims using both the physician claim and the corresponding facility claim to ensure the site of the colonoscopy service is attributed to the appropriate provider. As a second step, the measure matches: (1) Physician claims that contain HOPD as the POS that do not have a matching facility claim with (2) inpatient claims to identify potential HOPD colonoscopies resulting in an inpatient admission. This second additional step identifies HOPD colonoscopy claims affected by the 3-day window payment policy.

Therefore, we do not agree that ASCs will be adversely affected by use of POS billing to locate colonoscopies performed by physicians due to high levels of coding errors in POS coding on Part B for physician services because our measure calculation methodology addresses this concern.

We also have taken steps to educate physicians about the appropriate POS coding and actively audit physicians to improve the accuracy of POS coding *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7502.pdf*. In addition, from 2012 onwards, Medicare billing introduced the ''PD'' modifier to indicate physician claims affected by the 3-day window payment policy.

Comment: In reference to the statement in the CY 2015 OPPS/ASC proposed rule (79 FR 41047) that ''there are no publicly available quality of care reports for ASCs that conduct outpatient colonoscopies,'' one commenter stated that, on the *Physician Compare* Web site, CMS includes data on colonoscopy measures that provide a detailed look at the quality of colonoscopy services provided. This commenter suggested that CMS further enhance publicly available data by including measures captured by Qualified Clinical Data Registries to increase the robustness of publicly available data on colonoscopy provided across all sites of service.

Response: We thank the commenter for providing this input, but note that the cited information is available at the physician level. We believe that quality of care measure information also should be reported at the facility level, and that facilities have a role in monitoring the surgical procedures performed at their facility and subsequent adverse outcomes. Patients and facilities should be able to review reported quality of care measure information at the ASC-facility level. We thank the commenter for the suggestion to include measures captured by Qualified Clinical Data Registries to further enhance publicly available data such as the colonoscopy data and we may take this into consideration in future rule making.

Comment: While some commenters believed that a long collection period, such as three years, is needed in order to generate measure scores that are moderately reliable, they also were concerned that the publicly reported measure score would not be a reflection of current, or even recent, performance. Commenters were concerned that consumers could be misled by the outdated data.

Response: As discussed previously, we agree with the commenter that a longer data collection period may increase measure reliability. However, we must balance the reliability of the measure with the timeliness of the measure and, as discussed later, at this time, we believe that 1 year of data appropriately balances these competing interests. We will continue to assess this belief during the dry run.

Comment: Several commenters expressed concern that the measure that was put forth to NQF review retained elements of the inpatient measure. Commenters stated that including these elements was inappropriate, and interpreted this action to mean that the measure has not been thoroughly reviewed and fully adapted for outpatient use. These commenters gave examples of the alleged inappropriate inpatient elements: (1) Certain condition categories (CCs) are not included in risk adjustment if they are only recorded at the time of the colonoscopy, and yet they are considered to be possible adverse outcomes; and (2) although end stage renal disease (ESRD) would not be a complication of colonoscopy diagnosed and recorded at the time of the procedure, it was included on the list of CCs. Commenters urged CMS to ensure that revised specifications are developed and then independently reviewed to ensure outpatient adaptation is complete prior to measure implementation.

Response: We appreciate the commenters' concerns. In keeping with good practice, we have continued to review and seek comment on the measure specifications subsequent to measure development and implementation to ensure the measure remains up-to-date in view of any potential new information. As the commenters noted, the measure technical specifications included a list of CCs that the measure does not consider for risk adjustment if the CC(s) occurred at the time of colonoscopy. In view of the comments, we have revised the list of CCs and updated the measure specifications to ensure only conditions relevant to colonoscopy are included. Of note, the inclusion of ESRD on the list was an error; we have revised the list and will use the revised list in implementing the measure. We corrected the list in subsequent measure descriptions during the NQF public comment period.

Comment: Many commenters expressed concern that the ASC–12 measure includes hospital visits unrelated to colonoscopy. Some commenters requested explanation for why the measure uses an all-cause categorization rather than only admissions related to colonoscopies.

Response: We clarify that this measure is purposely designed to use a broad outcome of hospital visits following surgery rather than a narrow set of easily identifiable complications. From a patient and health system perspective, the goal of this measure is to encourage and inform ASC efforts to minimize all potential acute complications, not just those narrowly related to procedural technique. This is important as the literature suggests,[41, 42, 43, 44] that hospital visits following colonoscopy occur due to a range of adverse events relating to the bowel preparation, anesthesia, the colonoscopy procedure itself, and follow-up care. These include a range of symptoms and signs such as abdominal pain, bloating, dizziness and collapse, electrolyte disturbances, and cardiorespiratory symptoms (from sedation use), in addition to complications that are directly related to procedural technique such as bleeding and bowel perforation. The broad outcome of unplanned hospital visits captures all of these potential acute complications of colonoscopy.

[41] Ko CW, Dominitz JA. Complications of colonoscopy: magnitude and management. Gastrointest Endosc Clin N Am 2010;20:659–71.

[42] ASGE Standards of Practice Committee, Fisher DA, Maple JT, et al. Complications of colonoscopy. Gastrointest Endosc 2011;74:745–52.

[43] Baudet JS, Diaz-Bethencourt D, Aviles J, et al. Minor adverse events of colonoscopy on ambulatory patients: the impact of moderate sedation. Eur J Gastroenterol Hepatol 2009;21:656–61.

[44] Ko CW, Riffle S, Shapiro JA, et al. Incidence of minor complications and time lost from normal activities after screening or surveillance colonoscopy. 2007;65:648–56.

Our goal for the measure is to encourage ASCs to be mindful of reducing post-colonoscopy admissions caused by the prior colonoscopy procedure performed at their facility. For example, patients may be at higher risk of falls post-colonoscopy secondary to dehydration following the bowel preparation for the procedure and there may be opportunities for ASCs to minimize this risk. We removed planned admissions from the measure outcome adapting CMS' Planned Readmission Algorithm version 3.0.[45 46] This algorithm removes nonacute admissions for scheduled procedures (for example, total hip replacement) and other types of care always considered planned (for example, rehabilitation or maintenance chemotherapy) from the outcome. That is, we removed planned admissions from the outcome because planned admissions do not reflect differences in colonoscopy quality of care.

Comment: One commenter requested that CMS clarify how the numerator and denominator for ASC–12 are calculated.

Response: The measure score is the ratio of predicted hospital visits (numerator) over the expected hospital visits (denominator) multiplied by the crude national rate. The measure score numerator is the predicted rate, which is the number of unplanned hospital visits the facility is predicted to have within 7 days of colonoscopy, and it accounts for the observed unplanned hospital visit rate, the number of colonoscopies performed at the facility, and the facility's case mix. This is sometimes referred to as the ''adjusted actual rate.''

The measure score denominator is the expected rate, which is the number of unplanned hospital visits the facility is expected to have, based on the nation's performance with that facility's case-mix. It is the sum of all patients' expected probabilities of a hospital visit, given their risk factors and the risk of readmission at an average hospital. The contribution of each risk factor (for example, age) to the patient's risk of a hospital admission is based on all of the patients in the measure cohort. The crude national rate is the average rate of hospital visits following colonoscopy observed in the entire measure cohort. We also refer readers to the measure discussion above and measure specifications (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=75057*) for a more detailed discussion of how the numerator and denominator are calculated.

Comment: Many commenters were concerned that facilities would lack actionable information generated from ASC–12. Several of these commenters questioned whether this measure will benefit facilities and patients because each facility will only receive a report with an aggregate number of claims that will be based on historical data, which will make it difficult for the facility to set a course for improvement if needed. Commenters requested that CMS clarify its plan to report detailed patient-level data confidentially to ASCs that indicates whether the patient had a hospital visit, the type of visit (admission, emergency department visit, or observational stay), the admitting facility, and the principal discharge diagnosis to assist facilities with quality improvement, to enable facilities to understand their performance and take steps where remediation is needed. Several commenters also noted that ASCs do not provide post-operative follow-up care after patient discharges and do not have direct access to the records of other health care facilities. Consequently, this constraint would limit their ability to identify improvements based on the data provided by this measure.

Response: The primary purpose of this measure is to illuminate the quality differences in colonoscopies that are presently not visible to patients and may not be visible to some facilities. In measure development, we found the facility variations in the measure score suggest some facilities provide worse than expected care. We believe the detailed patient-level data that we will provide confidentially to ASCs will help them identify areas for improvement efforts. The data would indicate whether the patient had a hospital visit, the type of visit (admission, emergency department visit, or observational stay), the admitting facility, and the principal discharge diagnosis. The dry run will enable ASCs to see the measure score reports and have the opportunity to receive individual patient data and information contained within individual patient records. We will continue to generate these reports for ASCs after we implement the measure beginning with the CY 2018 payment determination. ASCs can use the information to identify performance gaps and develop quality improvement strategies.

We understand the challenges involved in following up with ASC patients. The colonoscopy measure addresses these challenges by providing feedback to facilities and clinicians about the outcomes experienced by their patients following colonoscopy. Many clinical experts noted that facilities were often unaware of patients' return visits to hospitals. They noted that many patients would often return to a different facility or an emergency department. One study noted that physicians were unaware of 75 percent of return hospital visits following colonoscopy at a major tertiary center.[47]

Comment: Several commenters expressed concern that ASC–12 does not include risk-adjustment to account for patient differences, stating that CMS does not report the variation between ASCs once this risk adjustment has been applied and that there may be no statistically significant difference between an ASC's risk-adjusted visit rate and the national average making it impossible to identify low performers and high performers. One commenter specifically recommended that patients with conditions such as inflammatory bowel disease and diverticulitis should be included with appropriate risk adjustment. Commenters recommended CMS consider the drawbacks of the current methodology, conduct analysis to test the variation of the measure between ASCs, and reconsider this measure for inclusion in future proposals.

Response: We thank the commenters for all the suggestions to improve the measure. In the measure application for NQF endorsement, we note that the measure, following risk-adjustment, is able to detect statistically significant variation between outpatient facilities by demonstrating measure score variation using the 2010 HCUP data from four States (California, New York, Nebraska, and Florida). Using a very conservative sampling technique (sampling with replacement),[48] we constructed 95 percent interval estimates around the facility measure score (similar to confidence intervals) and used the estimates to place facilities into three performance categories: Worse than expected; no different than expected; and better than expected. Based on this analysis, we identified 5 outlier facilities among a total of 992

[45] Horwitz L, Grady J, Dorsey K, Zhang W, Keenan M, Keshawarz A, Cohen D, Ngo C, Okai M, Nwosu C, Lin Z, Bhat K, Krumholz H, Bernheim S,. 2014 Measures Updates and Specifications Report: Hospital-Wide All-Cause Unplanned Readmission—Version 3.0. 2014: Centers for Medicare & Medicaid Services, 2014.

[46] Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[47] Leffler DA, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. Arch Intern Med 2010;170:1752–7.

[48] Efron, B. (1979). Bootstrap methods: Another look at jackknife. Ann. Stat. 7, 1–26.

ASCs and HOPDs. This analysis included only about one-tenth of all outpatient facilities in the United States. Typically, we see greater variation between facilities when 100 percent of nationwide facilities are included for actual measure implementation and reporting.

As to the commenter's recommendation to risk-adjust patients with certain conditions, we excluded patients with inflammatory bowel disease (IBD) and diverticulitis because it is difficult to assess from claims data whether these patients have an active or inactive disease which may alter their risk of the outcome. We determined that we could not adequately risk-adjust for the risk of the outcome for these patients. Second, our analysis suggested that nearly half of the patients with IBD and diverticulitis have post-colonoscopy hospital visits with a primary diagnosis of IBD and diverticulitis respectively. We could not tell from the claims data whether these visits were planned or unplanned. We did test for variation among ASCs and HOPDs independently using HCUP data from California (see Measure Technical Report). As we previously discussed, the measure was able to adequately detect variation in the measure score among ASCs.

As for the inquiry about further testing the measure, we have more time to further test the measure because, in response to comments, we are finalizing the adoption of this measure beginning with the CY 2018 payment determination, rather than beginning with the CY 2017 payment determination as proposed. We plan to perform a dry run (a preliminary analysis) of the measure in 2015. We refer readers to our discussion of the dry run above, in response to a previous comment.

Comment: One commenter expressed concern that ASCs would have difficulty gathering and reporting the information for the proposed ASC–12 measure.

Response: We thank the commenter for providing this input and note that this measure will be calculated completely from data obtained from paid Medicare FFS claims submitted by ASCs, hospitals, and physicians. For this reason, it will not require any additional information-gathering on the part of ASCs.

We continue to believe that quality of care measurement in the clinical area of outpatient colonoscopy is an important gap area with ample room for improvement and that this measure has sufficient reliability and validity for use in the ASCQR Program. Therefore, after consideration of the public comments we received, we are finalizing our proposal to adopt the ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure for the ASCQR Program. However, to allow ASCs sufficient time to review their measure data from the dry run and utilize the confidential facility reports with patient-level associated hospital event information, we are finalizing the adoption of this measure for the CY 2018 payment determination and subsequent years, instead of the CY 2017 payment determination and subsequent years as proposed.

We plan to perform a dry run (a preliminary analysis) of the measure in 2015. Also, with national implementation of a dry run of this measure, we also will review the appropriate cutoff volume for facilities, if necessary, in reporting the measure score. We refer readers to our discussion of the dry run and the cutoff volume above, in our response to a previous comment.

The finalized measure set for the ASCQR Program CY 2017 payment determination and subsequent years, is listed below.

FINALIZED ASC PROGRAM MEASURE SET 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	Hospital Transfer/Admission.
ASC–5	0264	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.*

* Measure voluntarily collected starting as set forth in section XIV.E.3.c. of this final rule with comment period.

The finalized measure set for the ASCQR Program CY 2018 payment determination and subsequent years, which includes previously finalized measures and the newly-adopted measure, ASC–12, is listed below.

FINALIZED ASC PROGRAM MEASURE SET 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	Hospital Transfer/Admission.
ASC–5	0264	Prophylactic Intravenous (IV) Antibiotic Timing.
ASC–6	N/A	Safe Surgery Checklist Use.

FINALIZED ASC PROGRAM MEASURE SET FOR THE CY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

ASC No.	NQF No.	Measure name
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	Pending	Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.**

* Measure voluntarily collected starting as set forth in section XIV.E.3.c. of this final rule with comment period.
** New measure finalized for CY 2018 payment determination and subsequent years.

6. ASCQR Program Measures for Future Consideration

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494), where we finalized our approach to future measure selection for the ASCQR Program. We seek to develop a comprehensive set of quality measures to be available for widespread use for informed ''patient decision-making 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 proposed rule (79 FR 41048 through 41049), 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.

Comment: Commenters supported CMS' alignment efforts. One commenter supported the direction of the ASCQR Program to align future measures with the NQS priorities, noting that doing so will make the ASCQR Program more consistent with the Hospital IQR Program. Another commenter agreed with the goal of aligning measures in the ASCQR Program with the Hospital OQR Program and the Hospital IQR Program, and urged that the alignment should eliminate confusion and avoid disadvantaging ASCs.

Response: We thank the commenters for supporting our alignment efforts. To the extent practicable, we strive to align measures with national priorities, including the NQS priorities as well as across our quality reporting and value-based purchasing programs.

Comment: Several commenters requested that CMS collaborate with stakeholder communities to develop and implement appropriate ophthalmic measures for the ASC setting, potentially including measures of incidence of toxic anterior segment syndrome in cataract surgery patients, incorrect intraocular lens implantation in cataract surgery patients, and unplanned anterior vitrectomy in cataract surgery patients. Another commenter suggested that CMS consider several new measures in the future, including adverse outcomes from high-volume procedures such as cataract removals, other eye procedures, endoscopies, musculoskeletal procedures, and colonoscopies. This commenter also encouraged CMS to develop composite measures of common surgical infections and to involve consumers and purchasers in refinement of the CAHPS survey for the outpatient setting. In addition, this commenter urged CMS to continue to analyze and address the role of the survey and discuss the comparative roles of PQRS CAHPS, ACO CAHPS, S–CAHPS, or the HOSD/ASC CAHPS surveys.

Response: We thank the commenters for these recommendations and will consider these types of measures in future years. We have included an unplanned anterior vitrectomy in cataract surgery patients and patient experience of care survey measures in our Measures under Consideration (MUC) list for the MAP for the ASC setting. We agree that the adoption and implementation of appropriate cataract surgery measures are important for the ASCQR Program, given the number of such procedures performed on Medicare beneficiaries in this setting.

We use patient experience of care surveys in a variety of health care settings. We agree that, to the extent feasible, survey instruments should be aligned and coordinated across settings. The developmental process of CAHPS and patient experience of care surveys involves several opportunities for input from patients, patient advocates, and stakeholders from the HOPD and ASC industry, including professional associations, clinicians, accreditation organizations, and the government.

Comment: One commenter requested that CMS provide additional guidance with respect to the process for suggesting and submitting future ASCQR Program measures. This commenter further requested that CMS distinguish, when establishing reporting requirements, between ASCs that are equipped for the performance of sterile surgical operations and ambulatory endoscopy centers that are equipped to perform nonsurgical endoscopy procedures.

Response: We generally request comments on future ASCQR Program measure topics through the rulemaking process and did so in the CY 2014 OPPS/ASC proposed rule (78 FR 43664). We also accepted measures for consideration from associations through ONC's measure project tracking system (*http://oncprojectracking.org/*); associations were invited via the CMS Listserv to attend a training session for how to submit measures into this system. Regarding distinguishing ASCs by the services provided, we are aware that ASCs vary in the types of services they provide. This variety presents challenges in devising a measure set that can glean applicable quality of care information across ASCs. With respect to current claims-based measures that include surgical procedures, at this time, we are not able to identify facilities that would never perform surgical procedures from the

information on claims. Therefore, we are not able to distinguish ineligibility for a measure from non-reporting.

Comment: One commenter recommended that CMS consider the following measure topics for the ASCQR Program: (1) Equipment Reprocessing (for patient safety, high-level disinfection and sterilization, with a particular emphasis on endoscope reprocessing); and (2) Sedation Safety—A possible anesthesia-related measure could include the use of reversal agents to patients given moderate sedation agents (medications used to rescue patients from deeper levels of sedation than intended).

Response: We thank the commenter for these recommendations and will consider these measure topics for the ASCQR Program in future years.

Comment: One commenter noted that the program currently includes a measure on hospital transfer or admission after a procedure, which tracks whether patients are transferred or admitted directly to a hospital (including a hospital emergency room) upon discharge from an ASC. This commenter believed that this measure could be expanded to include patients who return home after the ASC procedure, but are admitted to a hospital shortly thereafter because of a problem related to the procedure because doing so would enable us to more comprehensively track patients who experience serious complications or medical errors related to an ASC procedure.

Response: We thank the commenter for providing this information and note that the ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure includes all unplanned hospital visits (emergency department visits, observation stays and inpatient admissions) within 7 days following the procedure. We will continue to consider additional measures that track hospital visits following ASC procedures as appropriate in the future.

Comment: One commenter recommended that CMS develop a measure to track surgical site infection rates for ambulatory surgeries in ASCs. The commenter observed that CMS stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74503 through 74504) that we would consider proposing an SSI measure and requested an update.

Response: We agree that it is important to encourage the reduction of SSIs. In the CY 2012 OPPS/ASC rulemaking, we proposed but did not finalize the Surgical Site Infection Rate measure (NQF #0299), but stated that we will consider proposing the measure once a suitable set of procedures and a protocol for ASCs and HOPDs has been developed (76 FR 74504). We are not aware of any updates to this measure, but will consider these types of measures in future years.

Comment: One commenter recommended that the ASCQR Program should move to a value-based purchasing model no later than 2016, rewarding high-performing ASCs and penalizing low-performing ASCs.

Response: We thank the commenter for this recommendation. As we noted in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75122), we currently do not have express statutory authority to implement a value-based purchasing program for ASCs.

Comment: One commenter requested that CMS publish each year, as part of the proposed rule, a 2-year or 3-year timeline of anticipated changes to the ASCQR Program to facilitate ASC facility planning.

Response: We thank the commenter for the comment and note that we seek to provide information to ASC facilities in advance whenever possible to support future planning. For example, in the CY 2012 OPPS/ASC rulemaking, we finalized measures sets for the CY 2014, CY 2015, and CY 2016 payment determinations (76 FR 74496 to 74511). Similarly, in the CY 2013 OPPS/ASC final rule with comment period, we finalized a data collection and processing period policy for claims-based measures using QDCs for the CY 2015 payment determination and subsequent years (77 FR 68497 through 68498), and in the CY 2014 OPPS/ASC final rule with comment period, we finalized our policy regarding participation status for the CY 2016 payment determination and subsequent years (78 FR 75134 through 75135). In this year's rulemaking, we also are finalizing policies that span more than one year, such as including the ASC–12 measure in the ASCQR Program measure set for the CY 2018 payment determination and subsequent years, the process for removing measures, and topped-out criteria. While we cannot commit to providing a 2-year or 3-year timeline at this point due to the rapidly evolving quality measurement and program environment, we will continue to provide information to ASCs through the QualityNet Web site, the ASCQR Program ListServe, and the rulemaking process as appropriate.

Comment: Several commenters stated that they would welcome opportunities to work with CMS to explore alternative reporting options for measures that cut across CMS quality reporting programs, particularly measures that are included in both the ASCQR Program and PQRS.

Response: We thank the commenters for their offer to collaborate with CMS on alternative reporting options. We will continue to look for opportunities to work with ASC community stakeholders to continuously improve the ASCQR Program.

Comment: Several commenters expressed concern about the MAP, specifically the public comment process and the practice of submitting measure concepts for consideration. These commenters believed that the MAP does not adequately consider public comments, and stated that the MAP session agendas scheduled voting activities prior to public comments, which limited the ability of comments to impact voting, and that the public could not address the Coordinating Committee until after deliberations were completed. These commenters also stated that the public could comment on the draft MAP Pre-Rulemaking Report, but that these comments were not considered by the Coordinating Committee and, therefore, did not result in revisions to the final report. These commenters recommended that public comments be solicited prior to, rather than, after voting on agenda items, and that the MAP Coordinating Committee be required to formally consider and respond to public comments on the draft report. Several other commenters expressed concern regarding the MAP's review of measure ''concepts'' that have not been fully developed, saying that recommendations are premature for measure concepts or measure drafts. These commenters recommended that when ''concepts'' are presented, the MAP should determine whether the measure concept/draft would fill a measure gap but reserve further judgment for the completed measure. These commenters are further concerned that the inclusion of measure ''concepts'' results in an unreasonably large number of items for the MAP to consider, which can limit the time allotted to consider each measure.

Response: We thank the commenters for their comments and concerns, but note that they do not directly address any proposals included in the CY 2015 OPPS/ASC proposed rule; rather, they are directed towards MAP-specific processes. We invite the commenters to submit their MAP-specific concerns directly to the NQF, which convenes the MAP.

In response to the comments concerning the MAP's review of measure ''concepts'' that have not been fully developed, resulting in recommendations that are premature for

measure concepts or measure drafts, we interpret the commenters' use of the terms ''concept'' and ''draft'' to refer to measures under development as defined in our legend on page 87 of the List of Measures under Consideration for December 1, 2013 (*https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0CCAQFjAA&url=http%3A%2F%2Fwww.qualityforum.org%2FSetting_Priorities%2FPartnership%2FMeasures_Under_Consideration_List.aspx&ei=aQUuVJrsM6nIsAT61IDQAg&usg=AFQjCNFPjzG9-t7flmf-RFf-7o_rSvpxxQ&sig2=V6Hi_GdCM2OUcP5xkoudcw&bvm=bv.76802529,d.cWc*). We strive to ensure that the pre-rulemaking process allows for thorough review by the MAP and other stakeholders of all measures under consideration.

Comment: Some commenters suggested that CMS consider developing additional outcomes measures specific to colonoscopies and consider developing a measure of whether or not colonoscopy patients remain cancer free, specifically suggesting that we work with stakeholders to improve existing measures.

Response: We thank the commenter for their recommendations and will consider these types of measures in future years.

We also thank all commenters for providing their views and we will consider them as we develop future measures for the ASCQR Program.

7. 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) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131), 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. These specifications are updated as we continue to develop the ASCQR 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=1228772475754*.

Many of the quality measures used in Medicare and Medicaid reporting programs are NQF-endorsed. We note that two of the measures previously adopted for the ASCQR Program are not NQF-endorsed, and NQF endorsement is not a program requirement. However, for those measures that are NQF-endorsed, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years as part of its regular maintenance process for NQF-endorsed performance measures. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes with the NQF on an annual basis. The NQF solicits information from measure stewards for annual reviews, and it reviews measures for continued endorsement in a specific 3-year cycle.

We note that the NQF's annual or triennial maintenance processes for endorsed measures may result in the NQF requiring updates to measures in order to maintain endorsement status. Other non-NQF measures may undergo maintenance changes as well. We believe that it is important to have in place the subregulatory process that we have adopted for the ASCQR Program to incorporate nonsubstantive updates into the measure specifications for measures so that the measure specifications remain current. We also recognize that some changes to measures are substantive in nature and might not be appropriate for adoption using a subregulatory process.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41049), we did not propose any changes to this policy.

8. 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. When available, these data will be displayed at the CCN level; we intend to make data collected under the ASCQR program publicly available in CY 2015. In the CY 2015 OPPS/ASC proposed rule (79 FR 41049), we did not propose any changes to this policy.

Comment: One commenter urged CMS to make the data submitted by ASCs available to the public after giving ASCs an opportunity to preview the data.

Response: We thank the commenter for their comment, and note that 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. These data will be displayed at the CCN level. We did not propose any changes to this policy (79 FR 41049).

C. 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 final rule with comment period.

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 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 final rule with comment period, 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 and radiology services where payment is based on the MPFS PE RVU 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, as discussed in section XII.C.1.b. of this final rule with comment period) 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 this final rule with comment period, we are finalizing 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 would 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 OPPS/ASC final rule with comment period (78 FR 75132), we did not make any changes to these policies. In the CY 2015 OPPS/ASC proposed rule (79 FR 41049 through 41050), we did not propose any changes to these policies.

D. Administrative Requirements

We received a public comment on the ASCQR Program requirements in general.

Comment: One commenter expressed appreciation that CMS did not propose any substantial changes to participatory requirements, stating that this will provide ASCs with valuable time to stabilize the processes for what is currently required without adding additional burden on resources.

Response: We interpret the commenter as referring to program administrative requirements overall, and not to just participation status as the commenter makes reference to issues of burden. We thank the commenter for this support. We agree that program administrative process stability to the extent possible is important in developing the ASCQR Program. We continue to look for ways to minimize burden as we pursue the quality objectives of the ASCQR Program.

1. Requirements Regarding QualityNet Account and Security Administrator

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75132 through 75133) for a detailed discussion of the QualityNet security administrator requirements, including setting up a QualityNet account, and the associated timelines, for the CY 2014 payment determination and subsequent years. In the CY 2015 OPPS/ASC proposed rule (79 FR 41050), we did not propose any changes to these policies.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75133 through 78 FR 75135) for a complete discussion of the participation status requirements for the CY 2014 payment determination and subsequent years. In the CY 2015 OPPS/ASC proposed rule (79 FR 41050), we did not propose any changes to these policies.

E. Form, Manner, and Timing of Data Submitted for the ASCQR Program

We received public comments on alternate methods for submitting data for the ASCQR Program.

Comment: One commenter recommended that CMS allow ASCs to meet the requirements of the ASCQR Program using registry-based reporting, noting that using a registry is an option under the PQRS and that other registries are already in existence. This commenter recommended CMS issue proposals regarding this option in next year's proposed rule. The commenter also recommended that ASCs should also have the option of submitting quality data to CMS through an EHR-based reporting mechanism, as there are ASCs that have implemented this technology and could benefit from this option.

Response: We thank the commenter for these suggestions. We agree that it could reduce burden to have a registry-based mechanism for data submission. We have not proposed a registry-based reporting option because currently, there is not a registry in place that is collecting information on the quality measures that we have adopted for this program. Should registry-based reporting of the ASC quality measures adopted for the ASCQR Program become available in the future, we will explore further the viability of incorporating a registry-based reporting mechanism in the ASCQR Program.

Regarding the use of EHR systems for reporting quality data, we agree that reporting by this method could reduce reporting burden. However, we are not aware of quality measures for ASCs that have been specified for electronic reporting. If such measures do exist, an understanding of the level of EHR adoption and capabilities of ASCs to utilize this method would be necessary before proposing their adoption by the ASCQR Program. As we discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124 through 75126), in a recent environmental scan, which included an assessment of the readiness of ASC to electronically report quality data, we found evidence of low levels of EHR use by ASCs. We believe that ASCs continue to be slow to adopt EHRs because many of these facilities are small and the cost of EHRs may pose a barrier to adoption. Further, there has been no incentive program to encourage such adoption by ASCs.

Comment: One commenter requested a batch-processing data submission option for entities that own multiple ASCs.

Response: We interpret this comment as referring to the ability to send quality measure data electronically in a format that allows for data submission for multiple ASCs, rather than requiring individual ASC data entry as is currently required for data submitted via a CMS online data submission tool measure data. We thank the commenter for their request and are considering how to implement this capability into our data submission processes. In the event this method can be available for data submission, we would issue proposals through rulemaking for ASCQR Program implementation.

1. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs for the CY 2014 payment determination and subsequent years. In the CY 2015 OPPS/ASC proposed rule (79 FR 41050), we did not propose any changes to these policies.

We did not receive any public comments on data submission for claims-based measures using QDCs.

2. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135 through 75137) for a complete discussion of the minimum thresholds, minimum case volume, and data completeness for successful reporting for the CY 2014 payment determination and subsequent years. In the CY 2015 OPPS/ASC proposed rule (79 FR 41050), we did not propose any changes to these policies.

We received the following public comments on data collection using QDCs.

Comment: One commenter recommended that CMS raise the 50 percent threshold for claims meeting measure specifications containing QDCs, noting that many of the issues in the early years of the program that led to this standard have been resolved.

Response: We thank the commenter for the recommendation and, while we did not propose any changes to our QDC use threshold in this rulemaking, we will consider this comment as we move forward with program planning as ASCs now have experience in submitting data in this manner.

Comment: One commenter supported CMS' decision not to propose any changes to minimum thresholds, minimum case volume, and data completeness for successful reporting, noting that program stability is important. Specifically, the commenter supports maintaining the sample size requirements for the endoscopy measures, ASC–9 and ASC–10.

Response: We thank the commenter for its support of these data-related policies, including the maintenance of the sample size requirements for the endoscopy measures.

3. Requirements for Data Submitted Via a CMS Online Data Submission Tool

a. Data Collection for ASC–6 and ASC–7

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74509) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75137 through 75138) for a complete discussion of the requirements for data collection and submission for the ASC–6: Safe Surgery Checklist Use and ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures measures for the CY 2015 payment determination and subsequent years. In the CY 2015 OPPS/ASC proposed rule (79 FR 41050), we did not propose any changes to these policies.

b. Delayed Data Collection for ASC–9 and ASC–10

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124 through 75130), we adopted 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), two additional chart-abstracted measures, and we finalized a policy that aggregate data (numerators, denominators, and exclusions) on all ASC patients would be collected via an online Web-based tool that would be made available to ASCs via the QualityNet Web site.

We finalized that the data collection time period would be the calendar year (January 1 to December 31) 2 years prior to the affected payment determination year, and the data collected would be submitted during the time period of January 1 to August 15 in the year prior to the affected payment determination year. Thus, for the CY 2016 payment determination, ASCs would be required to submit aggregate-level encounter data from January 1, 2014 to December 31, 2014 using our Web-based tool during

the data submission window of January 1, 2015 to August 15, 2015 (78 FR 75138 through 75139).

On December 31, 2013, we issued guidance stating that we would delay the implementation of ASC–9 and ASC–10 for 3 months for the CY 2016 payment determination, with a resulting encounter period of April 1, 2014 to December 31, 2014 instead of January 1, 2014 to December 31, 2014 (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772879036*). The data submission timeframe and the encounter period for subsequent years remain as previously finalized (78 FR 75139).

c. Delayed Data Collection and Exclusion for ASC–11 for the CY 2016 Payment Determination and Voluntary Data Collection for ASC–11 for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period, where we adopted ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) beginning with the CY 2016 payment determination (78 FR 75129), and finalized the data collection and data submission timelines (78 FR 75138 to 75139). This measure assesses the rate of patients 18 years and older (with a diagnosis of uncomplicated cataract) in a sample who had improvement in visual function achieved within 90 days following cataract surgery based on completing both a pre-operative and post-operative visual function survey.

Since our adoption of this measure, we have come to believe that it can be operationally difficult at this time for ASCs to collect and report this measure. Specifically, we are concerned that the results of the survey used to assess the pre-operative and post-operative visual function of the patient may not be shared across clinicians and facilities, making it difficult for ASCs to have knowledge of the visual function of the patient before and after surgery. We are also concerned about the surveys used to assess visual function; the measure allows for the use of any validated survey and results may be inconsistent should clinicians use different surveys.

