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Department of Health and Human Services

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42 CFR Parts 405, 410, 412, et al.

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 405, 410, 412, 419, 475, 476, 486, and 495****[CMS–1601–FC]****RIN 0938–AR54****Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule with comment period and final rules.

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 2014 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, the ASC Quality Reporting (ASCQR) Program, and the Hospital Value-Based Purchasing (VBP) Program.

In the final rules in this document, we are finalizing changes to the conditions for coverage (CfCs) for organ procurement organizations (OPOs); revisions to the Quality Improvement Organization (QIO) regulations; changes to the Medicare fee-for-service Electronic Health Record (EHR) Incentive Program; and changes relating to provider reimbursement determinations and appeals.

DATES: *Effective Dates:* The final rule with comment period and final rules in this document are effective on January 1, 2014, with the exception of 42 CFR 412.167; 42 CFR 486.316 and 486.318; 42 CFR 475.1 and 475.100 through 475.107; and 42 CFR 495.4 and 495.104, which are effective on January 27, 2014.

Implementation Date: The implementation date for the policies specified under section II.A.2.e. of the final rule with comment period relating to comprehensive Ambulatory Payment Classification (APC) groups is January 1, 2015.

Comment Period: We will consider comments on the payment classification assigned to HCPCS codes identified in Addenda B, AA, and BB of this final rule with comment period with the “NI” comment indicator, and on other areas specified throughout this rule, received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on January 27, 2014.

Application Deadline—New Class of New Technology Intraocular Lenses: Request for review of applications for a new class of new technology intraocular lenses must be received by 5 p.m. EST on March 3, 2014.

ADDRESSES: In commenting, please refer to file code CMS–1601–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–1601–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–1601–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.

Applications for a new class of new technology intraocular lenses: Requests for review of applications for a new class of new technology intraocular lenses must be sent by regular mail to: ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Marjorie Baldo, (401) 786–4617, for issues related to new CPT and Level II HCPCS codes, exceptions to the 2 times rule, platelet rich plasma, and stereotactic radiosurgery services.

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 Advisory Panel on Hospital Outpatient Payment (HOP Panel).

Erick Chuang, (410) 786–1816, for issues related to OPPS APC weights, mean calculation, copayments, wage index, outlier payments, cost-to-charge ratios (CCRs), and rural hospital payments.

Diane Corning, (410) 786–8486, for issues related to the Conditions for Coverage for Organ Procurement Organizations (OPOs).

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

Roxanne Dupert-Frank, (410) 786-4827, for issues related to the Hospital Value-Based Purchasing (VBP) Program.

Dan Duvall, (410) 786-4592, for issues related to comprehensive APCs.

Shaheen Halim, (410) 786-0641, for issues related to the Hospital Outpatient Quality Reporting Program (OQR)—Measures Issues and Publication of Hospital OQR Program Data, and Ambulatory Surgical Center Quality Reporting (ASCQR) Program—Measures Issues and Publication of ASCQR Program Data.

James Hart, (410) 786-9520, for issues related to the Medicare fee-for-service Electronic Health Record (EHR) Incentive Program.

Jeneen Iwugo, (410) 786-1028, for issues related to the revisions of the Quality Improvement Organization (QIO) Regulations.

Twi Jackson, (410) 786-1159, for issues related to blood products, device-dependent APCs, extended assessment and management composite APCs, hospital outpatient visits, inpatient-only procedures, and no cost/full credit and partial credit devices.

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

Barry Levi, (410) 786-4529, for issues related to OPPS pass-through devices, brachytherapy sources, intraoperative radiation therapy (IORT), brachytherapy composite APC, multiple imaging composite APCs, and cardiac electrophysiologic evaluation and ablation composite APC.

Ann Marshall, (410) 786-3059, for issues related to packaged items/services, hospital outpatient supervision, proton beam therapy, therapy caps in CAHs, incident to physician or nonphysician practitioner services, and provider-based issues.

Danielle Moskos, (410) 786-8866, or Michael Zleit, (410) 786-2050, for issues related to Provider Reimbursement Determination Appeals.

James Poyer, (410) 786-2261, for issues related to the Hospital Outpatient Quality Reporting—Program Administration, Validation, and Reconsideration Issues.

Char Thompson, (410) 786-2300, for issues related to OPPS drugs, radiopharmaceuticals, biologicals, blood clotting factors, new technology intraocular lenses (NTIOLs), and ambulatory surgical center (ASC) payments.

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

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Addenda Available Only Through the Internet on the CMS Web site

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

Alphabetical List of Acronyms Appearing in This Federal Register Document

AHA American Hospital Association
AMA American Medical Association
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, Pub. L. 105-33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Pub. L. 106-113
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106-554
BLS Bureau of Labor Statistics
CAH Critical access hospital
CAP Competitive Acquisition Program
CASPER Certification and Survey Provider Enhanced Reporting
CAUTI Catheter associated urinary tract infection
CBSA Core-Based Statistical Area
CCI Correct Coding Initiative
CCN CMS Certification Number
CCR Cost-to-charge ratio
CDC Centers for Disease Control and Prevention
CEO Chief executive officer
CERT Comprehensive Error Rate Testing
CfC [Medicare] Condition for coverage
CFR Code of Federal Regulations
CLFS Clinical Laboratory Fee Schedule
CMHC Community mental health center
CMS Centers for Medicare & Medicaid Services
CoP [Medicare] Condition of participation
CPI-U Consumer Price Index for All Urban Consumers
CPT Current Procedural Terminology (copyrighted by the American Medical Association)
CQM Clinical quality measure
CR Change request
CSAC Consensus Standards Approval Committee
CY Calendar year
DFO Designated Federal Official
DRA Deficit Reduction Act of 2005, Pub. L. 109-171
DRG Diagnosis-Related Group
DSH Disproportionate share hospital
EACH Essential access community hospital
eCQM Electronically specified clinical quality measure
ECT Electroconvulsive therapy
ED Emergency department
E/M Evaluation and management
EHR Electronic health record
ESRD End-stage renal disease
FACA Federal Advisory Committee Act, Pub. L. 92-463
FDA Food and Drug Administration
FFS [Medicare] Fee-for-service
FY Fiscal year
FFY Federal fiscal year
GAO Government Accountability Office
HAI Healthcare-associated infection
HCERA Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152
HCPCS Healthcare Common Procedure Coding System
HCRIS Hospital Cost Report Information System
HEU Highly enriched uranium

HIPAA Health Insurance Portability and Accountability Act of 1996, Pub. L. 104–191

HITECH Health Information Technology for Economic and Clinical Health [Act] (found in the American Recovery and Reinvestment Act of 2009, Pub. L. 111–5)

HOP Hospital Outpatient Payment [Panel]

HOPD Hospital outpatient department

ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification

ICD Implantable cardioverter defibrillator

ICU Intensive care unit

IHS Indian Health Service

IMRT Intensity Modulated Radiation Therapy

I/OCE Integrated Outpatient Code Editor

IOL Intraocular lens

IOM Institute of Medicine

IORT Intraoperative radiation treatment

IPPS [Hospital] Inpatient Prospective Payment System

IQR [Hospital] Inpatient Quality Reporting

LDR Low dose rate

LOS Length of Stay

LTCH Long-term care hospital

MAC Medicare Administrative Contractor

MAP Measure Application Partnership

MedPAC Medicare Payment Advisory Commission

MEI Medicare Economic Index

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, Pub. L. 109–432

MIPPA Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110–275

MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173

MMEA Medicare and Medicaid Extenders Act of 2010, Pub. L. 111–309

MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Pub. L. 110–173

MPFS Medicare Physician Fee Schedule

MRA Magnetic resonance angiography

MRI Magnetic resonance imaging

MSA Metropolitan Statistical Area

NCCI National Correct Coding Initiative

NHSN National Healthcare Safety Network

NQF National Quality Forum

NTIOL New technology intraocular lens

NUBC National Uniform Billing Committee

OACT [CMS] Office of the Actuary

OBRA Omnibus Budget Reconciliation Act of 1996, Pub. L. 99–509

OIG [HHS] Office of the Inspector General

OMB Office of Management and Budget

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

PCR Payment-to-cost ratio

PE Practice expense

PEPPER Program for Evaluating Payment Patterns Electronic Report

PHP Partial hospitalization program

PHS Public Health Service [Act], Pub. L. 96–88

PPI Producer Price Index

PPS Prospective payment system

PQRS Physician Quality Reporting System

PT Physical therapy

QDC Quality data code

QIO Quality Improvement Organization

RFA Regulatory Flexibility Act

RTI Research Triangle Institute, International

RVU Relative value unit

SCH Sole community hospital

SCOD Specified covered outpatient drugs

SI Status indicator

SIR Standardized infection ratio

SLP Speech-language pathology

SNF Skilled Nursing Facility

SRS Stereotactic Radiosurgery

TEP Technical Expert Panel

TMS Transcranial Magnetic Stimulation Therapy

TOPs Transitional Outpatient Payments

UR Utilization review

USPSTF United States Preventive Services Task Force

UTI Urinary tract infection

VBP Value-based purchasing

WAC Wholesale acquisition cost

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Regulation Text**I. Summary and Background***A. Executive Summary of This Document***1. Purpose**

In the final rule with comment period of this document, 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, 2014. 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, the final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Hospital Value-Based Purchasing (VBP) Program.

In the final rules in this document, we are finalizing changes to the conditions for coverage (CfCs) for organ procurement organizations (OPOs); revisions to the Quality Improvement Organization (QIO) regulations; changes to the Medicare fee-for-service Electronic Health Record (EHR) Incentive Program; and changes relating to provider reimbursement determinations and appeals.

After publication of our annual proposed rule for CY 2014, we discovered that in applying our established and proposed methodologies to develop the CY 2014 proposed OPPS and ASC payment rates, specific cost estimation errors occurred in the OPPS modeling process. The errors resulting from the cost modeling used to develop the CY 2014 proposed OPPS payment rates were isolated to a few specific ambulatory payment classifications (APCs). However, because the OPPS is a budget neutral payment system, there was a resulting impact on other proposed OPPS payment rates. In addition, because the ASC payment rates are based on the OPPS relative payment weights for the majority of items and services that are provided at ASCs, corrections to the proposed CY 2014 OPPS relative payment weights also had an impact on the proposed CY 2014 ASC relative payment weights and ASC payment

rates. Therefore, we released corrected data files on August 28, 2013, and extended the comment period to September 16, 2013, on the technical corrections noted in the correcting document published in the **Federal Register** on September 6, 2013 (78 FR 54842). This final rule with comment period refers to the corrected OPPS and ASC information.

2. Summary of the Major Provisions

- **OPPS Update:** For CY 2014, we are increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.7 percent. This increase is based on the final hospital inpatient market basket percentage increase of 2.5 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the multifactor productivity (MFP) adjustment of 0.5 percentage points, and minus a 0.3 percentage point adjustment required by the Affordable Care Act. Under this final rule with comment period, we estimate that total payments for CY 2014, including beneficiary cost-sharing, to the approximately 4,100 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers (CMHCs)), will be approximately \$50.4 billion, an increase of approximately \$4.372 billion compared to CY 2013 payments, or \$600 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 2014, we are continuing our policy to provide additional payments to cancer hospitals so that the hospital's payment-to-cost ratio (PCR) with the payment adjustment is equal to the weighted average PCR for the other OPPS hospitals using the most recent

submitted or settled cost report data. Based on those data, a target PCR of 0.89 will be used to determine the CY 2014 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment amount associated with the cancer hospital payment adjustment will be the additional payment needed to result in a PCR equal to 0.89 for each cancer hospital.

- **Payment of Drugs, Biologicals, and Radiopharmaceuticals:** For CY 2014, payment for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status will be set at the statutory default of average sales price (ASP) plus 6 percent.

- **Packaging Policies:** Beginning in CY 2014, we are unconditionally or conditionally packaging the following five categories of items and services and adding them to the list of OPPS packaged items and services in 42 CFR 419.2(b):

- (1) Drugs, biologicals, and radiopharmaceuticals used in a diagnostic test or procedure;

- (2) Drugs and biologicals when used as supplies in a surgical procedure;

- (3) Certain clinical diagnostic laboratory tests;

- (4) Procedures described by add-on codes; and

- (5) Device removal procedures.

Further details are provided in section II.A.3. of this document.

- **Establishing Comprehensive APCs:** In order to improve the accuracy and transparency of our payment for certain device-dependent services, we are finalizing our policy to establish 29 comprehensive APCs to prospectively pay for the most costly hospital outpatient device-dependent services, but we are delaying implementation of this policy until CY 2015. We have defined a comprehensive APC as a classification for the provision of a primary service and all adjunct services provided to support the delivery of the primary service. For services that trigger a comprehensive APC payment, the comprehensive APC will treat all individually reported codes on the claim as representing components of the comprehensive service, resulting in a single prospective payment based on the cost of all individually reported codes on the claim. We will make a single payment for the comprehensive service based on all charges on the claim, excluding only charges for services that cannot be covered by Medicare Part B or that are not payable under the OPPS. We also have modified our methodology to make larger payments for many complex and costly multiple device procedures. Due to our decision to delay

implementation until CY 2015 for operational reasons, we are inviting comment on this section of the final rule. We have published tables in the rule to demonstrate how this policy would have been implemented in CY 2014, and we will be considering comments as we update the policy for CY 2015 to account for changes that may occur in the CY 2013 claims data.

- *Payment of Hospital Outpatient Visits:* For CY 2014, we are finalizing our proposal to replace the current five levels of visit codes for each clinic visit with a new alphanumeric Level II HCPCS code representing a single level of payment for clinic visits. We are finalizing our proposal to assign the new alphanumeric Level II HCPCS to newly created APC 0634 with CY 2014 OPPS payment rates based on the total mean costs of Level 1 through Level 5 clinic visit codes obtained from CY 2012 OPPS claims data. For CY 2014, we are not finalizing our proposal to replace the current five levels of visit codes for each Type A ED, and Type B ED visits with two new alphanumeric Level II HCPCS codes representing a single level of payment for two types of ED visits, respectively.

- *OPPS Nonrecurring Policy Changes:* The enforcement instruction for the supervision of outpatient therapeutic services furnished in CAHs and small rural hospitals will expire at the end of CY 2013. In addition, we are amending the conditions of payment for “incident to” hospital or CAH outpatient services (sometimes referred to as hospital or CAH “therapeutic” services) to explicitly require that individuals furnishing these services be in compliance with State law. In the CY 2014 OPPS/ASC proposed rule, we solicited public comments regarding a potential new claims or other data element that would indicate that the services were furnished in an off-campus provider-based department, which we discuss in this final rule with comment period. Finally, we refer readers to the CY 2014 Medicare Physician Fee Schedule (MPFS) final rule (CMS–1600–F) to review Medicare’s policies on application of the therapy caps and related provisions under section 1833(g) of the Act to physical therapy (PT), speech-language pathology (SLP) and occupational therapy (OT) (“therapy”) services that are furnished by a CAH, effective January 1, 2014.

- *Ambulatory Surgical Center Payment Update:* For CY 2014, we are increasing payment rates under the ASC payment system by 1.2 percent. This increase is based on a projected CPI-U update of 1.7 percent minus a

multifactor productivity adjustment required by the Affordable Care Act that is projected to be 0.5 percent. 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 2014 will be approximately \$3.992 billion, an increase of approximately \$143 million compared to estimated CY 2013 payments.

- *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are adopting four new quality measures for the CY 2016 payment determination and subsequent years: Three where aggregate data (numerators, denominators, and exclusions) are collected and data submitted via an online Web-based tool located on a CMS Web page and one HAI measure submitted through the CDC’s NHSN. We also are removing two measures and are codifying administrative procedures.

- *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are adopting three new quality measures for the CY 2016 payment determination and subsequent years where data collection will begin in CY 2014. We are collecting aggregate data (numerators, denominators, and exclusions) on all ASC patients for these four chart-abstracted measures via an online Web-based tool located on a CMS Web page. We also are adopting, for the CY 2016 payment determination and subsequent years’ payment determinations, requirements for a QualityNet account and security administrator, facility participation, a minimum threshold and minimum volume for claims-based measures, and data collection and submission for new measures and for certain previously finalized measures.

- *Changes to Organ Procurement Organization (OPO) Regulations.* In section XVI. of this document, we are finalizing our proposals to modify the current requirement that OPOs meet all three outcome measures set forth in 42 CFR 486.318. Specifically, the final rule provides that an OPO must meet two out of the three outcome measures. This change to the outcome measures requirement will allow those OPOs that fail only one outcome measure to avoid automatic decertification in the 2014 recertification cycle.

- *Revisions to the Quality Improvement Organizations Regulations.* We are updating the regulations at 42 CFR Parts 475 and 476 based on the recently enacted Trade Adjustment Assistance Extension Act of 2011 (TAAEA) (Pub. L. 112–40, Section

261) whereby Congress authorized numerous changes to the original legislation and included additional flexibility for the Secretary in the administration of the QIO program. The existing regulations at 42 CFR Part 475 include definitions and standards governing eligibility and the award of contracts to QIOs. In this final rule with comment period, we are finalizing the partial deletion and revision of the regulations under 42 CFR Parts 475 and 476, which relate to the QIO program, including the following: (1) Replace nomenclature in Parts 475 and 476 that has been amended by the TAAEA; (2) revise the existing definition for the term “physician”; (3) add new definitions as necessary to support the new substantive provisions in Subpart C; and (4) replace some of the substantive provisions in Subpart C in their entirety to fully exercise the Secretary’s authority for the program and update the contracting requirements to align with contemporary quality improvement.

- *Changes to the Medicare Fee-for-Service Electronic Health Record (EHR) Incentive Program.* We are revising the regulations to provide a special method for making hospital-based determinations for 2014 only in the cases of those eligible professionals (EPs) who reassign their benefits to Method II CAHs. Previously, we have been unable to make EHR payments to these EPs for their CAH II claims, or to take those claims into consideration in making hospital-based determinations because of systems limitations. Finalizing the adoption of our method for 2014 will allow us to begin making payments based on CAH II one year earlier than we would be able to do under existing regulations. We also are adopting a minor clarification to the regulations concerning the cost reporting period to be used in determining final EHR payments for hospitals.

3. Summary of Costs and Benefits

In sections XXIII. and XXIV. 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 55 in section XXIII. 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 2014 compared to all

estimated OPPS payments in CY 2013. We estimate that the policies in this final rule will result in a 1.8 percent overall increase in OPPS payments to providers. We estimate that the increase in OPPS expenditures, including beneficiary cost-sharing, will be approximately \$600 million, not taking into account potential changes in enrollment, utilization, and case-mix. Taking into account estimated spending changes that are attributable to these factors, we estimate an increase of approximately \$4.372 billion in OPPS expenditures, including beneficiary cost-sharing, for CY 2014 compared to CY 2013 OPPS expenditures. We estimate that total OPPS payments, including beneficiary cost-sharing, will be \$50.4 billion for CY 2014.

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 1.8 percent increase in CY 2014 payments to CMHCs relative to their CY 2013 payments.

(2) Impacts of Policies Other Than Outpatient Laboratory Test Packaging

We estimate that our final policies other than packaging outpatient laboratory tests will have a less significant impact than we proposed for CY 2014, as several proposed policies were not finalized. These final policies include packaging drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (stress agents and Cysview), drugs and biologicals that function as supplies when used in a surgical procedure (skin substitutes), certain procedures described by add-on codes, and device removal procedures; new cost report data for estimating CT and MRI relative weights; and revisions to coding and APC structure for stereotactic radiosurgery.

(3) Impacts of Packaging Outpatient Laboratory Tests

Packaging laboratory services modestly reduces payment to rural and major teaching hospitals, as they will no longer receive separate payment for common laboratory tests.

(4) Impacts of the Updated Wage Indices

Adjustments to the wage indices other than the frontier State wage adjustment will not significantly affect most hospitals and CMHCs. The nonbudget neutral frontier wage index adjustment

will result in payment increases to rural and urban hospitals in West North Central and Mountain States.

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

There are no significant impacts of our CY 2014 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.

(6) Impacts of the OPD Fee Schedule Increase Factor

We estimate that, for many hospitals, the application of the OPD fee schedule increase factor of 1.7 percent to the conversion factor for CY 2014 will mitigate the small negative impacts of the budget neutrality adjustments. While most classes of hospitals will receive an increase that is in line with the 1.7 percent overall increase after the update is applied to the budget neutrality adjustments, some hospitals will receive smaller but still generally positive overall increases.

b. Impacts of the ASC Payment Update

For impact purposes, the procedures on the ASC list of covered surgical 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 2014 payment rates compared to estimated CY 2013 payment rates ranges between – 11 percent for ancillary items and services and 14 percent for respiratory system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our CY 2014 final 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 2014 final policies to significantly affect the number of ASCs that do not receive a full annual payment update beginning in CY 2015.

e. Impacts for the QIO Program Changes

We estimate the effects of the QIO Program changes to be consistent with the Congressional Budget Office's 2011 Cost Estimate of the Trade Bill (H.R. 2832) which included a reduction in spending of \$330 million over the 2012–

2021 period. According to the CBO Estimate and subsequently the regulatory changes “would modify the provisions under which CMS contracts with independent entities called “[Q]uality Improvement Organizations (QIOs)[”] in Medicare. QIOs, generally staffed by health care professionals, review medical care, help beneficiaries with complaints about the quality of care, and implement care improvements. H.R. 2832 would make several changes to the composition and operation of QIOs, and would harmonize QIO contracts with requirements of the Federal Acquisition Regulation. Among those changes are a modification to expand the geographic scope of QIO contracts and a lengthening of the contract period. CBO estimates that those provisions would reduce spending by \$330 million over the 2012–2021 period.”

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 OPSS, we pay for hospital outpatient 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 OPSS 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 OPSS 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 OPSS 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 OPSS 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 OPSS 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 OPSS. While most hospital outpatient services are payable under the OPSS, 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 originally exercised the authority granted under the statute to also exclude from the OPSS those 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 MPFS; 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 OPSS in regulations at 42 CFR 419.22. This final rule with comment period modifies 42 CFR 419.22 and includes in the OPSS some of these previously excluded services.

Under § 419.20(b) of the regulations, we specify the types of hospitals and entities that are excluded from payment under the OPSS. These excluded entities include: Maryland hospitals, but only for services that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act; 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 OPSS 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 OPSS, 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 OPSS, 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), Formerly Named the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Pub. L. 106–113, and redesignated by section 202(a)(2) of Pub. L. 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 OPSS. 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 meetings taking place on

March 11, 2013 and August 26–27, 2013. 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 OPSS (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 2013 meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the March 2013 and August 2013 Panel meetings are included in the sections of this final rule that are specific to each recommendation. For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPSS/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 in Response to the CY 2014 OPSS/ASC Proposed Rule

We received approximately 2,677 timely pieces of correspondence on the CY 2014 OPSS/ASC proposed rule that appeared in the **Federal Register** on July 19, 2013 (78 FR 43534) and the correcting document published in the **Federal Register** on September 6, 2013

(78 FR 54842). This final rule with comment period refers to the corrected information wherever applicable. We note that we received some public comments that were outside the scope of the proposed rule and that are not addressed in this final rule with comment period. Summaries of the public comments to the proposed rule and the correcting document 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 subject-matter headings.

G. Public Comments Received on the CY 2013 OPSS/ASC Final Rule With Comment Period

We received approximately 27 timely pieces of correspondence on the CY 2013 OPSS/ASC final rule with comment period that appeared in the **Federal Register** on November 15, 2012 (77 FR 68210), some of which contained comments on the interim APC assignments and/or status indicators of HCPCS codes identified with comment indicator "NI" in Addenda B, AA, and BB to that final rule. Summaries of these public comments on topics that were open to comment and our responses to them are set forth in various sections of this final rule with comment period under the appropriate subject-matter headings.

II. Updates Affecting OPSS 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 OPSS 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 2014 OPSS/ASC proposed rule (78 FR 43544), for the CY 2014 OPSS, we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2014, and before January 1, 2015 (CY 2014), using the same basic methodology that we described in the CY 2013 OPSS/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 2014, we used approximately 146 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, 2012, and before January 1, 2013. For this final rule with comment period, for the purpose of recalibrating the final APC relative payment weights for CY 2014, we used approximately 158 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, 2012, and before January 1, 2013. For exact counts of claims used, we refer readers to the claims accounting narrative under supporting documentation for the CY 2014 OPSS/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 158 million final action claims for services provided in hospital outpatient settings used to calculate the CY 2014 OPSS payment rates for this final rule with comment period, approximately 125 million claims were the type of bill potentially appropriate for use in setting rates for OPSS services (but did not necessarily contain services payable under the OPSS). Of the approximately 125 million claims, approximately 6 million claims were not for services paid under the OPSS 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 119 million claims, we created approximately 125 million single records, of which approximately 80 million were “pseudo” single or “single session” claims (created from approximately 31 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 124 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 2014 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 2012 that were processed through June 30, 2013. While prior to CY 2013 we had historically based the payments on median hospital costs for services in the APC groups, beginning with the CY 2013 OPSS, we established the cost-based relative payment weights for the OPSS using geometric mean costs, as discussed in the CY 2013 OPSS/ASC final rule with comment period (77 FR 68259 through 68271). For the CY 2014 OPSS, 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 OPSS 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 2014 payment rates.

b. Use of Single and Multiple Procedure Claims

For CY 2014, in general, 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 OPSS 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 2013 OPSS/ASC final rule with comment period (77 FR 68227 through 68229). 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 2013. 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 OPSS relative weights on which payments are based. We have continued the composite APCs for multiple imaging services through CY 2013, and as we proposed, we are continuing this policy for CY 2014. In addition, as we proposed, we are further expanding our packaging policies for CY 2014. We refer readers to section II.A.2.f. of this final rule with comment period for a discussion of the use of claims in modeling the costs for composite APCs and to section II.A.3. of this final rule with comment period for a discussion of our packaging policies for CY 2014.

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 2014 OPSS. This methodology enabled us to create, for this final rule with comment period, approximately 80 million “pseudo” single procedure claims, including

multiple imaging composite “single session” bills (we refer readers to section II.A.2.f.(5) of this final rule with comment period for further discussion), to add to the approximately 43 million “natural” single procedure claims.