Therefore, on December 31, 2013, we issued guidance stating that we would delay data collection for ASC–11 for 3 months (data collection would commence with April 1, 2014 encounters) for the CY 2016 payment determination (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772879036*). We issued additional guidance on April 2, 2014, stating that we would further delay the implementation of ASC–11 for an additional 9 months, until January 1, 2015 for the CY 2016 payment determination, due to continued concerns (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228773811586*).

In the CY 2015 OPPS/ASC proposed rule (79 FR 41051), we proposed to exclude 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. We would not subject ASCs to a payment reduction with respect to this measure for the CY 2016 payment determination.

We continue to believe that this measure addresses an area of care that is not adequately addressed in our current measure set and the measure serves to drive coordination of care (78 FR 75129). Further, we believe ASCs should be a partner in care with physicians and other clinicians using their facility and that this measure provides an opportunity to do so. Therefore, we are continuing to include this measure in the ASCQR Program measure set for the CY 2017 payment determination and subsequent years. However, we understand the concerns and, therefore, proposed that data collection and submission be voluntary for this measure for the CY 2017 payment determination and subsequent years. ASCs would not be subject to a payment reduction for failing to report this measure during the period of voluntary reporting. For ASCs that choose to submit data, we continue to request that they submit such data using the means and timelines finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75138 to 75139). Data submitted voluntarily will be publicly reported as discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 75138 to 75139).

We invited public comment on this proposal.

Comment: Some commenters stated that complications following cataract surgery are not acceptable and believed that ASC–11 tracks patient-centered clinical outcomes. The commenters stated that the measure would promote and improve care coordination among providers. Some commenters commended CMS' recognition of the associated operational issues and taking the approach to delay implementation of this measure as well as allowing voluntary collection.

Response: We appreciate the commenters that supported and agreed with our view and the approach we take for this measure. We agree that complications following cataract surgery are not acceptable. While ASC–11 does not address complications following cataract surgery, it does address improvement in visual function following cataract surgery and it tracks an important patient-centered clinical outcome.

Comment: Some commenters did not support voluntary data reporting based on concerns regarding the extent to which ASCs would report data for ASC–11 if reporting was voluntary. Some commenters stated that incomplete display of data is not meaningful to consumers. Other commenters expressed concerns that the display of data from some ASCs but not others would lead some patients to conclude that some ASCs are more committed to improving cataract surgery. Several other commenters predicted that very few ASCs will report data for the ASC–11 measure, leading to an insufficient sample.

Response: We thank the commenters for their views. We note that the proposal, which we are finalizing in this final rule with comment period, is for the measure to be voluntarily reported by ASCs. Therefore, ASCs would be able to choose whether to implement data collection and reporting processes for this measure. We continue to believe the ASC–11 measure has value in this care setting. We do not agree that an insufficient sample of facilities will report data for the ASC–11 measure because we also have self-reports from ASCs that some did put processes in place to collect data for this measure, and that these ASCs would like to report data for this measure because they view the measure as an important quality measure for facilities.

We do not agree that ASC–11 data reported on a voluntary basis would not be meaningful for consumers. There are many situations where ASCs do not submit information to the ASCQR Program because they do not have such information due to lack of cases or low case volume. 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. Therefore, when ASCs' information is submitted, we will make this information publicly available. Where this information is not submitted, we will state that the information is not

available. We also do not agree that reporting of measure data by some ASCs and not others under voluntary reporting would affect the validity of data reported for this Web-based measure because this situation is no different than any other measure where not all ASCs had cases.

Comment: Many commenters requested that CMS remove the ASC–11 measure from the program entirely, rather than delaying implementation and allowing voluntary reporting. These commenters reiterated similar concerns expressed in the CY 2014 OPPS/ASC final rule with comment period regarding associated burden, suitability for ASCQR Program versus PQRS, program alignment of this measure, nonstandardization of collected information, NQF endorsement, MAP recommendation, and coordination challenges faced by facilities.

Response: We continue to believe this measure addresses the importance area of care coordination and responsibility for monitoring patient outcomes between performing physicians, practitioners that assess visual function, and facilities where procedures are performed; therefore, we are not removing ASC–11 from the ASCQR Program measure set for the CY 2017 payment determination and subsequent years.

With respect to the concerns raised by commenters about the measure, we refer commenters to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124 through 75126, 75129, and 75138 through 75139) where we previously have responded to these concerns.

After consideration of the public comments we received, for the reasons discussed above, we are finalizing our proposal to allow voluntary data collection and reporting of this measure for the CY 2017 payment determination and subsequent years. We also are finalizing our proposal to exclude the measure entirely from the CY 2016 payment determination measure set. ASCs will be able to begin reporting with January 1, 2015 services as described above in section XIV.E.3. of this final rule with comment period. For ASCs that choose to submit data, we request that they submit such data using the means and timelines finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75138 to 75139). ASCs will not be subject to a payment reduction for failing to report this measure during the period of voluntary reporting. Data voluntarily submitted will be publicly reported.

4. Claims-Based Measure Data Requirements for the New Measure for the CY 2018 Payment Determination and Subsequent Years

In the CY 2015 OPPS/ASC proposed rule (79 FR 41046–41048), we proposed to adopt the ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure, which is a claims-based measure that does not require any additional data submission apart from standard Medicare FFS claims. In the CY 2015 OPPS/ASC proposed rule (79 FR 41051), we also proposed that, for this measure, which uses ASC Medicare claims data as specified in the ASCQR Specifications Manual and does not require any additional data submission such as QDCs, we would use paid Medicare FFS claims from a 12-month period from July 1 of the year 3 years before the payment determination year to June 30 of the following year. Thus, we stated, for the CY 2017 payment determination for this measure, claims from July 1, 2014 to June 30, 2015 would be used. We noted that we proposed to adopt this measure under the ASCQR Program as well as the Hospital OQR Program, as described in section XIII.H.2.c. of the proposed rule. We stated that this ASCQR Program time period provides for the timeliest data possible while aligning the proposed data submission requirements with our Hospital OQR Program proposal, which would use the claims-based measure data submission requirements for the CY 2015 payment determination and subsequent years that we adopted in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75111 through 75112).

We invited public comment on this proposal.

Comment: Many commenters expressed concern that, if finalized, the ASC–12 measure's data collection period would begin July 1, 2014, several months before adoption of the measure is finalized. Several commenters recommended that data collection begin July 1, 2015.

Response: As we stated above in section XIV.B.5. of this final rule with comment period, we are finalizing the adoption of ASC–12 for the CY 2018 payment determination and subsequent years instead of the CY 2017 payment determination and subsequent years as proposed. We are finalizing the data submission time period for ASC–12 to use paid Medicare FFS claims from the calendar year 2 years before the payment determination calendar year. For the CY 2018 payment determination, we will use paid Medicare FFS claims from January 1, 2016 to December 31, 2016. We believe the reliability of the measure using 1 year of data is sufficiently reliable. While we believe that measure reliability may be further improved by using a longer time period, we must balance the reliability of the measure with the timeliness of the measure. At this time, we believe that 1 year of data appropriately balances these competing interests, but we will continue to assess this belief during the dry run.

After consideration of the public comments we received, we are not finalizing our proposal to use paid Medicare FFS claims from a 12-month period from July 1 of the year 3 years before the payment determination year to June 30 of the following year. Instead, we will use paid Medicare FFS claims from the calendar year 2 years before the payment determination calendar year. Specifically, with respect to the CY 2018 payment determination, for calculating ASC–12, we will use paid Medicare FFS claims from January 1, 2016 to December 31, 2016.

5. Data Submission Requirements for ASC–8 (Influenza Vaccination Coverage Among Healthcare Personnel) Reported via the National Healthcare Safety Network (NHSN) for the CY 2016 Payment Determination and Subsequent Years

a. Previously Adopted Requirements for the CY 2016 Payment Determination

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74510) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75139 through 75140) for a complete discussion of the ASC–8 measure (Influenza Vaccination Coverage among Healthcare Personnel) (NQF #0431), including the data collection timeframe and the data reporting standard procedures for the CY 2016 payment determination.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75139 through 75140), we finalized our proposal to use the data submission and reporting standard procedures that have been set forth by the CDC for NHSN participation in general and for submission of this measure to NHSN. We refer readers to the CDC's NHSN Web site for detailed procedures for enrollment (*http://www.cdc.gov/nhsn/ambulatory-surgery/enroll.html*), set-up (*http://www.cdc.gov/nhsn/ambulatory-surgery/setup.html*), and reporting (*https://sams.cdc.gov*) (user authorization through Secure Access Management Services (SAMS) is required for access to NHSN). We note

that the reporting link was updated in the CY 2015 OPPS/ASC proposed rule (79 FR 41051).

b. Data Collection Timeframes for the CY 2017 Payment Determination and Subsequent Years and Submission Deadlines for the CY 2016 Payment Determination and Subsequent Years

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74510), we finalized our policy that data collection for the CY 2016 payment determination would be from October 1, 2014 through March 31, 2015 (the 2014–2015 influenza season data). In the CY 2015 OPPS/ASC proposed rule (79 FR 41051 through 41052, we proposed that for the CY 2017 payment determination and subsequent years, ASCs would collect data 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. For example, the CY 2017 payment determination would require data collection from October 1, 2015 to March 31, 2016.

In the CY 2014 OPPS/ASC proposed rule, we proposed that ASCs would have until August 15, 2015 to submit their 2014–2015 influenza season data (October 1, 2014 through March 31, 2015) to NHSN. We stated that this date is the latest date possible for data entry that would provide sufficient time for us to make the CY 2016 payment determinations and is aligned with the data entry deadline for the measures entered via the CMS online tool (78 FR 43670). While some commenters supported this proposal, others expressed disagreement with this proposal because it differed from the May 15 deadline proposed for the Hospital IQR Program (78 FR 27700, 50822) and the Hospital OQR Program (78 FR 43656, 75116 through 75117) and they believed this difference in deadlines could cause confusion, thereby disadvantaging ASCs (78 FR 75140). Other commenters believed that providing ASCs with a later deadline would provide an unfair advantage because ASCs would have longer to submit their data. Due to these concerns, we did not finalize the August 15, 2015 deadline. We stated that we intended to propose a submission deadline for this measure for the CY 2016 payment determination in this proposed rule.

In the proposed rule, we proposed that May 15 of the year in which the influenza season ends be the submission deadline for each payment determination year, similar to the Hospital IQR and OQR Programs. For example, for the CY 2016 payment determination, ASCs would be required to submit their 2014–2015 influenza season data (October 1, 2014 through March 31, 2015) by May 15, 2015. Similarly, for the CY 2017 payment determination, ASCs would be required to submit their 2015–2016 influenza season data (October 1, 2015 through March 31, 2016) by May 15, 2016. We believe a May 15 reporting deadline would enable ASCs to use data summarizing the results of their previous influenza vaccination campaign to set targets and make plans for their influenza vaccination campaigns prior to the next influenza season. This deadline also would enable us to post and the public to review the summary data before the start of the next influenza season. Finally, this date aligns to the May 15 deadline used in the Hospital IQR and OQR Programs for this measure.

We invited public comment on this proposal.

Comment: Many commenters supported the proposed submission deadline of May 15 for ASC–8. One commenter expressed concern that there is a time lag for reporting this data, and urged that the public should have access to the data at the time the data is most useful.

Response: We thank the commenters for their support. We believe a May 15 reporting deadline will enable ASCs to use data summarizing the results of their previous influenza vaccination campaign to set targets and make plans for their influenza vaccination campaigns prior to the next influenza season. This deadline also will enable us to post and the public to review the summary data before the start of the next influenza season. Finally, this date aligns with the May 15 deadline used in the Hospital IQR and OQR Programs for this measure.

Comment: Several commenters opposed setting the submission deadline for ASC–8 to May 15, arguing that the August 15 deadline considered in the prior year rule was better aligned with the other measures in the ASCQR Program and would minimize confusion and reporting burden. One commenter suggested that the Hospital IQR and Hospital OQR Programs should move their deadlines to August 15 to support program alignment.

Response: We thank the commenters for supporting last year's proposal regarding a data submission deadline for the ASC–8 measure. We proposed an August 15 data submission deadline in the CY 2014 OPPS/ASC proposed rule (78 FR 43670), but did not finalize this proposal due to commenters' concerns with nonalignment with other quality reporting programs (78 FR 75140).

While we seek to align reporting deadlines whenever possible within the ASCQR Program (78 FR 75140), we believe alignment across programs with the May 15 reporting deadline will prevent confusion in reporting across different facilities. We also believe this earlier deadline will enable us to make the data publicly available in time for ASCs to use the data summarizing the results of their previous influenza vaccination campaign to set targets and make plans for their influenza vaccination campaigns prior to the next influenza season. This would be very difficult to achieve with an August 15 reporting deadline.

After consideration of the public comments we received, for the reasons set forth above, we are finalizing our proposal without modification to adopt May 15 of the year in which the influenza season ends as the data submission deadline for the ASC–8 measure for each payment determination year, beginning with the CY 2016 payment determination. We also are finalizing our proposal without modification that, for the CY 2017 payment determination and subsequent years, ASCs will collect data 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.

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 Medicare Administrative Contractors) or Web-based measures for the ASCQR Program, which is in alignment with our requirements for the Hospital IQR and OQR Programs. In the CY 2015 OPPS/ASC proposed rule (79 FR 41052), we did not propose any changes to this policy.

We received the following comment on data validation for the ASCQR Program.

Comment: One commenter recommended that CMS develop an ASCQR data validation program to assure the accuracy and integrity of quality data that will be publicly reported under the ASCQR Program.

Response: We thank the commenter for the comment, and note that we continue to evaluate the feasibility of data validation for the ASCQR Program.

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 Medicare Administrative Contractors) or Web-based measures for the ASCQR Program. At this time, we believe that it would be overly burdensome to validate the reported data given the inexperience that ASCs have with reporting quality data to CMS coupled with the low incidence of cases for the claims-based measures. As we gain more experience with the ASCQR Program, we will reassess whether a data validation process for claims-based measures and measures where aggregate data are reported via an online tool is needed.

7. Extraordinary Circumstances Extensions or Exemptions for the CY 2017 Payment Determination and Subsequent Years

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 through 75141) for a complete discussion of our extraordinary circumstances extension or waiver process under the ASCQR Program. In the CY 2015 OPPS/ASC proposed rule (79 FR 41052), we did not propose any substantive changes to these policies or the processes. However, in the future, we will refer to the process as the ''Extraordinary Circumstances Extensions or Exemptions'' process rather than the ''Extraordinary Circumstances Extensions or Waivers'' process.

We also are in the process of revising the Extraordinary Circumstances/Disaster Extension or Waiver Request form (CMS–10432), approved under OMB control number 0938–1171. We are updating the instructions and the form so that a hospital or facility may apply for an extension for all applicable quality reporting programs at the same time. In addition, the instructions for the form will be updated.

8. ASCQR Program Reconsideration Procedures for the CY 2017 Payment Determination and Subsequent Years

We refer readers to 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) for a complete discussion of our informal reconsideration process for the ASCQR Program for the CY 2014 payment determination and subsequent years. In the CY 2015 OPPS/ASC proposed rule (79 FR 41052), we did not propose any changes to the informal reconsideration process.

XV. Changes to the Rural Provider and Hospital Ownership Exceptions to the Physician Self-Referral Law: Expansion Exception Process

A. Background

1. Statutory Basis

Unless the requirements of an applicable exception are satisfied, section 1877 of the Act, also known as the ''physician self-referral law''—(1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship (ownership or compensation); and (2) prohibits the entity from submitting claims to Medicare (or billing another individual, entity, or third party payer) for those designated health services furnished as a result of a prohibited referral. The Act establishes a number of specific exceptions to the physician self-referral law and grants the Secretary the authority to create regulatory exceptions for financial relationships that the Secretary determines pose no risk of program or patient abuse. Since the original enactment of the statute in 1989, we have published a series of final rules interpreting the statute and promulgating numerous exceptions.

Section 1877(d) of the Act sets forth exceptions related to ownership and investment interests held by a physician (or an immediate family member of a physician) in an entity that furnishes designated health services. Section 1877(d)(2) of the Act provides an exception for ownership and investment interests in rural providers. Under the provision of section 1877(d)(2) of the Act, in order for an ownership or investment interest to qualify for the exception, the designated health services must be furnished in a rural area (as defined in section 1886(d)(2) of the Act), and substantially all of the designated health services furnished by the entity must be furnished to individuals residing in a rural area. Section 1877(d)(3) of the Act provides the hospital ownership exception, often referred to as the ''whole hospital exception,'' for ownership and investment interests in a hospital located outside of Puerto Rico, provided that the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

2. Affordable Care Act Amendments to the Rural Provider and Hospital Ownership Exceptions to the Physician Self-Referral Law

Section 6001(a) of the Affordable Care Act amended the rural provider and whole hospital exceptions to the physician self-referral law to impose additional restrictions on physician ownership and investment in rural providers and hospitals. Section 6001(a) defines a ''physician owner or investor'' as a physician, or immediate family member of a physician, who has a direct or indirect ownership or investment interest in a hospital. We refer to hospitals with direct or indirect physician owners or investors as ''physician-owned hospitals.''

Section 6001(a)(3) of the Affordable Care Act established new section 1877(i) of the Act, which imposes additional requirements for physician-owned hospitals to qualify for the rural provider or whole hospital exception. In addition to other requirements, section 1877(i)(1) of the Act prohibits a physician-owned hospital from expanding its facility capacity beyond the number of operating rooms, procedure rooms, and beds for which the hospital was licensed as of March 23, 2010, unless an exception is granted by the Secretary.

Section 1877(i)(3) of the Act requires the Secretary to establish and implement an exception process to the prohibition on expansion of facility capacity. We refer to this process as the ''expansion exception process.'' Section 1877(i)(3)(A)(i) of the Act provides that a hospital qualifying as an ''applicable hospital'' or a ''high Medicaid facility'' may apply for an expansion exception. Section 1877(i)(3)(E) of the Act sets forth the eligibility criteria for applicable hospitals, which include criteria concerning inpatient Medicaid admissions, bed capacity, and bed occupancy. Section 1877(i)(3)(F) of the Act sets forth the eligibility criteria for high Medicaid facilities, which include a criterion concerning inpatient Medicaid admissions.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72240), we addressed many of the additional requirements that were established by section 6001(a) of the Affordable Care Act for the rural provider and whole hospital exceptions, including the prohibition on expansion of facility capacity. In that final rule with comment period, we finalized regulations at 42 CFR 411.362(b)(2) that prohibit a physician-owned hospital from increasing the number of operating rooms, procedure rooms, and beds

beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a physician-owned hospital that did not have a provider agreement in effect as of that date, but did have a provider agreement in effect on December 31, 2010, the effective date of such agreement), if the hospital seeks to avail itself of the rural provider or whole hospital exception.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74517), we promulgated regulations under 42 CFR 411.362(c) that govern the expansion exception process. Section 411.362(c)(2) sets forth the criteria for a physician-owned hospital to qualify for an expansion exception as an applicable hospital. Specifically, § 411.362(c)(2) states that: (1) The hospital's annual percent of total inpatient admissions under Medicaid must be equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located during the most recent fiscal year for which data are available as of the date that the hospital submits its exception request; (2) the hospital must be located in a State in which the average bed capacity in the State is less than the national average bed capacity during the most recent fiscal year for which data are available as of the date that the hospital submits its request; and (3) the hospital must have an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which data are available as of the date that the hospital submits its request.

Section 411.362(c)(3) specifies the criteria for a physician-owned hospital seeking an exception under the expansion exception process on the basis that it is a high Medicaid facility, including the requirement that, with respect to each of the three most recent fiscal years for which data are available as of the date that the hospital submits its exception request, the hospital must have an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42350 through 42352), we proposed that filed Medicare hospital cost report data from the CMS Healthcare Cost Report Information System (HCRIS) be used to determine whether a hospital satisfies the inpatient Medicaid admissions, bed capacity, and bed occupancy criteria for applicable hospitals and the inpatient Medicaid admissions criterion for high Medicaid facilities. We requested public comments concerning alternative data sources that could result in more accurate determinations as to whether a hospital satisfies the relevant criteria (76 FR 42350). The public comments that we received provided no persuasive support for a data source more accurate than the filed hospital cost report data reported to HCRIS. Therefore, we finalized the requirement to use filed hospital cost report data for purposes of facility capacity expansion exception requests in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74518). In this final rule with comment period, we refer to the filed hospital cost report data that are required under our existing regulations as ''HCRIS data.''

As required by section 1877(i)(3)(A) of the Act, the regulations addressing the expansion exception process in the CY 2012 OPPS/ASC final rule with comment period were issued by January 1, 2012, and the process was implemented on February 1, 2012.

B. Limitations Identified by Stakeholders Regarding the Required Use of HCRIS Data

Following the implementation of the expansion exception process on February 1, 2012, industry stakeholders informed us of what they believed to be certain limitations regarding the required use of HCRIS data under the regulations at 42 CFR 411.362. In the CY 2015 OPPS/ASC proposed rule (79 FR 41053), we discussed the existing required use of HCRIS data and certain limitations of the data that were identified by stakeholders and CMS. We do not repeat that information here; rather, we refer readers to the proposed rule for a complete discussion of the issues. To address the limitations regarding the required use of HCRIS data, we proposed to modify the expansion exception process to permit the use of certain non-HCRIS data sources for the inpatient Medicaid admissions, bed capacity, and bed occupancy criteria.

As of the publication date of the CY 2015 OPPS/ASC proposed rule, a correctly completed hospital cost report did not include Medicaid managed care admissions or discharges and, therefore, Medicaid managed care admissions and discharges were not available in HCRIS. As a result, the information collected to date through HCRIS cannot be used to estimate reliably Medicaid managed care admissions or discharges for purposes of estimating the percentages of inpatient Medicaid admissions under §§ 411.362(c)(2)(ii) and (c)(3)(ii). In addition, a hospital that has not participated as a provider in the Medicare program for each of the 3 most recent fiscal years for which data is available would be precluded from seeking a facility expansion exception as a high Medicaid facility. It would be similarly prohibitive if the requesting hospital is seeking an exception as either an applicable hospital or high Medicaid facility, and the hospitals in the county in which the requesting hospital is located were not Medicare participating providers or were not participating in the Medicare program during each of the years for which comparisons are required under the statute and our regulations.

We believe that some physician-owned hospitals that serve a significant number of Medicaid managed care patients and are interested in the expansion exception process may fail to qualify for an exception due to the exclusion of Medicaid managed care data. Accordingly, as detailed in section XV.C. of the CY 2015 OPPS/ASC proposed rule (79 FR 41054), we proposed to revise the expansion exception process to permit physician-owned hospitals to use filed hospital cost report data, data from internal data sources, or data from external data sources to estimate the required percentages of inpatient admissions under Medicaid. (We referred in the proposal to the non-HCRIS internal data sources and external data sources that we proposed to permit for purposes of the expansion exception process as ''supplemental data sources.'') Also, as explained in section XV.B. of the CY 2015 OPPS/ASC proposed rule (79 FR 41054), we proposed to revise the expansion exception process to permit the use of supplemental data sources for the bed capacity and bed occupancy criteria for applicable hospitals.

C. Changes to the Physician-Owned Hospital Expansion Exception Process

Below we discuss the provisions of the proposed rule and summarize and respond to the public comments we received in response to our proposals. For ease of reference, we have divided the comments and responses into the following categories: supplemental data sources; fiscal year standard; community input and timing of complete request; and additional considerations.

1. Supplemental Data Sources

Given the limitations regarding the required use of HCRIS data (which we described in sections XV.B.1. and XV.B.2. of the CY 2015 OPPS/ASC proposed rule (79 FR 41053 through 41054)), we proposed to revise our

regulations at §§ 411.362(c)(2)(ii), (c)(2)(iv), (c)(2)(v), and (c)(3)(ii) to permit physician-owned hospitals to use data from certain internal data sources or external data sources, in addition to HCRIS data, in order to estimate the percentages of inpatient Medicaid admissions, and to determine the bed capacities and the bed occupancy rates referenced in those sections. We stated in the proposed rule that we were not prescribing that hospitals use a specific individual data source or combination of data sources.

We proposed that, for purposes of the expansion exception process, internal data sources would be sources generated, maintained, or under the control of the Department, and we gave as examples the Healthcare Cost and Utilization Project (HCUP), the Medicaid Statistical Information System (MSIS), and the Medicaid Analytic Extract (MAX). We sought public comments that recommended other possible internal data sources. We also proposed that, for purposes of the expansion exception process, ''external data sources'' would be data sources generated, maintained, or under the control of a State Medicaid agency, and we sought public comments that recommended other possible external data sources, including those of other State agencies or departments. Finally, we proposed to amend 42 CFR 411.351: (1) to define ''internal data source'' to include only non-HCRIS data sources that are reliable and transparent, and that maintain or generate data that are accurate, complete, and objectively verifiable for purposes of the expansion exception process, and to define ''external data source'' to include only data sources that are reliable and transparent, and that maintain or generate data that are accurate, complete, and objectively verifiable for purposes of the expansion exception process; and (2) to state that internal data sources and external data sources must maintain data that are readily available and accessible to the requesting hospital, comparison hospitals, and to CMS for purposes of the expansion exception process.

We noted in the proposed rule that the expansion exception process includes both the physician-owned hospital's completion of its request and CMS' consideration of the physician-owned hospital's request.

We stated in the proposed rule that we believe that the supplemental data sources should—

- Be transparent regarding what comprises the data, where the data originated, and the manner and method by which the data source received the data;
- Be maintained on a secure database that prevents distortion or corruption of data and that ensures the accuracy of the data;
- Contain sufficient information to enable accurate estimates of the percentages of inpatient Medicaid admissions, and accurate determinations of bed capacities and bed occupancy rates;
- Contain sufficient information to enable the comparisons required by § 411.362(c)(2)(ii), (c)(2)(iv), (c)(2)(v), and (c)(3)(ii) for the fiscal year(s) at issue; and
- Contain sufficiently clear and detailed data that will enable multiple users to produce consistent results and outcomes when using the same data set.

In the proposed rule, we recognized that, if a physician-owned hospital uses data from a supplemental data source, the hospital may ultimately need to make estimates or determinations in addition to those referenced in our existing regulations. Accordingly, we proposed to revise our regulations to allow for the additional estimates or determinations that may be necessary under our revised process. Specifically, we proposed to permit a requesting hospital to use data from a supplemental data source to:

- Estimate its own annual percentage of inpatient Medicaid admissions (§ 411.362(c)(2)(ii)).
- Estimate the average percentage with respect to such admissions for all hospitals located in the county in which the hospital is located (§ 411.362(c)(2)(ii)).
- Determine the average bed capacity in the State in which the hospital is located (§ 411.362(c)(2)(iv)).
- Determine the national average bed capacity (§ 411.362(c)(2)(iv)).
- Determine its own average bed occupancy rate (§ 411.362(c)(2)(v)).
- Determine the average bed occupancy rate for the State in which the hospital is located (§ 411.362(c)(2)(v)).
- Estimate its annual percentage of total inpatient admissions under Medicaid for each of the 3 most recent fiscal years for which data are available (§ 411.362(c)(3)(ii)).
- Estimate the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the hospital is located for each of the 3 most recent fiscal years for which data are available (§ 411.362(c)(3)(ii)).

We respond below to the specific comments that we received in response to our proposal.

a. Internal Data Sources

Comment: All of the commenters supported CMS' efforts to permit physician-owned hospitals to use supplemental data sources in the expansion exception process because of the limitations of the HCRIS data, especially with respect to the inpatient Medicaid admissions criteria. The commenters generally agreed that a more flexible approach would help ensure that the physician-owned hospitals that satisfy the statutory criteria are able to expand facility capacity under the CMS process.

Response: We appreciate the commenters' support. Accordingly, we are finalizing a number of our proposals to revise the expansion exception process to provide for the flexibility called for by the commenters and other industry stakeholders to effectuate the purpose of section 6001(a) of the Affordable Care Act.

Comment: One commenter stated that it appreciated CMS' efforts to permit physician-owned hospitals to use supplemental data sources but also expressed concern that an internal data source as defined in the proposed rule would have limited utility in the expansion exception process. With respect to the internal data sources provided as examples in the proposed rule, the commenter identified limitations concerning the data sources' completeness for purposes of the expansion exception process. Specifically, the commenter stated that certain States do not provide information to the HCUP and that the MSIS does not provide sufficient detail at the State or county level for purposes of the expansion exception process. The commenter added that the Medicaid Analytic Extract (MAX) would not be appropriate for the expansion exception process because it may not be used for nonresearch purposes.

Response: We share the concerns identified by the commenter. After publication of the proposed rule, we made additional inquiries into the utility of internal data sources with respect to the inpatient Medicaid admissions criteria. As a result of those inquiries and further review, we agree with the commenter that these data sources contain significant limitations, including incomplete data for purposes of the exception process, as well as issues related to timeliness, availability, and accessibility of the data. Accordingly, we do not believe that the three sources listed in the proposed rule satisfy all of the standards that we set forth in the proposed rule for supplemental data sources (79 FR

41055), which we continue to believe are critical for any supplemental data source that could be used in the expansion exception process. None of the commenters provided information regarding other potentially acceptable internal data sources, and we are unaware of any other internal data sources that could be used to estimate accurately and reliably the percentages of inpatient Medicaid admissions required. Therefore, we are not finalizing our proposal to permit the use of any non-HCRIS internal data source for the inpatient Medicaid admissions criteria required at §§ 411.362(c)(2)(ii) and (c)(3)(ii).

We also believe that many of the limitations that the commenter and our review identified regarding the proposed internal data sources would also apply to the bed capacity and bed occupancy criteria at § 411.362(c)(2)(iv) and (c)(2)(v). Specifically, we do not believe that internal data sources other than HCRIS would include relevant and adequate information to determine accurately the average bed capacity for hospitals within a State or nationally; nor do we believe internal data sources other than HCRIS would include information to determine accurately bed occupancy rates in a State. Accordingly, we are not finalizing our proposed revisions to §§ 411.362(c)(2)(iv) and (c)(2)(v) that would permit the use of any non-HCRIS internal data source for those criteria. Because no internal data source, other than HCRIS, will be permitted in the expansion exception process under this final rule with comment period, we are not finalizing our proposal to add a definition of ''internal data source'' to § 411.351.

Comment: One commenter recommended that physician-owned hospitals be allowed to use as an internal data source the same Medicaid eligibility determination process that hospitals use for Medicare disproportionate share hospital (DSH) determinations.

Response: Medicare DSH determinations are based on Medicaid days, not admissions (or discharges). Based on our review, we do not believe that Medicaid days, without additional detailed information for the requesting and each comparison hospital, could be used in calculations to estimate accurately or reliably the required percentages of inpatient Medicaid admissions. The commenter did not explain how Medicaid eligibility data could be used to estimate inpatient admissions under Medicaid for the requesting hospital and each comparison hospital, when required. Without further explanation, we cannot agree that the Medicaid eligibility determination process that hospitals use for Medicare DSH determinations should be considered a data source.

b. External Data Sources

Comment: Most commenters urged CMS to finalize its proposal to permit the use of data from external data sources for the inpatient Medicaid admissions criteria. One commenter stated that its State Medicaid agency's data on inpatient Medicaid admissions includes fee-for-service and managed care data, and that the data on total patient admissions are readily available from the Medicaid agency. The commenter indicated that the State Medicaid agency data could be used to determine accurately the percentages of inpatient Medicaid admissions referenced in § 411.362(c)(2)(ii) and (c)(3)(ii). The commenter also stated that the State did not charge a fee for providing the necessary data.

Response: We believe that States have a significant interest in ensuring that data generated, maintained, or under the control of the State Medicaid agency are accurate and reliable. In general, submission of data to a State Medicaid agency is not voluntary, and hospitals are incented to provide accurate data and other information to receive payment for the services that they provide to the State's Medicaid enrollees. Accordingly, we are persuaded to finalize our proposal to permit the use of an external data source for the inpatient Medicaid admissions criteria at § 411.362(c)(2)(ii) and (c)(3)(ii) with the modification stemming from the recent revision to the Medicare hospital cost report described in this response. We also are adopting as final our proposed definition of ''external data source'' with no modification. We are adding this definition at § 411.362(a), rather than at § 411.351 as proposed, because the definition of ''external data source'' applies only to our regulations at § 411.362.