For CY 2014, we proposed to bypass 179 HCPCS codes that were identified in Addendum N to the CY 2014 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 2014, data available for the March 11, 2013 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) from CY 2012 claims processed through September 30, 2012, and CY 2011 claims data processed through June 30, 2012, used to model the payment rates for CY 2013) to determine whether it would be appropriate to add additional codes to the previous year’s bypass list. For CY 2014, we proposed to continue to bypass all of the HCPCS codes on the CY 2013 OPPS bypass list, with the exception of HCPCS codes that we proposed to delete for CY 2014, which were listed in Table 1 of the proposed rule (78 FR 43546). 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 2014 bypass list are affected by the CY 2014 packaging final 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 2014 HCPCS codes not on the CY 2013 bypass list that, using either the CY 2013 final rule data (CY 2011 claims) or the March 11, 2013 Panel data (first 9 months of CY 2012 claims), met the empirical criteria for the bypass list that are summarized below. Finally, to remain consistent with the CY 2014 final policy 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 2014 (including the codes that remain on the bypass list from prior years) was open to public

comment in the CY 2014 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. As we proposed, 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 2013, we proposed to continue to establish the CY 2014 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 2013 OPPS/ASC final rule with comment period (77 FR 68221), we proposed for CY 2014 to continue to update the packaged cost threshold by the market basket increase. By applying the final CY 2013 market basket increase of 1.8 percent to the prior nonrounded dollar threshold of \$53.76 (77 FR 68221), we determined that the threshold remains for CY 2014 at \$55 (\$54.73 rounded to \$55, the nearest \$5 increment). Therefore, we proposed to set the geometric mean packaged cost threshold on the CY 2012 claims at \$55 for a code to be considered for addition to the CY 2014 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 2014 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 2014 proposal to remove certain codes from the bypass list, in particular for the anatomic pathology procedures, suggesting 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 proposed CY 2014 OPPS.

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.

As discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 43545 through 43546), we proposed to remove the bypass codes listed in Table 1 of the proposed rule, several of which were affected by the CY 2014 proposed packaging policy. Codes that would not be separately paid in the prospective year, whether because of prospective packaging policies or deletions prior to the claims year, would not be appropriately applied to the bypass process. Bypassing packaged codes would potentially remove costs that would otherwise be used in calculating payment weights for other separately payable procedures, which would be inappropriate. We note that OPPS payment rates may fluctuate from year

to year based on a variety of other factors, including updated data, APC recalibration, and increased packaging.

Comment: Several commenters believed that an inconsistency existed in the application of the bypass policy and the E&M codes. They noted that visit codes 99211 and 99215 were not included on the proposed CY 2014 OPPS bypass list, and that because those codes were part of the proposed new visit APC 0634 (Hospital Clinic Visits), which also would be used in calculating the OPPS relative payment weights, an error had occurred.

Response: We acknowledge that the proposed CY 2014 OPPS bypass list did not include several of the E&M codes. With the exception of CPT code 99205, which we proposed to add to the CY 2014 OPPS bypass list, the other visit codes already had been on the bypass list in prior years based on the empirical criteria previously described. Applying those empirical criteria would continue to exclude the remaining E&M codes from the bypass list. Therefore, we do not believe that those exclusions are an error. While we recognize that there are interactions between the visits policy discussed in section VII. of this final rule with comment period and the bypass process to derive more information, those interactions allow for policy interpretations based on the individual rules and goals being applied. In developing the proposed CY 2014 OPPS bypass list, we tried to retain the principles and guidelines we have used in the past while accommodating other proposals where they might interact, such as with the CY 2014 OPPS proposed packaging policy. We appreciate the meaningful policy comments that stakeholders provide, especially where these policy intersections occur. We will continue to review the codes on the bypass list and their appropriateness, especially in the context of the packaging policies described in section II.A.3. of this final rule with comment period.

We note that while we proposed that the new CY 2014 visit APC 0634 would be the new base APC on which the scaled weights would be calculated, it was selected as a baseline because clinic visits are one of the most frequently performed services in the hospital outpatient setting, similar to APCs 0606 and 0601 in prior years. However, choice of the APC on which to base the proposed relative payment weights for all other APCs does not affect the payments made under the OPPS because the weights are scaled for budget neutrality. Therefore, any potential miscalculations or policy issues related to an APC would

generally be concentrated in those APCs because, for scaling purposes, it would be similar to selecting any number as a baseline, which would later be budget neutralized through a weight scaler. The CY 2014 OPPS weight scaler is discussed in section II.A.4. of this final rule with comment period.

Comment: One commenter noted that many of the codes on the bypass list may no longer be appropriate because the proposed CY 2014 packaging policy would potentially cause many of the natural single major claims, to which CMS applies the empirical criteria, to exceed the packaged cost thresholds.

Response: We appreciate the issue that the commenter has raised regarding the application of the bypass list and its interaction with our proposed CY 2014 policies. In prior years, we generally continued bypassing codes that were on the previous year's bypass list under the assumption that packaging, billing, and clinical patterns would generally remain similar from year to year. As the commenter noted, under the proposed CY 2014 OPPS packaging policies, the data on which we identify codes potentially added to the bypass list may change. We will continue to examine the cost patterns for codes which may be appropriately added or removed from the bypass list.

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 2014 bypass list back on the CY 2014 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 2014.

The list of bypass codes contains codes that were reported on claims for services in CY 2012 and, therefore, includes codes that were in effect in CY 2012 and used for billing but were deleted for CY 2013. We retained these deleted bypass codes on the CY 2014 bypass list because these codes existed in CY 2012 and were covered OPD services in that period, and CY 2012 claims data are used to calculate CY 2014 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 2014 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 2014 bypass list for CY 2014 (78 FR 43546). Table 1 below contains the list of codes that we are removing from the final CY 2014 bypass list because these codes were either deleted from the HCPCS before CY 2012 (and therefore were not covered OPD services in CY 2012) or were not separately payable codes under

the CY 2014 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 2014 OPPS packaging policy described in section II.A.3. of this final rule with comment period.

TABLE 1.—HCPCS CODES REMOVED FROM THE CY 2014 BYPASS LIST

HCPCS Code	HCPCS Short Descriptor
17003	Destruct premalg les 2-14
88185	Flowcytometry/tc add-on
88311	Decalcify tissue
88314	Histochemical stains add-on
90472	Immunization admin each add
90474	Immune admin oral/nasal addl
96371	Sc ther infusion reset pump

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

In the CY 2014 OPPS/ASC proposed rule (78 FR 43547), 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 2014 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 2012 claims data from the most recent available hospital cost reports, in most cases, cost reports beginning in CY 2011. For the CY 2014 OPPS proposed rates, we used the set of claims processed during CY 2012. 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 2012 (the year of

claims data we used to calculate the proposed CY 2014 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2012 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). One longstanding exception to this general methodology for calculation of CCRs used for converting charges to costs on each claim, as detailed in the CY 2007 OPPS/ASC final rule with comment period, is the calculation of blood costs, as discussed in section II.A.2.d.(2) of this final rule with comment period and which has been our standard policy since the CY 2005 OPPS.

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 2012 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 2011. 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 2014 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 2014.

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-500-2005-00291/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). For the CY 2014 OPPS, as we proposed, we are continuing to use data from the “Implantable Devices Charged to Patients” cost center to create a distinct CCR for use in calculating the OPPS relative payment weights.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create new standard cost centers for “Computed Tomography (CT),” “Magnetic Resonance Imaging (MRI),” and “Cardiac Catheterization,” and to require that hospitals report the costs and charges for these services under these new cost centers on the revised Medicare cost report Form CMS 2552–10. As we discussed in the FY 2009 IPPS and CY 2009 OPPS/ASC proposed and final rules, RTI also found that the costs and charges of CT scans, MRIs, and cardiac catheterization differ

significantly from the costs and charges of other services included in the standard associated cost center. RTI concluded that both the IPPS and the OPPS relative payment weights would better estimate the costs of those services if CMS were to add standard costs centers for CT scans, MRIs, and cardiac catheterization in order for hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the cost from charges on claims data. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a more detailed discussion on the reasons for the creation of standard cost centers for CT scans, MRIs, and cardiac catheterization. The new standard cost centers for CT scans, MRIs, and cardiac catheterization were effective for cost report periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10.

Using the December 2012 HCRIS update which we used to estimate costs in the CY 2014 OPPS ratesetting process, as discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 43549), we were able to calculate a valid implantable device CCR for 2,936 hospitals, a valid MRI CCR for 1,853 hospitals, a valid CT scan CCR for 1,956 hospitals, and a valid Cardiac Catheterization CCR for 1,367 hospitals. We believed that there was a sufficient amount of data in the Form CMS 2552–10 cost reports from which to generate a meaningful analysis of the impact on CCRs associated with using the new MRI, CT, and cardiac catheterization cost centers. We provided the data analyses in Tables 2 and 3 of the proposed rule (and are republishing them below) demonstrating the changes as a result of including the distinct CCRs calculated from the new standard cost centers into the CY 2014 OPPS ratesetting process.

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TABLE 2.—MEDIAN CCRs CALCULATED USING DIFFERENT COST REPORT DISTRIBUTIONS

Calculated CCR	“New” Standard Cost Center	Using Form CMS-2552-96 CCRs only	Using Form CMS-2552-96 and Form CMS-2552-10 CCRs
Cardiology		0.2915	0.5112
Cardiac Catheterization	*	0.1685	0.1590
Radiology – Diagnostic		0.2025	0.2279
Magnetic Resonance Imaging (MRI)	*	0.1074	0.0959
CT Scan	*	0.0568	0.0502
Medical Supplies Charged to Patient		0.3389	0.3315
Implantable Devices Charged to Patient	*	0.4371	0.4190

TABLE 3.—PERCENTAGE CHANGE IN ESTIMATED COST FOR THOSE APCs SIGNIFICANTLY AFFECTED BY USE OF THE NEW STANDARD COST CENTER CCRs IN THE FORM CMS-2552-10 COST REPORTS

APC	APC Descriptor	Percentage Change in Estimated Cost
0282	Miscellaneous Computed Axial Tomography	-38.1%
0332	Computed Tomography without Contrast	-34.0%
8005	CT and CTA without Contrast Composite	-33.9%
0331	Combined Abdomen and Pelvis CT without Contrast	-32.9%
8006	CT and CTA with Contrast Composite	-29.0%
0334	Combined Abdomen and Pelvis CT with Contrast	-28.8%
0662	CT Angiography	-27.0%
0283	Computed Tomography with Contrast	-27.0%
0333	Computed Tomography without Contrast followed by Contrast	-26.3%
0383	Cardiac Computed Tomographic Imaging	-24.8%
0336	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast	-19.3%
8008	MRI and MRA with Contrast Composite	-18.9%
8007	MRI and MRA without Contrast Composite	-18.5%
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast	-18.2%
0284	Magnetic Resonance Imaging and Magnetic Resonance	-14.9%

APC	APC Descriptor	Percentage Change in Estimated Cost
	Angiography with Contrast	
0080	Diagnostic Cardiac Catheterization	-8.7%
0276	Level I Digestive Radiology	15.2%
0378	Level II Pulmonary Imaging	15.2%
0396	Bone Imaging	15.5%
0390	Level I Endocrine Imaging	15.8%
0395	GI Tract Imaging	16.2%
0402	Level II Nervous System Imaging	16.2%
0398	Level I Cardiac Imaging	16.3%
0262	Plain Film of Teeth	16.9%
0377	Level II Cardiac Imaging	17.0%
0267	Level III Diagnostic and Screening Ultrasound	17.2%
0406	Level I Tumor/Infection Imaging	17.4%
0403	Level I Nervous System Imaging	18.9%
0266	Level II Diagnostic and Screening Ultrasound	25.1%
0265	Level I Diagnostic and Screening Ultrasound	29.9%
8004	Ultrasound Composite	30.2%

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In our CY 2014 OPPS/ASC proposed rule discussion, we noted that 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 concludes 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 in CY 2013 OPPS ratesetting, as discussed above.

As we have indicated in prior rulemaking (77 FR 68223 through 68225), once we have 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, beginning in the CY 2014 OPPS, we proposed to calculate the OPPS relative payment weights using distinct CCRs for cardiac catheterization, CT scan, and MRI and to continue using a distinct CCR for implantable medical devices. Section XXIII. of this final rule with comment period includes the impacts of calculating the CY 2014 OPPS relative payment weights using these new standard cost centers.

Comment: Commenters generally supported the proposals to implement the standard cost center CCRs for implantable devices and cardiac catheterization. However, many commenters requested that CMS reconsider the impact of distinct CCRs for MRI and CT scan cost centers before adopting them. Various commenters opposed the implementation of distinct MRI and CT scan CCRs, expressing concern that doing so would result in very low CCRs for these services because of gross hospital cost reporting

practices that allocate capital costs for MRIs and CT scans across the entire hospital, rather than to the appropriate CT scan and MRI cost centers. Specifically, commenters reported that some hospitals currently use an imprecise "square feet" allocation methodology for the costs of large moveable equipment like CT scan and MRI machines. They indicated that while CMS recommends using two alternative allocation methods, "direct assignment" or "dollar value," as a more accurate methodology for directly assigning equipment costs, industry analysis suggests that approximately only half of the reported cost centers for CT scans and MRIs rely on these preferred methodologies. The commenters expressed concern that "square feet" allocation results in CCRs that lack face validity because the proposed CCRs for CT scans and MRIs are less than the proposed CCR for general diagnostic radiology, inaccurately reflecting the higher resources used for MRIs and CT scans relative to the less expensive plain film x-rays. These commenters also noted that, under the CY 2014 OPPS proposed policy of using standard CT and MRI cost center data from the Medicare cost report Form CMS 2552-10, payment for certain x-rays would be similar to that

of CT imaging services, despite their belief that CT services would cost significantly more to perform. Other commenters suggested that if CMS were to finalize the new CCRs, CMS should only use cost report data that meet minimum data quality standards, such as only including: (1) Cost report data based on dollar value or direct assignment cost allocation methods; (2) “plausible” costs for CT and MRI cost centers; and (3) data when there is evidence of reclassified costs from diagnostic radiology to standard CT and MRI cost centers. Commenters also raised concerns with CMS’ analysis and indicated that similarity of the APC payment impacts in the CY 2014 OPPS proposed rule and those in the RTI report did not confirm the validity of the proposed CCRs. Commenters asserted that more time is needed by hospitals to modify their cost reporting practices, while other commenters suggested that it was unrealistic to expect hospitals to adopt cost allocation methods that would improve the accuracy of the cost data at all, due to the significant expenses involved and the limited benefit to each individual hospital.

Commenters also noted that the Deficit Reduction Act (DRA) of 2005 sets the technical component (TC) of advanced imaging services under the Medicare Physician Fee Schedule (MPFS) to the lesser of: (1) The payment under the MPFS; or (2) the payment under the OPPS. The commenters stated that, as proposed, the separate cost centers for MRI and CT scans would result in significant cuts to the MPFS technical component payments and that such payment cuts could affect beneficiary access to care. The commenters urged CMS not to use the proposed CCRs for MRIs and CT scans until the payment effects have been thoroughly analyzed.

Response: We appreciate the comments regarding the use of standard cost center CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. We appreciate the support for our proposal to use distinct CCRs for implantable devices and cardiac catheterization. We have reviewed the comments objecting to implementation of distinct CCRs for MRIs and CT scans. We note that the new standard cost centers for CT scans, MRIs, and cardiac catheterization have been in effect since cost reporting periods beginning on or after May 1, 2010, on the revised Medicare cost report Form CMS–2552–10. Therefore, the cost reports that we are using to develop the CY 2014 OPPS relative payment weights were either the first or

the second opportunity for hospitals to submit cost reports with the new CT scan and MRI cost centers (lines 57 and 58 of Worksheets A and C, Part I of the Form CMS–2552–10), depending on the hospital’s cost reporting period. Simultaneous with implementing the new CT scan and MRI cost centers, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50077) and the CY 2011 OPPS/ASC final rule (75 FR 71824), we also notified hospitals of the need and importance of properly reporting the capital costs of moveable equipment on the Medicare cost report.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50078), we explained that, in accordance with Section 104 of CMS Pub. 15–1, Chapter 1, CT scans and MRIs are major moveable equipment, and the costs should be reported together with the rest of the hospital’s major moveable equipment cost in the Capital-Related Costs—Moveable Equipment cost centers on Worksheet A (lines 2 and 4 on the Form CMS–2552–96 and line 2 on the Form CMS–2552–10). The costs in these cost centers are allocated to all the hospital’s cost centers that use major moveable equipment (including CT and MRI), using “dollar value” (which is the “recommended” or default statistical basis, in accordance with the cost reporting instructions contained in Section 4095 of CMS Pub. 15–2, for the Form CMS–2552–10). Alternatively, the hospital may have obtained the contractor’s approval under Section 2313 of CMS Pub. 15–1 to use the simplified cost allocation methodology known as “square feet.” However, a hospital that historically has been using “square feet” and is concerned that this method of allocation may result in inaccurate CCRs (on Worksheet C, Part I) for the CT scan, MRI, and other ancillary cost centers may request contractor approval in accordance with Section 2307 of the CMS Pub. 15–1 to use the “direct assignment” allocation method, and directly assign the cost of moveable equipment to all of the hospital’s cost centers that use moveable equipment, including CT scans and MRIs, using the provider’s routine accounting process. This would ensure that the cost of the CT scanning and MRI equipment would be reflected in the CCR that would be calculated for those departments and that would be used to estimate the cost of CT scan and MRI services. In any case, hospitals should correct their cost reporting practices to come into compliance with CMS’ longstanding policy regarding the “Capital-Related Costs—Moveable Equipment” cost center, by either using

the recommended statistical allocation method of “dollar value” for costs in Worksheet A, Column 2 for Capital-Related Costs—Moveable Equipment or by requesting contractor approval in accordance with Section 2307 of CMS Pub. 15–1 to use the “direct assignment” allocation method. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53283), we reiterated this policy, and added that “Hospitals that still need to correct their cost reporting practices in this regard should do so soon” so that distinct CT and MRI cost center CCRs would accurately reflect the costs associated with providing those services.

In the CY 2014 OPPS/ASC proposed rule, we provided information about the CT and MRI cost center CCRs and the estimated effects on APC payment of adopting those cost centers. We noted the similarities between our estimations and the RTI report results not only to demonstrate that they were generally consistent with each other, but to again note that any concerns and criticisms of the data and its corresponding impact on the payment rates would be the same as were expected when the report was initially published in July 2008, absent any improvements in cost reporting practice. We further note that some of the concerns that commenters described related to differentials in payment for plain film x-rays based on proposed CY 2014 OPPS payment rates being similar to those of the CT and MRI services have abated because the ancillary services and diagnostic tests on the bypass list packaging proposals are not being finalized for CY 2014. Various packaged items and services under those proposals may have created some of the estimated increase in service cost for plain film x-rays.

While some commenters believe that it is unrealistic for hospitals to adopt cost allocation methods that improve data and payment accuracy, we believe that those recommended changes are critical in the shared goal of developing OPPS relative payment weights that accurately reflect service costs. We also believe that because approximately half of hospitals reporting either the new CT scan or MRI standard cost center thus far have adopted one of the more accurate cost allocation methods, other hospitals also should be able to do so. Of the 1,961 hospitals reporting a new CT scan standard cost center, 1,055 hospitals reported using either “direct assignment” or “dollar value” as the cost allocation method. Similarly, of the 1,871 hospitals reporting a new MRI standard cost center, approximately 985 hospitals report using either “direct assignment” or “dollar value” as the

cost allocation method. Commenters have previously recognized the significant impact that the CT scan and MRI standard cost center data would have on multiple payment systems, and we believe that the significant effects of these data on payment should inherently encourage more accurate cost reporting (75 FR 71824). Standard cost centers for CT and MRI services were developed in the revised Medicare cost report Form CMS-2552-10 to more accurately capture the costs associated with providing these important services. Not including the cost report data derived from these cost centers in ratesetting with no future indication of improvement would be contrary to their purpose and our goal to develop OPPS relative payment weights that accurately reflect service costs.

We have considered the public comments recommending that if CMS does finalize distinct CCRs for CT scans and MRIs for the OPPS relative payment weights, CMS adopt certain minimum quality standards, such as using only cost report data of hospitals that use either direct assignment or the dollar value statistical allocation method, have at least \$250,000 of cost in the CT scan or MRI cost center, and have reclassified overhead costs from the diagnostic radiology cost center to the CT scan and/or MRI cost centers. We appreciate the commenters' shared concern surrounding the goal of using the best available information to estimated costs associated with these new standard cost centers.

For the FY 2014 IPPS/LTCH PPS final rule, we did not agree with the adoption of commenters' suggested minimum data standards because doing so would have ignored the fact that many hospitals have chosen (at least up to this point) to employ the square feet statistical allocation methodology, perhaps for reasons unrelated to the costs of MRIs and CT scans, and, therefore, those data reflect, in large part, the best available data that we have. It also is not administratively feasible for CMS to determine, using HCRIS data, whether hospitals have reclassified overhead costs from the diagnostic radiology cost center to the CT scan and/or MRI cost centers. However, in the FY 2014 IPPS/LTCH PPS final rule, we recognized that while only a fraction of the negative impact would be manifested in the IPPS MS-DRGs, the OPPS relative payment weights would be more significantly affected by the adoption of the new standard cost center CCRs (78 FR 50521).

We took note of the many comments regarding the ramifications of

developing distinct CT scan and MRI CCRs on beneficiary access to care and other payment systems. We understand that any such change could have significant payment impacts under the MPFS where the TC payment for many imaging services is capped at the OPPS payment. These significant payment effects based on adoption of the new CT scan and MRI standard cost center CCRs further underscore the need for accurate cost reporting for ratesetting purposes. Although these payment effects are significant, we do not believe that they would likely significantly affect beneficiary access to imaging because imaging is readily available at different sites of service and the magnitude of the payment effects are not so drastic that providers and suppliers of imaging would likely discontinue offering CT and MRI services.

We appreciate the concerns expressed by the commenters related to payment changes of implementing these cost center CCRs, and the importance of not providing an incentive for hospitals to furnish, or not furnish, certain services. However, we are not convinced that further delay or further trimming of CCR values is necessary in order to implement all of the proposed CCRs. Although hospitals have been permitted to use the alternative basis cost allocation (that is, "square feet") under Section 2313 of CMS Pub. 15-1, this methodology does not ensure precise CCRs for CT scans and MRIs. Therefore, we encouraged hospitals over the past several years to use the most precise cost reporting methods in response to the new cost report lines. Specifically, the longstanding cost report instructions contained in Section 4020 (previously Section 3617) of CMS Pub. 15-2 state that "The statistical basis shown at the top of each column on Worksheet B-1 is the recommended basis of allocation of the cost center indicated which must be used by all providers completing this form (Form CMS-2552-10), even if a basis of allocation other than the recommended basis of allocation was used in the previous iteration of the cost report (Form CMS-2552-96)." Under Table 1 of the Medicare cost report, which lists the Record Specifications for the cost centers on Worksheet B-1, "dollar value" is specified as the recommended statistical allocation method for Column 2, Capital-Related Costs—Moveable Equipment. While the "dollar value" statistical allocation method is more precise than "square feet," to ensure even more precise CCRs for CT scans and MRIs, 90 days prior to the beginning of their next cost reporting period, hospitals may request

permission from their Medicare contractors in accordance with Section 2307 of CMS Pub. 15-1 to use the "direct assignment" allocation method on Worksheet B, Part II, Column 0. Although "direct assignment" is the preferred and most precise allocation method, hospitals that do not have the resources to directly assign the costs of every cost center are strongly encouraged to instead use the "dollar value" statistical allocation method. (We note that, under Section 2313 of CMS Pub. 15-1, hospitals not currently using "dollar value" should notify their contractor of their intention to switch their statistical allocation basis to "dollar value" at least 90 days prior to the end of a cost reporting period.) We also intend to communicate with the Medicare contractors to facilitate approval of hospitals' requests to switch from the square feet statistical allocation method to the "direct assignment" or "dollar value" allocation method for the costs of major moveable equipment. We believe that, by adopting more refined CCRs, we are fostering more careful cost reporting. Therefore, we generally do not believe that the concerns expressed by the commenters warrant further delay in implementing the proposed CCRs for CT scans and MRIs for use in OPPS ratesetting.

However, we recognize the commenters' concerns with regard to the application of the new CT and MRI standard cost center CCRs and their use in OPPS ratesetting. As compared to the IPPS, there is increased sensitivity to the cost allocation method being used on the cost report forms for these new standard imaging cost centers under the OPPS due to the limited size of the OPPS payment bundles and because the OPPS applies the CCRs at the departmental level for cost estimation purposes. As a means of addressing the commenters' concerns related to the new CT and MRI standard cost centers, when calculating the CT and MRI cost center CCRs used to estimate costs for the CT and MRI APCs listed in Table 4 below, we removed all claims from providers that use "square feet" as a cost allocation method. We identified providers using "square feet" as the cost allocation method by extracting HCRIS data on Worksheet B-1. Table 4 displays information about the relative effect on CT and MRI APC payments after removing cost data for providers that report CT and MRI standard cost centers using "square feet" as the cost allocation method. Table 5 below provides statistical values based on the CT and MRI standard cost center CCRs

using the different cost allocation methods.