We note that CMS recently revised the hospital cost report to require the reporting of Medicaid managed care discharges in addition to Medicaid fee-for-service discharges. As a result of this revision, a correctly completed hospital cost report will include Medicaid managed care discharges and, thus, Medicaid managed care discharges eventually will be available in HCRIS. At such time, the limitations that led to our proposal will be resolved, and HCRIS should be sufficiently complete to estimate the percentages of Medicaid inpatient admissions required in § 411.362(c)(2)(ii) and (c)(3)(ii). However, we anticipate that it will take several years before physician-owned hospitals that are interested in requesting an expansion exception will be able to utilize the necessary Medicaid managed care data through HCRIS. Therefore, we are permitting physician-owned hospitals to use data from an external data source for the inpatient Medicaid admissions criteria until such time that the Secretary determines that HCRIS contains sufficiently complete inpatient Medicaid discharge data. At that time, going forward, physician-owned hospitals may use only filed Medicare hospital cost report data for the inpatient Medicaid admissions criteria. For additional information about the recent revisions to the hospital cost report, we refer readers to Transmittal 6 on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R6P240.html.*

We did not receive any public comments regarding whether an external data source would contain adequate information to determine the remaining four calculations required for the Secretary to grant an exception to the facility expansion prohibition for an applicable hospital (that is, the average bed capacity in the State where the requesting hospital is located, national average bed capacity, the requesting hospital's average bed occupancy, and the average bed occupancy for all hospitals in the State where the requesting hospital is located). Based on our own review, we do not believe that an external data source would meet the standards set forth in the proposed rule when used for the criteria at § 411.362(c)(2)(iv) and (c)(2)(v). Therefore, we are not finalizing our proposal to permit the use of external data sources for the four calculations specified in this paragraph and, thus, we are limiting the use of external data sources to the estimations of the percentages of inpatient Medicaid admissions at § 411.362(c)(2)(ii) and (c)(3)(ii).

Comment: One commenter suggested that physician-owned hospitals seeking an expansion exception be permitted to use the most current external data available, regardless of source.

Response: We interpret the comment as a suggestion that a requesting hospital should be able to use multiple external data sources to achieve the goal of using the ''most current'' data available when requesting an expansion exception, provided that each data source meets the criteria for an ''external data source.'' We disagree with the commenter because we believe that the use of more than one data

source would add unnecessary complexity to the Secretary's review and lead to inconsistent results, including from year to year where multiple-year comparisons are required. In order to ensure accurate and consistent estimates and determinations and to facilitate the Secretary's review of a physician-owned hospital's request for a facility expansion exception, all of the data necessary for a physician-owned hospital to estimate or determine the percentages of inpatient Medicaid admissions referenced in §§ 411.362(c)(2)(ii) and (c)(3)(ii) must come from a single data source. Specifically, the same data source, whether HCRIS or an external data source, must be used in the numerator and denominator when determining or estimating the percentages of inpatient admissions under Medicaid for the requesting hospital and any other comparison hospital required under § 411.362(c)(2)(ii) and (c)(3)(ii). We will continue to monitor the use of data sources in the expansion exception process and, if necessary, we will provide additional guidance on the CMS Web site regarding how an external data source should be used for the inpatient Medicaid admissions criteria.

Comment: One commenter identified potential shortcomings in the data that its State Medicaid agency collects. Specifically, this commenter stated that its State collects Medicaid inpatient admissions data from general acute care hospitals but not psychiatric or specialty hospitals. (The commenter did not define ''specialty hospital.'') For this reason, the commenter claimed that its State Medicaid agency data would be incomplete if the requesting hospital is a psychiatric or specialty hospital or must compare itself to a psychiatric or specialty hospital.

Response: Although we understand the potential implication of a State Medicaid agency not requiring a particular type of hospital to report admissions (or discharges) data to the agency, we note that HCRIS remains available under the policies set forth in this final rule with comment period. No Medicare participating hospital is exempt from reporting cost report data in HCRIS. Hospitals requesting an exception to the Affordable Care Act's facility expansion prohibition may use HCRIS data to make the necessary estimates and determinations required under the statute and our regulations.

Comment: One commenter recommended that physician-owned hospitals be permitted to use a State-provided listing of Medicaid DSH-eligible hospitals as an external data source. The commenter suggested that, if a hospital has been determined by its State Medicaid agency to be eligible for Medicaid DSH payments, the supporting data that show the Medicaid inpatient utilization rate or low-income utilization rate status of the hospital would be an adequate external data source.

Response: We do not believe that a listing of Medicaid DSH-eligible hospitals, even if developed by a State Medicaid agency, qualifies as an external data source under our proposed definition. Moreover, we are not persuaded to expand the definition of ''external data source'' to include such a listing because we are unclear how a listing, by itself, could provide the data necessary to estimate the percentages of inpatient Medicaid admissions required under the statute and our regulations.

Comment: One commenter suggested that admissions data, which it was able to obtain from the State health and human services commission, should be preferred over discharge data for purposes of the inpatient Medicaid admissions criteria.

Response: In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74519), we determined that discharge data may be used to estimate the percentages of inpatient Medicaid admissions. We did not propose to revise this policy in the CY 2015 OPPS/ASC proposed rule. However, we are clarifying in this CY 2015 OPPS/ASC final rule with comment period that either admissions data or discharge data may be used to either determine or estimate the percentages referenced in § 411.362(c)(2)(ii) and (c)(3)(ii), provided that the data being used are from a permitted data source. We are not persuaded to rank or prioritize these types of data. The Secretary will determine whether an estimate is accurate or appropriate given the specific facts and circumstances underlying a physician-owned hospital's expansion exception request.

c. Completeness of Supplemental Data Sources

Comment: One commenter expressed concern about the utility of an external data source, as defined in the proposed rule, for purposes of the expansion exception process. The commenter stated that, in some States, certain types of hospitals are not required to report any data to the States in which they are located. The commenter did not provide information regarding whether State Medicaid agencies can or do generate on their own (that is, without relying on reported information from hospitals) inpatient admissions data for those hospitals not required to report such data. The commenter requested that CMS clarify whether the State Medicaid sources would be considered ''complete'' for purposes of the expansion exception process under such circumstances.

Response: We recognize the possibility that a State Medicaid agency may not generate, maintain, or otherwise control a data source that would contain sufficient data for the inpatient Medicaid admissions criteria, the only eligibility criteria for which we are permitting the use of an external data source in this final rule with comment period. Thus, the utility of the external data sources that we are permitting likely will depend on the State in which the physician-owned hospital is located.

Whether an external data source is considered complete depends on the facts and circumstances of the particular situation. For example, if a physician-owned hospital is seeking to qualify as a high Medicaid facility and the State's data source does not include data on one of the comparison hospitals, the State's data would not be considered complete for purposes of the process because a high Medicaid facility must compare itself against each other hospital in the county in which it is located.

d. Other Issues Related to Supplemental Data Sources

Comment: One commenter expressed concern that contradictory data sources could create confusion for requesting physician-owned hospitals, those who wish to comment on an expansion exception request, and the Secretary in her review of a request. The commenter provided an example where a physician-owned hospital chooses to utilize available HCRIS data for its expansion request, but the available data from the State Medicaid agency conflict with the HCRIS data, appearing to show that the physician-owned hospital was not the highest Medicaid facility in a more recent fiscal year(s). Two commenters recommended that CMS consider issuing guidance as to how external data sources will be characterized or measured in comparison to HCRIS data, how CMS and the Secretary will evaluate comments received from opposing hospitals, and what criteria the Secretary intends to rely upon to make the ultimate determinations. Another commenter recommended that CMS not prioritize or rank additional data sources, given that access to supplemental data sources will vary based upon the entity requesting an expansion exception.

Response: Determinations regarding expansion exception requests will be made on a case-by-case basis, with consideration given to all information available to CMS at the time of the review. We are not able to provide the specific guidance requested by the first commenter because the example provided is hypothetical in nature and not part of an actual request for the Secretary's consideration. As we stated in the proposed rule, we believe that permissible data sources should, among other things, be transparent, be secure, enable accurate estimates of the percentages of inpatient Medicaid admissions, and provide for consistent results in order to enable the Secretary to make an informed decision regarding whether a requesting physician-owned hospital satisfies the statutory requirements for an exception to the facility expansion prohibition. We continue to believe in the importance of these attributes, and all data sources utilized by a requesting hospital and any community comments provided during the exception expansion process will be evaluated with them in mind. Because each request will be reviewed on a case-by-case basis, we decline to issue guidance regarding the relative priority of data sources. The Secretary will make determinations based on the criteria enumerated in the Affordable Care Act, as set forth in section 1877(i)(3) of the Act and our regulations.

Comment: One commenter recommended that, in addition to considering other data sources, CMS consider other factors when reviewing an expansion exception request. The commenter claimed that Medicaid patient days are a better metric than Medicaid admissions because Medicaid patient days reflect a hospital's use of resources to care for a Medicaid patient. The commenter also suggested that CMS consider the specialty services, such as neonatal intensive care unit (NICU) services, that a hospital provides. Specifically, the commenter suggested that CMS consider the bed occupancy of a particular specialty service if that service treats a very large Medicaid population.

Response: We do not have the authority to revise the expansion exception process to incorporate the factors that the commenter recommended. Section 6001(a) of the Affordable Care Act established criteria that physician-owned hospitals must satisfy in order to qualify for an expansion exception request, including criteria concerning inpatient Medicaid admissions. As we understand the comment, the commenter is recommending that we substitute (or additionally consider) a hospital's inpatient Medicaid days as a criterion for granting an exception to the prohibition on facility expansion. The statute does not provide the Secretary discretion to consider inpatient Medicaid days in lieu of the inpatient Medicaid admissions criteria. Similarly, we lack the authority to consider the bed occupancy of specific specialty services, a factor which, even if permissible, would complicate our review of an exception request.

e. Summary of Final Provisions Regarding Supplemental Data Sources

After consideration of the public comments we received on the use of supplemental data sources, we are not finalizing the proposed revisions to § 411.362(c)(2)(ii) and (c)(3)(ii) that would permit physician-owned hospitals to use data from an internal data source other than HCRIS to estimate the percentages of inpatient Medicaid admissions referenced in those sections. Accordingly, we are not finalizing our proposal to add a definition of the term ''internal data source'' under § 411.351. As finalized, § 411.362(c)(2)(ii) and (c)(3)(ii) reflect modifications from our proposal that would have permitted physician-owned hospitals to use data from an external data source to estimate the percentages of inpatient Medicaid admissions referenced in those sections. Specifically, we are revising these sections to require the use of HCRIS data once they are complete and permit the use of data from an external data source only until then. We also are finalizing the definition of ''external data source'' without modification, although we are adding the definition at § 411.362(a), rather than at § 411.351 as proposed. Finally, we are not finalizing the proposed revisions to those sections that would permit physician-owned hospitals to use data from a non-HCRIS data source to determine State average bed capacity, national averaged bed capacity, the requesting physician-owned hospital's average bed occupancy rate, or the State average bed occupancy rate. We provide the following chart of the final provisions to assist the reader.

Regulation	Requirement	Permissible data source(s)	Limitations
§ 411.362(c)(2)(ii)	Estimate the requesting hospital's own annual percentage of inpatient Medicaid admission.	HCRIS, external data source.	An external data source may be used only until such time as the Secretary determines that HCRIS contains sufficiently complete inpatient Medicaid discharge data.
§ 411.362(c)(2)(ii)	Estimate the average percentage with respect to such admissions for all hospitals located in the county in which the requesting hospital is located.	HCRIS, external data source.	An external data source may be used only until such time as the Secretary determines that HCRIS contains sufficiently complete inpatient Medicaid discharge data.
§ 411.362(c)(2)(iv)	Determine the average bed capacity in the State in which the requesting hospital is located.	HCRIS	
§ 411.362(c)(2)(iv)	Determine the national average bed capacity	HCRIS	
§ 411.362(c)(2)(v)	Determine the requesting hospital's own average bed occupancy rate.	HCRIS	
§ 411.362(c)(2)(v)	Determine the average bed occupancy rate for the State in which the requesting hospital is located.	HCRIS	
§ 411.362(c)(3)(ii)	Estimate the requesting hospital's annual percentage of total inpatient admissions under Medicaid for each of the three most recent fiscal years for which data are available.	HCRIS, external data source.	An external data source may be used only until such time as the Secretary determines that HCRIS contains sufficiently complete inpatient Medicaid discharge data.

Regulation	Requirement	Permissible data source(s)	Limitations
§ 411.362(c)(3)(ii)	Estimate the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the requesting hospital is located for each of the three most recent fiscal years for which data are available.	HCRIS, external data source.	An external data source may be used only until such time as the Secretary determines that HCRIS contains sufficiently complete inpatient Medicaid discharge data.

2. Fiscal Year Standard

Section 1877(i)(3)(F) of the Act requires that a high Medicaid facility use data from each of the 3 most recent fiscal years for which data are available. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74518), we stated that we consider the most recent fiscal year for which data are available to be the most recent year for which HCRIS contains data from at least 6,100 hospitals. We currently apply this standard to expansion exception requests for both applicable hospitals and high Medicaid facilities.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41055), we proposed to revise our standard so that the most recent fiscal year for which data are available would be the year for which the data source(s) used in an expansion exception request contain sufficient data to perform the comparisons required under § 411.362(c)(2)(ii), (c)(2)(iv), (c)(2)(v), and (c)(3)(ii). Specifically, we proposed that data sources, either alone or in combination with other data sources, would be considered to contain ''sufficient data'' if they contain all data from the requesting hospital and each hospital to which the requesting hospital must compare itself that are necessary to perform the estimates required in the expansion exception process. In addition, with respect to a hospital seeking an expansion exception as an applicable hospital, we proposed that, in order to be considered to contain ''sufficient data,'' the data sources, either alone or in combination with other data sources, must contain the data necessary to determine the State and national average bed capacity and the average bed occupancy rate in the State in which the requesting hospital is located for purposes of the expansion exception process.

We also proposed to require that data from the same fiscal year be used for the applicable hospital eligibility criteria at § 411.362(c)(2)(ii), (c)(2)(iv) and (c)(2)(v), even if the hospital uses multiple data sources for those criteria. We stated our belief that requiring the use of data from the same fiscal year will ensure consistency and equitability in the expansion exception process. We sought public comments on our proposal to revise the standard that determines the most recent fiscal year(s) for which data are available, as well as other ways to define ''sufficient data'' for purposes of the expansion exception process.

a. Summary of Public Comments and Our Responses Regarding the Fiscal Year Standard

Comment: All of the commenters that addressed this issue supported CMS' proposal to revise the interpretation of the standard ''the most recent fiscal year for which data are available.'' The commenters stated generally that external data sources often have more recent data than the fiscal year for which HCRIS contains data from at least 6,100 hospitals. Two commenters recommended deeming a data source ''sufficient'' and, thus, acceptable for use in an expansion exception request, if it contains all of the information necessary to complete the calculations required to determine eligibility for an exception as a high Medicaid facility or applicable hospital. Another commenter similarly supported the proposal and suggested that CMS consider the sufficiency of data on a case-by-case basis.

Response: We agree with the commenters that recommended that we deem a data source ''sufficient'' and, thus, acceptable for use in an expansion exception request, if it contains all of the information necessary to complete the calculations required to determine eligibility for an exception as a high Medicaid facility or applicable hospital. Although determining the sufficiency of a data source on a case-by-case basis could significantly lengthen the period of time required for a thorough review of an expansion exception request, we believe that evaluating the sufficiency of data on a modified case-by-case basis is nonetheless appropriate, as explained more fully below.

We are adopting separate standards to determine the sufficiency of data sources for the Medicaid inpatient admissions criteria and the bed capacity and occupancy criteria set forth in our regulations. For purposes of the Medicaid inpatient admissions estimates required in § 411.362(c)(2)(ii) and (c)(3)(ii), we are adopting a standard under which we will consider a data source sufficient when it contains data from the requesting hospital and every hospital located in the same county as the requesting hospital. This applies to both external data sources and HCRIS. The statutory criteria at sections 1877(i)(3)(E)(ii) and (i)(3)(F)(ii) of the Act afford no flexibility to make these determinations based on data from fewer than all of the hospitals located in the same county as the requesting hospital. For purposes of the bed capacity and occupancy determinations required in § 411.362(c)(2)(iv) and (c)(2)(v), we will consider HCRIS sufficient for a particular fiscal year on a State-by-State basis, rather than the current ''6,100 hospitals reporting'' standard. Specifically, this final rule with comment period requires a requesting physician-owned hospital to satisfy the bed capacity criterion in § 411.362(c)(2)(iv) during the most recent fiscal year for which HCRIS contains data from a sufficient number of hospitals in the requester's State to determine the State's average bed capacity and a sufficient number of hospitals nationally to determine the national average bed capacity. In addition, this final rule with comment period requires a requesting physician-owned hospital to satisfy the bed occupancy criterion in § 411.362(c)(2)(v) during the most recent fiscal year for which HCRIS contains data from a sufficient number of hospitals in the State to determine the requesting hospital's average bed occupancy rate and the State's average bed occupancy rate. ''Sufficient number'' means that enough hospitals have reported data such that the determinations in § 411.362(c)(2)(iv) and (c)(2)(v) would not materially change after additional hospital data are reported.

We will consult with the CMS Office of the Actuary to determine whether average bed capacity and bed occupancy rates would materially change upon additional hospital reporting. CMS intends to report on its Web site each State's average bed capacity, the national average bed capacity, and each State's average bed occupancy, per fiscal year, as they become available. A

requesting physician-owned hospital may use only the averages posted on the CMS Web site as of the date that the hospital submits its expansion exception request.

We provide the following examples to illustrate the application of the standard applicable to the determinations required in § 411.362(c)(2)(iv) and (c)(2)(v). Assume that, for FY 2013, the requesting hospital is one of 200 Medicare-participating hospitals located in State A. Assume also that, after consultation with the CMS Office of the Actuary, we determine that State A's FY 2013 average bed capacity and bed occupancy rates would not materially change once HCRIS contains data from at least 85 percent of State A hospitals (170 hospitals). Finally, assume that CMS is able to determine the FY 2013 national average bed capacity rate once 5,500 hospitals have reported bed capacity data in HCRIS, and that this rate would not materially change even if the remaining Medicare-participating hospitals reported data in HCRIS. Under the standard adopted in this final rule with comment period, the requesting hospital may use FY 2013 HCRIS data to make the State bed capacity and occupancy determinations required in § 411.362(c)(2)(iv) and (c)(2)(v) once HCRIS contains data from at least 170 of the Medicare-participating hospitals in State A for that fiscal year. The requesting hospital may use FY 2013 HCRIS data to determine the national average bed capacity required in § 411.362(c)(2)(iv) once HCRIS contains data from at least 5,500 Medicare-participating hospitals for that fiscal year.

In contrast, assume that, for FY 2013, there are only 10 Medicare-participating hospitals in State B. Assume also that, after consultation with the CMS Office of the Actuary, we determine that State B's FY 2013 average bed capacity and bed occupancy rates would materially change unless HCRIS contains data from all of State B's hospitals. Thus, a physician-owned hospital located in State B could not use FY 2013 HCRIS data until all 10 Medicare-participating hospitals in State B reported their bed capacity and occupancy data in HCRIS for that fiscal year.

With respect to external data sources, because we recognize that State Medicaid agencies likely will have varying collection time periods that may not line up with the Federal fiscal year end for which HCRIS data are available (for example, calendar year or State fiscal year), we are permitting the use of any 12-month period for the data, provided that all 3 years use the same 12-month cycle. For example, a State Medicaid agency may collect Medicaid inpatient admissions data on a calendar year cycle. A physician-owned hospital requesting an expansion exception as a high Medicaid facility may use calendar years 2013, 2012 and 2011 if the external data source, for each of those years, contains all data from the requesting hospital and every hospital located in the same county as the requesting hospital.

We note that, if the latest year for which HCRIS contained data sufficient to determine the average bed capacity in the State in which the requesting hospital is located and the national bed capacity was FY 2011, but HCRIS contained FY 2012 data sufficient to determine the requesting hospital's own average bed occupancy and the average bed occupancy rate for the State in which the requesting hospital is located, the hospital could use FY 2011 data for the determinations required in § 411.362(c)(2)(iv) and FY 2012 data for the determinations required in § 411.362(c)(2)(v). We recognize that using different years from the same permissible data source to make the estimates or determinations set forth in the criteria for applicable hospitals may require additional review of an expansion exception request by the Secretary. However, in light of our interpretation that each criterion that a physician-owned hospital seeking a facility expansion exception must meet is analyzed separately, we believe that allowing a requesting hospital to use data from 12-month periods that may be different for each criterion will permit use of the most recent data, result in more accurate determinations, and best effectuate the plain meaning of the statutory and regulatory language regarding these criteria.

b. Summary of Final Provisions Regarding the Fiscal Year Standard

After consideration of the public comments we received on the standard regarding the most recent available data, we are finalizing our proposals with several modifications. For purposes of the estimates required in § 411.362(c)(2)(ii) and (c)(3)(ii), the most recent 12-month period for which data are available is the most recent 12-month period for which the data source used contains all data from the requesting hospital and each hospital to which the requesting hospital must compare itself. For purposes of the determinations required in § 411.362(c)(2)(iv), we require a requesting physician-owned hospital to satisfy the criterion during the most recent fiscal year for which HCRIS contains data from a sufficient number of hospitals to determine the relevant State's average bed capacity and the national average bed capacity. For purposes of the determinations required in § 411.362 (c)(2)(v), we require a requesting physician-owned hospital to satisfy the criterion during the most recent fiscal year for which HCRIS contains data from a sufficient number of hospitals to determine the requesting hospital's average bed occupancy rate and the relevant State's average bed occupancy rate. Because we are continuing to require the use of HCRIS data for the determinations required in § 411.362(c)(2)(iv) and (c)(2)(v), we believe that this bifurcated approach is necessary.

Finally, we note that we analyze each estimate or determination required under § 411.362(c)(2) separately. We interpret the statute and our regulations to allow the use of different time periods for each estimate or determination, provided that the data source (or time period) used to perform the necessary calculation contains: (1) for purposes of § 411.362(c)(2)(ii) and (c)(3)(ii), all data from the requesting hospital and each hospital to which the requesting hospital must compare itself; (2) for purposes of § 411.362(c)(2)(iv), data from a sufficient number of hospitals to determine the relevant State's average bed capacity and the national average bed capacity; and (3) for purposes of § 411.362(c)(2)(v), data from a sufficient number of hospitals to determine the requesting hospital's average bed occupancy rate and the relevant State's average bed occupancy rate, respectively. CMS will continue to determine and make available on its Web site State bed capacity and occupancy rates and the national average bed capacity rate. ''Sufficient number'' means that enough hospitals have reported data such that the determinations in § 411.362(c)(2)(iv) and (c)(2)(v) would not materially change even if data that may be missing from comparison hospitals were included.

3. Community Input and Timing of a Complete Request

In the CY 2015 OPPS/ASC proposed rule (79 FR 41055 through 41056), we proposed to require that a physician-owned hospital requesting an expansion exception provide actual notification directly to hospitals whose data are part of the comparisons set forth under § 411.362(c)(2)(ii) and (c)(3)(ii) of the regulations. Under proposed § 411.362(c)(5), the notification must be in writing, in either electronic or hard copy form, and must be provided at the same time that the hospital discloses on

any public Web site for the hospital that it is requesting an exception. We stated in the proposed rule that we believe that this additional safeguard would ensure that comparison hospitals are aware of the opportunity to confirm or dispute the accuracy or reliability of the data in the physician-owned hospital's request.

Our existing regulations at § 411.362(c)(5) set forth the process for community input and the timing of a complete expansion exception request. These regulations provide for a 30-day comment period following publication in the **Federal Register** of notice of the physician-owned hospital's expansion exception request and a 30-day rebuttal period for the requesting hospital to respond, if it chooses, to any written comments that CMS receives from the community. Currently, an expansion exception request is considered complete at the end of the 30-day comment period if CMS does not receive written comments from the community. If CMS receives written comments from the community, the request is considered complete at the end of the 30-day rebuttal period, regardless of whether the requesting hospital submits a rebuttal statement.

In the proposed rule, we explained that permitting the use of non-HCRIS data in an expansion exception request would likely require additional time for our review of the request, including any comments submitted with respect to the request. Therefore, we proposed to revise our regulations at § 411.362(c)(5) to extend the date by which certain expansion exception requests will be deemed complete. Specifically, we proposed to revise § 411.362(c)(5) to provide that, where the request, any written comments, and any rebuttal statement include only HCRIS data, the current timeframes would apply. That is, such an expansion exception request would be deemed complete no later than: (1) The end of the 30-day comment period if no written comments from the community are received; and (2) the end of the 30-day rebuttal period if written comments from the community are received, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement. We also proposed that, where the request, any written comments, or a rebuttal statement includes data from a supplemental data source, an expansion exception request would be deemed complete no later than: (1) 180 days after the end of the 30-day comment period if no written comments from the community are received; and (2) 180 days after the end of the 30-day rebuttal period if written comments from the community are received, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement.

a. Summary of Public Comments and Our Responses Regarding Community Input and Timing of a Complete Request

Comment: Some commenters encouraged CMS not to finalize the actual notification requirement, stating that it would impose a burden (both procedural and financial) on the requesting hospital or could lead to an increase in comments regarding each request and the complexity of those comments. One commenter stated that requiring actual notification to other hospitals located in the same county as the requesting hospital goes beyond the intent of the Congress in enacting this provision of the Affordable Care Act.

Response: We believe that an actual notification requirement is important to ensure that comparison hospitals are aware of the opportunity to confirm or dispute the accuracy or reliability of the data in the physician-owned hospital's request, and that any burden on the requesting hospital is outweighed by the facilitation of robust community input that can help inform the Secretary's review of an expansion exception request. We believe that thorough vetting of all relevant information, both from the requesting hospital and the community in which the hospital is located, in fact, was the intent of the Congress. We disagree with the commenter that stated that this requirement goes beyond the congressional intent or our statutory authority.

Comment: One commenter opposed CMS' proposal to deem an expansion exception request that relies on a non-HCRIS data source complete no later than 180 days after the end of the 30-day comment period if no written comments from the community are received, and 180 days after the end of the 30-day rebuttal period if written comments from the community are received, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement. The commenter stated that the additional time beyond the 30-day period provided for in our existing regulations is particularly unnecessary if the requesting hospital uses inpatient admissions data from a State Medicaid agency that shows the percentage of Medicaid admissions for all of the hospitals operating in the same county as the requesting hospital.

Response: The purpose of our proposed policy extending the timeframe for deeming complete an expansion exception request where the request itself, any community input, or any rebuttal statement includes non-HCRIS data is to provide CMS with sufficient time to address any potential conflicts between data presented by the requesting hospital and data or other information presented by a commenter or in the possession of CMS. As we noted in the CY 2012 OPPS/ASC final rule with comment period, the limitations on data sources that may be used in a physician-owned hospital's expansion exception request do not apply to members of the community or to CMS (76 FR 74522). Therefore, it is possible (if not likely) that, when reviewing an expansion exception request, CMS would need to verify the data (and other information, if any) provided by the requesting hospital and any commenters, as well as consider the data in light of the information otherwise available to CMS. This review could involve the use of internal experts or contractors, which will require additional time. We note that the timeframe for deeming an expansion exception request complete will be ''no later than'' 180 days after the end of the 30-day comment period (if no written comments from the community are received) and 180 days after the end of the 30-day rebuttal period (if written comments from the community are received) does not preclude an earlier timeframe where the information submitted by the requesting hospital does not conflict with any community input or information otherwise available to CMS.

b. Final Provisions Regarding Community Input and Timing of a Complete Request

After consideration of the public comments we received on community input and timing of a complete response, we are finalizing our proposal, without modification, recognizing that, under this final rule with comment period, the only permissible supplemental data sources are external data sources, as defined in this final rule with comment period at § 411.362.

D. Additional Considerations

We recognize the importance of an accurate and consistent expansion exception process. We stated in the CY 2015 OPPS/ASC proposed rule (79 FR 41056) that we are aware that data sources have unique characteristics due to their inputs, collection methods, compilation, and other factors, and that we would take this into consideration if we finalized our proposal to permit the use of supplemental data sources. In an effort to implement an accurate and consistent expansion exception process,

we solicited comments on the utility, appropriateness, and limitations of our proposal to permit the use of supplemental data sources. Specifically, we sought comments that:

- Address whether permitting the use of supplemental internal or external data sources would significantly affect the outcomes for any of the estimates or determinations required in our regulations.
- Address whether permitting the use of supplemental data sources would materially affect a physician-owned hospital's ability to request an exception or CMS' determination on an exception request.
- Describe the length of time that would be necessary to obtain or generate the required data from a specific data source.
- Address whether and when the data will be available and accessible per fiscal year.
- Address whether the data will be available and accessible in a format that enables the requesting hospital to perform the necessary comparisons.
- Describe how supplemental data sources could or should be prioritized, including, but not limited to, rankings related to accuracy or reliability.
- Describe how data from a particular data source could be used in the expansion exception process. We encouraged commenters to specify whether a particular data source already maintains the percentages or rates required, or whether calculations will be necessary to generate the required percentages or rates. If calculations will be necessary, we requested that commenters describe the calculations.
- Describe the cost to industry stakeholders, State governments, and the Federal government for obtaining or generating data from any potential data sources. We consider cost to include both resources (for example, human capital and information technology) and actual financial burden (for example, fees to use or purchase the data).

We also solicited comments on whether any additional burdens would affect the quality of care for beneficiaries as a result of additional costs borne by a requesting hospital.

We note that our inquiries were limited to solicitations of comments intended to inform our decision making regarding our actual proposals and, therefore, do not require a response in this final rule with comment period. However, we have chosen to summarize and respond to the comments that addressed ranking or prioritizing data sources and types of data because we believe discussion of these issues helps clarify how our revisions to the expansion exception process that we are finalizing will be implemented.

Comment: A few commenters who addressed the additional considerations set forth in the proposed rule discussed ranking or prioritizing permitted data sources. One commenter recommended that CMS not prioritize or rank additional data sources, given that access to supplemental data sources will vary based on the hospital seeking the exception. Another commenter suggested that CMS give the highest priority to admissions data from State Medicaid agencies for the inpatient Medicaid admissions criteria. The commenter stated that the State in which the commenter is located provides an unbiased, reliable, single source of inpatient Medicaid admissions percentages that would eliminate the need for independent calculations by the requesting hospital and individuals and entities in the community in which the hospital is located. The commenter further suggested that if actual admissions data are unavailable through the State Medicaid agency, CMS permit the use of other data, including estimates of Medicaid admissions based on discharges using supplemental data.

Response: We share the concerns of the commenters that noted that the external data sources available to requesting hospitals will vary from State to State. We also believe that the quality and completeness of the external data sources available to requesting hospitals will vary in the same manner. We further note the complexity involved in making a generally applicable policy as to how to rank or prioritize various data sources. Therefore, we decline to provide guidance regarding the rank or prioritization of potentially available data sources for use in the expansion exception process. Our goal remains to ensure a fair, accurate, and consistent process to implement section 6001 of the Affordable Care Act. As discussed elsewhere in this preamble, each expansion exception request will be considered on a case-by-case basis. The Secretary will consider only reliable, credible information to determine whether a requesting physician-owned hospital qualifies for an exception to the facility expansion prohibition.

E. Summary of the Final Provisions Regarding the Expansion Exception Process Under the Rural Provider and Hospital Ownership Exceptions to the Physician Self-Referral Law

In this final rule with comment period, we are finalizing the following policies related to the expansion exception process for physician-owned hospitals:

- We are permitting the use of external data sources to estimate a physician-owned hospital's annual percentage of inpatient admissions under Medicaid (§ 411.362(c)(2)(ii) and (c)(3)(ii)), the average percentage of inpatient admissions under Medicaid of all hospitals in the county in which a physician-owned hospital requesting an expansion exception as an ''applicable hospital'' is located (§ 411.362(c)(2)(ii)), and the annual percentage of inpatient admissions under Medicaid of any other hospital in the county in which a physician-owned hospital requesting an expansion exception as a ''high Medicaid facility'' is located (§ 411.362(c)(3)(ii)). However, on or after such date that the Secretary determines that HCRIS contains sufficiently complete inpatient Medicaid discharge data, a hospital may use only filed Medicare hospital cost report data to estimate the percentages of inpatient Medicaid admissions referenced in § 411.362(c)(2)(ii) and (c)(3)(ii).
- We are defining ''external data source'' at § 411.362 to mean a data source that (1) is generated, maintained, or under the control of a State Medicaid agency; (2) is reliable and transparent; (3) maintains data that, for purposes of the process described in § 411.362(c), are readily available and accessible to the requesting hospital, comparison hospitals, and CMS; and (4) maintains or generates data that, for purposes of the process described in § 411.362(c), are accurate, complete, and objectively verifiable. We are not finalizing our proposed definition of ''internal data source.''
- For purposes of § 411.362(c)(2)(ii) and (c)(3)(ii), we are interpreting the most recent 12-month period for which data are available as the most recent 12-month period for which the data source used contains all data from the requesting hospital and each hospital to which the requesting hospital must compare itself.
- For purposes of the determinations required in § 411.362(c)(2)(iv), we require a requesting physician-owned hospital to satisfy the criterion during the most recent fiscal year for which HCRIS contains data from a sufficient number of hospitals to determine a State's average bed capacity and the national average bed capacity. For purposes of the determinations required in § 411.362 (c)(2)(v), we require a requesting physician-owned hospital to satisfy the criterion during the most recent fiscal year for which HCRIS contains data from a sufficient number of hospitals to determine the requesting hospital's average bed occupancy rate and the relevant State's average bed

occupancy rate. ''Sufficient number of hospitals'' means in this final rule with comment period that enough hospitals have reported data such that the determinations in § 411.362(c)(2)(iv) and (c)(2)(v) would not materially change even if data that may be missing from comparison hospitals were included.