TABLE 4.—PERCENTAGE CHANGE IN ESTIMATED COST FOR CT AND MRI APCs WHEN EXCLUDING CLAIMS FROM PROVIDERS USING “SQUARE FEET” AS THE COST ALLOCATION METHOD

CY 2014 APC	CY 2014 APC Descriptor	Percent Change
0282	Miscellaneous Computed Axial Tomography	17.7%
0283	Computed Tomography with Contrast	8.7%
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast	4.5%
0331	Combined Abdomen and Pelvis CT without Contrast	10.4%
0332	Computed Tomography without Contrast	14.0%
0333	Computed Tomography without Contrast followed by Contrast	11.6%
0334	Combined Abdomen and Pelvis CT with Contrast	9.3%
0336	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast	8.3%
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast	6.1%
0383	Cardiac Computed Tomographic Imaging	2.6%
0662	CT Angiography	9.9%
8005	CT and CTA without Contrast Composite	12.4%
8006	CT and CTA with Contrast Composite	8.7%
8007	MRI and MRA without Contrast Composite	7.4%
8008	MRI and MRA with Contrast Composite	6.4%

TABLE 5.—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	0.049	0.063	0.093	0.118
Square Feet Only	0.038	0.049	0.081	0.101
Direct Assign	0.061	0.070	0.112	0.126
Dollar Value	0.059	0.070	0.106	0.129
Direct Assign and Dollar Value	0.058	0.070	0.108	0.129

As we have stated in prior rulemaking (77 FR 53281 through 53283 and 77 FR 68224), once we determined that a sufficient amount of cost report data were available from which to generate a meaningful analysis, we would propose,

and finalize if appropriate, the use of the distinct CCRs described above in the calculation of the OPPS relative payment weights. We believe that the analytic findings described in the proposed rule, and the volume of

hospitals that have “valid” CCRs described above, computed using the July 2013 HCRIS update, support our original decision to create new cost centers and distinct CCRs for implantable devices, MRIs, CT scans,

and cardiac catheterization, and we see no reason to further delay implementation of the CCRs of each of these cost centers for the OPSS.

Therefore, we are finalizing a policy for the CY 2014 OPSS 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 identified in Table 4. 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 OPSS relative payment weights are developed. 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 will sunset this policy in 4 years once the updated cost report data become available for ratesetting purposes. We believe that 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.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to use data from the “Implantable Devices Charged to Patients” and “Cardiac Catheterization” cost centers to create distinct CCRs for use in calculating the OPSS relative payment weights for CY 2014. For the “Magnetic Resonance Imaging (MRI)” and “Computed Tomography (CT) Scan” APCs identified in Table 4 earlier in this section, we are modifying our proposal so that the final policy will remove claims from cost modeling for those providers using “square feet” as the cost allocation statistic.

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 OPSS payment rates for CY 2014. The Hospital OPSS 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 “OPSS Limited Data Set,” which now includes the additional variables previously available only in the OPSS Identifiable Data Set, including ICD–9–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2012 claims that were used to calculate the final payment rates for the CY 2014 OPSS.

In the history of the OPSS, 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 OPSS/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 OPSS/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 OPSS 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 2014, as we proposed, we are continuing to use geometric mean costs to calculate the relative weights on which the CY 2014 OPSS payments 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 OPSS payment rates for CY 2014 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.

Comment: Commenters expressed concern with respect to the volatility of the OPSS payment rates from year to year. One commenter suggested a “dampening policy” that would limit declines in payment service from year to year.

Response: As previously discussed in the CY 2013 OPSS/ASC final rule with comment period (77 FR 68225), there are a number of factors that contribute to cost fluctuations from one year to the

next, including (but not limited to) hospital behavior in adjusting mix of services, changes in hospital costs and charges each year resulting in changes to the CCRs, reassignments of HCPCS codes, changes to OPSS payment policy (for example, changes to packaging policies), and implementation of composite APCs. We cannot stabilize hospital-driven fundamental inputs to the calculation of OPSS payment rates. However, we have strived to resolve some of the other potential reasons for instability from year to year. Specifically, we continue to seek ways to use more claims data so that we have fewer APCs for which there are small numbers of single bills used to set the APC costs. Moreover, we have tried to eliminate APCs with very small numbers of single bills where we could do so. We recognize that changes to payment policies, such as the packaging of payment for ancillary and supportive services and the implementation of composite APCs, may contribute to volatility in payment rates in the short term. However, we believe that larger payment packages and bundles should help to stabilize payments in the long term by enabling us to use more claims data and by establishing payments for larger groups of services. Further, in seeking to mitigate fluctuations in the OPSS, we believe that implementing the policy suggested by the commenters would make payments less reflective of the true service costs. Limiting decreases to payments across all APCs in a budget neutral payment system could unfairly reduce the payments for other services due to the effects of the scaling that is necessary to maintain budget neutrality and would distort the relativity of payment that is based on the cost of all services.

a. Claims Preparation

For this final rule with comment period, we used the CY 2012 hospital outpatient claims processed through June 30, 2013, to calculate the geometric mean costs of APCs that underpin the relative payment weights for CY 2014. (For the proposed rule, we used CY 2012 hospital outpatient claims processed through December 31, 2012.) To begin the calculation of the relative payment weights for CY 2014, we pulled all claims for outpatient services furnished in CY 2012 from the national claims history file. This is not the population of claims paid under the OPSS, 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 125 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, of which we use a subset for the limited number of services in these claims that are paid under the OPPS.

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, as we proposed, we are continuing the CY 2013 payment policy for separately payable drugs and biologicals. We refer readers to section V.B.3. of this final rule with comment period for a complete discussion of our CY 2014 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," "V," or "X," 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 2013 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 2014, as we proposed, we are continuing the policy we implemented for CY 2013 to exclude line-item data for pass-through drugs and biologicals

(status indicator “G” for CY 2012) and nonpass-through drugs and biologicals (status indicator “K” for CY 2012) 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 2013 OPPS/ASC final rule with comment period (77 FR 68226) 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 2014 OPPS, as part of our packaging of certain clinical diagnostic laboratory tests, we also apply the line item trim to these services if they did not receive payment in the claims year. Removing these lines ensures that, in establishing the CY 2014 OPPS relative payments weights, we appropriately allocate the costs associated with packaging these services. For a more detailed discussion of the final policy to package certain clinical diagnostic laboratory tests, we refer readers to section II.A.3.b.(3) of this final rule with comment period.

b. Splitting Claims and Creation of “Pseudo” Single Procedure Claims

(1) Splitting Claims

For the CY 2014 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 final CY 2014 OPPS packaging policy, we are not deleting status indicator “X” and not revising 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. For CY 2014, as we proposed, we are continuing our current policy of

defining major procedures as any HCPCS code having a status indicator of “S,” “T,” or “V”; defining minor procedures as any code having a status indicator of “F,” “G,” “H,” “K,” “L,” “R,” “U,” or “N”; and classifying “other” procedures as any code having a status indicator other than one that we have classified as major or minor. For CY 2014, we had originally proposed to delete status indicator “X” as part of our proposal to package ancillary services under that status indicator. However, as discussed in section II.A.3. of this final rule with comment period, we are not establishing that policy in CY 2014 and may reexamine that policy in the future. Therefore, for CY 2014, we are defining HCPCS codes having a status indicator of “X” as major procedure, due to the retention of the status indicator. For CY 2014, we are continuing to assign status indicator “R” to blood and blood products; status indicator “U” to brachytherapy sources; status indicator “Q1” to all “STVX-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 2014 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,” “V,” or “X” which includes codes with status indicator “Q3”); claims with one unit of a status indicator “Q1” code (“STVX-packaged”) where there was no code with status indicator “S,” “T,” “V,” or “X” 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,” “V,” or “X” 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,” “V,” or “X”). 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” (“STVX-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” (“STVX-packaged”) or more than one unit of a code with status indicator “Q1” but no codes with status indicator “S,” “T,” “V,” or “X” 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” (“STVX-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 2014 “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 2014 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” (“STVX-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 2013 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 2013 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 2013 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 2013 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 2013 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 2013 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” (“STVX-packaged”), we selected the T-packaged status indicator “Q2” HCPCS code that had the highest relative payment weight for CY 2013 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 2013 relative payment weight; other codes with status indicator “Q2”; codes with status indicator “Q1” (“STVX-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 2013 relative payment weights. If a status indicator “Q1” HCPCS code had a higher CY 2013 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 2014 OPPS.

We did not receive any public comments on this proposal, and therefore are finalizing our proposal to continue to apply the methodology described above for the purpose of creating “pseudo” single procedure claims for the CY 2014 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 6 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 2014 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 2014 to the revenue codes that the I/OCE will package for CY 2014 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 2014, as we did for CY 2013, we reviewed the changes to revenue codes that were effective during CY 2012 for purposes of determining the charges reported with revenue codes but without HCPCS codes that we proposed to package for CY 2014. We believe that the charges reported under the revenue codes listed in Table 6 below continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes. Therefore, for CY 2014, 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 6 below for purposes of calculating the geometric mean costs on which the final CY 2014 OPPS/ASC payment rates are based.

Comment: One commenter recommended that CMS consider examining revenue codes not currently on the list of CY 2014 packaged revenue codes for potential addition to the list of packaged revenue codes. The commenter stated that with increased packaging of ancillary and adjunctive services, it becomes more important to ensure that all OPPS service costs are packaged into the pertinent OPPS furnished service.

Response: In the CY 2010 OPPS/ASC proposed rule and the final rule with comment period, we reviewed the revenue code-to-cost center crosswalk and the revenue codes which are considered for use in OPPS ratesetting. Although there was an extensive discussion in the CY 2010 OPPS/ASC final rule with comment period about the use of revenue codes in OPPS ratesetting, we did not receive any public comments regarding additions or removals of revenue codes from the packaged revenue code list (78 FR 43554). Similarly, commenters’ specific concerns have typically been isolated to the adoption of the new standard cost center CCRs in the Medicare cost report Form CMS–2552–10. However, we recognize the commenter’s concern and believe that an examination of both the current packaged revenue code list and potential addition or removal of revenue codes in the future may be worth performing.

After consideration of the public comments we received, we are finalizing the proposed packaged revenue codes for CY 2014, which are identified in Table 6 below, without

modification. We note that these revenue codes include only revenue codes that were in effect in CY 2012, the	year of the claims data on which the	final CY 2014 OPPS payment rates are based. BILLING CODE 4120-01-P
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TABLE 6.—CY 2014 PACKAGED REVENUE CODES

Revenue Code	Description
0250	Pharmacy; General Classification
0251	Pharmacy; Generic Drugs
0252	Pharmacy; Non-Generic Drugs
0254	Pharmacy; Drugs Incident to Other Diagnostic Services
0255	Pharmacy; Drugs Incident to Radiology
0257	Pharmacy; Non-Prescription
0258	Pharmacy; IV Solutions
0259	Pharmacy; Other Pharmacy
0260	IV Therapy; General Classification
0261	IV Therapy; Infusion Pump
0262	IV Therapy; IV Therapy/Pharmacy Svcs
0263	IV Therapy; IV Therapy/Drug/Supply Delivery
0264	IV Therapy; IV Therapy/Supplies
0269	IV Therapy; Other IV Therapy
0270	Medical/Surgical Supplies and Devices; General Classification
0271	Medical/Surgical Supplies and Devices; Non-sterile Supply
0272	Medical/Surgical Supplies and Devices; Sterile Supply
0275	Medical/Surgical Supplies and Devices; Pacemaker
0276	Medical/Surgical Supplies and Devices; Intraocular Lens
0278	Medical/Surgical Supplies and Devices; Other Implants
0279	Medical/Surgical Supplies and Devices; Other Supplies/Devices
0280	Oncology; General Classification
0289	Oncology; Other Oncology
0343	Nuclear Medicine; Diagnostic Radiopharmaceuticals
0344	Nuclear Medicine; Therapeutic Radiopharmaceuticals
0370	Anesthesia; General Classification
0371	Anesthesia; Anesthesia Incident to Radiology
0372	Anesthesia; Anesthesia Incident to Other DX Services
0379	Anesthesia; Other Anesthesia
0390	Administration, Processing and Storage for Blood and Blood Components; General Classification
0392	Administration, Processing and Storage for Blood and Blood Components; Processing and Storage
0399	Administration, Processing and Storage for Blood and Blood Components; Other Blood Handling
0621	Medical Surgical Supplies – Extension of 027X; Supplies Incident to Radiology
0622	Medical Surgical Supplies – Extension of 027X; Supplies Incident to Other DX Services
0623	Medical Supplies – Extension of 027X, Surgical Dressings
0624	Medical Surgical Supplies – Extension of 027X; FDA Investigational Devices
0630	Pharmacy – Extension of 025X; Reserved

Revenue Code	Description
0631	Pharmacy – Extension of 025X; Single Source Drug
0632	Pharmacy – Extension of 025X; Multiple Source Drug
0633	Pharmacy – Extension of 025X; Restrictive Prescription
0681	Trauma Response; Level I Trauma
0682	Trauma Response; Level II Trauma
0683	Trauma Response; Level III Trauma
0684	Trauma Response; Level IV Trauma
0689	Trauma Response; Other
0700	Cast Room; General Classification
0710	Recovery Room; General Classification
0720	Labor Room/Delivery; General Classification
0721	Labor Room/Delivery; Labor
0732	EKG/ECG (Electrocardiogram); Telemetry
0762	Specialty services; Observation Hours
0801	Inpatient Renal Dialysis; Inpatient Hemodialysis
0802	Inpatient Renal Dialysis; Inpatient Peritoneal Dialysis (Non-CAPD)
0803	Inpatient Renal Dialysis; Inpatient Continuous Ambulatory Peritoneal Dialysis (CAPD)
0804	Inpatient Renal Dialysis; Inpatient Continuous Cycling Peritoneal Dialysis (CCPD)
0809	Inpatient Renal Dialysis; Other Inpatient Dialysis
0810	Acquisition of Body Components; General Classification
0819	Acquisition of Body Components; Other Donor
0821	Hemodialysis-Outpatient or Home; Hemodialysis Composite or Other Rate
0824	Hemodialysis-Outpatient or Home; Maintenance – 100%
0825	Hemodialysis-Outpatient or Home; Support Services
0829	Hemodialysis-Outpatient or Home; Other OP Hemodialysis
0942	Other Therapeutic Services (also see 095X, an extension of 094x); Education/Training
0943	Other Therapeutic Services (also see 095X, an extension of 094X), Cardiac Rehabilitation
0948	Other Therapeutic Services (also see 095X, an extension of 094X), Pulmonary Rehabilitation

BILLING CODE 4120-01-C

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 on or after July 1, 2004, 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 OPs) for which the fiscal intermediary or 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 2014 OPs.

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 and final rule 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 OPSS, 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.

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 OPSS, and claims for services not paid under the OPSS, approximately 119 million claims were left. Using these approximately 119 million claims, we created approximately 125 million single and “pseudo” single procedure claims, of which we used approximately 124 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 2014 geometric mean cost development and ratesetting.

As discussed above, the OPSS has historically developed the relative weights on which APC payments are based using APC median costs. For the CY 2013 OPSS, we calculated the APC relative payment weights using geometric mean costs, and we do the same for CY 2014. 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 2014 OPSS/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 2014 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 OPSS/ASC final rule with comment period (77 FR 68270), as part of the CY 2013 policy to develop the OPSS relative payment weights based on geometric mean costs, we also applied the 2 times rule based on geometric mean costs. For the CY 2014 OPSS, 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 124 million single procedure or single session claims we use for establishing geometric mean costs. Similarly, a HCPCS code for which there are fewer than 99 single bills and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC geometric mean. We note that this method of identifying significant HCPCS codes within an APC for purposes of the 2 times rule was used in prior years under the median-based cost methodology. Under our proposed CY 2014 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.

Comment: Several commenters remarked on the quality of the data and the degree to which technical errors caused modeling problems throughout the rest of the system. These commenters believed that CMS did not provide adequate data to allow hospitals to assess the impact of the major revisions. Commenters also commented on the complexity inherently in the payment system and increased by the many interactions between various proposed and existing policies. These commenters remarked that CMS had not fully explained the impacts of each proposal in a manner that would allow stakeholders to provide meaningful input. Based on the assertions about a lack of transparency, impact analysis, guidance on how rates were developed, policy details, technical errors, etc., commenters suggested that those proposals be delayed until more accurate and detailed information was available. Other commenters stated that CMS had ignored previous HOP Panel suggestions on analyzing the impact of expanded packaging policies, and believed that the potential for unintended downstream consequences existed.

Response: We appreciate the commenters' concerns with regards to the complexity of modeling the OPSS. There are many interactions between the various goals and pieces of the payment system. For example, as discussed in section II.A.1.b. of this final rule with comment period, the goal of extracting more data from the available claims through the bypass list process is also balanced by the impact of any packaged costs that may be redistributed as a result of that data process. In developing the CY 2014 OPSS/ASC proposed rule, we strived to provide as accurate information as possible with regard to the calculated rates. We discovered that, in the process of applying established and proposed methodologies to develop the CY 2014 proposed OPSS and ASC payment rates, specific cost estimation errors occurred in the OPSS modeling process. We released corrected data files on August 28, 2013, and extended the comment period to September 16, 2013, on the technical corrections noted in the correcting document published in the **Federal Register** on September 6, 2013 (78 FR 54842). While, in a budget neutral system, changes to any OPSS

relative payment weights have redistributive effects throughout the system, any policy change or data update has the potential to do the same. Therefore, the technical corrections described in the correcting document were made to address issues where the calculated payment rates were not appropriately reflective of the proposed policies. While, as discussed in the correcting document to the CY 2014 OPPS/ASC proposed rule, new proposed visit APC 0634 contained a technical error that excluded certain packaged costs from the APC, the fact that we proposed to use APC 0634 as the baseline APC for scaling the aggregate CY 2014 OPPS weight for budget neutrality, did not distort the relativity of the OPPS payment weights. As discussed in section II.A.4. of this final rule with comment period, the selection of the base APC or any other number, from which to establish the relative payment weights, does not have an impact because OPPS weights are scaled for budget neutrality.

With regard to the adequacy of available data, each year, CMS makes available an extensive amount of OPPS data that can be used for any data analysis an interested party would care to perform. Specifically, we make available a considerable amount of data for public analysis each year through the supporting data files that are posted on the CMS Web site in association with the display of the proposed and final rules. In addition, we make available the public use files of claims, including, for CY 2008 and later, supplemental line item cost data for every HCPCS code under the OPPS and a detailed narrative description of our data process for the annual OPPS/ASC proposed and final rules that the public can use to perform any desired analyses. Therefore, we believe commenters are able to examine and analyze these data to develop specific information to assess the impact and effect of packaging for the services of interest to them. This information is available to support their requests for changes to payments under the OPPS, whether with regard to separate payment for a packaged service or other issues. We understand that the OPPS is a complex payment system and that it may be difficult to determine the quantitative amount of packaged cost included in the geometric mean cost for every independent service. However, commenters routinely provide us with meaningful analyses at a very detailed and service-specific level based on the claims data we make available. We routinely receive complex and detailed public comments, including extensive

code-specific data analysis on packaged and separately paid codes using the data from this and prior proposed and final rules. Among the public comments received in response to the CY 2014 OPPS/ASC proposed rule, we received many detailed public comments that included data analysis.

We disagree that the CY 2014 OPPS policy proposals should be delayed as a result of the data concerns that commenters have raised. While we are sympathetic to the challenges that have been described, we develop policy and model the OPPS payment rates under those same constraints. In general, we have tried to limit the changes beyond the current year OPPS with regards to data modeling, so that little additional logic changes would be necessary and would instead be built off existing processes. While we continuously examine ways in which the data process could be simplified or made clearer, we also welcome and appreciate public comment with regards to potential improvements. Similarly, we appreciate the meaningful comments that stakeholders provide 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.

The technical errors described in the correcting document published in the **Federal Register** on September 6, 2013 (78 FR 54842) were generally isolated to specific policy areas and did not substantively affect the proposed policies described in the CY 2014 OPPS/ASC proposed rule. The correcting document merely corrected the underlying data errors to conform to the proposed policies clearly intended in the preamble of the proposed rule.

As commenters have described, modeling the OPPS payment rates can sometimes be a complex undertaking. We have tried to alleviate some of those concerns about the complexity and transparency of the OPPS cost modeling process by having an extensive discussion of the data process in the preamble discussion, through providing code lists, isolating the impacts of certain proposals in the regulatory impact analysis, and providing a claims accounting with documented claims volume throughout each stage of the process. Commenters have stated that CMS has not provided data regarding packaging policies to the Advisory Panel on Hospital Outpatient Payment (referred to in this document as the Panel). However, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68573), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60409 through 60412), the CY 2011 OPPS/ASC

final rule with comment period (75 FR 71682 through 71868), the CY 2012 OPPS/ASC final rule with comment period (76 FR 74184 through 74185), and the CY 2013 OPPS/ASC final rule with comment period (77 FR 68273 through 68274), we describe various data analyses we have provided to the Panel based on its recommendations.

After consideration of the public comments we received, we are finalizing our proposed CY 2014 methodology for calculating the geometric mean costs upon which the CY 2014 OPPS payment rates are based.

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 2013 meeting of the Panel, we discussed the claims accounting process for the CY 2014 OPPS proposed rule, the proposed adoption of the new standard cost centers for CT, MRI, and cardiac catheterization in the new Medicare cost report Form CMS-2552-10, as well as the CY 2014 OPPS policy of calculating OPPS relative payment weights using geometric mean costs.

At the August 2013 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 John Marshall, C.R.A., R.C.C, R.T., serve as chair of the Data Subcommittee.

CMS Response: We are accepting this recommendation.

In addition, the Panel requested that CMS provide additional information about the impacts of certain CY 2014 policy proposals at the 2014 spring

meeting. Depending upon the CY 2014 final policy decisions, we will consider providing additional relevant information to the Panel at the Spring 2014 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; do 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 proposed rule (78 FR 43558 through 43561), for CY 2014, we proposed in section II.A.2.e. to define 29 device-dependent APCs as single complete services and to assign them to comprehensive APCs that would provide all-inclusive payments for those services. As we explained in that section, we proposed this policy as a further step to improve the accuracy and transparency of our payments for these services where the cost of the device is large compared to the other costs that contribute to the cost of the service. Table 5 of the proposed rule provided a list of the 39 APCs currently recognized as device-dependent APCs and identified those 29 APCs that we proposed to include in the comprehensive APCs proposal (78 FR 43557). We proposed to treat the remaining 10 device-dependent APCs

by applying our standard APC ratesetting methodology to calculate their CY 2014 payment rates. We initially adopted a specific device-dependent APC ratesetting methodology because commenters had previously expressed concerns that the costs associated with certain high-cost devices were not always being accurately reported and included in the calculation of relative payment weights for the associated procedures. As we stated in the proposed rule, we do not believe that it is necessary to continue to apply the more specific device-dependent APC ratesetting methodology to ensure accurate ratesetting for the 10 APCs that were not included in the comprehensive APCs proposal because hospitals now have had several years of experience reporting procedures involving implantable devices and have grown accustomed to ensuring that they code and report charges so that their claims fully and appropriately reflect the costs of those devices. Therefore, we believe that it is possible to calculate the payment rates for these APCs using our standard APC ratesetting methodology (78 FR 43556).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43556 through 43557), beginning in CY 2014, we also proposed to no longer implement procedure-to-device edits and device-to-procedure edits for any APCs. We explained that, under this proposal, hospitals would still be 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. We stated that we believe that this is appropriate because of the experience hospitals now have had in coding and reporting these claims fully and because, for the more costly devices, the proposed comprehensive APCs would reliably reflect the cost of the device if it is included anywhere on the claim. Therefore, we do not believe that the burden on hospitals of adhering to the procedure-to-device edits and device-to-procedure edits, and the burden on the Medicare program of maintaining those edits, continue to be warranted. 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.

Comment: Commenters urged CMS not to finalize its proposal to eliminate device-to-procedure edits and procedure-to-device edits in order to ensure continued complete and accurate

cost reporting by hospitals. In addition, one commenter requested that CMS, if it elects to delete these edits, commit to only using complete and correctly coded claims from CY 2014 for the CY 2016 ratesetting process. Some commenters, while supporting elimination of the contractor edits, opposed dropping the use of the edit criteria when selecting the set of claims to be used to calculate the geometric mean costs of services. One commenter requested that CMS remove APC 0648 from the list of device-dependent APCs.

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 and because, for the more costly devices, the proposed comprehensive APCs would reliably reflect the cost of the device if it is 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. 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 expect the CY 2014 claims that we will use for the CY 2016 ratesetting to reflect this correct coding and cost reporting. While we believe that device-to-procedure edits and procedure-to-device edits are no longer necessary at this time, we are sensitive to the commenters' concerns that all relevant costs for the 39 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 are further assessing whether we need to continue claims processing edits requiring a device code to be on the claim under the comprehensive APCs in CY 2015.

We believe that APC 0648 is appropriately included in the current list of device-dependent APCs, as APC 0648 is populated by HCPCS codes that usually, but not always, require that a device be implanted or used to perform the procedure.

After consideration of the public comments we received, and in conjunction with our finalized comprehensive APC policy, which is fully discussed in section II.A.2.e. of this final rule with comment period, we are finalizing our proposal to no longer apply the current device-dependent APC ratesetting methodology to the 10 currently recognized device-dependent APCs not included in the

comprehensive APC proposal and apply our standard APC ratesetting methodology to calculate their payment rates, but delaying the implementation of this finalized policy until CY 2015. For CY 2014, we will continue to apply

the current device-dependent APC ratesetting methodology to the 39 currently recognized device-dependent APCs.
Table 7 below provides a list of the 39 APCs currently recognized as device-

dependent APCs for CY 2014 and identifies those 29 APCs that we are including in the finalized comprehensive APCs policy for CY 2015.