- Where the request, any written comments, and any rebuttal statement include only HCRIS data, we will consider a request for an expansion exception complete no later than: (1) The end of the 30-day comment period if no written comments from the community are received; and (2) the end of the 30-day rebuttal period if written comments from the community are received, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement (§ 411.362(c)(5)(i)).
- Where the request, any written comments, or any rebuttal statement include data from an external data source (as defined in this final rule with comment period), we will consider a request for an expansion exception complete no later than: (1) 180 days after the end of the 30-day comment period if no written comments from the community are received; and (2) 180 days after the end of the 30-day rebuttal period if written comments from the community are received, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement (§ 411.362(c)(5)(ii)).

We are not finalizing our proposal to revise the bed capacity and bed occupancy criteria at § 411.362(c)(2)(iv) and (c)(2)(v) to permit the use of non-HCRIS data sources. However, we are revising §§ 411.362(c)(2)(iv) and (c)(2)(v) to clarify the fiscal year periods that requesting hospitals must use to make the determinations required in those sections.

XVI. Revision of the Requirements for Physician Certification of Hospital Inpatient Services Other Than Psychiatric Inpatient Services

In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27644 through 27650), we discussed the statutory requirement for certification of hospital inpatient services for payment under Medicare Part A. The certification requirement for inpatient services other than psychiatric inpatient services is found in section 1814(a)(3) of the Act, which provides that Medicare Part A payment will only be made for such services ''which are furnished over a period of time, [if] a physician certifies that such services are required to be given on an inpatient basis.''

As discussed in the CY 2015 OPPS/ASC proposed rule (79 FR 41056 through 41058), in commenting on our FY 2014 proposal mentioned above, some commenters argued that the statutory reference to services furnished ''over a period of time'' and the then-existing regulation's lack of any specific deadline for physician certifications in nonoutlier cases indicated that no certification was required for short-stay cases. In support of their argument, the commenters cited the legislative history of section 1814(a)(3) of the Act, which these commenters interpreted as indicating that the certification requirements should apply only to certain long-term stays.

As we indicated in our response to these public comments in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50939), we do not agree with the assertion that the only possible interpretation of the statute is that the requirement for physician certification only applies to long-stay cases. The statute does not define ''over a period of time,'' and further provides that ''such certification shall be furnished only in such cases, and with such frequency, and accompanied by such supporting material . . . as may be provided by regulations.'' By this language, Congress explicitly delegated authority to the agency to elucidate this provision of the statute by regulation.

In our previous regulations, we interpreted the statute's requirement of a physician certification for inpatient hospital services furnished ''over a period of time'' to apply to all inpatient admissions. While this is not the only possible interpretation of the statute, we believe that it is a permissible interpretation.

We continue to believe that an order from a physician or other qualified practitioner in order to trigger an inpatient hospital admission as specified in 42 CFR 412.3 is necessary for all inpatient admissions. As described more fully in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50938 through 50954), the requirement for a physician order for a hospital inpatient admission has long been clear in the Medicare hospital conditions of participation (CoPs), and we promulgated § 412.3 to make more explicit that admission pursuant to this order is the means whereby a beneficiary becomes a hospital inpatient and, therefore, is required for payment of hospital inpatient services under Medicare Part A. A beneficiary becomes a hospital inpatient when admitted as such after a physician (or other qualified practitioner as provided in the regulations) orders inpatient admission in accordance with the CoPs, and Medicare pays under Part A for such an admission if the order is documented in the medical record. The order must be supported by objective medical information for purposes of the Part A payment determinations. Thus, the physician order must be present in the medical record and be supported by the physician admission and progress notes in order for the hospital to be paid for hospital inpatient services.

As further noted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50938 through 50954), we believe the additional certification requirements now specified under § 424.13(a)(2), (a)(3), and (a)(4) (that is, the reason for hospitalization, the estimated time the patient will need to remain in the hospital, and the plan of posthospital care, if applicable) generally can be satisfied by elements routinely found in a patient's medical record, such as progress notes.

However, as we look to achieve our policy goals with the minimum administrative requirements necessary, and after considering previous public comments and our experience with our existing regulations, we believe that, in the majority of cases, the additional benefits (for example, as a program safeguard) of formally requiring a physician certification may not outweigh the associated administrative requirements placed on hospitals. Because we continue to believe that an inpatient admission order is necessary for all inpatient admissions, we proposed in the CY 2015 OPPS/ASC proposed rule (79 FR 41057) to require such orders as a condition of payment based upon our general rulemaking authority under section 1871 of the Act rather than as an element of the physician certification under section 1814(a)(3) of the Act. Section 1871 of the Act authorizes the Secretary to ''prescribe such regulations as may be necessary to carry out the administration of the insurance programs under [Title XVIII].'' A clear regulatory definition of when and how a beneficiary becomes an inpatient is necessary to carry out the administration of Medicare Part A. Section 1861(b) of the Act defines ''inpatient hospital services'' as certain items and services furnished to ''an inpatient of a hospital,'' but does not define ''an inpatient of a hospital.'' Accordingly, § 412.3 provides the necessary definition for purposes of Medicare Part A payment by clarifying when ''an individual is considered an inpatient of a hospital, including a critical access hospital.'' We proposed to remove paragraph (c) from § 412.3. As

we proposed to rely on a different statutory authority for such regulation, we proposed that an admission order would no longer be a required component of physician certification of medical necessity.

As to the physician certification requirement, we maintain that our prior longstanding policy was based upon a permissible interpretation of section 1814(a)(3) of the Act pursuant to that provision's express delegation of authority to the agency to determine the circumstances under which such certification should be required. Nonetheless, after consideration of public feedback, our experience under the then-existing regulations, and our policy goals, in the CY 2015 OPPS/ASC proposed rule (79 FR 41057), we proposed to change our interpretation of section 1814(a)(3) of the Act to require a physician certification only for long-stay cases and outlier cases.

As noted above, we believe that, in most cases, the admission order, medical record, and progress notes will contain sufficient information to support the medical necessity of an inpatient admission without a separate requirement of an additional, formal, physician certification. However, we believe that evidence of additional review and documentation by a treating physician beyond the admission order is necessary to substantiate the continued medical necessity of long or costly inpatient stays. While granting the Secretary broad discretion to determine the circumstances under which a physician certification should be required, the statute specifies that the certification by a physician with respect to inpatient hospital services (other than inpatient psychiatric hospital services) ''shall be furnished no later than the 20th day'' of the stay. Because the statute specifically requires that certification must occur no later than the 20th day, we believe that, at a minimum, Congress intended that physicians should conduct a more thorough review of such cases to help ensure that all requirements of medical necessity continue to be met. We also note the regulations at § 424.13(f)(2) specify our longstanding requirement that the physician certification for cost outlier cases occur no later than 20 days into the hospital stay, and we did not propose to change the requirements for these cases. Therefore, we believe that, for nonoutlier cases, 20 days is also an appropriate minimum threshold for the physician certification, and we proposed to define long-stay cases as cases with stays of 20 days or longer.

Specifically, in the CY 2015 OPPS/ASC proposed rule (79 FR 41057), we proposed to revise paragraph (a) of § 424.13 to specify that Medicare Part A pays for inpatient hospital services (other than inpatient psychiatric facility services) for cases that are 20 inpatient days or more, or are outlier cases under subpart F of Part 412 of this chapter, only if a physician certifies or recertifies the following:

(1) The reasons for either—

(i) Continued hospitalization of the patient for medical treatment or medically required diagnostic study; or (We note that, in setting out the corresponding regulation text for this provision in the proposed rule (79 FR 41083), we inadvertently omitted the word ''Continued'' at the beginning of this paragraph (a)(1)(i). We are making a conforming correction in this final rule with comment period. We do not believe that this conforming correction results in any substantive change in policy.)

(ii) Special or unusual services for cost outlier cases (under the prospective payment system set forth in subpart F of Part 412 of this chapter).

(2) The estimated time the patient will need to remain in the hospital.

(3) The plans for posthospital care, if appropriate.

We also proposed to revise paragraph (b) of § 424.13 to specify that certifications for long-stay cases must be furnished no later than 20 days into the hospital stay.

Because the care furnished in inpatient psychiatric facilities is often purely custodial and therefore not covered under Medicare and because the primary purpose of the certification of these cases is to help ensure that Medicare pays only for services of the type appropriate for Medicare coverage, we did not propose changes to the certification requirements for inpatient psychiatric hospital services.

As discussed more fully in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50942 through 50943), there also are inherent differences in the operation of and beneficiary admission to IRFs. Therefore, we also did not propose any changes to the admission requirements for IRFs.

We invited public comment on these proposals. Summaries of the public comments we received and our responses to those public comments are set forth below.

Comment: Most commenters were supportive of the proposal to eliminate physician certification requirements for the majority of inpatient cases (other than long stay and cost outlier cases). Many commenters stated that the proposal would improve efficiency and would reduce the overall administrative burden on hospitals. Several commenters stated that the proposal would resolve ongoing issues within hospitals wherein certain practitioners routinely and appropriately admit patients, but are unable to complete the certification requirement because they do not meet the statutory definition of a physician. The commenters indicated that, because these cases rarely exceed 20 days, and do not typically exceed outlier thresholds, these practitioners would not be required to seek approval from a physician to complete a physician certification statement.

Response: We thank the commenters for their support of our proposal to apply certification requirements at § 424.13 only to long-stay and outlier cases. We agree that our proposal would reduce administrative burden in general, and in particular would reduce the administrative burden associated with the majority of cases involving an admission order issued by a practitioner qualified to issue the order but who did not meet the statutory definition of a physician and therefore could not certify the case.

Comment: Several commenters, while appreciative of the proposal to limit physician certification requirements, continued to disagree that CMS has the statutory authority to require signed admission orders for all inpatient cases. The commenters contended that CMS cannot use its general rulemaking authority under section 1871 of the Act to require a signed physician order for every inpatient admission. These commenters argued that that the continued requirement for admission orders is essentially the same as the certification requirement and stated that section 1814(a)(2) of the Act is explicit in requiring physician certification only for services ''furnished over a period of time'' and not for all services.

Response: We disagree with these commenters. While the inpatient admission order was a required component of the physician certification under our previous policy, the order and the physician certification do not serve identical policy goals under our proposal, which we are now finalizing. For all cases, a properly authorized and documented admission order is necessary because the admission order is integral to a clear regulatory definition of when and how a beneficiary becomes an inpatient. Such a definition is necessary to carry out the administration of Medicare Part A because, as noted previously, section 1861(b) of the Act defines ''inpatient hospital services'' as certain items and services furnished to ''an inpatient of a hospital,'' but does not define ''an

inpatient of a hospital.'' Accordingly, for all cases, our admission order requirements at § 412.3 provide the necessary definition for purposes of Medicare Part A payment by clarifying when ''an individual is considered an inpatient of a hospital, including a critical access hospital.'' The development of admission order requirements is a necessary and appropriate use of our general rulemaking authority under section 1871 of the Act.

In most cases, the admission order, along with the medical record and progress notes, may also provide sufficient information to support the medical necessity of an inpatient admission without the separate requirement of an additional, formal, physician certification. However, for long or very costly inpatient stays, we believe that additional review and documentation by a treating physician are necessary to help substantiate the continued medical necessity of such stays, and a physician certification provides evidence of such additional review. The fact that we have determined, in the majority of cases, that the additional benefits (for example, as a program safeguard) of formally requiring a physician certification do not outweigh the associated administrative requirements placed on hospitals in no way changes the necessity and appropriateness of requiring a signed admission order for all cases.

Comment: Some commenters requested that CMS require the admission order to be signed by the time of billing, not before discharge, as is permitted for CAH certification requirements. The commenters cited the administrative burden and logistical challenges involved with CMS' requirements.

Response: We believe that, in most cases, matters relating to the determination of patient status should be resolved before discharge, due to the consequences that flow from such a determination. For example, whether services are billed under Medicare Part A or Part B can have a significant impact on a beneficiary's financial liability. Therefore, we do not believe it is appropriate to change our existing policy which requires that inpatient orders be signed prior to discharge by a practitioner familiar with the case and authorized by the hospital to admit inpatients.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50163 through 50165), we did finalize a provision to allow CAHs to complete certification requirements (including completion of the admission order) no later than 1 day before the date on which the claim for payment is submitted as they had been allowed to do prior to FY 2014. However, this policy exists in part to provide CAHs with greater flexibility in meeting certification requirements unique to CAHs. For example, CAHs face a statutory requirement that a physician certify that a patient will be expected to be transferred or discharged within 96 hours of admission. We do not believe it would be appropriate to apply this historical CAH policy more broadly to hospitals that do not face the same circumstances as CAHs.

Comment: Several commenters requested that CMS provide additional guidance regarding the required content and format of the physician certification statement. Some commenters asked that CMS confirm that the policy requiring physician certification only for long-stay and outlier cases did not otherwise alter the inpatient hospital admission guidelines discussed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50944 through 50953). Others commenters requested general guidance and clarification regarding CMS policies in this area.

Response: As discussed previously in the section, the physician certification requirements at § 424.13 generally may be satisfied by elements routinely found in a patient's medical record, such as progress notes. CMS does not require that a physician certification comply with a specific standard or format—only that it ensures that the conditions at § 424.13(a) were met. If the medical record adequately describes the reasons for continued hospitalization, the estimated time the patient is expected to require inpatient care, and discharge planning (where appropriate), and the medical record is signed by a physician involved with and responsible for the patient's care, this would satisfy certification requirements.

Our proposed policy change regarding the physician certification requirements does not change unrelated requirements implemented in the FY 2014 IPPS/LTCH PPS final rule such as the requirements related to the 2-midnight policy. It also does not alter or remove any requirements for hospitals regarding admission orders.

We are committed to continuing to work closely with and provide outreach to stakeholders regarding inpatient admission policies and certification requirements.

Comment: Some commenters requested that CMS provide guidance on how MACs will review cases in the interim time period between publication of this final rule and the effective date of the regulation changes (January 1, 2015).

Response: Since the effective date of the FY 2014 IPPS/LTCH PPS final rule, we have worked closely with the MACs to ensure that the 2-midnight policy and related certification requirements are applied appropriately. As discussed previously, we believe that physician certification requirements for a high percentage of inpatient stays can be readily satisfied by elements routinely found in the medical record. Hospitals need to comply with all existing certification requirements until the finalized policy changes in this final rule with comment period go into effect on January 1, 2015. We are committed to continue to work with the MACs to prioritize medical review cases.

In summary, after consideration of the public comments we received, we continue to believe our certification proposal satisfies our policy goals while reducing the administrative burden on hospitals. Therefore, we are finalizing the policy as proposed in the CY 2015 OPPS/ASC proposed rule, which limits the requirement for physician certification to long-stay (20 days or longer) and outlier cases. We are finalizing our proposed revisions of paragraph (a) of § 424.13, with one minor modification. We are adding the word ''Continued'' at the beginning of paragraph (a)(1)(i), which we inadvertently omitted when we set out the regulation text in the proposed rule. We note that the preamble discussion in the proposed rule included this word (79 FR 41057), as discussed earlier. We also are finalizing our proposed revision of paragraph (b) of § 424.13, without modification, to specify that certifications for long-stay cases must be furnished no later than 20 days into the hospital stay.

XVII. CMS-Identified Overpayments Associated With Payment Data Submitted by Medicare Advantage (MA) Organizations and Medicare Part D Sponsors (§§ 422.330 and 423.352)

A. Background

Medicare Part C and Part D payments to Medicare Advantage (MA) organizations and Part D sponsors are determined, in part, using data submitted to CMS by the MA organizations and Part D sponsors. These ''payment data'' include diagnosis data that are used by CMS to risk adjust Part C and Part D payments, Prescription Drug Event (PDE) data that are used by CMS to cost reconcile various Part D subsidies, as well as other types of data discussed below. MA organizations and Part D sponsors are

obliged to submit accurate, complete, and truthful payment-related data, as described in regulations at 42 CFR 422.504(l) and 423.505(k). Through our review and oversight of payment data submitted by MA organizations and Part D sponsors, CMS identifies situations where MA organizations and/or Part D sponsors have submitted payment data to CMS that should not have been submitted either because the data submitted are inaccurate or because the data are inconsistent with Part C and Part D requirements. (Throughout this section, we refer to these data submissions as ''erroneous payment data.'') If an MA organization or Part D sponsor submits erroneous payment data to CMS, the MA organization or Part D sponsor can address errors by submitting corrected data to CMS payment systems. Our approach thus far to these types of situations has been to request that MA organizations and Part D sponsors make these data corrections voluntarily.

However, in instances where the MA organization or Part D sponsor fails to make the requested data correction, the payment amount for the plan, calculated using that erroneous payment data, may also be incorrect. As a result, we have concluded that CMS needs to establish a formal process that allows us to recoup overpayments that result from the submission of erroneous payment data by an MA organization or Part D sponsor in the limited circumstances when the organization fails to correct those data. We emphasize that, in our experience, the circumstance where an MA organization or Part D sponsor fails to correct identified erroneous payment data arises very infrequently.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41058 through 41063), we proposed a new process that is not intended to replace established recovery and appeals processes such as the Risk Adjustment Data Validation (RADV) audit dispute and appeal process described at 42 CFR 422.311 or the Part D payment appeals process described at 42 CFR 423.350. We stated that this proposed process would not constitute a change to the existing Part C or Part D payment methodologies. Rather, we merely proposed to adopt a procedural mechanism for recouping overpayments that CMS will use in those limited circumstances when an MA organization or Part D sponsor fails to correct erroneous payment data after notice and request from CMS to do so. The established recovery and appeals processes do not support this scenario. Section 1856(b) of the Act establishes authority for CMS to add standards for Part C and MA organizations. Section 1853 of the Act for Part C and sections 1860D–14 and 1860D–15 of the Act for Part D establish the methodology for computing payments to MA organizations and Part D sponsors, respectively. We believe that inherent in the methodology under which we calculate payments to MA organizations and Part D sponsors is the authority for CMS to establish a process for identifying and recouping overpayments in order to ensure that payments are made consistent with the payment framework established in the statute. Therefore, we proposed to implement such a process through changes to our regulations.

1. Medicare Part C Payment Background

For Medicare Part C, CMS makes prospective monthly payments to MA organizations for each enrollee in the plan. CMS' monthly Part C payment for each MA plan enrollee consists of two components: the capitated payment for each enrollee (calculated as the plan-specific county payment rate multiplied by the enrollee risk score), plus the plan rebate amount (if any). The plan-specific county rates and the plan rebate amount are based on the bid approved by CMS and are set in advance for a payment year. In addition, payment rates may be adjusted for enrollees with end-stage renal disease, enrollees in Medical Savings Account MA plans, and enrollees in religious fraternal benefit society MA plans under § 422.304. Prospective payments are made during the year, subject to a reconciliation after the end of the year.

CMS adjusts the plan-specific county payment rate for each enrollee based on an enrollee risk score. Enrollee risk scores are determined using the CMS-Hierarchical Condition Category (CMS–HCC) risk adjustment model in effect for the payment year, plan-submitted diagnoses for the data collection year, and other data that CMS determines to be appropriate to perform risk adjustment. The CMS–HCC model is prospective in that it uses diagnosis information from a base year (data collection year) to adjust payments for the next year (payment year or coverage year). For example, the risk adjustment model uses diagnosis data from 2013 to adjust payments to MA organizations for coverage in 2014.

To determine the appropriate risk score for each beneficiary, CMS uses demographic characteristics of beneficiaries and diagnostic information gathered in the administration of Original Medicare and submitted by MA organizations. MA organizations are currently required to submit an occurrence of an HCC model-relevant diagnosis only once during the data collection year, even though a beneficiary may have several service dates in a data collection year associated with a given diagnosis. The minimum data elements currently collected from MA organizations under § 422.310 are: Health Insurance Claim (HIC) Number; provider type (hospital inpatient, hospital outpatient, or physician); service from date; service through date; and ICD–9 codes at the level of specificity used by the HCC model. In addition, effective January 2012, CMS collects more detailed Part C utilization and cost data from MA organizations (often referred to as encounter data), that will be used in setting risk scores.

CMS allows 13 months after the end of a data collection year for MA organizations to update the risk adjustment data submitted under § 422.310; this period provides MA organizations an opportunity to identify and correct errors in data they have submitted for that data collection year (that is, by deleting diagnoses from CMS' systems) and to identify and submit additional diagnoses not submitted during the data collection year. During this 13-month period, CMS uses the diagnosis data that MA organizations have submitted up to that point to calculate interim beneficiary risk scores for adjusting prospective payments made during the payment year. The end of this 13-month period is called the final risk adjustment data submission deadline (§ 422.310(g)(2)(ii)).

For each payment year, we apply three sets of risk scores to adjust payments: initial and midyear risk scores during the payment year (both sets are based on incomplete diagnosis data from the data collection year) and final risk scores after the payment year using data MA organizations submitted as of the final deadline for risk adjustment data (which reflect complete data for the data collection year). During the year, CMS makes monthly prospective payments to MA organizations based on enrollment information and using interim risk scores calculated based on the data available before the final risk adjustment data submission deadline. CMS calculates the preliminary risk scores before the first payment is made (that is, for January of the payment year) and again in the middle of the payment year; an interim reconciliation is made so that the prospective payments to MA organizations are based on the most recent risk score available for each enrollee.

After the final risk adjustment data submission deadline, CMS conducts a

reconciliation, in which the prospective Part C payments made during the coverage year based on interim risk scores are compared to Part C payments recalculated using final risk scores and the latest enrollment data. While changes in enrollment data are updated every month by CMS' systems during the payment year (for example, disenrollments from MA organizations and dates of death from the Social Security Administration (SSA)), risk adjustment data are not finalized until the final risk adjustment data submission deadline.

We note that after the deadline for submission of final risk adjustment data, MA organizations are allowed to submit corrected diagnosis data to correct overpayments they received from CMS. However, after this deadline, MA organizations are not allowed to submit diagnosis codes for additional payment, as specified in § 422.310(g)(2)(ii); this provision was recently adopted in the final rule entitled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 29843). When such corrections are submitted, CMS conducts another reconciliation to correct the payments made to the MA organization using the established payment adjustment process. In addition, under § 422.311, CMS conducts Risk Adjustment Data Validation (RADV) audits of the risk adjustment data submitted by MA organizations pursuant to § 422.310. Such RADV audits are conducted at the MA organization contract level and are designed to calculate a contract–level error rate and payment adjustment amount for a specific payment year under audit.

2. Medicare Part D Payment Background

For Medicare Part D, the Medicare Prescription Drug Benefit, Improvement, and Modernization Act (MMA), which amended the Act by adding Part D under Title 18, provides four payment mechanisms: direct subsidy (codified at § 423.329(a)); reinsurance subsidy (codified at § 423.329(c)); low-income subsidy (codified at §§ 423.780 and 423.782); and risk sharing (codified at § 423.336(b)). As a condition of payment, section 1860D–15(d)(2)(A) of the Act requires that Part D sponsors submit data and information necessary for CMS to carry out those payment provisions. Part D sponsors submit PDE data, direct and indirect remuneration (DIR) data and risk adjustment data to CMS for payment purposes.

Throughout the coverage year, CMS makes prospective payments to Part D sponsors that cover three subsidies: the direct subsidy; the low-income cost-sharing subsidy; and the reinsurance subsidy. The payment amounts are based on information in the approved basic bid and on data received by CMS that are used to update payments throughout the year. Following the end of the coverage year, the prospective payments are reconciled against the actual costs of the Part D sponsor. Reconciliation of the low-income cost-sharing subsidy and reinsurance and the calculation of risk sharing are based on PDE and DIR data submitted by the Part D sponsor, as well as data captured from other CMS systems. CMS instructs Part D sponsors that they should continually monitor their submitted data throughout the year in order to ensure that the reconciliation and final payment determinations are accurate.

The final Part D payment determination may be reopened and revised at CMS discretion under § 423.346. In our final rule, ''Medicare Program; Medicare Prescription Drug Benefit'' published in the **Federal Register** on January 28, 2005 (70 FR 4194), we stated that including the Medicare Part D reopening provision at § 423.346 would ''ensure that the discovery of any overpayment or underpayments could be rectified'' (70 FR 4316). However, this is only possible to the extent that the data submitted by Part D sponsors are accurate. Accordingly, prior to making a payment determination for a coverage year, either through a reconciliation described at § 423.343 or a reopening described at § 423.346, CMS periodically makes requests that Part D sponsors correct payment data that do not comply with program requirements (that is, what we have defined as ''erroneous payment data''). These may be general requests to all Part D sponsors to look for a type of payment issue (see for example, the Health Plan Management System (HPMS) memorandum, ''Correcting Missing, Invalid, and Inactive Prescriber Identifiers on 2012 Prescription Drug Event (PDE) Records,'' dated February 4, 2013.) or targeted requests to specific Part D sponsors known to have particular payment issues (as was done in the ''Prescriber NPI Project'' announced in the HPMS memorandum, ''Announcement of Prescriber NPI Project and Web site Release,'' dated December 4, 2012). If a Part D sponsor fails to correct its payment data, the erroneous payment data remain in the payment system, rendering the reopening provision ineffective for rectifying overpayments as it was intended.

B. Provisions of the Proposed Rule and Final Policies

In the CY 2015 OPPS/ASC proposed rule (79 FR 41058 through 41063), we proposed to establish regulations at 42 CFR 422.330, relating to MA organizations, and at 42 CFR 423.352, relating to Part D sponsors, that would specify the procedural mechanism for CMS to recoup overpayments associated with data errors identified by CMS in payment data submitted by MA organizations and Part D sponsors. We also proposed to create a process whereby an MA organization or Part D sponsor can appeal the finding that payment data are erroneous.

We noted that our proposed policy is intended to establish a process to address data errors and payment adjustments that are not addressed by existing processes such as the RADV audit and appeal process or overpayments identified by the MA organization or Part D sponsor, which are subject to separate procedures. If an MA organization or a Part D sponsor self-identifies an overpayment, that overpayment must be reported and returned to CMS in accordance with section 1128J(d) of the Act, which was added by section 6402 of the Affordable Care Act. Regulations implementing section 1128J(d) have recently been adopted at §§ 422.326 and 423.360 in the final rule entitled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 29843).

Comment: Several commenters supported the establishment of a formal overpayment collection and appeals process.

Response: We appreciate the commenters' support.

Comment: Several commenters expressed concern about including Part C and Part D proposed provisions in the OPPS/ASC proposed rule. The commenters stated that these proposed provisions are unrelated to the OPPS and ASC payment systems.

Response: The Secretary generally has discretion to schedule and group topics for rulemaking, meaning any proposed and final rule published in the **Federal Register**, as long as proper public notice is given that includes an explanation of the proposed policies, the rationale and basis for the proposal, and the public is given an opportunity to comment.

Comment: A few commenters requested that CMS make clear that the proposal regarding CMS-identified overpayments has no relationship to other CMS overpayment regulations,

specifically the overpayment regulations that were promulgated to implement the requirements of section 6402 of the Affordable Care Act, codified at section 1128J(d) of the Act (79 FR 29847). Commenters expressed concern that, given the connection between plan-identified overpayments and the False Claims Act, there is a potential for confusion and significant unintended consequences.

Response: In the preamble to the CY 2015 OPPS/ASC proposed rule, we expressly limited the scope of our proposal to establishing a process to address data errors and payment adjustments that are not addressed by existing processes. We stated that overpayments identified by an MA organization or a Part D sponsor are subject to separate procedures and that if an MA organization or a Part D sponsor self-identifies an overpayment, the overpayment must be reported and returned to CMS in accordance with §§ 422.326 and 423.360 of the regulations. We are further clarifying here that the CMS-identified overpayment process that is being finalized is separate and distinct from the overpayment rule that implemented the Affordable Care Act requirements regarding plan-identified overpayments codified at section 1128J(d) of the Act.

Comment: A few commenters provided comments on and questioned the provisions of §§ 422.326 and 423.360 which relate to reporting and returning of overpayments identified by MA organizations and Part D sponsors, respectively.

Response: We consider these public comments to be out of the scope of the provisions of the proposed rule. The proposed rule was limited to the issue of CMS-identified overpayments arising from the submission of erroneous payment data. Therefore, we are not addressing these comments in this final rule.

Comment: A few commenters stated that it is essential that CMS has overall control over the CMS-identified overpayment process to ensure proper identification and monitoring of overpayments. The commenters stated that this control is necessary to ensure that requests from separate CMS components or the Department's Office of the Inspector General (OIG) for payment data changes are consistent with CMS-issued payment regulations and guidance. The commenters recommended that CMS provide adequate resources to the appropriate staff components in order to effectively coordinate and manage this process.

Response: In the CY 2015 OPPS/ASC proposed rule, we stated that we may identify payment data that need to be corrected through a variety of different mechanisms, including, but not limited to, CMS analyses of payment data, audits, and/or communications with the MA organization or Medicare Part D sponsor. Regardless of how a potential overpayment is identified, CMS will conduct an independent evaluation of the erroneous data finding, before issuing a data correction notice to an MA organization or Part D sponsor. Although CMS may utilize OIG reports or other information to help to identify erroneous payment data, it is CMS, not the OIG, which will issue the request to correct payment data. Likewise, other separate CMS components may identify erroneous payment data, but it is the Medicare Part C and Part D payment components at CMS that will determine if that erroneous payment data could result in an overpayment and whether or not the CMS-identified overpayment process will be used to correct the overpayment. In addition, requests to correct payment data will only be issued after CMS has thoroughly reviewed the source or the mechanism that identified the payment data and has concurred with the findings that the payment data were erroneous.

We appreciate and agree with the commenters' suggestion that the CMS administration should provide adequate resources to the payment staff in order to effectively coordinate and manage this process.

Comment: One commenter asked CMS to clarify whether this regulation would be used as a means to collect any alleged improper payments identified through the Recovery Audit Contractors (RAC) process.

Response: As we indicated in the preamble of the proposed rule, this process is not intended to replace established recovery and appeals processes. We do not anticipate using this process to collect any overpayments identified through the RAC process at this time.

Comment: Several commenters expressed concern that the proposed rule does not address underpayments identified by CMS or the health plan. A few commenters suggested that CMS add language to the regulation to explain how health plans recover underpayments that they or CMS have identified. One commenter suggested that CMS offset identified underpayments against overpayments before recouping any overpayments.

Response: The purpose of the proposed provisions is to recover overpayments identified by CMS and return them to the Medicare Trust Funds. The offset calculation used to determine the overpayments will follow the Medicare Part C and Part D payment rules, and, as a result, the offset calculation may capture some underpayments. The extent to which underpayments will be recognized in the offset calculation to net out an overpayment will be limited and will vary depending on the circumstance surrounding the overpayment. The purpose of the provisions is not to provide the opportunity for MA organizations and Part D sponsors to secure additional payment by submitting additional data after the data submission deadlines. As noted in the preamble of the proposed rule, MA organizations and Part D sponsors have a period of time after the end of the data collection and coverage years, respectively, to update and supplement the payment data submitted throughout the year. In Part C, that period is 13 months, and in the Part D context, it is approximately 6 months. We believe that these periods are adequate for MA organizations and Part D sponsors to ensure that they have submitted the data necessary to substantiate their payments.

Comment: One commenter expressed concern that MA organizations' or Part D sponsors' benefit filings, current business dealings, and statutory rights and obligations may be affected if the plan's financial information is rendered uncertain due to an overpayment recovery by CMS.

Response: While we understand the commenter's concern that the possibility of returning overpayments may introduce some financial uncertainty for MA organizations and Part D sponsors, CMS has an obligation to ensure that payments to MA organizations and Part D sponsors are made consistent with the applicable program requirements. Thus, we believe that CMS has the authority to recover, and MA organizations and Part D sponsors have an obligation to return, identified overpayments.

Comment: A few commenters stated that overpayment recoupments from Part D sponsors may negatively impact beneficiaries. Commenters urged CMS to ensure that any adjustments made to recoup CMS overpayments from Part D sponsors continue to be appropriate to ensure that beneficiaries are not financially negatively impacted.

Response: We understand the commenters' concerns that overpayment recoupments not negatively affect beneficiaries. However, CMS has previously issued regulations that address this issue. Section 423.466(a) of the regulations states that whenever a Part D sponsor receives information that

necessitates a retroactive claims adjustment, the Part D sponsor must process the adjustment and issue refunds or recovery notices within 45 days of the Part D sponsor's receipt of complete information regarding the claims adjustment. In addition, § 423.466(b) states that Medicare Part D sponsors must coordinate benefits with State Pharmaceutical Assistance Programs (SPAPs), other entities providing prescription drug coverage, beneficiaries, and other third party entities paying on the beneficiaries' behalf for a period not to exceed 3 years from the date on which the prescription for a covered Part D drug was filled.

Comment: A few commenters expressed concern about the burden imposed on providers. Commenters stated that the overpayment recovery process might cause financial consequences or penalties for physicians. Commenters expressed concern over the burden of related documentation requests. One commenter urged CMS to ensure that any associated provider record requests are limited to the specific instance of erroneous data under dispute. The commenter suggested that the plan requesting medical records be required to provide documentation on the scope of the erroneous data dispute identified by CMS and to limit the data request to the specific data issue identified.

Response: These commenters appear to be focused on Part C and risk adjustment data. We recognize the commenters' concerns that recoupment of overpayments may entail negative financial consequences for physicians. However, it is CMS' responsibility to make payments to MA organizations and Part D sponsors that are consistent with the applicable statutes and regulations; this includes the authority to recover overpayments and return them to the Medicare Trust Funds. In addition, CMS is not allowed to interfere with the financial arrangements between MA organizations and their providers. Therefore, CMS is limited in how we can respond to the commenters' concern. While we recognize there may be some burden relating to the request for documentation, it is important for the integrity of the payment process that overpayments are properly identified and documented.

Comment: One commenter suggested that any Medical Loss Ratio (MLR) remittances paid by the plan to CMS should be considered when computing the overpayment recovery amount. For example, if a plan had an MLR below the statutory minimum and paid an MLR remittance to CMS, and then, at a later date, it was determined that the plan was overpaid for that year, the remittance would reduce the overpayment recovery amount.

Response: From a conceptual perspective, we believe that the impact or relationship between an MLR remittance and the overpayment offset amount is an issue about the payment calculation methodology and MLR administration, rather than a procedural issue. This regulation narrowly specifies a procedural mechanism for, first, recovering overpayments from MA organizations and Part D sponsors and, second, providing an appeals process related to the accuracy and correctness of the payment data underlying the offset. Therefore, we believe that these comments relating to MLR remittances are out of the scope of the provisions of the proposed rule.

Comment: One commenter expressed concern that there might be a large number of complications in situations where a contract has been terminated, or where there have been mergers or acquisitions involving the sponsor, or where other significant plan changes have occurred. The commenter requested guidance from CMS on the process in these situations. The commenter also asked that CMS be flexible in these scenarios.

Response: We hold entities contracting with CMS responsible for returning overpayments, regardless of their merger and acquisition history.

After consideration of the public comments we received, we are finalizing the proposal to establish a process for recovering CMS-identified overpayments associated with erroneous payment data submitted by MA organizations and Part D sponsors.

1. Definitions of ''Payment Data'' and ''Applicable Reconciliation Date''

In the CY 2015 OPPS/ASC proposed rule (79 FR 41060), we proposed to define ''payment data'' to mean data controlled and submitted to CMS by an MA organization or a Part D sponsor that is used for payment purposes (proposed §§ 422.330(a) and 423.352(a)). The MA organization or Part D sponsor is responsible for the accuracy of such data. MA organizations and Part D sponsors are currently required to attest to the accuracy, completeness, and truthfulness of such data under § 422.504(l) and § 423.505(k), respectively. For Medicare Part C, the data submitted by the MA organization to CMS include, for example, enrollment data and risk adjustment data specified at § 422.310. For Medicare Part D, data submitted by the Part D sponsor to CMS include enrollment data and data submitted under § 423.329(b)(3) (risk adjustment data), § 423.336(c)(1) (cost data), § 423.343 (data for retroactive adjustments and reconciliations), and data provided for purposes of supporting allowable reinsurance costs and allowable risk corridor costs as defined in § 423.308, which include data submitted to CMS regarding direct or indirect remuneration (DIR).

There are additional payment-related data that CMS uses to calculate Part C and Part D payments that are submitted directly to CMS by other entities, such as SSA. These entities are the authoritative source for data that they submit to CMS, and MA organizations and Part D sponsors are not the official source for data submitted by these other entities. For example, the SSA is the authoritative source for date of death of Medicare beneficiaries. An MA organization or a Part D sponsor generally does not submit a beneficiary's date of death directly to CMS' systems; such data come from the SSA data feed. When the SSA submits corrected data regarding a beneficiary's date of death to CMS, CMS' systems recalculate the payments made to the plan for that beneficiary and correct any incorrect payment through a routine retroactive payment adjustment process. Therefore, we proposed to define ''payment data'' as only data that the MA organization or Part D sponsor controls and submits to CMS for payment purposes.

For MA organizations under Part C, in the CY 2015 OPPS/ASC proposed rule (79 FR 41060), we proposed that the ''applicable reconciliation date'' occurs on the date of the annual final risk adjustment data submission deadline set under § 422.310(g)(2)(ii). While changes in enrollment data are updated every month by CMS' systems during the payment year (for example, disenrollments from MA organizations and dates of death from the SSA), risk adjustment data are not finalized until the final risk adjustment data submission deadline. Prior to that deadline, CMS allows the MA organization to continue submitting corrected and new diagnosis data. However, once the final risk adjustment data submission deadline has passed, CMS uses this final diagnosis data to calculate the final risk scores for the payment year. CMS then uses those final risk scores for payment reconciliation. By proposing that the applicable reconciliation date occurs on the risk adjustment data submission deadline, we intend to signal that the normal payment process for the year has been concluded.

For Part D sponsors, in the CY 2015 OPPS/ASC proposed rule (79 FR 41060), we proposed that the ''applicable reconciliation date'' is the later of either: the annual deadline for submitting PDE data for the annual Part D payment reconciliations referenced in § 423.343(c) and (d); or the annual deadline for submitting DIR data. The annual deadline for submitting PDE data is the last Federal business day prior to June 30 of the year following the coverage year being reconciled. The annual deadline for submitting DIR data is announced annually through subregulatory guidance and generally occurs around the last business day in June of the year following the coverage year being reconciled. We selected these events to define the Part D applicable reconciliation date because data must be submitted by these deadlines in order to be used for the purposes of the final Part D payment reconciliation.

We noted in the proposed rule that the proposed definitions of ''applicable reconciliation date'' are nearly identical to the definitions of ''applicable reconciliation'' at existing §§ 422.326 and 423.360. Similarly, the proposed definitions of ''payment data'' are nearly identical to the definitions of ''funds'' at existing §§ 422.326 and 423.360. Although proposed §§ 422.330 and 423.352 addressed overpayments to MA organizations and Part D sponsors that have been identified by CMS, whereas §§ 422.326 and 423.360 address overpayments that are identified by the MA organization or Part D sponsor, we stated in the proposed rule that we do not believe that the issue of which entity (CMS or the plan) identified the overpayment is relevant to the question of when the overpayment occurred or what information is at issue. Both the regulations regarding overpayments identified by MA organizations and Part D sponsors finalized earlier this year in the final rule entitled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' and the regulations we proposed in the CY 2015 OPPS/ASC proposed rule to establish offset and appeal procedures for CMS-identified overpayments were intended to address circumstances in which an overpayment has been identified; therefore, we believe it would be appropriate and avoid unnecessary confusion to use similar definitions.

Comment: A few commenters requested that CMS clarify the definition of ''payment data.'' Specifically, commenters stated that the definition of ''payment data'' in the proposed rule is supposed to correspond to the definition of ''funds'' at §§ 422.326 and 423.360. However, the commenters pointed out that, in the proposed rule, CMS defined ''payment data'' as ''data controlled and submitted by'' an MA organization or a Part D sponsor. Commenters noted that definition of ''funds'' omits the word ''controlled.'' Commenters expressed concern over the inclusion of the word ''controlled'' in the definition of ''payment data'' because MA organizations and Part D sponsors do not control all relevant data. Commenters requested that CMS revise the definition of ''payment data'' to conform to the definition of ''funds'' at §§ 422.326 and 423.360.

Response: We agree with the commenters. Our intent was to align the definitions of ''payment data'' with the definition of ''funds'' at §§ 422.326 and 423.360 (79 FR 41060). Therefore, we are removing the word ''controlled'' from the regulatory definition of ''payment data'' in this final rule.

Comment: One commenter requested that CMS define ''erroneous claims data'' as used in the proposed rule.

Response: We did not use the phrase ''erroneous claims data'' in the preamble language or regulation text of the proposed rule. In the preamble of the proposed rule, we used the phrase ''erroneous payment data'' to mean ''. . .payment data. . .that should not have been submitted—either because the data submitted are inaccurate or because the data are inconsistent with Part C and Part D requirements'' (79 FR 41058). We are adding the definition of ''erroneous payment data'' to the final regulation text at §§ 422.330(a) and 423.352(a).

Comment: A few commenters noted that, in the preamble of the proposed rule, CMS referenced specific provisions of §§ 422.504 and 423.505 of the regulations and stated that MA organizations and Part D sponsors are required to certify the accuracy, completeness, and truthfulness of their payment data. Commenters were concerned that CMS did not include the phrase ''based on best knowledge, information, and belief'' that is included under §§ 422.504 and 423.505. Commenters requested that CMS revise the preamble language of the final rule to acknowledge the ''best knowledge, information, and belief'' standard articulated at §§ 422.504 and 423.505 and to remove any incorrect references suggesting that MA organizations (or Part D sponsors) bear unqualified responsibility for data accuracy.

Response: We did not intentionally exclude ''based on best knowledge, information, and belief'' from the preamble discussion. We acknowledge that MA organizations and Part D sponsors certify, based on best knowledge, information, and belief, the accuracy, completeness, and truthfulness of all data related to payment as stated at §§ 422.504 and 423.505. After a review of the preamble language, we do not believe that additional edits are necessary as a result of the omission.

After consideration of the public comments we received, we are finalizing the proposed regulatory definition of ''payment data,'' with a modification to remove the reference to ''controlled,'' as described earlier. We also are adding a definition of ''erroneous payment data'' in the final regulation text at §§ 422.330(a) and 423.352(a).

2. Request for Corrections of Payment Data

Because MA organizations and Part D sponsors are required to submit accurate payment data, we have the authority to request that erroneous data be corrected when errors are discovered. In the CY 2015 OPPS/ASC proposed rule (79 FR 41060), we proposed a mechanism for recouping overpayments in situations where CMS has identified an error in payment data, the MA organization or Part D sponsor has not corrected that erroneous data upon request, and CMS determines that, as a result of the erroneous payment data, an overpayment was made. Under proposed §§ 422.330(b) and 423.352(b), we proposed that CMS would make the request through a data correction notice that would contain or make reference to the specific payment data identified by CMS as erroneous, the reason why CMS believes that the payment data are erroneous, and the timeframe in which the MA organization or Part D sponsor must make corrections to the data. This proposal was not intended to limit our authority to request correction of erroneous payment data to only those narrow circumstances in which an overpayment has already been identified. CMS may identify payment data that need to be corrected through a variety of different mechanisms, including, but not limited to, CMS analyses of payment data, CMS audits, or communications with the MA organization or Part D sponsor.

We understand that, at some point, it would no longer be practical for MA organizations and Part D sponsors to correct payment data for coverage years that have long since been reconciled. Therefore, consistent with the look-back period for overpayments that are

identified by the MA organization or Part D sponsor found at existing §§ 422.326 and 423.360, in the CY 2015 OPPS/ASC proposed rule (79 FR 41060), we proposed that CMS would request corrections to erroneous payment data only if the erroneous data affects payments for one or more of the 6 most recently completed payment years. That would mean, for example, that after the initial reconciliation takes place for Part D payments under § 423.343 (that is, the determination of the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low-income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336) for contract year 2015 (which would take place in 2016), CMS may request corrections to erroneous payment data for contract years 2010 through 2015. We proposed to use the same 6-year look-back period as applies to plan-identified overpayments under existing §§ 422.326 and 423.360 because both overpayment policies are intended to address circumstances in which an overpayment has been identified, and we do not believe that the issue of which entity (CMS or the plan) identified the overpayment is relevant to the length of the look-back period.

We proposed that the timeframes for correcting payment data would be the same as under our current practice for correcting payment data described in existing procedural rules and subregulatory guidance and would be explained in additional procedural rules and subregulatory guidance, as necessary. For example, current Part D guidance states that corrections to PDE data must be completed within 90 days from discovery of the issue. We refer readers to the Health Plan Management System (HPMS) memorandum entitled ''Revision to Previous Guidance Titled 'Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs,''' dated October 6, 2011.

Comment: A few commenters believed that the proposed rule on CMS-identified overpayments should only apply to actual overpayments, not merely the submission of incorrect payment data. These commenters were concerned that CMS incorrectly assumes that erroneous payment data equates to an overpayment.

Response: We understand that correcting erroneous payment data submitted by an MA organization or a Part D sponsor and rerunning the payment process to determine the payment that should have been made may reflect an underpayment, overpayment, or no change when comparing the two results. Consistent with §§ 422.504(l) and 423.505(k), MA organizations and Part D sponsors must submit accurate payment data (based on best knowledge, information, and belief). We clarify that CMS may make the request to correct erroneous payment data, regardless of whether or not that data would result in an overpayment under our existing and inherent authority related to administration of the payment processes; this rule does not change or limit that authority. Rather, this rule provides authority to initiate an offset to recover overpayments when erroneous payment data have been submitted, the erroneous payment data resulted in an overpayment, and the erroneous payment data were not subsequently corrected upon request from CMS. The intent of the provisions at §§ 422.330 and 423.352 is to provide a process whereby CMS-identified overpayments can be recovered; this process begins with CMS' request for correction of the erroneous payment data that caused the overpayment to occur. We will establish the existence and extent of an overpayment by applying the Part C and Part D payment rules and formulas applicable to the payment year in question.

Comment: Commenters requested that CMS clarify that the overpayment recoupment process would apply only to contract years for which CMS has completed final reconciliation. Commenters noted that CMS did not link the proposed regulatory definition of ''applicable reconciliation date'' to other subsections of the proposed regulations. The commenters stated that based on the proposed regulations, if CMS identifies an error in payment data and the payment error identified affects payments for any of the 6 most recently completed payment years, CMS may send a data correction notice to the MA organization or the Part D sponsor. However, CMS does not define ''recently completed'' or correlate the definition with the phrase ''applicable reconciliation date.'' Commenters requested that CMS clarify its intention to recoup overpayments only following the ''applicable reconciliation date.''

Response: Our determination that an overpayment has occurred will be made after the applicable reconciliation date, as defined in this final rule, for the contract year in which the erroneous payment data were identified. In addition, the payment error must affect payment in one of the 6 most recently completed payment years. For example, after the initial reconciliation takes place for Part D payments under § 423.343 (that is, the determination of the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low-income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336) for contract year 2015 (which would take place in 2016), the 6 most recently completed payment years would be 2010 through 2015.

Consistent with our statements above regarding our existing and inherent authority related to administration of the payment processes to make the request to correct erroneous payment data, regardless of whether or not that data would result in an overpayment, we believe we have authority to request the correction of erroneous data at any time. Accordingly, we are moving the language that limits CMS to the 6-year look-back period at §§ 422.330(b) and 423.352(b), ''Request to correct payment data,'' and associating it with §§ 422.330(c) and 423.352(c), ''Payment offset,'' in order to clarify that, while we may request the correction of erroneous payment data at any time, we will only use the payment offset procedures established in this rule to recover overpayments in the 6 most recently completed payment years.

Therefore, we are modifying proposed §§ 422.330(c) and 423.352(c) to indicate that when the MA organization or Part D sponsor fails to correct payment data in response to a request under §§ 422.330(b) and 423.352(b), CMS will conduct a payment offset against payments made to the MA organization or Part D sponsor if: (1) the payment error affects payments for any of the 6 most recently completed payment years; and (2) the payment error for a particular payment year is identified after the applicable reconciliation date for that payment year.

Comment: One commenter requested that CMS institute a single, uniform timeframe to correct any payment data errors before CMS initiates payment-offset procedures. The commenter believed that the different time periods associated with the resubmission or correction of various data points can lead to unnecessary confusion and the potential for missed deadlines. This commenter recommended that CMS create a uniform timeframe of at least 120 days to submit data corrections. The commenter expressed concern that the process for collecting and verifying corrected data will involve numerous steps and that the process also likely will involve third parties, potentially including vendors no longer under contract, which would add additional

steps and time to the process of collecting and validating the data. The commenter stated that a turnaround time of less than 120 days creates a risk for not being able to collect the payment data and conduct a diligent and fulsome analysis before responding to CMS.

Response: We understand that it makes sense to have a uniform timeframe for submitting corrected payment data in response to a CMS notification of CMS-identified erroneous payment data. We also understand that different timeframes for submitting corrected data could lead to confusion and missed deadlines. However, we disagree with the commenter that 120 days is necessary to correct all types of payment data. As we cited in the preamble of the proposed rule, current Part D guidance in the HPMS memorandum dated October 6, 2011, states that corrections to PDE data must be completed within 90 days from discovery of the issue. We have no reason to believe that the 90-day timeframe for correcting Part D data under this provision is inadequate. Therefore, we will not be making changes to this policy at this time. Timeframes for correcting Part C payment data will be explained in additional procedural rules and subregulatory guidance.

Comment: One commenter requested clarification regarding the submission of payment data corrections between the final risk adjustment submission deadline and when a payment reconciliation or payment rerun is conducted.

Response: This commenter's request appears to be directed at Part C and risk adjustment data. An overpayment may exist once applicable reconciliation has occurred, which is the final deadline for the submission of risk adjustment data for Part C. MA organizations should submit data corrections to correct an overpayment the MA organization has identified as soon as the MA organization recognizes the overpayment has occurred (§ 422.326). In the context of that rule and the process adopted under this rule, the operational action of conducting a risk adjustment payment rerun will be implemented according to our policy and schedules. The submission of data corrections should not be delayed relative to the timing of a risk adjustment rerun. If the data correction is not submitted, and we have identified the erroneous risk adjustment payment data, we may move forward with a payment offset. We agree that additional information on this issue would be helpful to MA organizations and will be providing further guidance as needed.

Comment: A few commenters noted that, in the proposed rule, CMS stated that if the MA organization or Part D sponsor submits corrected payment data in response to CMS' request, CMS will perform a reconciliation in the payment system using the established payment adjustment process. The commenters requested that CMS clarify that the referenced reconciliation is in reference to the established reopening of a payment adjustment reconciliation process. The commenter stated that the current reopening process is well-established and equitable, balancing the rights and obligations of Part D sponsors and CMS, and, therefore, there is an appropriate adjustment of both overpayments and underpayments to the Part D sponsor. The commenters urged CMS to invest additional operational resources to strengthen the existing reopening process.

Response: If an MA organization or a Part D sponsor submits corrected payment data, as requested by CMS, we will recoup any overpayment amounts by performing a payment reconciliation according to our payment processing policies and schedules. We appreciate the commenter's suggestion to invest additional operational resources to strengthen the existing reopening process, and will take this suggestion into consideration.

Comment: Several commenters expressed concern regarding the length of the 6-year look-back period. Some of the commenters indicated the length of the look-back period would place undue burden on plans and providers. Another commenter stated that a 6-year timeframe is typically reserved for fraud and abuse processes and is not considered appropriate for routine operational processes. A few commenters recommended that the look-back period be 3 years.

Response: We believe that a 6-year look-back period is an appropriate timeframe for identifying overpayments. As stated in the proposed rule, the 6-year look-back period is consistent with the look-back period established for overpayments that are identified by MA organizations or Part D sponsors (§§ 422.326 and 423.360). Also as stated in the proposed rule, we proposed to use the same 6-year look-back period as applies to plan-identified overpayments because both overpayment policies are intended to address circumstances in which an overpayment has occurred and has been identified. We do not believe that the issue of which entity (CMS or the plan) identified the overpayment is relevant to the length of the look-back period.

Comment: A few commenters recommended that the look-back period be implemented prospectively. One commenter stated that a 6-year look-back period could affect many distributed risk arrangements between plans and providers that cross multiple years and have already been reconciled. Another commenter asked that CMS phase in the look-back period, beginning with a 1-year look-back period and each year adding an additional year to the look-back period, until 2020 when a 6-year look-back could be applied.

Response: We disagree with the commenters' recommendations to implement the look-back period prospectively. We proposed 6 years as the length of the look-back period because we believe that this timeframe best balances the government's interest in having overpayments returned with entities' interest in finality. We note that the statute of limitations related to the False Claims Act is 6 years from the date of the violation or 3 years from the date the relevant government official learns of the situation, but in no case more than 10 years from the date of the violation. Furthermore, under § 422.504(d) and § 423.505(d), MA organizations and Part D sponsors are required to maintain, for 10 years books, records, documents, and other evidence of accounting procedures and practices related to costs, financial statements, cash flow, among others.

After consideration of the public comments we received, we are finalizing proposed §§ 422.330(b) and 423.352(b) and proposed §§ 422.330(c) and 423.352(c) with modifications. We are moving the language regarding the 6-year look-back period from proposed §§ 422.330(b) and 423.352(b) to §§ 422.330(c)(1) and 423.352(c)(1) in order to indicate that if the MA organization or Part D sponsor fails to correct payment data, CMS will conduct a payment offset if the payment error affects payments for any of the 6 most recently completed payment years and the payment error for a particular payment year is identified after the applicable reconciliation date for that payment year.

3. Payment Offset

If the MA organization or Part D sponsor submits corrected payment data in response to CMS' request pursuant to proposed § 422.330(b) and § 423.352(b), CMS will perform a reconciliation in the payment system using the established payment adjustment process. CMS' systems will conduct a payment reconciliation and determine the associated payment adjustment based

on the corrected data using established payment policies and procedures. However, if the MA organization or Part D sponsor fails to correct the erroneous payment data, in the CY 2015 OPPS/ASC proposed rule (79 FR 41061), we proposed that CMS would conduct a payment offset from plan payments (proposed §§ 422.330(c) and 423.352(c)).

a. Offset Amount

Because the data would not have been corrected in the routine payment process, in the CY 2015 OPPS/ASC proposed rule (79 FR 41061 through 41062), we proposed, to be codified at §§ 422.330(c) and 423.352(c), that CMS determine the overpayment offset amount by applying a payment calculation algorithm to simulate the payment calculations currently applied by CMS to produce the routine Part C and Part D payments. The payment calculation algorithm would apply the Part C or Part D payment rules for the applicable year to calculate what the correct payment should have been using corrected payment data. CMS currently simulates payment error amounts for a variety of different purposes, including for the annual Part C and Part D error rate reporting (required by the Improper Payment Elimination and Recovery Act (IPERA) and subject to the annual agency's Chief Financial Officer's (CFO) audit and reported in the annual Agency Financial Report (AFR)), RADV payment error estimation (subject to public comment), and the Part C and Part D monthly payment validation required by CFO auditors. These payment error calculations are all conducted outside of the suite of payment systems that CMS uses to make routine payments to MA organizations and Part D sponsors. In the proposed rule, we stated that we believe that these calculations are reliable and an accurate reflection of what the routine payment systems would calculate using the corrected data if the MA organization or Part D sponsor had submitted corrected payment data.

The actual process for calculating the overpayment will be different for Part C and Part D because of the different payment rules for the two programs. The Part C and Part D programs are both subject to risk adjustment payment error resulting from invalid diagnoses and to payment error due to inaccurate enrollment data. The Part D program is further subject to payment reconciliation error resulting from errors in PDE data and/or DIR data. The two programs also are subject to different schedules with regard to the applicable reconciliation date and subsequent payment reconciliation processes.

When new payment-related data are submitted to CMS payment systems, there is generally a change to the correct amount of payment once CMS conducts a payment reconciliation using the established payment adjustment process. However, it is not sufficient for the plan to just submit the new corrected risk adjustment, PDE, or DIR data to CMS systems because data submission does not automatically trigger a system reconciliation and payment adjustment. A change in payment will only occur if a payment reconciliation is conducted. If the applicable reconciliation has already been performed, CMS, at its discretion, may conduct risk adjustment reruns or Part D reopenings to ensure that payments also are corrected to reflect the newly corrected data.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41061), we proposed that, under the payment calculation algorithm, CMS would calculate the payment to the MA organization or Part D sponsor with and without the corrected data as of a specified date. The difference in the two amounts—that is, the amount by which the payments already made to the MA organization or Part D sponsor exceed the payments that should have been made as reflected in the calculation using the corrected data—would be the payment recovery or offset amount. We provided the following examples of how the offset amount would be calculated for Part C and Part D overpayments relative to two different types of payment data errors to illustrate our proposal:

- *Part C Offset Calculation.* The example for Part C relates to incorrect diagnosis data identified by CMS in the process of calculating the national payment error estimate. A beneficiary's final risk score and annual payment will be recalculated outside of the routine payment system without the invalid diagnoses but using all the other data used in the routine payment system. The year-appropriate CMS–HCC risk adjustment methodology will be used to produce the revised risk scores. The difference in payment for the beneficiary pre- and post-change in the invalid diagnosis will be the offset amount. This offset amount—generated using the same process for each beneficiary for whom erroneous payment data are identified by CMS—will be summed across all beneficiaries.
- *Part D Offset Calculation.* The example for Part D relates to the situation in which a Part D plan sponsor has submitted PDE records for a beneficiary that include invalid National Drug Codes (NDCs). For payment purposes, PDEs are required to reference valid NDCs. In order to calculate the Part D payment offset amount, all of the beneficiary's entire post-reconciliation PDE data will be pulled, and the incorrect PDEs will be deleted or adjusted. The programmed calculation logic will keep track of a variety of payment-related information; for example, a beneficiary's benefit phase, gross covered drug cost, true out-of-pocket (TrOOP) costs, low-income cost-sharing subsidies (if any), and plan payment as the beneficiary progresses through the Part D coverage benefit. The calculation algorithm will tap into a variety of different data sets, such as health plan benefit parameters, beneficiary low-income subsidy status, and standard low-income cost-sharing subsidy parameters. Reports will then be produced on Gross Covered Drug Cost (GCDC) and low-income cost-sharing subsidy payment differentials. These payment differential amounts will be incorporated into final reinsurance, low-income cost-sharing subsidy, and risk sharing summary totals for a contract. DIR adjustments will be factored into these calculations to arrive at the related payment offset amount to be applied at the contract level. The difference in reinsurance, low-income cost-sharing subsidy, and risk sharing dollars with and without the correction to the PDEs will constitute the payment offset related to the beneficiaries with the incorrect PDEs.

If the erroneous payment data in question is subsequently corrected through the CMS payment system, the offset amount will be reversed, and the payment to the MA organization or Part D sponsor will be updated through the routine payment process. However, if the data in the CMS system are not corrected and CMS conducts a reconciliation or reopening for the applicable payment year after the offset has been determined, the data will not be properly synchronized, and it is possible that the resulting payment adjustments could be incorrect. In order to resolve this problem, CMS may reverse the original offset and recalculate the offset using the more recent data used in the most recent payment reconciliation or reopening. The new offset amount will replace the previous offset amount, and CMS would need to evaluate and act on the resulting overpayment or underpayment.

Comment: A few commenters expressed concern about the payment calculation algorithm that will be used to determine the overpayment amount that should be recouped. Other commenters stated that they could not understand why CMS cannot simply

correct the data in the payment systems of record and ''run a reopening.'' Commenters requested that CMS clarify why the traditional reopening process cannot adequately address the types of payment issues outlined in the proposed rule. The commenters noted that CMS has used its existing authority in the past to remove PDEs it believed should not have been submitted. One commenter stated that this proposal creates an environment where the sponsor's records of the PDEs and the TrOOP accumulators would be out of sync with CMS systems timing and would pose challenges during the reconciliations of PDEs and payment data, as well as readjudication of beneficiary claims, and as a result, recommended that CMS withdraw the proposal and assess whether there are other current less onerous mechanisms that can be adopted to better meet its goals.

Response: For the Part C program and the Part D program, we believe that the traditional risk adjustment rerun and other reopening processes are the best mechanisms to recoup overpayments. We believe that these processes will be adequate to recoup overpayments in most cases because we assume that the majority of MA organizations and Part D sponsors will adjust their payment data upon request by CMS. However, as we stated in the preamble to our proposed rule, if an MA organization or Part D sponsor fails to correct erroneous payment data, the established risk adjustment rerun and reopening processes are inadequate. Because the data would not have been corrected in the CMS payment system, we will have to determine the overpayment amount by applying a payment calculation algorithm to simulate the payment calculations currently applied by CMS systems to produce routine Part C and Part D payments. It is true, as one commenter stated, that, in the Part D program, CMS has used existing authority to remove PDE data that should not have been submitted. We use that authority in very limited circumstances when the erroneous data is PDE data. Part D payment data also includes, however, direct and indirect remuneration (DIR) data, for which we do not have a means to ''correct'' erroneous data. Likewise, we do not have a process in place to ''correct'' erroneous data in the Part C program. In addition, because we only expect to conduct these types of data corrections in a limited set of circumstances, and it would require significant resources to make the payment system changes to support such corrections, CMS is prepared to use a more economical process based on running a payment calculation algorithm to recover the improper payments.

As stated in the proposed rule, CMS already simulates Part C and Part D payments outside of the core payment systems to accurately calculate payments and payment errors for a variety of different purposes. Therefore, we believe that this procedural mechanism is the least onerous mechanism that can be adopted to recoup overpayments, return them to the Medicare Trust Funds, and ensure that payments are made consistent with the payment framework established in statute. Therefore, we are not withdrawing the proposal, as one commenter recommended.

Comment: One commenter stated that CMS should not implement any type of extrapolation methodology when calculating the payment offset for MA organizations or Part D sponsors. The commenter believed that CMS may seek to extrapolate the results of erroneous payment data to all beneficiaries enrolled under a contract if the MA organization or Part D sponsor does not submit corrected data as requested by CMS. The commenter believed that the proposed provision could be interpreted to mean that CMS may apply the offset amount to all beneficiaries, even though not all beneficiaries may have been affected by the incorrect data. The commenter opined that it would not be appropriate to extrapolate payment-offset calculations without providing MA organizations and Part D sponsors with notice or an explanation of the methodologies that CMS would employ. Commenters recommended that CMS expressly state that extrapolation will not be involved in payment recoupment under the CMS-identified overpayment regulations, and the payment offsets should be applied based on payment errors that have been determined for specific beneficiaries.

Response: CMS may identify erroneous payment data submitted by MA organizations or Part D sponsors through a variety of different means. In the proposed rule, we discussed the procedures that CMS would undertake when erroneous payment data are identified, but did not address the means by which CMS would identify erroneous payment data. Therefore, this comment is outside the scope of the proposed rule.

Comment: Several commenters raised the issue that, in cases where a CMS-identified overpayment is a result of errors in diagnosis data submitted by MA organizations, CMS' determination of the overpayment amount should take into account the fact that the CMS–HCC risk adjustment model used to risk-adjust payments to MA organizations is calibrated on diagnoses from Medicare fee-for-service claims not MA organizations' claims. Commenters referred to this as the ''data inconsistency issue.'' Specifically, commenters noted that CMS has recognized, in the contract-level RADV context, that individual errors in risk adjustment data cannot be equated with overpayments without first accounting for the error rate in the fee-for-service (''FFS'') claims data. Commenters also stated that CMS has acknowledged when calculating overpayments based on medical record review for RADV audits that it must ''account for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims).'' Further, commenters noted that, to address this problem, CMS implemented a ''FFS Adjuster'' that offsets the payment recovery amount to account for FFS and MA program differences in documentation standards. These commenters believed that CMS' application of the ''FFS Adjuster'' in the RADV context does fulfill the actuarial equivalence requirement under the risk adjustment provisions in the Act, and failure to maintain logical consistency by applying this adjuster in the context of the CMS-identified overpayments addressed by this rule would be contrary to the actuarial standard in statute.

Response: We understand from these comments that commenters are specifically recommending that any risk adjustment payment recovery amounts be adjusted to reflect medical record coding documentation differentials between FFS providers and MA organizations. We note that this type of adjustment would not apply to other types of data errors, such as those that might be found in PDE data. We further interpret the commenters to be saying that the overpayment amounts should be adjusted downward to take the medical record coding documentation differential into account. From a conceptual perspective, we believe that the application of a FFS adjuster is a payment calculation methodology issue, rather than a procedural issue. Our proposal was narrowly tailored to specify a procedure for correcting the inaccurate data that MA organizations and Part D sponsors have submitted for payment and providing an appeals process. Therefore, we believe that these

comments relating to data inconsistency and the application of a FFS adjuster to overpayments are outside the scope of the proposed provision.

After consideration of the public comments we received, we are finalizing our proposal, as proposed, without modification.

b. Payment Offset Notification

In the CY 2015 OPPS/ASC proposed rule (79 FR 41062), we proposed that CMS would provide a payment offset notice to the MA organization or Part D sponsor (proposed §§ 422.330(d)(1) through (d)(3) and 423.352(d)(1) through (d)(3)). The notice would provide the dollar amount to be offset against a plan's monthly prospective payments and an explanation of how the erroneous data were identified and of the calculation of the payment offset amount. Under our proposal, the payment offset notice would also explain that, in the event that the MA organization or Part D sponsor disagrees with the payment offset, it may request an appeal within 30 days of the issuance of the payment offset notice.

Comment: A number of commenters requested that CMS provide for an appeals process prior to conducting the payment recovery or offset.

Response: We are concerned that if we allow for appeals prior to the offset, we are at risk of having an extensive process that inordinately delays the offset and the recovery of the overpayment. However, we are willing to engage in a dialogue with plans prior to the offset. We anticipate that this dialogue will help to resolve data issues prior to implementing the payment offset and recovery. Therefore, we are not making the requested changes to the proposed process for payment offset notification.