**TABLE 7.—APCs CURRENTLY RECOGNIZED AS DEVICE-DEPENDENT
APCs**

APC	APC Title
0039*	Level I Implantation of Neurostimulator Generator
0040*	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes
0061*	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes
0082*	Coronary or Non-Coronary Atherectomy
0083*	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization
0084	Level I Electrophysiologic Procedures
0085*	Level II Electrophysiologic Procedures
0086	Level III Electrophysiologic Procedures
0089*	Insertion/Replacement of Permanent Pacemaker and Electrodes
0090*	Level I Insertion/Replacement of Permanent Pacemaker
0104*	Transcatheter Placement of Intracoronary Stents
0106*	Insertion/Replacement of Pacemaker Leads and/or Electrodes
0107*	Level I Implantation of Cardioverter-Defibrillators (ICDs)
0108*	Level II Implantation of Cardioverter-Defibrillators (ICDs)
0115	Cannula/Access Device Procedures
0202*	Level VII Female Reproductive Procedures
0227*	Implantation of Drug Infusion Device
0229*	Level II Endovascular Revascularization of the Lower Extremity
0259*	Level VII ENT Procedures
0293*	Level VI Anterior Segment Eye Procedures
0315*	Level II Implantation of Neurostimulator Generator
0318*	Implantation of Neurostimulator Pulse Generator and Electrode
0319*	Level III Endovascular Revascularization of the Lower Extremity
0384	GI Procedures with Stents
0385*	Level I Prosthetic Urological Procedures
0386*	Level II Prosthetic Urological Procedures
0425*	Level II Arthroplasty or Implantation with Prosthesis
0427	Level II Tube or Catheter Changes or Repositioning
0622	Level II Vascular Access Procedures
0623	Level III Vascular Access Procedures
0648*	Level IV Breast Surgery
0652	Insertion of Intraperitoneal and Pleural Catheters
0653	Vascular Reconstruction/Fistula Repair with Device
0654*	Level II Insertion/Replacement of Permanent Pacemaker
0655*	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing
0656*	Transcatheter Placement of Intracoronary Drug-Eluting Stents
0674*	Prostate Cryoablation
0680*	Insertion of Patient Activated Event Recorders
0687	Revision/Removal of Neurostimulator Electrodes

*Denotes comprehensive APC for CY 2015.

(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 2014 OPPS/ASC proposed rule (78 FR 43557), for CY 2014, 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 would then 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 stated that we calculated the costs upon which the proposed CY 2014 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe the hospital-specific, blood-specific CCR methodology best 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 2014 would result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposed policy, without modification, 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, for CY 2014. We continue to believe that this methodology in CY 2014 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 this final rule with comment period, we are establishing comprehensive APCs that will provide all-inclusive payments for certain device-dependent procedures. Under this policy, we will include the costs of blood and blood products when calculating the overall costs of these comprehensive APCs. We note that we will 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. 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 payment rates of the comprehensive APCs), we will not make separate payments for blood and blood products when they appear on the same claims as services assigned to the comprehensive APCs.

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 CY 2014 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 Source Payment

Section 1833(t)(2)(H) of the Act provides that the Secretary shall create 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, in a manner that reflects the number, isotope, and radioactive intensity of the brachytherapy sources furnished and must include separate groups for palladium-103 and iodine-125 sources, and for stranded and non-stranded devices furnished on or after July 1, 2007. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60533 through 60537), we adopted for CY 2010 the general OPPS prospective payment methodology for brachytherapy sources, consistent with section 1833(t)(2)(C) of the Act, with payment rates based on source-specific costs, which has been utilized for each year's brachytherapy source payment since CY 2010 (74 FR 60537; 75 FR 71980; 76 FR 74162; 77 FR 68242). As we have previously stated, we believe that adoption of the general OPPS prospective payment methodology for brachytherapy sources is appropriate (77 FR 68240).

Comment: Commenters expressed concern regarding CMS' brachytherapy source data and stated that there are longstanding problems with CMS' OPPS data used to set brachytherapy source payment rates. Commenters also stated that the brachytherapy source data continue to show huge variation in per unit costs across hospitals. Commenters noted that high dose rate (HDR) brachytherapy sources decay over a 90-day period and are used to treat multiple patients. Therefore, the commenters believed that the true cost of brachytherapy sources per use depends on the number of patients treated during the 90-day period, which makes it difficult to establish fair and adequate payment rates. Commenters also believed that CMS' claims data contain rank order anomalies between the high-activity palladium-103 source (HCPCS code C2635) and the low-activity palladium-103 sources (HCPCS codes C2640 and C2641), and stated that the high-activity palladium-103 source always costs more than low-activity palladium-103 sources.

Response: We believe that the claims data used for brachytherapy ratesetting

are adequate to ensure accurate payment for these services. Also, as we have stated in previous OPPTS/ASC proposed and final rules, 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 (72 FR 66782; 74 FR 60534; 75 FR 71979; 76 FR 74161; and 77 FR 68241). We have also explained in previous OPPTS/ASC proposed and final rules that a prospective payment system such as the OPPTS relies on the concept of averaging, where the payment may be more or less than the estimated cost of providing a service for a particular patient, and with the exception of outlier cases, the prospective payment is adequate to ensure access to appropriate care (72 FR 66782; 74 FR 60535; 75 FR 71979; and 77 FR 68241). 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 OPPTS because higher variability in costs for some component items and services is not balanced with lower variability in costs for other component items and services. In addition, relative payment weights are typically estimated using a smaller set of claims.

As we have stated in previous OPPTS/ASC proposed and final rules, we agree that HDR brachytherapy sources such as HDR iridium-192 have a fixed active life and must be replaced every 90 days (75 FR 71980; 76 FR 74162; and 77 FR 68242). As a result, hospitals' per-treatment cost for the source would be dependent on the number of treatments furnished per source. The source cost must be amortized over the life of the source. Therefore, when establishing their 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 their charges for the source accordingly (72 FR 66783; 74 FR 60535; 75 FR 71980; 76 FR 74162; and 77 FR 68242). For most of these OPPTS services, our practice is to establish prospective payment rates based on the 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 2012 claims data show that the hospitals' relative costs for the high-activity source as reported on hospital claims and in

cost report data are greater than the costs of the low-activity sources, as we have noticed in the past. However, this relationship is reversed for palladium-103 sources, as a few commenters pointed out. 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; and 77 FR 68242). For the high-activity palladium-103 source, only 7 hospitals reported this service in CY 2012, compared to 118 and 171 hospitals for the low-activity palladium-103 sources described by HCPCS codes C2640 and C2641, respectively. As we stated regarding this issue in the CYs 2010, 2011, 2012, and 2013 OPPTS/ASC final rules with comment period, 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 number of hospitals reporting the low-activity palladium-103 sources (74 FR 60535; 75 FR 71979; 76 FR 74162; and 77 FR 68242).

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 2014 final payment rates for brachytherapy sources are found in Addendum B to this final rule with comment period.

e. Establishment of Comprehensive APCs

(1) Definition and General Principles

During the initial development of a proposal for an outpatient prospective payment system in 1998 (63 FR 47552 through 48036), we considered developing the payment system based on a comprehensive outpatient bundle, as opposed to on a HCPCS component level. In 2000, we implemented an OPPTS based generally on making payments at the HCPCS level (65 FR 18434 through 18820). Since then, however, we have been steadily moving the OPPTS towards a more comprehensive approach that increases flexibility and opportunity for efficiencies in a prospective system.

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43534), for CY 2014, we proposed to create 29 comprehensive APCs to replace 29 existing device-dependent APCs. 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 proposal was 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 that delivery of the primary service. Specifically, we proposed to create comprehensive APCs for the 29 most costly device-dependent services, where the cost of the device is more expensive than the other costs that contribute to the cost of delivering the primary service.

We stated in the proposed rule that we believe that, under the authority of sections 1833(t)(1) and (t)(2) of the Act, the Secretary has the discretion to establish comprehensive APCs as part of developing the OPPTS classification system, and that this proposal furthers our ongoing efforts to move the OPPTS towards a more comprehensive payment system in support of our objectives to increase flexibility and efficiencies.

The OPPTS data we have accumulated over the past decade have enabled us to continue to address several longstanding goals, including: continuing to improve the validity of our payments to most accurately reflect costs; improving transparency and reducing complexity and administrative burden whenever possible; and increasing flexibility for hospitals to develop increased efficiencies in the delivery of quality care.

We stated that we believe that this proposal to establish comprehensive APCs will improve our ability to accurately set payment rates. In the normal process of setting payment rates, costs in certain cost centers ("uncoded costs") are added to the costs of services reported with specific HCPCS codes only when they can be reliably assigned to a single service. Under the proposal, the entire claim would be associated with a single comprehensive service so all costs reported on the claim may be reliably assigned to that service. This increases the accuracy of the payment for the comprehensive service and also increases the stability of the payment from year to year.

We also stated that we believe that our policy will enhance beneficiary understanding and transparency. Typically beneficiaries understand the primary procedure to be the OPPTS service they receive, and do not generally consider that the other HCPCS

codes are separate services. For example, beneficiaries believe that a single service includes procedures such as “getting my gall bladder removed” or “getting a pacemaker.” We believe that defining certain services within the OPPIs in terms of a single comprehensive service delivered to the beneficiary improves transparency for the beneficiary, for physicians, and for hospitals by creating a common reference point with a similar meaning for all three groups and using the comprehensive service concept that already identifies these same services when they are performed in an inpatient environment.

Finally, we believe that larger bundles that contain a wider mix of related services in the prospectively paid bundles increase the opportunities for providers to tailor services to the specific needs of individual beneficiaries, thereby increasing the opportunities for efficiencies and improving the delivery of medical care.

Comment: Overall, commenters were generally supportive of the concept of creating larger payment bundles, but were uncertain that they fully understood the specifics of the proposed comprehensive APC payment policy. Commenters acknowledged many potential advantages for hospitals, and possibly also for beneficiaries in terms of lower coinsurance payments and increased transparency, as well as for increased physician flexibility.

A few commenters fully endorsed the proposal for CY 2014. For example, MedPAC stated that it has long supported CMS’ efforts to expand the size of payment units in the OPPIs and supported this proposal, as well as other packaging proposals in this final rule with comment period. MedPAC stated that the comprehensive APC groups have similarities to the diagnosis related groups (DRGs) used in the inpatient prospective payment system (IPPS) and that this payment structure encourages hospitals to identify the most efficient and efficacious methods to provide care for each patient, which will help contain Medicare spending. Another commenter believed that the proposed device-dependent APCs were particularly appropriate for comprehensive APCs because the independent services that require these devices are generally clearly defined and the other services furnished during the encounter are generally furnished in order to facilitate the independent service. The commenter supported the ability of this proposal to use all claims data in establishing a payment rate for the comprehensive APC.

Several commenters recommended a more expansive policy. One commenter recommended that CMS identify other procedures that would be suitable for the creation of comprehensive APCs. Other commenters suggested that CMS require hospitals to report charges for all items and services for which comprehensive APC payment is being made as covered charges and specify that hospitals may not charge beneficiaries for these items and services (because the copayment for the APC constitutes the only beneficiary cost sharing for the package of services). Commenters also suggested that CMS limit the national unadjusted payment for each comprehensive APC under the OPPIs to no more than the standardized DRG amount that would be paid for the same service provided to an inpatient without complications or comorbidities.

Response: We appreciate the support of the commenters for our proposal to create comprehensive packages. We agree with the commenters that this would improve our ability to more accurately establish payment rates for these services by enabling us to use all claims for the primary service in a comprehensive APC when establishing payment for that APC. We appreciate the commenters’ interest in identifying other services that would be suitable for the creation of comprehensive APCs, as well as ways to consider setting payment relative to the IPPS. We agree with the commenters that hospitals should report charges for all items and services for which a comprehensive APC payment is being made, and note that it has been a longstanding requirement as stated in the Claims Processing Manual IOM 100–4, Chapter 4, Section. 10.4.A that hospitals must report all services that were furnished on an outpatient claim regardless of whether or not those services are separately paid, and that Medicare providers may not separately bill beneficiaries for services that are covered under Medicare.

Comment: The majority of commenters recommended that CMS delay implementation of the comprehensive APCs until CY 2015 or later. While they generally supported the idea of larger payment bundles, commenters were concerned that they could not verify the accuracy of the proposed payments and urged CMS not to implement these policies until the agency has verified that its calculations are accurate. Commenters asserted that it has become increasingly difficult for stakeholders to verify OPPI payment rates because the complexity of the modeling logic is far beyond other payment systems that CMS administers,

such as the IPPS. Some commenters were concerned that they were not able to replicate CMS’ calculations, preventing independent analyses and affecting their ability to develop comments and alternative proposals. Some commenters requested that CMS provide stakeholders with additional information about how estimated costs for these APCs are being calculated for CY 2014, and give stakeholders an opportunity to comment on the additional information provided.

Some commenters requested that CMS provide individual impacts of each proposed policy when proposing several policies that have an interactive effect. Several commenters stated that CMS’ packaging proposals discussed in section II.A.3. of the proposed rule, combined with this proposal to create 29 new comprehensive APCs, created a complicated “layering” effect that made their understanding of how final estimated costs for proposed comprehensive APCs would be calculated a much more involved process.

Finally, commenters recommended a delayed implementation to allow hospitals more time to assess the impact of such a new payment approach on their particular institution and to consider how they may need to adjust organizational processes. Commenters also suggested that we might need more time to implement revisions to our claims processing systems.

Response: We agree with the commenters that we should delay implementation of the proposed comprehensive APCs. As we discuss later in this section, we are finalizing our proposal to create 29 comprehensive APCs with modification, but we are delaying implementation and final configuration of those comprehensive APCs until CY 2015. We acknowledge commenters’ concerns that this is a complex proposal for a new payment structure under the OPPIs. We agree that hospitals should have time to prepare for a comprehensive payment structure, and we also agree with the commenters that a delay in implementation will allow us more time to operationalize changes necessary to process comprehensive payments.