After consideration of the public comments we received, we are finalizing our proposal. However, we are making a minor modification to the accompanying regulation text at § 422.330(d) and § 423.352(d) to clarify that the payment offset notice will include at least the information outlined in the regulation, but may include other information relevant to the payment offset.

4. Appeals Process for MA Organizations and Part D Sponsors

In the CY 2015 OPPS/ASC proposed rule (79 FR 41062), we proposed an appeals process for MA organizations and Part D sponsors with three levels of review, including reconsideration (described at proposed §§ 422.330(e)(1) and 423.352(e)(1)), an informal hearing (described at proposed §§ 422.330(e)(2) and 423.352(e)(2)), and an Administrator review (described at proposed §§ 422.330(e)(3) and 423.352(e)(3)).

a. Reconsideration

In the CY 2015 OPPS/ASC proposed rule (79 FR 41062), we proposed that an MA organization or Part D sponsor must file its request for reconsideration within 30 days from the date that CMS issued the payment offset notice to the MA organization or the Part D sponsor (proposed §§ 422.330(e)(1)(i) and 423.352(e)(1)(i)). At proposed §§ 422.330(e)(1)(ii) and 423.352(e)(1)(ii), we address the information that must be included in the MA organization's or Part D sponsor's request for reconsideration. The request would have to contain the findings or issues with which the MA organization or Part D sponsor disagrees, the reasons for its disagreement, and any additional documentary evidence that the MA organization or Part D sponsor wishes to submit in support of its position. This additional evidence would have to be submitted with the request for reconsideration. Under our proposal, any information submitted after this time would be rejected as untimely.

Under our proposal, the CMS reconsideration official would review the underlying data that were used to determine the amount of the payment offset and any additional documentary evidence that the MA organization or Part D sponsor timely submitted with its reconsideration request (§§ 422.330(e)(1)(iii) and 423.352(e)(1)(iii)). We note that, in some instances, the CMS reconsideration official's review of the underlying data may include review of information identifying or explaining the error in the payment data, such as information from the source that identified the erroneous payment data. We proposed at §§ 422.330(e)(1)(iv) and 423.352(e)(1)(iv) that the CMS reconsideration official would inform the MA organization or Part D sponsor of the decision. We proposed at §§ 422.330(e)(1)(v) and 423.352(e)(1)(v) that a reconsideration decision would be final and binding unless a timely request for an informal hearing is filed by the MA organization or Part D sponsor.

Comment: Several commenters stated that a 30-day window to submit an appeal request is too short. A few commenters asked that CMS provide at least 60 days from the time a data correction notice is issued for Part D sponsors to appeal the data correction decision. One commenter suggested a timeframe of 30 days to appeal and an additional 60 days for researching the issue and gathering supporting documents necessary for consideration.

Response: We have considered these concerns and suggestions, and we continue to believe that 30 days is sufficient time to file the appeal, particularly because the MA organization or Part D sponsor would have received an earlier notification and request to correct the erroneous data.

After consideration of the public comments we received, we are finalizing our proposal without modification.

b. Informal Hearing

In the CY 2015 OPPS/ASC proposed rule (79 FR 41062), we proposed that if the MA organization or Part D sponsor is dissatisfied with CMS' reconsideration decision, it would be entitled to request an informal hearing (proposed §§ 422.330(e)(2) and 423.352(e)(2)). As proposed at §§ 422.330(e)(2)(i) and 423.352(e)(2)(i), a request for an informal hearing must be made in writing and filed within 30 days of the date of CMS' reconsideration decision. The request must include a copy of CMS' reconsideration decision and must specify the findings or issues in the decision with which the MA organization or Part D sponsor disagrees and the reasons for its disagreement (proposed §§ 422.330(e)(2)(ii) and 423.352(e)(2)(ii)).

In the CY 2015 OPPS/ASC proposed rule (79 FR 41062), we set forth the proposed procedures for conducting the informal hearing at proposed §§ 422.330(e)(2)(iii) and 423.352(e)(2)(iii). Under these procedures, CMS would provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date of the hearing (proposed § 422.330(e)(2)(iii)(A) and § 423.352(e)(2)(iii)(A)); the informal hearing would be conducted by a CMS hearing officer. The hearing officer would be limited to reviewing the record that was before CMS when CMS made its reconsideration determination (proposed § 422.330(e)(2)(iii)(B) and § 423.352(e)(2)(iii)(B)). Under our proposal, no new or additional documentation or evidence may be submitted at this hearing. At proposed § 422.330(e)(2)(iii)(C) and § 423.352(e)(2)(iii)(C), we proposed that the CMS hearing officer would review the record of the proceeding before the CMS reconsideration official using the clearly erroneous standard of review. CMS' reconsideration decision would not be reversed unless the MA organization or Part D sponsor establishes that the decision was clearly erroneous in light of the evidence in the

record before the CMS reconsideration official.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41062), at proposed §§ 422.330(e)(2)(iv) and 423.352(e)(2)(iv), we proposed that the CMS hearing officer would send a written decision of the informal hearing to the MA organization or Part D sponsor explaining the basis for the decision. The CMS hearing officer's decision would be final and binding, unless the decision is reversed or modified by the Administrator (proposed §§ 422.330(e)(2)(v) and 423.352(e)(2)(v)).

Comment: One commenter recommended that CMS allow plans the opportunity to present oral arguments during the informal hearing appeal stage and that written notice addressing the time and location of the hearing be provided at least 30 days prior, as opposed to the proposed 10 days.

Response: As proposed and finalized, this rule will permit MA organizations and Part D sponsors, at the informal hearing stage, to present oral arguments regarding whether or not the CMS reconsideration official's decision was clearly erroneous. At the informal hearing, the hearing officer will review, and the parties may discuss, the contents of the administrative record, which was before the reconsideration official. We understand that 10 days' notice of the time and place of the hearing may be insufficient notice for some MA organizations and Part D sponsors to arrange for travel to the hearing location. Therefore, we are accepting the commenters' suggestion to extend the timeframe for CMS to provide written notice of the time and place of the hearing, and are extending that timeframe to 30 days before the scheduled date for the informal hearing.

Comment: A few commenters stated that with the ''clearly erroneous'' standard, CMS is unfairly placing the burden of proving CMS wrong completely on the MA organizations and Part D sponsors. Commenters pointed out that a sponsor may be unable—not unwilling—to collect the data required to refute CMS' assertions. One commenter stated that while the burden of proof falls to the sponsors to disprove CMS' claims, there is no explicit requirement that CMS must be able to substantiate its concerns regarding data before it triggers the proposed incorrect payment notification process. The commenter is concerned that without changes to these standards the possibility exists for abuse of the process, putting sponsors on a continual defensive cycle. The commenter suggested that CMS be obligated to provide reasonable substantiation of its overpayment claim and that the standard for review be that the MA organization or Part D sponsor provide reasonable evidence, in light of the available data, that the CMS claim is not supportable.

Response: The issue of whether or not payment data submitted by an MA organization or Part D sponsor are erroneous is a factual issue that is determined by looking at the payment data in relation to the payment framework established in statute and regulation, which the MA organizations and Part D sponsors agree to be contractually bound by when they sign the agreement with CMS to operate a Medicare Advantage and/or a Voluntary Medicare Prescription Drug Plan. Under the clearly erroneous standard of review, the hearing officer will only overturn the reconsideration official's decision if that decision, based on the record before the reconsideration official, contains plain errors of fact or law. Because the determination of whether or not payment data submitted by an MA organization or Part D sponsor are erroneous is a factual one, we believe that the clearly erroneous standard is appropriate. The CMS reconsideration official reviews the underlying data that were submitted by the MA organization or Part D sponsor and any additional documentary evidence timely submitted by the MA organization or Part D sponsor, and thus is in the best position to determine the facts underlying the determination that erroneous payment data have been submitted. Accordingly, the reconsideration official's decision should only be disturbed in the case of a clear error.

We believe commenters are concerned that there is no requirement that CMS substantiate its claims of an overpayment and that could lead to abuse of the process. To the contrary, paragraph (b) of both § 422.330 and § 423.352 imposes a burden and a requirement on CMS. Under these provisions, we can request corrections to payment data through a notice in which we are obligated to include or make reference to the specific data that need to be corrected and the reason why we believe that the data are erroneous. ''Erroneous payment data,'' as stated in the preamble of the proposed rule and the text of the regulations being adopted in this final rule, are data that should not have been submitted because the data are either inaccurate or inconsistent with Part C or Part D requirements. We will determine payment data to be erroneous based on the applicable statutes and regulations. Based on the payment framework established in statute and regulation, we will determine whether or not that erroneous data result in an overpayment prior to conducting the payment offset.

Commenters are concerned that they will be unable—not unwilling—to refute CMS' decision that the submission of erroneous payment data has resulted in an overpayment. As we stated in the preamble to our proposed rule, we proposed to establish a process for identifying and recouping overpayments to ensure that payments are made consistent with the payment framework established by statute. If we determine that an overpayment has occurred, the MA organization or Part D sponsor must be able to provide evidence to refute the finding that the underlying payment data are erroneous in order to succeed on appeal. As stated in the proposed rule at §§ 422.330(f) and 423.352(f), the MA organization or Part D sponsor must be able to prove by a preponderance of the evidence that our finding that the payment data are erroneous was incorrect or otherwise inconsistent with applicable program requirements. Thus, we believe that it is reasonable to expect that MA organizations and Part D sponsors provide evidence to support how their payment data are correct and consistent with program requirements in order for the CMS hearing officer to reverse both an initial determination by CMS and a reconsideration decision by the CMS reconsideration official that erroneous payment data have been submitted.

After consideration of the public comments we received, we are finalizing our proposals with respect to the procedures that will apply to a request for an informal hearing, with a modification to provide that we will provide written notice of the time and place of the hearing 30 days before the scheduled date, as described above.

c. Review by Administrator

In the CY 2015 OPPS/ASC proposed rule (79 FR 41062), we proposed that the MA organization or Part D sponsor may request review of the hearing officer's decision by the Administrator within 30 days of issuance of the hearing officer's decision (proposed §§ 422.330(e)(3)(i) and 423.352(e)(3)(i)). The MA organization or Part D sponsor may provide written arguments to the Administrator for review. Under proposed §§ 422.330(e)(3)(ii) and 423.352(e)(3)(ii), after receiving the request for review, the Administrator would have the discretion to elect to review the hearing determination or decline to review it. As provided at proposed §§ 422.330(e)(3)(iii) and

423.352(e)(3)(iii), if the Administrator declines to review the hearing officer's decision, the hearing officer's decision would be final and binding. At proposed §§ 422.330(e)(3)(iv) and 423.352(e)(3)(iv), we proposed that if the Administrator elects to review the hearing officer's decision, the Administrator would review the hearing officer's decision, as well as any other information included in the record of the hearing officer's decision and any written arguments submitted by the MA organization or Part D sponsor. The Administrator would be able to uphold, reverse, or modify the hearing officer's decision. The Administrator's determination would be final and binding (proposed §§ 422.330(e)(3)(v) and 423.352(e)(3)(v)).

We did not receive any public comments on the proposal for review by the Administrator and are finalizing this proposal without modification.

5. Matters Subject To Appeal and Burden of Proof

In the CY 2015 OPPS/ASC proposed rule (79 FR 41063), at proposed §§ 422.330(f)(1) and (2) and 423.352(f)(1) and (2), we proposed to limit the subject-matter that an MA organization or Part D sponsor may appeal under this provision and establish the burden of proof that the MA organization or Part D sponsor must meet in its appeal. Under this provision, an MA organization or a Part D sponsor would be able to appeal the notice of payment offset solely on the grounds that CMS' finding that the MA organization's or Part D sponsor's payment data were either erroneous or otherwise inconsistent with applicable program requirements. The MA organization or Part D sponsor would bear the burden of proof by a preponderance of the evidence in demonstrating that CMS' finding was incorrect or inconsistent with applicable program requirements.

At proposed §§ 422.330(g) and 423.352(g), we proposed that the appeals process under paragraph (e) of these sections would apply only to payment offsets described at proposed §§ 422.330(c) and 423.352(c). It would not apply to any other CMS payment offset process.

Comment: One commenter noted that, in the proposed rule, CMS stated that the burden of proof is on the MA organization or Part D sponsor to prove that the CMS finding was ''incorrect or otherwise inconsistent with applicable program requirements.'' This commenter asked that CMS clarify that plans would not be expected to conform to FFS requirements or business models in coding practices. The commenter stated that in the past there have been occasions when CMS has relied on the use of FFS requirements or customary practices in the absence of specific MA or Part D guidelines. The commenter stated that this creates an unreasonable burden of regulations, rules, manuals, notices, and bulletins that must be considered in the process of identifying, reporting, and appealing matters of data accuracy and potential overpayment. In addition, the commenter believed that this practice does not address the fact that an error may have been solely caused by provider error, over which a plan has no control, and therefore places an unreasonable burden on the plan.

Response: We are not clear about the commenter's concern. In the preamble of the proposed rule, the phrase ''applicable program requirements'' is referring to MA program requirements, not to FFS program requirements. If the commenter is asking about coding practices, CMS does not provide specific MA guidelines on how to code, but instead requires that MA organizations use the code sets and guidelines in whatever version of the International Classification of Diseases that is in effect for the classification and reporting of diseases for all U.S. health care settings (not just Medicare). Further, we are unsure as to what the commenter is referring in the statement ''in the past there have been occasions when CMS has relied on the use of FFS requirements or customary practices in the absence of specific MA or Part D guidelines.'' The commenter did not provide any examples, so we are unable to respond to this concern. Regarding the statement that an MA organization has no control over provider errors in data submission, we refer readers to the contracting provisions in the MA regulation at § 422.504 regarding the MA organization's responsibility for data submissions.

After consideration of the public comments we received, we are finalizing our proposal without modification.

6. Effective Date of Appeals Process Provisions

In the CY 2015 OPPS/ASC proposed rule (79 FR 41063), we proposed that this new procedural mechanism for a payment offset at proposed § 422.330 and § 423.352 would apply after the effective date of any final rule implementing the new payment offset and appeals process, but that requests to correct payment data under proposed §§ 422.330(b) and 423.352(b) and the payment offsets under proposed §§ 422.330(c) and 423.352(c) may apply to any payment year, subject to the 6-year limitation under §§ 422.330(b) and 423.352(b).

We invited public comments on these proposals regarding the effective date and application of the rule.

We did not receive any public comments on these proposals, and we are finalizing our proposals with the modification discussed above to codify the 6-year limitation in paragraph (c) of §§ 422.330 and 423.352.

In summary, we are finalizing the provisions at §§ 422.330 and 423.352, with the following modifications. We are removing the phrase ''controlled and'' from the definition of ''payment data'' at §§ 422.330(a) and 423.352(a). We are adding the definition of ''erroneous payment data'' to the final regulation text at §§ 422.330(a) and 423.352(a). At §§ 422.330(b) and 423.352(b), we are moving language regarding the 6-year look-back period to §§ 422.330(c)(1) and 423.352(c)(1) to indicate that if the MA organization or Part D sponsor fails to correct payment data, CMS will conduct a payment offset if the payment error identified affects payments for any of the 6 most recently completed payment years and the payment error for a particular payment year is identified after the applicable reconciliation date for that payment year. At §§ 422.330(c) and 423.352(c), we are adding paragraph (2) to clarify that CMS will calculate the payment offset amount using the *correct* payment data. In addition, we are making a minor modification to the regulation text at § 422.330(d) and § 423.352(d) to clarify that the payment offset notice will include at least the information outlined in the regulation, but may include other information relevant to the payment offset. Finally, we are revising §§ 422.330(e)(2)(iii)(A) and 423.352(e)(2)(iii)(A) to state that we will provide written notice of the time and place of the informal hearing at least 30 days before the scheduled date.

XVIII. Files Available to the Public via the Internet

Addendum J to this final rule with comment period is a new addendum that we proposed for CY 2015, in response to requests by public commenters on the CY 2014 OPPS/ASC final rule with comment period for additional data regarding ratesetting for the new comprehensive APCs established in that final rule with comment period, which are discussed in section II.A.2.e. of this final rule with comment period. Addendum J lists the HCPCS code pairs for which we are finalizing complexity adjustments for

CY 2015, by clinical family; the HCPCS codes finalized for exclusion from the comprehensive APC payment bundle; and the relevant cost statistics.

The public comments that we received related to the proposed Addendum J to the CY 2015 OPPS/ASC proposed rule are discussed in detail in section II.A.2.e. of this final rule with comment period. We are finalizing our proposal to create Addendum J without modification.

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 final rule comment period pertaining to CY 2015 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 ''1613–FC'' from the list of regulations. All OPPS Addenda to this final rule with comment period are contained in the zipped folder entitled ''2015 OPPS 1613–F Addenda'' at the bottom of the page. To view the Addenda to this final rule with comment period pertaining to the CY 2015 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 ''1613–FC'' from the list of regulations. All ASC Addenda to this final rule with comment period are contained in the zipped folders entitled ''Addendum AA, BB, DD1 and DD2,'' and ''Addendum EE''.

XIX. 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.

In the CY 2015 OPPS/ASC proposed rule (79 FR 741063 through 41067), we solicited public comments on each of the issues outlined above for the information collection requirements discussed below.

B. Requirements in Regulation Text: Changes to the Rural Provider and Hospital Ownership Exceptions to the Physician Self-Referral Law: Expansion Exception Process (§ 411.362)

As discussed in section XV.C. of the CY 2015 OPPS/ASC proposed rule (79 FR 41054 through 41056) and in section XV.C. of this final rule with comment period, we proposed to modify the physician-owned hospital expansion exception process under the rural provider and hospital ownership exceptions to the physician self-referral law. Specifically, we proposed to permit physician-owned hospitals to use certain non-HCRIS data sources to demonstrate satisfaction of the expansion exception process eligibility criteria.

In section XIX.B. of the CY 2015 OPPS/ASC proposed rule (79 FR 41063), we stated that we believe the burden associated with our modifications to the physician-owned hospital expansion exception process is exempt from the PRA under 5 CFR 1320.3(c) because the information collection will not impact 10 or more entities in a 12-month period. We did not receive any public comments on the proposed stated burden of our proposed modifications to the physician-owned hospital expansion exception process.

As discussed in section XV.C. of this final rule with comment period, we are finalizing our proposal with certain modifications. The provisions are exempt from the PRA under 5 CFR 1320.3(c) because the information collection will not impact 10 or more entities in a 12-month period.

C. Associated Information Collections Not Specified in Regulatory Text

In the CY 2015 OPPS/ASC proposed rule, we made 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 requirements, any public comments we received, and our responses to those public comments.

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), and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75170 through 75172) for detailed discussions of Hospital OQR Program information collection requirements we have previously finalized.

a. Revisions to the CY 2016 Payment Determination Estimates

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75103), we finalized the adoption of four new measures for the CY 2016 payment determination and subsequent years: (1) OP–27: Influenza Vaccination Coverage among Healthcare Personnel (NQF # 0431); (2) OP 29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF # 0658); (3) OP 30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF # 0659); and (4) OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF # 1536). In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we estimated measures OP–29, OP–30, and OP–31 would require 40 hours of reporting per quarter (96 cases × 0.417 hours). We also estimated that reporting these measures via our Web-based tool would take 10 minutes (or 0.167 hours) per measure per year (or 2.5 minutes for each quarter's data, which are submitted on an annual basis) (78 FR 75171 through 75172).

We noted in section XIII.D.2. of the CY 2015 OPPS/ASC proposed rule and this final rule with comment period that we have delayed reporting for OP–29 and OP–30 for the CY 2016 payment determination by one quarter. Therefore, we estimate a reduction in burden of 40 hours for each of these measures (40 hours per quarter for reporting + 2.5 minutes of reporting via the Web-based tool) per hospital for the CY 2016 payment determination. In addition, in section XIII.D.3. of the CY 2015 OPPS/ASC proposed rule and this final rule

with comment period, we are finalizing our proposal to exclude OP–31 from the CY 2016 payment determination measure set. Therefore, we estimate that there will be no burden for reporting OP–31 for the CY 2016 payment determination, and an overall reduction in burden of 160 hours ((40 hours per quarter for reporting × 4 quarters) + 0.167 hours per year for reporting via the Web-based tool) per hospital for the CY 2016 payment determination.

Combining the estimated reductions in burden for all three of these measures, we estimate a total reduction in burden of 240 hours (40 hours + 40 hours + 160 hours) per hospital for the CY 2016 payment determination due to delayed data collection for OP–29 and OP–30 and the exclusion of OP–31. We estimate that approximately 3,300 hospitals will participate in the Hospital OQR Program for the CY 2016 payment determination. Therefore, we estimate a total reduction in burden of 792,000 hours (240 hours × 3,300 hospitals) for the CY 2016 payment determination from our original estimate of 1.6 million hours (160 hours/measure × 3 measures × 3,300 hospitals) as discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171 through 75172) for all hospitals participating in the Hospital OQR Program based on the data collection delays for OP–29 and OP–30 and the exclusion of OP–31. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we estimated that these measures would result in a financial burden of $30 per hour. Therefore, we estimate that the changes to these three measures will result in a reduction in financial burden of $23.8 million ($30/hour × 792,000 hours) for the CY 2016 payment determination from our original estimate of $76.8 million ($1.6 million × $30) as discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171 through 75172).

b. Hospital OQR Program Requirements for the CY 2017 Payment Determination and Subsequent Years

As we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we believe there is a burden associated with successful participation in the Hospital OQR Program, where successful participation results in a full annual payment update (APU) for the particular payment determination. For the reasons stated in that rule, we believe that the burden associated with these requirements is 42 hours per hospital or 138,600 hours for all hospitals for the CY 2017 payment determination and subsequent years. We estimate a financial burden for these requirements of $4.2 million ($30/hour × 138,600) for all hospitals.

(1) Claims-Based Measures for the CY 2017 and CY 2018 Payment Determinations and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68530) for detailed discussions of the information collection requirements for the previously finalized claims-based measures (OP–8, OP–9, OP–10, OP–11, OP–13, OP–14, and OP–15). In section XIII.E. of this final rule with comment period, we are finalizing our proposal to adopt one additional claims-based measure, OP–32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, but are finalizing its inclusion in the measure set for the CY 2018 payment determination and subsequent years instead of for the CY 2017 payment determination and subsequent years as proposed. Before publicly reporting this measure, however, we will conduct a dry run (a preliminary analysis) for facilities to review their performance and provide feedback. For more detailed information about the dry run, we refer readers to our discussion in section XIII.E. of this final rule with comment period.

As we noted in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68530) and consistent with the modifications we are finalizing in this final rule with comment period, we calculate claims-based measures using Medicare FFS claims data that do not require additional hospital data submissions.

(2) Chart-Abstracted Measures for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68530 through 68531) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171) for detailed discussions of the information collection requirements for the previously finalized chart-abstracted measures (OP–1, OP–2, OP–3, OP–4, OP–5, OP–6, OP–7, OP–18, OP–20, OP–21, OP–22, OP–23, OP–29, OP–30, and OP–31).

In the CY 2015 OPPS/ASC proposed rule (79 FR 41034), we proposed to remove three chart-abstracted measures from the Hospital OQR Program beginning with the CY 2017 payment determination, OP–4: Aspirin at Arrival (NQF # 0286); OP–6: Timing of Prophylactic Antibiotics; and OP–7: Perioperative Care: Prophylactic Antibiotic Selection for Surgical Patients (NQF # 0528). In section XIII.C.3. of this final rule with comment period, we are finalizing our proposal to remove two of these measures (OP–6 and OP–7) from the Hospital OQR Program for the CY 2017 payment determination and subsequent years. We are not finalizing our proposal to remove OP–4 and refer readers to section XIII.C.3. of this final rule with comment period for a detailed discussion. We previously estimated that each participating hospital will spend 35 minutes (or 0.583 hours) per case to collect and submit the data required for the chart-abstracted measures finalized for the CY 2015 payment determination and subsequent years (OP–1, OP–2, OP–3, OP–4, OP–5, OP–6, OP 7, OP–18, OP–20, OP–21, OP–22, and OP–23) (78 FR 75171). Because we are finalizing our proposals to remove two of these measures, we believe that the time to chart-abstract measures will be reduced by 16.7 percent (2 of 12 measures) per case. Therefore, we estimate that hospitals will spend approximately 29 minutes (0.483 hours) per case to collect and submit these data.

Data submitted for the CY 2014 payment determination indicate that the average hospital will submit approximately 1,266 cases per year for these measures. Therefore, as a result of our removal of 2 chart-abstracted measures, we estimate that the time it will take for the average hospital to abstract data for all of the chart-abstracted measures will be 612 hours per year (1,266 cases × 0.483 hours). We estimate that there will be approximately 3,300 hospitals that participate in the Hospital OQR Program for the CY 2017 payment determination and subsequent years. Therefore, we estimate that the chart-abstracted measures for the CY 2017 payment determination and subsequent years will result in a burden of 2.02 million hours (612 hours × 3,300 hospitals) for all participating hospitals, for a total financial burden of approximately $61 million (2.02 million hours × $30/hour).

In addition, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we estimated that OP–29 and OP–30 would require 25 minutes (0.417 hours) per case per measure to chart-abstract. We also estimated that hospitals would abstract 384 cases per year for each of these measures. Our estimate for the CY 2017 payment determination and subsequent years has not changed from last year's estimate (although, as noted above, we have changed our estimate for the CY 2016 payment determination based on the delay of reporting OP–29 and OP–30).

Therefore, for the CY 2017 payment determination and subsequent years, we estimate a burden of 1.1 million hours (3,300 hospitals × 0.417 hours/case × 384 case/measure × 2 measures) for all participating hospitals for OP–29 and OP–30 for a total financial burden of approximately $33 million ($30/hour × 1.1 million hours).

In section XIII.D.3. of this final rule with comment period, we are finalizing our proposal to exclude OP–31 from the CY 2016 payment determination measure set and, for the CY 2017 payment determination and subsequent years, to change this measure from required to voluntary. Hospitals will not be subject to a payment reduction with respect to this measure for the CY 2016 payment determination or during the period of voluntary reporting. We continue to believe this measure addresses an important area of care, and anticipate that many facilities will report this measure on a voluntary basis. In the CY 2014 ASC/OPPS final rule with comment period (78 FR 75171), we estimated that OP–31 would require 25 minutes (0.417 hours) per case to chart-abstract. We also estimated that hospitals would abstract 384 cases per year for this measure. We estimate that approximately 20 percent of hospitals (660 hospitals (3,300 hospitals × 0.2)) will elect to report this measure on a voluntary basis. Therefore, we are revising the estimated burden for this measure to 105,685 hours (660 hospitals × 0.417 hours/case × 384 cases) for participating hospitals for the CY 2017 payment determination and subsequent years, for a total financial burden of approximately $3.2 million ($30/hour × 105,685 hours).

Therefore, for the chart-abstracted measures, we estimate a total burden for all participating hospitals of 3.23 million hours (2.02 million hours + 105,685 hours + 1.1 million hours) and $96.9 million (3.23 million hours × $30/hour) for the CY 2017 payment determination and subsequent years.

(3) Web-Based Measures Submitted Directly to CMS for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171) for detailed discussions of the information collection requirements for the previously finalized measures submitted via the Web-based tool. For the reasons stated in that final rule with comment period, we estimate that each participating hospital would spend 10 minutes per measure per year to collect and submit the data for the six measures (OP–12, OP–17, OP–25, OP–26, OP–29, and OP–30) submitted via the Web-based tool. Therefore, the estimated annual burden associated with these measures for all participating hospitals is 3,307 hours (3,300 hospitals × 0.167 hours/measure × 6 measures/hospital) for the CY 2017 payment determination and subsequent years.

As stated above, in section XIII.D.3. of this final rule with comment period, we are finalizing our proposal that hospitals have the option to voluntarily collect and submit OP–31 data beginning with the CY 2015 encounter period for the CY 2017 payment determination and subsequent years; failing to report this measure will not affect hospitals' payment determinations for CY 2017 and subsequent years. We continue to believe this measure addresses an important area of care and estimate that approximately 20 percent of hospitals or 660 hospitals (3,300 hospitals × 0.2) will elect to report this measure on a voluntary basis. Therefore, we are revising the estimated burden for this measure for all participating hospitals to 111 hours (660 hospitals × 0.167 hours) for the CY 2017 payment determination and subsequent years.

Moreover, we estimate that the financial burden incurred for the Web-based submission of these measures for all participating hospitals will be $119,070 ($30/hour × (3,858 hours + 111 hours)) for the CY 2017 payment determination and subsequent years.

(4) NHSN HAI Measure for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75172) for detailed discussions of the information collection requirements for OP–27: Influenza Vaccination Coverage among Healthcare Personnel. In section XIII.D.1. of this final rule with comment period, we are clarifying the submission deadline for this measure. We do not believe there will be a change in burden due to this clarification because it was a typographical error and our previous estimates were based on the correct submission timeframe. We also noted that facilities should collect and submit a single vaccination count for each health care facility enrolled in NHSN by the facility OrgID. Although we believe an overall reduction in burden will occur because hospitals will only be required to submit this information once for both the Hospital IQR Program and the Hospital OQR Program, we do not believe there is a reduction in burden that is directly attributable to the Hospital OQR Program. That is, this requirement is independent of the Hospital IQR Program requirements. Therefore, our burden analysis remains the same. For the reasons discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75172), we estimate a total burden for all participating hospitals of 106,940 hours and a total financial burden of $3,208,203 associated with this measure.

c. Review and Corrections Period Requirements for the CY 2017 Payment Determination and Subsequent Years

In section XIII.H.2.f. of this final rule with comment period, we are finalizing our proposal to formalize that the time during which hospitals submit chart-abstracted data is the review and corrections period for those data. Because this proposal does not require hospitals to submit additional data, we do not believe it will increase burden for these hospitals.

d. Hospital OQR Program Validation Requirements for the CY 2017 Payment Determination and Subsequent Years

In sections XIII.H.3.b. and XIII.H.3.e. of this final rule with comment period, we are finalizing three changes to our validation procedures: (1) A hospital will be eligible for random selection for validation if it submits at least 12 cases to the Hospital OQR Program Clinical Data Warehouse during the quarter containing the most recently available data (we note that this is a modification of our proposal that a hospital would be eligible for random selection for validation if it submitted 1 case); (2) hospitals will have the option to either submit paper copies of patient charts or securely transmit electronic versions of medical information for validation; and (3) hospitals must identify the medical records staff responsible for submission of records under the Hospital OQR Program to the designated CMS contractor. We do not believe that these changes to the eligibility requirements will result in additional burden because we will continue to select 500 hospitals for validation consistent with our previous burden estimates indicate (78 FR 75172). In addition, we do not believe requiring hospitals to identify the medical records staff responsible for submission of records will result in additional burden since hospitals must already submit this information to our designated contractors (the State QIO), and only the contractor to whom the data is submitted may change. However, we do believe that the second requirement regarding the method of submission may result in a change in burden.

We are finalizing our proposal that the requirement to submit patient charts for validation of Hospital OQR Program data may be met by employing either of the following options: (1) A hospital may submit paper medical records, the form in which we have historically requested them; or (2) a hospital may securely transmit electronic versions of medical information beginning in the CY 2017 payment determination and for subsequent years. We are finalizing our proposal that hospitals that choose to securely transmit electronic versions of medical information should either: (1) download or copy the digital image (that is., a PDF) of the patient chart onto an encrypted CD, DVD, or flash drive and ship the encrypted electronic media following instructions specified on the QualityNet Web site; or (2) securely submit PDFs of patient charts using a Secure File Transfer Portal on the QualityNet Web site. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50834 through 50835), the Hospital IQR Program previously finalized a similar policy that also allows hospitals to submit electronic versions of records for validation using the first method. In the FY 2015 IPPS/LTCH PPS final rule, the Hospital IQR Program finalized secure submission of digital images via a Secure File Transfer Portal (79 FR 50269). For the same reasons outlined in the Hospital IQR Program (78 FR 50956), we are finalizing our proposal to set a reimbursement rate of $3.00 per patient chart submitted electronically (using either of the finalized methods for electronic submission) for validation for the CY 2017 payment determination and subsequent years. We will continue to reimburse hospitals at a rate of 12 cents per page, plus shipping, for records provided on paper (76 FR 74577).

The burden associated with validation is the time and effort necessary to submit validation data to the CMS contractor. For some hospitals, we believe that submitting these data electronically may result in a reduction in burden; for others we believe that submitting paper copies will be the least burdensome option. As we have previously stated in the CY 2014 OPPS/ASC final rule with comment period, we sample 500 hospitals for validation, and we estimate that it will take each hospital 12 hours to comply with the data submission requirements (78 FR 75172). Therefore, because the number of hospitals we sample for validation will remain the same, 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) for the CY 2017 payment determination and subsequent years.

e. Extraordinary Circumstances Extensions or Exemptions Process

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), and 42 CFR 419.46(d) for a complete discussion of our extraordinary circumstances extension or waiver process under the Hospital OQR Program. In this final rule with comment period, we are finalizing our proposal to change the phrase ''extension or waiver'' to ''extension or exemption'' throughout the regulation. In section XIII.J. of this final rule with comment period, we note that we intend to make certain changes to the form to ensure that the form is consistent across CMS quality reporting programs. We do not anticipate that these minor changes will affect the collection of information burden estimates for this process.

f. Reconsideration and Appeals

While there is burden associated with filing a reconsideration request, the regulations at 5 CFR 1320.4 for the PRA (44 U.S.C. 3518(c)(1)(B)) exclude collection activities during the conduct of administrative actions such as reconsiderations or appeals.

We invited public comment on the burden associated with these information collection requirements. We did not receive any public comments on this burden.

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), and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75172 through 75174) for detailed discussions of the ASCQR Program information collection requirements we have previously finalized.

b. Revisions to the CY 2016 Payment Determination Estimates

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124 through 75130), we finalized the adoption of three new measures for the CY 2016 payment determination and subsequent years: 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). In that final rule with comment period, we estimated that each participating ASC would spend 35 minutes per case to collect and submit the data for these measures, resulting in a total estimated burden for ASCs with a single case per ASC of 3,067 hours (5,260 ASCs × 0.583 hours per case per ASC). We also stated that we expected ASCs would vary greatly as to the number of cases per ASC due to ASC specialization (78 FR 75173).

As we stated in section XIV.E.3. of the CY 2015 OPPS/ASC proposed rule and this final rule with comment period, we have delayed reporting for ASC–9 and ASC–10 for the CY 2016 payment determination by one quarter. Therefore, we estimate a 25-percent reduction in cases and burden for these measures for the CY 2016 payment determination. As we stated in section XIV.E.3.c. of the CY 2015 OPPS/ASC proposed rule and this final rule with comment period, we delayed reporting of ASC–11 by 1 year. We also are finalizing our proposal to exclude ASC–11 from the CY 2016 payment determination measure set. As a result, we do not believe there would be any burden associated with this measure for the CY 2016 payment determination.

c. Claims-Based Measures for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532) and 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 claims-based ASCQR Program measures (four outcome measures and one process measure). The five 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); and ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing (NQF # 0264). For the reasons we discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75172 through 75173), we estimate that the reporting burden to report Quality Data Codes (QDCs) for these five claims-

based outcome measures would be nominal for the CY 2017 payment determination and for subsequent years.

In section XIV.B.5. of this final rule with comment period, we are finalizing our proposal to add one additional claims-based measure to the ASCQR Program, but are finalizing its inclusion in the measure sets for the CY 2018 payment determination and subsequent years, instead of the measure set we proposed for the CY 2017 payment determination and subsequent years. Before publicly reporting this measure, we plan to perform a dry run (a preliminary analysis) of the measure in 2015. We refer readers to section XIV.B.5 of this final rule with comment period for a detailed discussion of the dry run.

Because this measure, ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, will be computed by CMS based on paid Medicare FFS claims, and will not require ASCs to submit QDCs, we do not anticipate that this measure would create additional burden to ASCs during the dry run or for the CY 2018 payment determination and subsequent years.

d. Web-Based Measures for the CY 2017 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532) and 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 1,756 hours (5,260 ASCs × 2 measures × 0.167 hours per ASC) and $52,680 (1,756 hours × $30.00 per hour) annually for the CY 2017 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 and $540,150 (18,005 hours × $30.00 per hour) annually for the CY 2017 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 and $92,010 (3,067 hours × $30.00 per hour) annually for the CY 2017 payment determination and for subsequent years.

In section XIV.E.3.c. of this final rule with comment period, we are finalizing 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), meaning we would not subject ASCs to a payment reduction with respect to this measure during the period of voluntary reporting. We continue to believe this measure addresses an important area of care, and anticipate that many facilities will report this measure on a voluntary basis. In the CY 2014 ASC/OPPS final rule with comment period (78 FR 75173), we estimated that each participating ASC would spend 35 minutes per case to collect and submit the data for this measure, making the total estimated burden for ASCs with a single case per ASC 3,067 hours (5,260 ASCs × 0.583 hours per case per ASC) annually. We expect that ASCs would vary greatly as to the number of cases per ASC due to ASC specialization. We estimate that approximately 20 percent of ASCs would elect to report this measure on a voluntary basis; therefore, we estimate the total estimated burden 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 2017 payment determination and subsequent years.

e. Extraordinary Circumstances Extension or Exemptions Process

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) for a complete discussion of our extraordinary circumstances extension or waiver process under the ASCQR Program. In the CY 2015 OPPS/ASC proposed rule, we did not propose to make any substantive changes to this process. However, in the future, we will refer to the process as the extraordinary circumstances extensions or exemptions process. In section XIV.E.7. of this final rule with comment period, we note that we intend to make certain changes to the form to ensure that the form is consistent across CMS quality reporting programs. We do not anticipate that these minor changes would affect the burden estimates for this process.

f. Reconsideration

While there is burden associated with filing a reconsideration request, the regulations at 5 CFR 1320.4 for the PRA (44 U.S.C. 3518(c)(1)(B)) exclude collection activities during the conduct of administrative actions such as reconsiderations.

We invited public comment on the burden associated with these information collection requirements. We did not receive any public comments on this burden.

XX. Waiver of Proposed Rulemaking and Response to Comments

A. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on a proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We utilize HCPCS codes for Medicare payment purposes. The HCPCS is a national coding system comprised of Level I codes (CPT codes) and Level II codes that are intended to provide uniformity to coding procedures,

services, and supplies across all types of medical providers and suppliers. CPT codes are copyrighted by the AMA and consist of several categories, including Category I codes which are 5-digit numeric codes, and Category III codes which are temporary codes to track emerging technology, services, and procedures. The AMA issues an annual update of the CPT code set each Fall, with January 1 as the effective date for implementing the updated CPT codes. The HCPCS, including both CPT codes and Level II codes, is similarly updated annually on a calendar year basis. Annual coding changes are not available to the public until the Fall immediately preceding the annual January update of the OPPS and the ASC payment system. Because of the timing of the release of these new codes, it is impracticable for us to provide prior notice and solicit comment on these codes and the payments assigned to them in advance of publication of the final rule that implements the OPPS and the ASC payment system. However, it is imperative that these coding changes be accounted for and recognized timely under the OPPS and the ASC payment system for payment because services represented by these codes will be provided to Medicare beneficiaries in hospital outpatient departments and ASCs during the calendar year in which they become effective. Moreover, regulations implementing the HIPAA (42 CFR Parts 160 and 162) require that the HCPCS be used to report health care services, including services paid under the OPPS and the ASC payment system. We assign interim payment amounts and status indicators to any new codes according to our assessment of the most appropriate APC based on clinical and resource homogeneity with other procedures and services in the APC. If we did not assign payment amounts to new codes on an interim basis, the alternative would be to not pay for these services during the initial calendar year in which the codes become effective. We believe it would be contrary to the public interest to delay establishment of payment amounts for these codes.

Therefore, we find good cause to waive the notice of proposed rulemaking for the establishment of payment amounts for selected HCPCS codes identified with comment indicator ''NI'' in Addendum B and Addendum BB to this final rule with comment period. We are providing a 60-day public comment period.

B. 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 final rule with comment period, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XXI. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this final rule with comment period, 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 final rule with comment period contains the impact and other economic analyses for the provisions that we are finalizing.

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 final rule with comment period 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 final rule with comment period 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 final rule with comment period. We solicited comments on the regulatory impact analysis in the proposed rule, and we address the public comments we received in this section below and in other sections of this final rule with comment period as appropriate.

2. Statement of Need

This final rule with comment period is necessary to update the Medicare hospital OPPS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2015. 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 revising the APC relative payment weights using claims data for services furnished on and after January 1, 2013, through and including December 31, 2013 and processed through June 30, 2014, and updated cost report information.

This final rule with comment period also is necessary to update the ASC payment rates for CY 2015, 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 2015. 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 OPPS and ASC Payment Provisions

We estimate that the total increase in Federal government expenditures under the OPPS for CY 2015 compared to CY 2014 due to the changes in this final rule with comment period, will be approximately $900 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate that the OPPS expenditures for CY 2015 will be approximately $5.135 billion higher relative to expenditures in CY 2014. Because this final rule with comment period is economically significant as measured by the threshold of an additional $100 million in expenditures in one year, we have prepared this regulatory impact analysis that, to the best of our ability,

presents its costs and benefits. Table 49 displays the redistributional impact of the CY 2015 changes in OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the update to the conversion factor and other adjustments (not including the effects of outlier payments, the pass-through estimates, and the application of the frontier State wage adjustment for CY 2015) will increase total OPPS payments by 2.2 percent in CY 2015. The changes to the APC weights, the changes to the wage indexes, the continuation of a payment adjustment for rural SCHs, including EACHs, and the payment adjustment for cancer hospitals will not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates will change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2014 and CY 2015, considering all payments, including 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, will increase total estimated OPPS payments by 2.3 percent.

We estimate the total increase (from changes to the ASC provisions in this final rule with comment period as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures under the ASC payment system for CY 2015 compared to CY 2014 to be approximately $236 million. Because the provisions for the ASC payment system are part of a final rule that is economically significant as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of the final rule with comment period. Table 50 and Table 51 of this final rule with comment period display the redistributional impact of the CY 2015 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 OPPS Changes in This Final Rule With Comment Period

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2015 policy changes on various hospital groups. As we did for the proposed rule, we post on the CMS Web site our hospital-specific estimated payments for CY 2015 with the other supporting documentation for this final rule with comment period. To view the 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–1613–FC'' 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 final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 49 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 final rule with comment period for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we do not make adjustments for future changes in variables such as service volume, service-mix, or number of encounters. In the CY 2015 OPPS/ASC proposed rule (79 FR 41068), we solicited 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 received are addressed in the applicable sections of the final rule with comment period that discuss the specific policies.

(2) Estimated Effects of OPPS Changes on Hospitals

Table 49 below shows the estimated impact of this final rule with comment period on hospitals. Historically, the first line of the impact table, which estimates the 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 49, 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 2015, we are continuing to pay CMHCs under APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) and APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs), and we are paying hospitals for partial hospitalization services under APC 0175 (Level I Partial Hospitalization (3 services) for hospital-based PHPs) and APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. 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 final rule with comment period. 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 IPPS market basket percentage increase for FY 2015 is 2.9 percent (79 FR 49994). Section 1833(t)(3)(F)(i) of the Act reduces that 2.9 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.5 percentage point for FY 2015 (which is also the MFP adjustment for FY 2015 in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49994)); 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 OPD fee schedule increase factor of 2.2 percent. We are using the OPD fee schedule increase factor of 2.2 percent in the calculation of the CY 2015 OPPS conversion factor. 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 2015 estimates in Table 49.

To illustrate the impact of the CY 2015 changes, our analysis begins with a baseline simulation model that uses the CY 2014 relative payment weights, the FY 2014 final IPPS wage indexes that include reclassifications, and the final CY 2014 conversion factor. Table

49 shows the estimated redistribution of the increase in payments for CY 2015 over CY 2014 payments to hospitals and CMHCs as a result of the following factors: The impact of the APC reconfiguration and recalibration changes between CY 2014 and CY 2015 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all the changes described in the preceding columns plus the 2.2 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the combined impact shown in Column 4 plus the CY 2015 frontier State wage index adjustment (Column 5); and the estimated impact taking into account all payments for CY 2015 relative to all payments for CY 2014, including the impact of changes in estimated outlier payments and changes to the pass-through payment estimate (Column 6).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are finalizing our proposal to maintain the current adjustment percentage for CY 2015. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2015 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 wage index changes on the hospital. However, total payments made under this system and the extent to which this final rule with comment period will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2014 and CY 2015 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the rates for CY 2015 will increase Medicare OPPS payments by an estimated 2.3 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 an estimated 2.3 percent increase in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 49 shows the total number of facilities (4,006), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2013 hospital outpatient and CMHC claims data to model CY 2014 and CY 2015 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 2014 or CY 2015 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 final rule with comment period. At this time, we are unable to calculate a disproportionate share hospital (DSH) variable for hospitals not participating in 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 (3,871), 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 72 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration—All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals will experience no change, with the impact ranging from an increase of 0.3 percent to a decrease of −0.1 percent, depending on the number of beds. Rural hospitals will experience no change, with the impact ranging from an increase of 0.3 percent to a decrease of −0.4 percent, depending on the number of beds. Major teaching hospitals will experience an increase of 0.7 percent overall.

Column 3: New Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration; the updates for the wage indexes with the fiscal year (FY) 2015 IPPS post-reclassification wage indexes; and the rural adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2014 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 updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis. This column excludes the effects of the frontier State wage index adjustment, which is not budget neutral and is included in Column 5. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are finalizing our proposal to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2015, as described in section II.E. of this final rule with comment period.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2015 scaled weights and a CY 2014 conversion factor that included a budget neutrality adjustment for the effect of changing the wage indexes between CY 2014 and CY 2015. The FY 2015 wage policy results in modest redistributions.

There is no difference in impact between the CY 2014 cancer hospital payment adjustment and the CY 2015 cancer hospital payment adjustment because we are finalizing our proposal to use the same payment-to-cost ratio target in CY 2015 as in CY 2014.

Column 4: All Budget Neutrality Changes Combined With the Market Basket Update

Column 4 demonstrates the combined impact of all the changes previously described and the update to the conversion factor of 2.2 percent. Overall, these changes will increase payments to urban hospitals by 2.3 percent and to rural hospitals by 1.9 percent. Most classes of hospitals will receive an increase in line with the 2.2 percent overall increase after the update is applied to the budget neutrality adjustments.

Column 5: All Adjustments With the Frontier State Wage Index Adjustment

This column shows the impact of all budget neutrality adjustments, application of the 2.2 percent OPD fee schedule increase factor, and the nonbudget-neutral impact of applying the CY 2015 frontier State wage adjustment. Rural hospitals in West North Central and Mountain States will experience estimated increases in payment of 3.4 and 4.2 percent, respectively, as a result of the frontier State wage index adjustment, while urban hospitals in those States will experience estimated increases of 3.2 and 2.5 percent, respectively.

Column 6: All Changes for CY 2015

Column 6 depicts the full impact of the CY 2015 policies on each hospital group by including the effect of all of the changes for CY 2015 and comparing them to all estimated payments in CY 2014. Column 6 shows the combined budget neutral effects of Column 2 and 3; the OPD fee schedule increase; the impact of the frontier State wage index adjustment; the impact of estimated OPPS outlier payments as discussed in section II.G. of this final rule with comment period; the 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 final rule with comment period); and the difference in 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 2014 update (and assumed, for modeling purposes, to be the same number for CY 2015), we included 37 hospitals in our model because they had both CY 2013 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2015 will increase payments to all facilities by 2.3 percent for CY 2015. We modeled the independent effect of all changes in Column 6 using the final relative payment weights for CY 2014 and the relative payment weights for CY 2015. We used the final conversion factor for CY 2014 of $72.672 and the CY 2015 conversion factor of $74.144 discussed in section II.B. of this final rule with comment period.

Column 6 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379) of 5.09 percent (1.0509) to increase individual costs on the CY 2013 claims, and we used the most recent overall CCR in the July 2014 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2014. Using the CY 2013 claims and a 5.09 percent charge inflation factor, we currently estimate that outlier payments for CY 2014, using a multiple threshold of 1.75 and a fixed-dollar threshold of $2,900 will be approximately 0.8 percent of total payments. The estimated current outlier payments of 0.8 percent are incorporated in the comparison in Column 6. We used the same set of claims and a charge inflation factor of 10.44 percent (1.1044) and the CCRs in the July 2014 OPSF, with an adjustment of 0.9821, to reflect relative changes in cost and charge inflation between CY 2013 and CY 2015, to model the CY 2015 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $2,775. The charge inflation and CCR inflation factors are discussed in detail in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379 through 50380).

We estimate that the anticipated change in payment between CY 2014 and CY 2015 for the hospitals failing to meet the Hospital OQR Program requirements will be negligible. Overall, we estimate that facilities will experience an increase of 2.3 percent under this final rule with comment period in CY 2015 relative to total spending in CY 2014. This projected increase (shown in Column 6) of Table 49 reflects the 2.2 percent OPD fee schedule increase factor, less 0.13 percent for the change in the pass-through estimate between CY 2014 and CY 2015, plus 0.18 percent for the difference in estimated outlier payments between CY 2014 (0.82 percent) and CY 2015 (1.0 percent), less 0.1 percent due to the frontier State wage index adjustment in CY 2014, plus 0.1 percent due to the frontier State wage index adjustment in CY 2015. We estimate that the combined effect of all changes for CY 2015 will increase payments to urban hospitals by 2.3 percent.

Overall, we estimate that rural hospitals will experience a 1.9 percent increase as a result of the combined effects of all changes for CY 2015. We estimate that rural hospitals that bill less than 5,000 lines of OPPS services will experience a decrease of −2.0 percent and rural hospitals that bill 11,000 or more lines of OPPS services will experience adjustments ranging from 0.9 to 2.1 percent.

Among hospitals by teaching status, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 3.1 percent for major teaching hospitals and 2.0 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated increase of 2.0 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience an increase of 2.4 percent, proprietary hospitals will experience an increase of 1.7 percent, and governmental hospitals will experience an increase of 2.1 percent.

TABLE 49—ESTIMATED IMPACT OF THE CY 2015 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals	APC Recalibration (all changes)	New wage index and provider adjustments	All budget neutral changes (combined cols 2, 3) with market basket update	All budget neutral changes and update (column 4) with frontier wage index adjustment	All changes
	(1)	(2)	(3)	(4)	(5)	(6)
ALL FACILITIES*	4,006	0.0	0.0	2.2	2.3	2.3
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,871	0.0	0.0	2.2	2.3	2.3
URBAN HOSPITALS	3,008	0.0	0.0	2.3	2.4	2.3
LARGE URBAN (GT 1 MILL.)	1,646	0.1	0.2	2.5	2.5	2.5
OTHER URBAN (LE 1 MILL.)	1,362	0.0	−0.1	2.1	2.3	2.1

TABLE 49—ESTIMATED IMPACT OF THE CY 2015 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals	APC Recalibration (all changes)	New wage index and provider adjustments	All budget neutral changes (combined cols 2, 3) with market basket update	All budget neutral changes and update (column 4) with frontier wage index adjustment	All changes
	(1)	(2)	(3)	(4)	(5)	(6)
RURAL HOSPITALS	863	0.0	−0.3	1.9	2.2	1.9
SOLE COMMUNITY	376	0.1	−0.2	2.2	2.6	2.2
OTHER RURAL	487	−0.2	−0.3	1.6	1.7	1.6
BEDS (URBAN):						
0–99 BEDS	1,067	0.0	0.0	2.3	2.4	2.3
100–199 BEDS	856	0.0	0.0	2.2	2.3	2.2
200–299 BEDS	458	−0.1	0.1	2.2	2.4	2.2
300–499 BEDS	410	−0.1	0.1	2.2	2.4	2.3
500 + BEDS	217	0.3	−0.1	2.4	2.4	2.5
BEDS (RURAL):						
0–49 BEDS	345	0.1	−0.2	2.2	2.4	2.2
50–100 BEDS	315	0.3	−0.3	2.2	2.5	2.2
101–149 BEDS	116	−0.3	−0.1	1.8	2.1	1.8
150–199 BEDS	46	−0.4	−0.4	1.4	2.1	1.4
200 + BEDS	41	−0.3	−0.4	1.5	1.5	1.5
VOLUME (URBAN):						
LT 5,000 Lines	544	−1.7	−0.3	0.2	0.4	0.4
5,000–10,999 Lines	135	−0.8	−0.2	1.3	1.3	1.4
11,000–20,999 Lines	117	−1.5	0.0	0.6	1.2	0.9
21,000–42,999 Lines	228	−0.7	0.0	1.5	1.5	1.6
42,999–89,999 Lines	526	−0.3	0.0	1.9	1.9	1.9
GT 89,999 Lines	1,458	0.1	0.0	2.3	2.4	2.4
VOLUME (RURAL):						
LT 5,000 Lines	34	−3.8	−0.3	−1.9	1.1	−2.0
5,000–10,999 Lines	27	−1.8	−0.5	−0.1	1.1	0.0
11,000–20,999 Lines	42	−1.1	−0.3	0.8	0.8	0.9
21,000–42,999 Lines	161	0.2	−0.3	2.1	2.7	2.1
GT 42,999 Lines	599	0.0	−0.3	1.9	2.1	1.9
REGION (URBAN):						
NEW ENGLAND	152	1.1	0.2	3.5	3.5	3.4
MIDDLE ATLANTIC	361	0.5	0.5	3.2	3.2	3.2
SOUTH ATLANTIC	482	−0.2	−0.3	1.7	1.7	1.7
EAST NORTH CENT.	473	0.1	−0.1	2.2	2.1	2.2
EAST SOUTH CENT.	179	−0.9	−0.5	0.9	0.9	0.9
WEST NORTH CENT.	194	0.0	−0.2	2.0	3.2	2.0
WEST SOUTH CENT.	527	−0.7	−0.5	1.0	1.0	1.1
MOUNTAIN	203	0.0	−0.1	2.1	2.5	2.2
PACIFIC	389	0.3	1.1	3.6	3.6	3.7
PUERTO RICO	48	−0.4	0.3	2.1	2.1	1.9
REGION (RURAL):						
NEW ENGLAND	23	1.6	−0.1	3.6	3.6	3.6
MIDDLE ATLANTIC	58	0.8	0.2	3.2	3.2	3.2
SOUTH ATLANTIC	130	−0.6	−0.5	1.0	1.0	1.0
EAST NORTH CENT.	120	0.0	0.0	2.2	2.2	2.1
EAST SOUTH CENT.	165	−0.8	−0.5	0.9	0.9	0.9
WEST NORTH CENT.	101	0.2	−0.2	2.2	3.4	2.1
WEST SOUTH CENT.	181	−0.7	−0.8	0.7	0.7	0.7
MOUNTAIN	61	0.7	−0.4	2.5	4.2	2.6
PACIFIC	24	0.8	0.9	4.0	3.9	3.9
TEACHING STATUS:						
NON–TEACHING	2,839	−0.2	0.0	2.0	2.1	2.0
MINOR	706	−0.2	−0.1	1.9	2.2	2.0
MAJOR	326	0.7	0.1	3.1	3.0	3.1
DSH PATIENT PERCENT:						
0	21	0.0	0.3	2.5	2.5	2.5
GT 0–0.10	328	0.3	0.2	2.7	2.8	2.7
0.10–0.16	334	0.1	0.0	2.3	2.5	2.3
0.16–0.23	680	0.1	0.0	2.2	2.3	2.2
0.23–0.35	1,076	0.0	0.0	2.1	2.3	2.1
GE 0.35	824	0.1	0.1	2.3	2.3	2.4
DSH NOT AVAILABLE**	608	−3.6	0.0	−1.4	−1.4	−1.5
URBAN TEACHING/DSH:						
TEACHING & DSH	938	0.2	0.0	2.4	2.6	2.5
NO TEACHING/DSH	1,477	−0.2	0.1	2.1	2.1	2.1
NO TEACHING/NO DSH	18	−0.1	0.4	2.5	2.5	2.5

TABLE 49—ESTIMATED IMPACT OF THE CY 2015 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals	APC Recalibration (all changes)	New wage index and provider adjustments	All budget neutral changes (combined cols 2, 3) with market basket update	All budget neutral changes and update (column 4) with frontier wage index adjustment	All changes
	(1)	(2)	(3)	(4)	(5)	(6)
DSH NOT AVAILABLE**	575	−3.3	0.1	−1.0	−0.9	−1.0
TYPE OF OWNERSHIP:						
VOLUNTARY	2,006	0.1	0.0	2.4	2.5	2.4
PROPRIETARY	1,322	−0.4	−0.1	1.7	1.8	1.7
GOVERNMENT	543	−0.1	−0.1	2.1	2.1	2.1
CMHCs	72	0.0	−0.5	1.7	1.7	1.3

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all CY 2015 OPPS policies and compares those to the CY 2014 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2015 hospital inpatient wage index, including all hold harmless policies and transitional wages. The 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 CY 2014.

Column (4) shows the impact of all budget neutrality adjustments and the addition of the 2.2 percent OPD fee schedule update factor (2.9 percent reduced by 0.5 percentage point for the final productivity adjustment and further reduced by 0.2 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).

Column (5) shows the nonbudget neutral impact of applying the frontier State wage adjustment in CY 2015.

Column (6) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, adding estimated outlier payments, and applying payment wage indexes.

* These 4,006 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 OPPS Changes on CMHCs

The last line of Table 49 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2014, CMHCs are paid under two APCs for these services: APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) and APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs). Hospitals are paid for partial hospitalization services under APC 0175 (Level I Partial Hospitalization (3 services) for hospital-based PHPs) and APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). We use our standard ratesetting methodology to derive the payment rates for each APC based on the cost data derived from claims and cost data for the provider-type-specific APC. For CY 2015, we are finalizing our proposal 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 will 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 2013 claims data used for this final rule with comment period. 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 will experience an overall 1.3 percent increase in payments from CY 2014 (shown in Column 6).

Column 3 shows that the estimated impact of adopting the FY 2015 wage index values will result in a small decrease of −0.5 percent to CMHCs. We note that all providers paid under the OPPS, including CMHCs, will receive a 2.2 percent OPD fee schedule increase factor. Column 4 shows that combining this OPD fee schedule increase factor, along with changes in APC policy for CY 2015 and the FY 2015 wage index updates, will result in an estimated increase of 1.7 percent. Column 5 shows that adding the frontier State wage index adjustment will result in no change to the cumulative 1.7 percent increase. Column 6 shows that adding the changes in outlier and pass-though payments will result in a −0.4 percent decrease in payment for CMHCs, for a total increase of 1.3 percent. This reflects all changes to CMHCs for CY 2015.

(4) Estimated Effect of 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 will increase for services for which the OPPS payments will rise and will decrease for services for which the OPPS payments will fall. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this final rule with comment period. 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 will be 20.0 percent for all services paid under the OPPS in CY 2015. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including recalibration of the APC relative payment weights, change in the portion of OPPS payments dedicated to pass-through payments, and the CY 2015 comprehensive APC payment policy discussed in section II.A.2.e. of this final rule with comment period.

(5) Estimated Effects of 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 final rule with comment period. No types of providers or suppliers other than hospitals, CMHCs and ASCs will be affected by the proposed changes in this final rule with comment period.

(6) Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be $900 million in additional program payments for OPPS

services furnished in CY 2015. The effect on the Medicaid program is expected to be limited to increased 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 XXI.A. of this final rule with comment period.

(7) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we proposed and are finalizing and the reasons for our selected alternatives are discussed throughout this final rule with comment period. In this section, we discuss some of the major issues and the alternatives considered.

- Alternatives Considered for the Establishment of Comprehensive APCs

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910 and 75184 through 75185) for a discussion of our policy to establish comprehensive APCs for CY 2015 and the alternatives we considered. We note that we published tables in that final rule with comment period to demonstrate how this policy would have been implemented in CY 2014, and stated that we would be considering any additional public comments we receive when we update the policy for CY 2015 to account for changes that may occur in the CY 2013 claims data.

b. Estimated Effects of CY 2015 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 final rule with comment period, we are setting the CY 2015 ASC relative payment weights by scaling the CY 2015 OPPS relative payment weights by the ASC scaler of 0.9225. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 50 and 51 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 2015 payment determinations will be based on the application of a 2.0 percentage point reduction to the annual update factor, which currently is the CPI–U. We calculated the CY 2015 ASC conversion factor by adjusting the CY 2014 ASC conversion factor by 0.9998 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2014 and CY 2015 and by applying the CY 2015 MFP-adjusted CPI–U update factor of 1.4 percent (projected CPI–U update of 1.9 percent minus a projected productivity adjustment of 0.5 percentage point). The CY 2015 ASC conversion factor is $44.071.

(1) Limitations of Our Analysis

Presented here are the projected effects of the changes for CY 2015 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2013 and CY 2015 with precision. We believe that the net effect on Medicare expenditures resulting from the CY 2015 changes will 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 will experience changes in payment that differ from the aggregated estimated impacts presented below.

(2) Estimated Effects of 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 update to the CY 2015 payments will 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 CY 2015 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2013 claims data. Table 50 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2014 payments to estimated CY 2015 payments and Table 51 shows a comparison of estimated CY 2014 payments to estimated CY 2015 payments for procedures that we estimate will receive the most Medicare payment in CY 2014.

Table 50 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 50.

- 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 2014 ASC Payments were calculated using CY 2013 ASC utilization (the most recent full year of ASC utilization) and CY 2014 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2014 ASC payments.
- Column 3—Estimated CY 2015 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 updates to ASC payment rates for CY 2015 compared to CY 2014.

As seen in Table 50, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the update to ASC rates for CY 2015 will result in a 1-percent decrease in aggregate payment amounts for eye and ocular adnexa procedures, a 6-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 increase in aggregate payment amounts for musculoskeletal system procedures, a 3-percent increase in aggregate payment amounts for genitourinary system procedures, and a 5-percent increase in aggregate payment amounts for integumentary system procedures.

An estimated increase in aggregate payment for the specialty group does not mean that all procedures in the group will experience increased payment rates. For example, the estimated increase for CY 2015 for digestive system procedures is likely due to an increase in the ASC payment weight for some of the high volume procedures, such as CPT code 43239 (Upper GI endoscopy biopsy) where estimated payment will increase by 9 percent for CY 2015.

Also displayed in Table 50 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 will decrease by 4 percent for CY 2015.

TABLE 50—ESTIMATED IMPACT OF THE CY 2015 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2015 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical specialty group (1)	Estimated CY 2014 ASC payments (in millions) (2)	Estimated CY 2015 percent change (3)
Total	$3,819	1
Eye and ocular adnexa	1,560	−1
Digestive system	781	6
Nervous system	568	1
Musculoskeletal system	472	2
Genitourinary system	165	3
Integumentary system	137	5
Respiratory system	53	3
Cardiovascular system	36	−1
Ancillary items and services	24	−4
Auditory system	14	1
Hematologic & lymphatic systems	6	14

Table 51 below shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2015. The table displays 30 of the procedures receiving the greatest estimated CY 2014 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2014 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2014 ASC Payments were calculated using CY 2013 ASC utilization (the most recent full year of ASC utilization) and the CY 2014 ASC payment rates. The estimated CY 2014 payments are expressed in millions of dollars.
- Column 4—Estimated CY 2015 Percent Change reflects the percent differences between the estimated ASC payment for CY 2014 and the estimated payment for CY 2015 based on the update.

TABLE 51—ESTIMATED IMPACT OF THE CY 2015 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short descriptor (2)	Estimated CY 2014 ASC payments (in millions) (3)	Estimated CY 2015 percent change (4)
66984	Cataract surg w/iol, 1 stage	$1,131	−1%
43239	Upper GI endoscopy, biopsy	170	10
45380	Colonoscopy and biopsy	167	7
45385	Lesion removal colonoscopy	107	6
66982	Cataract surgery, complex	93	−1
64483	Inj foramen epidural l/s	90	0
62311	Inject spine l/s (cd)	79	0
45378	Diagnostic colonoscopy	72	6
66821	After cataract laser surgery	63	3
64493	Inj paravert f jnt l/s 1 lev	47	0
G0105	Colorectal scrn; hi risk ind	45	1
64635	Destroy lumb/sac facet jnt	45	−5
63650	Implant neuroelectrodes	41	4
G0121	Colon ca scrn not hi rsk ind	41	1
64590	Insrt/redo pn/gastr stimul	38	−1
15823	Revision of upper eyelid	35	2

TABLE 51—ESTIMATED IMPACT OF THE CY 2015 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES—Continued

CPT/HCPCS Code (1)	Short descriptor (2)	Estimated CY 2014 ASC payments (in millions) (3)	Estimated CY 2015 percent change (4)
63685	Insrt/redo spine n generator	34	29
29827	Arthroscop rotator cuff repr	34	1
64721	Carpal tunnel surgery	32	−1
29881	Knee arthroscopy/surgery	30	−1
29824	Shoulder arthroscopy/surgery	27	1
29880	Knee arthroscopy/surgery	25	−1
43235	Uppr gi endoscopy diagnosis	23	10
62310	Inject spine c/t	23	0
29823	Shoulder arthroscopy/surgery	22	1
52000	Cystoscopy	22	1
G0260	Inj for sacroiliac jt anesth	21	0
45384	Lesion remove colonoscopy	21	7
67042	Vit for macular hole	21	1
26055	Incise finger tendon sheath	19	−2

(3) Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2015 update to the ASC payment system will be generally positive for beneficiaries with respect to the new procedures that we are adding to the ASC list of covered surgical procedures and for those that we are designating as office-based for CY 2015. 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 designating as office-based in CY 2015, the beneficiary coinsurance amount under the ASC payment system generally will 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 to the minor changes that we are making to the ASC payment system and the reasons that we have chosen specific options are discussed throughout this final rule with comment period. There are no major changes to ASC policies for CY 2015.

c. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget Web site at: *http://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 final rule with comment period. The first accounting statement, Table 52 below, illustrates the classification of expenditures for the CY 2015 estimated hospital OPPS incurred benefit impacts associated with the CY 2015 OPD fee schedule increase, based on the 2014 Trustee's Report. The second accounting statement, Table 53 below, illustrates the classification of expenditures associated with the 1.4 percent CY 2015 update to the ASC payment system, based on the provisions of this final rule with comment period and the baseline spending estimates for ASCs in the 2014 Trustee's Report. Lastly, the tables classify most estimated impacts as transfers.

TABLE 52—ACCOUNTING STATEMENT: CY 2015 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2014 TO CY 2015 ASSOCIATED WITH THE CY 2015 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$900 million.
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS.
Total	$900 million.

TABLE 53—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2014 TO CY 2015 AS A RESULT OF THE CY 2015 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$42 million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.
Total	$42 million.

d. Effects of Requirements for the Hospital OQR Program

In section XIII. of this final rule with comment period, we are finalizing policies affecting the Hospital OQR Program. Of 3,325 hospitals that met eligibility requirements for the CY 2014 payment determination, we determined that 88 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. Most of these hospitals (70 of the 88) chose not to participate in the Hospital OQR Program for the CY 2014 payment determination. We estimate that approximately 90 hospitals will not receive the full OPD fee schedule increase factor for the CY 2017 payment determination and subsequent years.

In section XIII.E. of this final rule with comment period, we are finalizing our proposal to add one claims-based quality measure, OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, for the Hospital OQR Program for the CY 2018 payment determination and subsequent years, instead of the CY 2017 payment determination and subsequent years as proposed. Because this measure is claims-based, it will not require additional burden from data reporting or other action on the part of the hospitals. Therefore, we do not anticipate that this measure will cause any additional facilities to fail to meet requirements the Hospital OQR Program for the CY 2018 payment determination and subsequent years.

In section XIII.C.3. of this final rule with comment period, for the CY 2017 payment determination and subsequent years, we are finalizing our proposal to remove OP–6 and OP–7 from the Hospital OQR Program. However, we are not finalizing our proposal to remove OP–4 and are retaining that measure in the Hospital OQR Program for reasons discussed in section XIII.C.3. In sections XIII.D.3.b. and c. of this final rule with comment period, we are also finalizing our proposal to exclude OP–31 from the CY 2016 payment determination measure set and to change that measure from required to voluntary for the CY 2017 payment determination and subsequent years. Hospitals will not be subject to a payment reduction with respect to this measure for the CY 2016 payment determination or during the period of voluntary reporting.

We anticipate a reduction in burden of approximately 840,517 hours or $25.2 million across participating hospitals from the two measures we are removing and the measure we are making voluntary, as further detailed in sections XIII.C.3. and XIII.D.3.c. of this final rule with comment period, respectively, and the information collection requirements in section XIX.C.1. of this final rule with comment period. We refer readers to the information collection requirements section of this final rule with comment period (section XIX.C.1. of this final rule with comment period) for a detailed discussion of the financial burden of the requirements of the Hospital OQR Program.

The validation requirements that we are finalizing for the CY 2017 payment determination and subsequent years will result in medical record documentation of approximately 6,000 cases per quarter (up to 12 cases per quarter for 500 hospitals) submitted to the designated CMS contractor. In section XIII.H.3.e. of this final rule with comment period, we are finalizing our proposal to allow hospitals to submit medical record documentation for validation using either of two methods: (1) Through paper medical records; or (2) by securely transmitting electronic versions of medical information by either (a) downloading or copying the digital image (that is, a PDF) of the patient chart onto CD, DVD, or flash drive and shipping the electronic media following instructions specified on the QualityNet Web site; or (b) securely submitting digital images (PDFs) of patient charts using a Secure File Transfer Portal on the QualityNet Web site.

As stated in prior rulemaking (76 FR 74577), we will pay for the cost of sending paper medical record documentation to the designated CMS contractor at the rate of 12 cents per page for copying and approximately $1.00 per case for postage. For both new electronic methods, we are finalizing our proposal in the information collection requirements section of this final rule with comment period to reimburse hospitals for sending medical records electronically at a rate of $3.00 per patient chart.

As we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75192), we have found that an outpatient medical chart generally contains up to 10 pages. However, because we do not yet know how many hospitals will choose to submit data electronically or through paper, we cannot estimate the total cost of expenditures and are unable to estimate the number of hospitals that will fail the validation documentation submission requirement for the CY 2017 payment determination. Because we will pay for the data collection effort, we believe that a requirement for medical record documentation for up to12 cases per quarter for 500 hospitals for CY 2015 represents a minimal burden to Hospital OQR Program participating hospitals.

e. Effects of CY 2015 Policies for the ASCQR Program

In section XIV. of this final rule with comment period, we are adopting policies affecting the ASCQR Program. Of 5,260 ASCs that met eligibility requirements for CY 2014, we determined that 116 ASCs did not meet the requirements to receive the full annual payment update.

In section XIV.B.5. of this final rule with comment period, we are finalizing the adoption of one claims-based quality measure, ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, for the ASCQR Program beginning with the CY 2018 payment determination, rather than beginning with the CY 2017 payment determination as proposed. The measure is claims-based and will not require additional data reporting or other action by ASCs. Therefore, we do not anticipate that this measure will cause any additional ASCs to fail to meet the ASCQR Program requirements. We present the time and burdens associated with our finalized policies and proposals in section XIX.C.2. of this final rule with comment period.

In section XIV.E.3.b. of this final rule with comment period, we noted the 3-

month delay in data collection for ASC–9 and ASC–10 for the CY 2016 payment determination. We do not believe that this 3-month delay in data collection will significantly affect the number of ASCs that meet the ASCQR Program requirements.

In section XIV.E.3.c. of this final rule with comment period, we are finalizing our proposal that ASC–11, which was to be first included in the CY 2016 payment determination, will not be included in the CY 2016 measure set, and that the measure will be voluntary for the CY 2017 payment determination and subsequent years. ASCs will not be subject to a payment reduction for the CY 2016 payment determination, nor will ASCs be subject to a payment reduction for the CY 2017 payment determination and subsequent years for failing to report this voluntary measure. Because this measure has not yet affected any payment determination, we do not believe that there will be any impact on the number of ASCs that meet the ASCQR Program requirements as a result of our decision not to include this measure in the measure set for the CY 2016 payment determination and to make this measure voluntary for the CY 2017 payment determination and subsequent years.

We do not believe that the other measures we previously adopted will cause any additional ASCs to fail to meet the ASCQR Program requirements. (We refer readers to the CY 2014 OPPS/ASC final rule with comment period for a list of these measures (78 FR 75130)).

Further, we do not believe that any of the other proposals we are finalizing in this final rule with comment period will significantly affect the number of ASCs that do not receive a full annual payment update for the CY 2017 payment determination. We are unable to estimate the number of ASCs that will not receive the full annual payment update based on the CY 2015 and CY 2016 payment determinations (78 FR 75192). For this reason, using the CY 2014 payment determination numbers as a baseline, we estimate that approximately 116 ASCs will not receive the full annual payment update in CY 2017 due to failure to meet the ASCQR Program requirements.

We invited public comment on the burden associated with these information collection requirements. We did not receive any public comments.

f. Effects of Changes to the Rural Provider and Hospital Ownership Exceptions to the Physician Self-Referral Law

Section 6001(a) of the Affordable Care Act amended the rural provider and hospital ownership exceptions to the physician self-referral law (sections 1877(d)(2) and (d)(3) of the Act, respectively) to impose additional restrictions on physician ownership or investment in hospitals. The amended rural provider and hospital ownership exceptions provide that a hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). We issued regulations addressing the prohibition against facility expansion in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72240).

Section 6001(a)(3) of the Affordable Care Act added section 1877(i)(3)(A)(i) of the Act to set forth that the Secretary shall establish and implement an exception process to the prohibition on expansion of facility capacity. We issued regulations that govern the expansion exception process in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74517) at 42 CFR 411.362(c). The regulations addressing the expansion exception process were issued by January 1, 2012, and the process was implemented on February 1, 2012.

As required by the statute, the expansion exception process provides that hospitals that qualify as an ''applicable hospital'' or a ''high Medicaid facility'' may request an exception to the prohibition on facility expansion. The existing expansion exception process requires the use of filed Medicare cost report data from the Healthcare Cost Report Information System (HCRIS) for hospitals to demonstrate that they satisfy the relevant eligibility criteria set forth in § 411.362(c)(2) for applicable hospitals and § 411.362(c)(3) for high Medicaid facilities (76 FR 42350 through 42352). As discussed in section XV.C. of the CY 2015 OPPS/ASC proposed rule (79 FR 41054 through 41056), we proposed to permit physician-owned hospitals to use certain non-HCRIS data sources to demonstrate satisfaction of the expansion exception process eligibility criteria. In section XV.C. of this final rule with comment period, we are finalizing our proposal with certain modifications. Under our policy, we will continue to require each hospital seeking to qualify for an expansion exception to access and utilize data for its estimations or determinations to demonstrate that the hospital meets the relevant criteria and to provide a detailed explanation regarding whether and how it satisfies each of the relevant criteria. We believe the impact of our modification on affected hospitals will be minimal, given that the use of data from a non-HCRIS data source is voluntary.

Our policy will require each requesting hospital also to provide actual notification that it is requesting an expansion exception directly to hospitals whose data are part of the comparisons set forth in § 411.362(c)(2)(ii) and (c)(3)(ii) of the regulations, in addition to performing the other methods of notification specified in our existing regulations. We are finalizing this policy, and we believe the impact of this additional requirement on physician-owned hospitals will be minimal.

We believe that our policy will affect a relatively small number of physician-owned hospitals. We estimate that there are approximately 265 physician-owned hospitals in the country. Since the process was implemented in February 2012, we have received only four requests, only one of which has been considered sufficiently complete to continue with publication in the **Federal Register**, under the current regulations. We anticipate receiving a similar number of requests each year. We do not believe that we can use the four requests to estimate accurately the potential increase in operating rooms, procedure rooms, and beds pursuant to approved expansion exception requests, and we are not aware of any data that may indicate such an increase. At this time, we also have no data or projections that may help estimate the number of physicians that will be affected by these proposals as a result of their ownership interests in hospitals.

We believe that beneficiaries may be positively impacted by our policies. Specifically, an increase in operating rooms, procedure rooms, and beds may augment the volume or nature of services offered by physician-owned hospitals. An expansion in the number of hospital beds may also permit additional inpatient admissions and overnight stays. Increased operating rooms, procedure rooms, and beds may result in improved access to health care facilities and services. We believe that our policies are necessary to conform our regulations to the amendments to section 1877 of the Act.

We solicited public comments on each of the issues outlined above that contain estimates of the costs and benefits of the proposed rule. We specifically solicited comments on the potential impact on State governments, because we proposed to define external

data sources as data sources generated, maintained, or under the control of a State Medicaid agency. We did not receive any public comments on our estimates.

g. Effects of Policies Related to CMS-Identified Overpayments Associated With Payment Data Submitted by Medicare Advantage (MA) Organizations and Medicare Part D Sponsors

In section XVII. of this final rule with comment period, we discuss our final decisions to set forth in regulations a formal process, including appeals processes, that allows us to recoup overpayments in the limited set of circumstances where CMS makes a determination that an overpayment to an MA organization or Part D sponsor occurred because the organization or sponsor submitted erroneous payment data to CMS. It is difficult to predict how many times CMS will annually determine an overpayment due to erroneous payment data submitted to CMS by an MA organization or Part D sponsor and that, therefore, will be subject to the offset and appeals regulations. However, we predict that it will be highly unlikely to exceed 10 cases a year and will probably be fewer. Further, electing to appeal a CMS overpayment determination under the final regulations is completely at the discretion of the MA organization or Part D sponsor. The MA organization or Part D sponsor may agree that the data require correction and resubmit the data; MA organizations and Part D sponsors that receive notification of an overpayment are under no obligation to initiate the appeal process. If the MA organization or Part D sponsor chooses not to appeal, there are no costs or burden associated with the appeal. If the MA organization or Part D sponsor chooses to appeal the overpayment determination, there will be costs associated with preparing the appeal request.

We are establishing three levels of appeal (reconsideration, informal hearing, and Administrator review), each of which the MA organization or Part D sponsor will have to request. Once the appeal has been filed, however; there will be little or no cost experienced by the MA organization or Part D sponsor because the appeal process is on the record and will not involve oral testimony. The extent to which there will be costs associated with preparing the appeal request is subject to preference and choice. We estimate that it will take a plan 5 hours to prepare and file a reconsideration request. In terms of cost, it has been our experience that most appeals have been prepared by high-level officials of the plan or lawyers. According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2012, the mean hourly wage for the category of ''Lawyers''—which we believe, considering the variety of officials who have submitted appeals, is the most appropriate category—is $62.93. Multiplying this figure by 50 hours (10 submissions × 5 hours) results in a projected annual cost burden of $3,147. We estimate the preparation and filing of a request for a hearing, or for Administrator's review will take 2 hours, at most, because the MA organization or Part D sponsor cannot submit new evidence. The hearing officer or Administrator is limited to a review of the record. Multiplying this figure by 40 hours (10 submissions × 4 hours) results in a projected annual cost burden of $2,517. It is estimated that if the costs of benefits and overhead are included, the total annual costs for requests at the three levels will be approximately $11,000.

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. Most ASCs and most CMHCs are considered small businesses with total revenues of $15 million or less in any single year. We estimate that this final rule with comment period may have a significant impact on approximately 2,006 hospitals with voluntary ownership. 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 final rule with comment period may have a significant impact on approximately 709 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 $141 million. This final rule with comment period does not mandate any requirements for State, local, or tribal governments, or for the private sector.

D. Conclusion

The changes we are making in this final rule with comment period will affect all classes of hospitals paid under the OPPS and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS will experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2015. Table 49 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that will result in a 2.3 percent increase in payments for all services paid under the OPPS in CY 2015, after considering all of the changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, estimated payment for outliers, and changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS will experience more significant gains and others will experience modest losses in OPPS payments in CY 2015.

The updates to the ASC payment system for CY 2015 will 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 50 demonstrates the estimated distributional impact among ASC surgical specialties of the

MFP-adjusted CPI–U update factor of 1.4 percent for CY 2015.

XXII. 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 final rule with comment period 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 49 of this final rule with comment period, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) will increase by 2.1 percent under this final rule with comment period. 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 final rule with comment period, in conjunction with the remainder of this document, demonstrate that this final rule with comment period is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This final rule with comment period will 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 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

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.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance, organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health professions, Medicare.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is amending 42 CFR Chapter IV as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATION ON MEDICARE PAYMENT

■ 1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

■ 2. Section 411.362 is amended by—

■ a. Under paragraph (a), adding a definition of ''External data source'' in alphabetical order.

■ b. Revising paragraphs (c)(2)(ii), (c)(2)(iv), (c)(2)(v), (c)(3)(ii), and (c)(5).

The addition and revisions read as follows:

§ 411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) * * *

External data source means a data source that—

(1) Is generated, maintained, or under the control of a State Medicaid agency;

(2) Is reliable and transparent;

(3) Maintains data that, for purposes of the process described in paragraph (c) of this section, are readily available and accessible to the requesting hospital, comparison hospitals, and CMS; and

(4) Maintains or generates data that, for purposes of the process described in paragraph (c) of this section, are accurate, complete, and objectively verifiable.

* * * * *

(c) * * *

(2) * * *

(ii) *Medicaid inpatient admissions.* Has an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located during the most recent 12-month period for which data are available as of the date that the hospital submits its request. For purposes of this paragraph, the most recent 12-month period for which data are available means the most recent 12-month period for which the data source used contains all data from the requesting hospital and each hospital located in the same county as the requesting hospital.

(A) Until such time that the Healthcare Cost Report Information System (HCRIS) contains sufficiently complete inpatient Medicaid discharge data, a hospital may use filed Medicare hospital cost report data or data from an external data source (as defined in paragraph (a) of this section) to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located.

(B) On or after such date that the Secretary determines that HCRIS contains sufficiently complete inpatient Medicaid discharge data, a hospital may use only filed Medicare hospital cost report data to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located.

* * * * *

(iv) *Average bed capacity.* Is located in a State in which the average bed capacity in the State is less than the national average bed capacity during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine a State's average bed capacity and the national average bed capacity. CMS will provide on its Web site State average bed capacities and the national average bed capacity. For purposes of this paragraph, ''sufficient number'' means the number of hospitals, as determined by CMS, that would ensure that the determination under this paragraph would not materially change after additional hospital data are reported.

(v) *Average bed occupancy.* Has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number

of hospitals to determine the requesting hospital's average bed occupancy rate and the relevant State's average bed occupancy rate. A hospital must use filed hospital cost report data to determine its average bed occupancy rate. CMS will provide on its Web site State average bed occupancy rates. For purposes of this paragraph, ''sufficient number'' means the number of hospitals, as determined by CMS, that would ensure that the determination under this paragraph would not materially change after additional hospital data are reported.

(3) * * *

(ii) *Medicaid inpatient admissions.* With respect to each of the 3 most recent 12-month periods for which data are available as of the date the hospital submits its request, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located. For purposes of this paragraph, the most recent 12-month period for which data are available means the most recent 12-month period for which the data source used contains all data from the requesting hospital and every hospital located in the same county as the requesting hospital.

(A) Until such time that the Healthcare Cost Report Information System (HCRIS) contains sufficiently complete inpatient Medicaid discharge data, a hospital may use filed Medicare hospital cost report data or data from an external data source (as defined in paragraph (a) of this section) to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the hospital is located.

(B) On or after such date that the Secretary determines that HCRIS contains sufficiently complete inpatient Medicaid discharge data, a hospital may use only filed Medicare hospital cost report data to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the hospital is located.

* * * * *

(5) *Community input and timing of complete request.* Upon submitting a request for an exception and until the hospital receives a CMS decision, the hospital must disclose on any public Web site for the hospital that it is requesting an exception and must also provide actual notification that it is requesting an exception, in either electronic or hard copy form, directly to hospitals whose data are part of the comparisons in paragraphs (c)(2)(ii) and (c)(3)(ii) of this section. Individuals and entities in the hospital's community may provide input with respect to the hospital's request no later than 30 days after CMS publishes notice of the hospital's request in the **Federal Register**. Such input must take the form of written comments. The written comments must be either mailed or submitted electronically to CMS. If CMS receives written comments from the community, the hospital has 30 days after CMS notifies the hospital of the written comments to submit a rebuttal statement.

(i) If only filed Medicare hospital cost report data are used in the hospital's request, the written comments, and the hospital's rebuttal statement—

(A) A request will be deemed complete at the end of the 30-day comment period if CMS does not receive written comments from the community.

(B) A request will be deemed complete at the end of the 30-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(ii) If data from an external data source are used in the hospital's request, the written comments, or the hospital's rebuttal statement—

(A) A request will be deemed complete no later than 180 days after the end of the 30-day comment period if CMS does not receive written comments from the community.

(B) A request will be deemed complete no later than 180 days after the end of the 30-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

* * * * *

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.

§ 412.3 [Amended]

■ 4. Section 412.3 is amended by—

■ a. Removing paragraph (c).

■ b. Redesignating paragraphs (d) and (e) as paragraphs (c) and (d), respectively.

■ c. In redesignated paragraph (d)(1), removing the cross-reference ''paragraph (e)(2)'' and adding in its place the cross-reference ''paragraph (d)(2)''.

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 paragraphs (a)(11) and (b)(5) to read as follows:

§ 416.164 Scope of ASC services.

(a) * * *

(11) Radiology services for which separate payment is not allowed under the OPPS and other diagnostic tests or interpretive services that are integral to a surgical procedure, except certain diagnostic tests for which separate payment is allowed under the OPPS;

* * * * *

(b) * * *

(5) Certain radiology services and certain diagnostic tests for which separate payment is allowed under the OPPS.

* * * * *

■ 7. Section 416.171 is amended by revising paragraphs (b)(1), (b)(2), and (d) introductory text to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) * * *

(1) Covered ancillary services specified in § 416.164(b), with the exception of radiology services and certain diagnostic tests as provided in § 416.164(b)(5);

(2) The device portion of device-intensive procedures, which are procedures assigned to an APC with a device cost greater than 40 percent of the APC costs when calculated according to the standard OPPS APC ratesetting methodology.

* * * * *

(d) *Limitation on payment rates for office-based surgical procedures and covered ancillary radiology services and certain diagnostic tests.* Notwithstanding the provisions of paragraph (a) of this section, for any covered surgical procedure under § 416.166 that CMS determines is commonly performed in physicians' offices or for any covered ancillary radiology service or diagnostic test

under § 416.164(b)(5), excluding those listed in paragraphs (d)(1) and (d)(2) of this section, the national unadjusted ASC payment rates for these procedures and services will be the lesser of the amount determined under paragraph (a) of this section or the amount calculated at the nonfacility practice expense relative value units under § 414.22(b)(5)(i)(B) of this chapter multiplied by the conversion factor described in § 414.20(a)(3) of this chapter.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 8. 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).

■ 9. Section 419.2 is amended by revising paragraphs (b)(7) and (b)(16) to read as follows:

§ 419.2 Basis of payment.

* * * * *

(b) * * *

(7) Ancillary services;

* * * * *

(16) Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals);

* * * * *

■ 10. Section 419.22 is amended by revising paragraph (j) to read as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

* * * * *

(j) Except as provided in § 419.2(b)(11), prosthetic devices and orthotic devices.

* * * * *

■ 11. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(*6*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*6*) For calendar year 2015, a multifactor productivity adjustment (as determined by CMS) and 0.2 percentage point.

* * * * *

§ 419.46 [Amended]

■ 12. Section 419.46 is amended by—

■ a. In paragraph (c)(1), removing the phrase ''section 1833(17)(C)'' and adding in its place the phrase ''section 1833(t)(17)(C)''.

■ b. In paragraph (d) introductory text and paragraph (d)(1), removing the term ''waiver'' and adding in its place the term ''exception'' each time it appears.

■ c. In paragraph (d)(2), removing the term ''waivers'' and adding in its place the term ''exceptions''.

■ d. In paragraph (e) introductory text, removing the phrase ''section 1833(17)(C)'' and adding in its place the phrase ''section 1833(t)(17)(C)''.

■ 13. Section 419.64 is amended by revising paragraph (a)(4)(iv) to read as follows:

§ 419.64 Transitional pass-through payments: Drugs and biologicals.

* * * * *

(a) * * *

(4) * * *

(iv) A biological that is not a skin substitute or similar product that aids wound healing.

* * * * *

■ 14. Section 419.66 is amended by revising paragraph (b)(3) and removing paragraph (b)(4)(iii) to read as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(b) * * *

(3) The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 15. The authority citation for Part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 16. A new § 422.330 is added to subpart G to read as follows:

§ 422.330 CMS-identified overpayments associated with payment data submitted by MA organizations.

(a) *Definitions.* For purposes of this section—

Applicable reconciliation date occurs on the date of the annual final deadline for risk adjustment data submission described at § 422.310(g)(2)(ii).

Erroneous payment data means payment data that should not have been submitted either because the data submitted are inaccurate or because the data are inconsistent with Medicare Part C requirements.

Payment data means data submitted by an MA organization to CMS and used for payment purposes, including enrollment data and data submitted under § 422.310.

(b) *Request to correct payment data.* (1) When CMS identifies erroneous payment data submitted by an MA organization (other than an error identified through the process described in § 422.311), CMS may send a data correction notice to the MA organization requesting that the MA organization correct the payment data.

(2) The notice will include or make reference to the specific payment data that need to be corrected, the reason why CMS believes that the payment data are erroneous, and the timeframe for correcting the payment data.

(c) *Payment offset.* (1) If the MA organization fails to submit the corrected payment data within the timeframe as requested in accordance with paragraph (b) of this section, CMS will conduct a payment offset against payments made to the MA organization if—

(i) The payment error affects payments for any of the 6 most recently completed payment years; and

(ii) The payment error for a particular payment year is identified after the applicable reconciliation date for that payment year.

(2) CMS will calculate the payment offset amount using the correct payment data and a payment algorithm that applies the payment rules for the applicable year.

(d) *Payment offset notification.* CMS will issue a payment offset notice to the MA organization that includes at least the following:

(1) The dollar amount of the offset from plan payments.

(2) An explanation of how the erroneous data were identified and used to calculate the payment offset amount.

(3) An explanation that, if the MA organization disagrees with the payment offset, it may request an appeal within 30 days of issuance of the payment offset notification.

(e) *Appeals process.* If an MA organization does not agree with the payment offset described in paragraph (c) of this section, it may appeal under the following three-level appeal process:

(1) *Reconsideration.* An MA organization may request reconsideration of the payment offset described in paragraph (c) of this section, according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 30 days from the date that CMS issued the payment offset notice to the MA organization.

(ii) *Content of request.* The written request for reconsideration must specify the findings or issues with which the MA organization disagrees and the reasons for its disagreement. As part of its request for reconsideration, the MA organization may include any additional documentary evidence in support of its position. Any additional evidence must be submitted with the request for reconsideration. Additional information submitted after this time will be rejected as untimely.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the underlying data that were used to determine the amount of the payment offset and any additional documentary evidence timely submitted by the MA organization.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the MA organization of its decision on the reconsideration request.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (e)(2) of this section.

(2) *Informal hearing.* An MA organization dissatisfied with CMS' reconsideration decision made under paragraph (e)(1) of this section is entitled to an informal hearing as provided for under paragraphs (e)(2)(i) through (e)(2)(v) of this section.

(i) *Manner and timing for request.* A request for an informal hearing must be made in writing and filed with CMS within 30 days of the date of CMS' reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the MA organization disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing will be conducted in accordance with the following:

(A) CMS provides written notice of the time and place of the informal hearing at least 30 days before the scheduled date.

(B) The informal hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not timely presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before the CMS reconsideration official when CMS made its reconsideration determination.

(C) The CMS hearing officer will review the proceeding before the CMS reconsideration official on the record made before the CMS reconsideration official using the clearly erroneous standard of review.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the MA organization explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (e)(3) of this section.

(3) *Review by the Administrator.* The Administrator review will be conducted in the following manner:

(i) An MA organization that has received a hearing officer's decision may request review by the Administrator within 30 days of the date of issuance of the hearing officer's decision under paragraph (e)(2)(iv) of this section. The MA organization may submit written arguments to the Administrator for review.

(ii) After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (e)(3)(iv) of this section or to decline to review the hearing officer's decision.

(iii) If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iv) If the Administrator elects to review the hearing officer's decision, the Administrator will review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the MA organization, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(v) The Administrator's determination is final and binding.

(f) *Matters subject to appeal and burden of proof.* (1) The MA organization's appeal is limited to CMS' finding that the payment data submitted by the MA organization are erroneous.

(2) The MA organization bears the burden of proof by a preponderance of the evidence in demonstrating that CMS' finding that the payment data were erroneous was incorrect or otherwise inconsistent with applicable program requirements.

(g) *Applicability of appeals process.* The appeals process under paragraph (e) of this section applies only to payment offsets under paragraph (c) of this section.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 17. The authority citation for Part 423 continues to read as follows:

Authority: Secs. 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

■ 18. A new § 423.352 is added to read as follows:

§ 423.352 CMS-identified overpayments associated with payment data submitted by Part D sponsors.

(a) *Definitions.* For purposes of this section—

Applicable reconciliation date occurs on the later of either the annual deadline for submitting—

(1) Prescription drug event (PDE) data for the annual Part D payment reconciliations referred to in § 423.343(c) and (d); or

(2) Direct and indirect remuneration data.

Erroneous payment data means payment data that should not have been submitted either because the data submitted are inaccurate or because the data are inconsistent with Medicare Part D requirements.

Payment data means data submitted by a Part D sponsor to CMS and used for payment purposes, including enrollment data and data submitted under § 423.329(b)(3), § 423.336(c)(1), and § 423.343, and data provided for purposes of supporting allowable reinsurance costs and allowable risk corridor costs as defined in § 423.308, including data submitted to CMS regarding direct and indirect remuneration.

(b) *Request to correct payment data.* (1) When CMS identifies erroneous payment data submitted by a Part D sponsor, CMS may send a data correction notice to the Part D sponsor requesting that the Part D sponsor correct the payment data.

(2) The notice will include or make reference to the specific payment data that need to be corrected, the reason why CMS believes that the payment data are erroneous, and the timeframe for correcting the payment data.

(c) *Payment offset.* (1) If the Part D sponsor fails to submit the corrected payment data within the timeframe as requested in accordance with paragraph (b) of this section, CMS will conduct a payment offset against payments made to the Part D sponsor if—

(i) The payment error affects payments for any of the 6 most recently completed payment years; and

(ii) The payment error for a particular payment year is identified after the applicable reconciliation date for that payment year.

(2) CMS will calculate the payment offset amount using the correct payment data and a payment algorithm that applies the payment rules for the applicable year.

(d) *Payment offset notification.* CMS will issue a payment offset notice to the Part D sponsor that includes at least the following:

(1) The dollar amount of the offset from plan payments.

(2) An explanation of how the erroneous data were identified and used to calculate the payment offset amount.

(3) An explanation that, if the Part D sponsor disagrees with the payment offset, it may request an appeal within 30 days of issuance of the payment offset notification.

(e) *Appeals process.* If a Part D sponsor does not agree with the payment offset described in paragraph (c) of this section, it may appeal under the following three-level appeal process:

(1) *Reconsideration.* A Part D sponsor may request reconsideration of the payment offset described in paragraph (c) of this section, according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 30 days from the date that CMS issued the payment offset notice to the Part D sponsor.

(ii) *Content of request.* The written request for reconsideration must specify the findings or issues with which the Part D sponsor disagrees and the reasons for its disagreement. As part of its request for reconsideration, the Part D sponsor may include any additional documentary evidence in support of its position. Any additional evidence must be submitted with the request for reconsideration. Additional information submitted after this time will be rejected as untimely.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the underlying data that were used to determine the amount of the payment offset and any additional documentary evidence timely submitted by the Part D sponsor.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the Part D sponsor of its decision on the reconsideration request.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (e)(2) of this section.

(2) *Informal hearing.* A Part D sponsor dissatisfied with CMS' reconsideration decision made under paragraph (e)(1) of this section is entitled to an informal hearing as provided for under paragraphs (e)(2)(i) through (e)(2)(v) of this section.

(i) *Manner and timing for request.* A request for an informal hearing must be made in writing and filed with CMS within 30 days of the date of CMS' reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing will be conducted in accordance with the following:

(A) CMS provides written notice of the time and place of the informal hearing at least 30 days before the scheduled date.

(B) The informal hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not timely presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before the CMS reconsideration official when CMS made its reconsideration determination.

(C) The CMS hearing officer will review the proceeding before the CMS reconsideration official on the record made before the CMS reconsideration official using the clearly erroneous standard of review.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the Part D sponsor explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (e)(3) of this section.

(3) *Review by the Administrator.* The Administrator review will be conducted in the following manner:

(i) A Part D sponsor that has received a hearing officer's decision may request review by the Administrator within 30 days of the date of issuance of the hearing officer's decision under paragraph (e)(2)(iv) of this section. The Part D sponsor may submit written arguments to the Administrator for review.

(ii) After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (e)(3)(iv) of this section or to decline to review the hearing officer's decision.

(iii) If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iv) If the Administrator elects to review the hearing officer's decision, the Administrator will review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the Part D sponsor, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(v) The Administrator's determination is final and binding.

(f) *Matters subject to appeal and burden of proof.* (1) The Part D sponsor's appeal is limited to CMS' finding that the payment data submitted by the Part D sponsor are erroneous.

(2) The Part D sponsor bears the burden of proof by a preponderance of the evidence in demonstrating that CMS' finding that the payment data were erroneous was incorrect or otherwise inconsistent with applicable program requirements.

(g) *Applicability of appeals process.* The appeals process under paragraph (e) of this section applies only to payment offsets under paragraph (c) of this section.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 19. The authority citation for Part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 20. Section 424.13 is amended by—

■ a. Revising paragraph (a) introductory text.

■ b. Removing paragraph (a)(1).

■ c. Redesignating paragraphs (a)(2), (3), and (4) as paragraphs (a)(1), (2), and (3), respectively.

■ d. Revising redesignated paragraph (a)(1)(i).

■ e. Revising paragraph (b).

The revisions read as follows:

§ 424.13 Requirements for inpatient services of hospitals other than inpatient psychiatric facilities.

(a) *Content of certification and recertification.* Medicare Part A pays for inpatient hospital services (other than inpatient psychiatric facility services) for cases that are 20 inpatient days or more, or are outlier cases under subpart F of part 412 of this chapter, only if a

physician certifies or recertifies the following:

(1) * * *

(i) Continued hospitalization of the patient for medical treatment or medically required diagnostic study; or

* * * * *

(b) *Timing of certification.* For outlier cases under subpart F of Part 412 of this chapter, the certification must be signed and documented in the medical record and as specified in paragraphs (e) through (h) of this section. For all other cases, the certification must be signed and documented no later than 20 days into the hospital stay.

* * * * *

Dated: October 22, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 26, 2014.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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