In response to public commenters’ requesting additional detail on our calculation of the comprehensive APC relative payment weights, we provide a granular discussion of our methodology for constructing the comprehensive APC payment rates later in this section, as well as the specific APC configurations we would implement for CY 2014 if we had not delayed implementation until CY 2015. We also believe that the delay

in implementation will give hospitals more time to study the final methodology for calculating APC relative payment weights that we discuss in this section for the modification that recognizes resource differences in complex and simple versions of the same primary service. We are taking advantage of the delay in implementation and requesting additional public comments on this methodology.

With regard to the commenters' concern that they could not fully model the proposal, we provide all of the information we would have used to create APC relative payment weights for CY 2014 using the CY 2012 claims data to illustrate the final methodology below. We believe that this will assist interested parties in replicating our methodology. We will recalibrate all of the comprehensive APC relative payment weights for CY 2015 using CY 2013 claims data consistent with our annual recalibration of APC relative payment weights to reflect the most recently available claims and cost report information in next year's rulemaking cycle. We discuss the limited methodological errors that we discovered in the proposed rule and subsequent correcting document in section II.A.3. of this final rule with comment period.

With regard to the availability of detailed impacts, we believe that a delay in implementation until CY 2015 along with the illustrations of the methodology included in this section will give stakeholders the requested time to model this final policy and assess the impact on their organization. We will incorporate the proposed payment rates for CY 2015 comprehensive APCs in our CY 2015 impact analysis in the CY 2015 OPPI/ASC proposed rule.

Comment: Commenters were also concerned that this proposal would impose a significant administrative burden on providers and that there is not sufficient time for information system technology vendors and operational processes to adjust to the new regulations or to allow hospitals enough time to fully understand how the proposals would affect their outpatient finances, making hospital budgeting for the upcoming year nearly impossible. Moreover, several commenters were concerned that neither CMS nor its Medicare Administrative Contractors (MACs) would be prepared to implement the proposed changes for CY 2014.

Other commenters believed that providers are likely to have increased costs and challenges in their efforts to

accurately separate claims for unrelated services. One commenter recommended that CMS make the necessary operational changes to billing instructions before moving forward with its proposal, and implement the proposed comprehensive APCs only after the agency has used the new billing instructions long enough to have claims data that identify related services for the purpose of defining a comprehensive APC.

Response: This proposal does not require any changes in provider coding and billing practices, nor would we expect providers to change their billing and coding practices in response to a change in payments. We do expect providers to assess their delivery of these comprehensive services in light of internal organizational processes. As previously stated, we are finalizing the comprehensive APC proposal with modification in this final rule with comment period, but we are delaying implementation of the finalized policy until CY 2015. This will allow us sufficient time to develop appropriate claims processing systems protocols for comprehensive APCs and to test those new protocols prior to implementation.

Comment: Many commenters were concerned that a comprehensive DRG-like payment would provide a single payment for a wide range of cases characterized by widely varying complexity and widely varying costs. Such a system could potentially disadvantage hospitals willing to take on the treatment of sicker, more complex and costly cases while rewarding those that handle less complex and less costly cases. One commenter was specifically concerned that the level of payment was not sufficient to support the higher level of diagnostic testing and ancillary services that occur at academic medical centers. Another commenter stated that the costs of these cases are relatively fixed when they are dependent on one or more expensive devices and hospitals can either perform these complex procedures at a loss or cease performing them altogether, which has implications for beneficiary access to care. One commenter stated that hospitals have only limited ability to reduce costs for complex procedures and recommended that CMS incorporate a "severity level" APC similar to the Medicare Severity Diagnosis Related Group (MS-DRG) system where there is a base DRG, a complication or comorbidity DRG (CC DRG), and a major complication or comorbidity DRG (MCC DRG). In adapting the concept to the APC classification system, the commenter recommended that complexity could be

based on the included components, for example, an ICD insertion comprehensive APC and another higher-weighted comprehensive APC for ICD insertion with removal of previously implanted device.

A few commenters believed that the comprehensive payment may have unintended consequences that could include quality consequences, cost consequences, and payment consequences. Several commenters were concerned that the quality of care could suffer because the commenters believed that there are currently no outcome programs or measures in place, similar to inpatient quality measures, readmission reduction programs and value based purchasing incentives, to monitor the quality of care provided under an encounter-based payment that creates an incentive for hospitals to improve delivery efficiency. The commenters believed that inappropriate attempts to garner additional profit could lead to reduced access and lower quality of health care services provided in the hospital outpatient setting. Several commenters were concerned that there might be unintended Medicare cost consequences if hospitals split services and delayed ancillary procedures until a subsequent encounter. Some of these commenters believed that the proposal should be tested or evaluated through a demonstration project or some other appropriate mechanism before broader introduction, while one commenter objected to the CY 2014 implementation because CMS had not proposed mechanisms to retrospectively assess the ramifications of these proposed policy changes on patients. Finally, one commenter opined that the proposal does not conform the requirement under section 1833(t)(2) of the Act that items and services shall not be treated as comparable with respect to the use of resources if the highest mean cost for an item or service is more than 2 times greater than the lowest mean cost.

Response: We agree with the commenters that there is wide spread variation in the comprehensive costs of individual claims within each primary procedure, and we further agree with the commenters that we do not want to financially disadvantage hospitals that treat beneficiaries who require more complex and costly procedures. We also understand that complex beneficiaries may require more diagnostic tests. We agree with the commenters that there are constraints on individual hospitals' ability to reduce costs associated with complex procedures, and we agree with the commenters who recommended recognizing the level of resources

associated with more complex forms of a procedure not unlike the severity levels used in the IPPS. Therefore, we are modifying our proposed policy for creating comprehensive APCs to recognize variation in the complexity of services that will be paid through comprehensive APCs for CY 2015.

We do not believe that there is any issue with 2 times rule violations in the proposed rule or in this final rule with comment period. The statute directs the Secretary to establish groups of covered OPD services that are comparable both clinically and with respect to use of resources. In doing so, the statute requires the Secretary to compare the mean cost of items and services within a group and ensure that the highest mean cost item or service is no more than 2 times greater than the lowest mean cost item or service within a group (2 times rule). With respect to each proposed comprehensive APC, no 2 times rule violations were observed. However, as noted above, we do observe widespread variation within the comprehensive costs of primary services. As we discuss below in more detail, our final policy recognizes differences in complexity and resource costs of complex forms of the primary service to address variation within the comprehensive costs of individual primary procedures.

Commenters raised concerns about quality decreases because of economic pressures, and access issues because of a reluctance of facilities to provide these device-intensive procedures to certain beneficiaries if the expected costs for complex cases would greatly exceed the comprehensive APC payment. We note that these same concerns were raised with the introduction of both the IPPS and the OPDS, but that claims data continue to show that hospitals continue to provide complex services to beneficiaries. We believe that hospitals understand that there will be considerable variation in the costs of providing a comprehensive primary service to individual beneficiaries relative to the comprehensive payment amount.

We disagree with the commenters on the need for greater outcomes measures prior to implementation of the comprehensive APC payment policy. As noted, in this final rule with comment period, we are recognizing the resource differential for complex forms of primary procedures. Further, we believe that outpatient procedures, such as these device-intensive procedures, that are also performed on an inpatient basis benefit from hospital protocols established for inpatient hospital quality programs such as quality measures,

readmission reduction programs, and value-based purchasing incentives. Therefore, we do not agree with the commenters who were concerned that patient care might suffer or that quality measures need to be strengthened before implementation of the comprehensive APC policy.

We are concerned by some of the comments that imply that some providers might change their practice of providing a comprehensive service and instead perform split or staged procedures in order to maximize payment. Although we do not believe that practitioners or facilities would voluntarily expose beneficiaries to an increased risk of additional surgery and anesthesia, we recognize that payment can influence behavior. When we implement the finalized comprehensive APC policy in CY 2015, we will closely monitor billing patterns for split or staged procedures and consider claims processing edits or other approaches to ensure that our prospective payments uniformly apply to complete services, if necessary.

With regard to the commenters' request for evaluation under a demonstration project before full implementation, we do not believe that comprehensive APCs are sufficiently different from our historical hospital payment practices to warrant a demonstration project. Further, we are adopting the proposed policy with modification and are delaying implementation of the comprehensive APC policy until CY 2015 in this final rule with comment period to the public to allow us and the public time to transition to this new payment approach.

(2) Comprehensive APCs for Device-Dependent Services

(a) Identification of High-Cost Device-Dependent Procedures

As we discussed in the CY 2014 OPDS/ASC proposed rule, in order to identify those services for which comprehensive packaging would have the greatest impact on cost validity, payment accuracy, beneficiary transparency, and hospital efficiency, we ranked all APCs by CY 2012 costs and then identified 29 device-dependent APCs where we believe that the device-dependent APC is characterized by a costly primary service with relatively small cost contributions from adjunctive services.

Comment: Several commenters asked for additional information on the criteria utilized by CMS to create the comprehensive APCs and how CMS would evaluate services and procedures

to qualify for comprehensive APCs going forward. One commenter asked why the other 10 device-dependent APCs were not included, and why no other nondevice-dependent APCs were classified as a comprehensive APC. Another commenter recommended that CMS consider the comprehensive approach for a smaller number of APCs (four or five), while other commenters recommended that additional APCs be paid as comprehensive APCs, including recommendations for a broader application of the comprehensive APC criteria to all claims dominated by a single procedure and specifically recommended procedures such as those assigned to APC 0067 (Stereotactic Radiosurgery).

Response: As we stated in the proposed rule, we initially proposed a subset of device-dependent APCs for conversion to comprehensive APCs because we believed that these procedures represented a cohesive subgroup with which to introduce a broader packaging initiative. We stated that comprehensive APCs are appropriate when they reflect a single global service that the beneficiary would be receiving from the hospital. In this case, we have identified procedures where the beneficiary would reasonably consider the encounter to be for the implantation of a device, and we limited our proposal to the most costly procedures where the geometric mean cost of the comprehensive procedure was approximately five times the current beneficiary inpatient deductible or greater. This created a consistent group of services with similar clinical and resource characteristics, which were archetypal for our definition of a comprehensive service.

However, we agree with the commenters that there is no reason that comprehensive payments could not be extended in future years to other procedures. In addition, we do not agree with the commenters that we should limit the comprehensive APCs to a small trial of four or five APCs. We are adopting the proposed policy with modification and are delaying implementation of the comprehensive APC policy until CY 2015 in this final rule with comment period to the public to allow us and the public time to transition to this new payment approach. We believe that the identified subgroup of device-related APCs is clinically cohesive and similar in resource construction. We will consider possibly adding a comprehensive APC for single session cranial stereotactic radiosurgery (procedures assigned to APC 0067) in CY 2015.

(b) Creation of Comprehensive APCs for Certain Device-Dependent Procedures

In the CY 2014 OPPI/ASC proposed rule (78 FR 43534), for CY 2014, we proposed to create 29 comprehensive APCs to prospectively pay for device-dependent services associated with 136 HCPCS codes. We proposed to base the single all-inclusive comprehensive APC payment on all outpatient charges reported on the claim, excluding only charges that cannot be covered by Medicare Part B or that are not payable under the OPPI. This comprehensive APC payment would include: (1) packaged payment for all packaged services and supplies in CY 2014 and as discussed in section II.A.3. of this final rule with comment period; and (2) packaged payment for all adjunctive services, which are those services and supplies that typically would receive separate payment when appearing on any claim that does not contain a HCPCS code reported as a primary service assigned to a comprehensive APC, including certain items and services currently paid through other fee schedules. We present these two categories for ease of presentation, but generally consider both sets of services to be “adjunctive” in that they are integral and ancillary to, supportive of, and dependent on the primary procedure. Therefore, we consider all outpatient services on a comprehensive APC claim to be adjunctive to the primary service with a few exceptions, such as mammography services and ambulance services, which are never payable as hospital outpatient services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which must receive separate payment under section 1833(t)(2)(H) of the Act; and pass-through drugs and devices, which also require separate payment under section 1833(t)(6) of the Act.

(3) Inclusion of Otherwise Packaged Services and Supplies

As part of the comprehensive APCs, we proposed to package all services that are packaged in CY 2013, and all services proposed for unconditional or conditional packaging for CY 2014.

We did not receive any separate public comments on this proposal outside of the public comments we received on our proposal to create comprehensive APCs for CY 2014 (which final policy with modification, we are delaying implementation until CY 2015) discussed in section II.A.3. of this final rule with comment period.

(4) Inclusion of Adjunctive Services

We previously noted in section II.A.3.a. of the proposed rule that it has been a goal of the OPPI to package services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service. We proposed to package into the comprehensive APCs all of these integral, ancillary, supportive, dependent, and adjunctive services, hereinafter collectively referred to as “adjunctive services,” provided during the delivery of the comprehensive service. This includes the 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; outpatient department services delivered by therapists as part of the comprehensive 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 for mammography services and ambulance services, which are never payable as OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act.

Comment: Several commenters expressed concerns regarding the packaging of unrelated services reported on the claim. Given that a single claim can span multiple days, a few commenters believed that under current billing instructions this proposal would arbitrarily package all services occurring within a 30-day or 60-day period. Currently, there is no means on outpatient claims to differentiate between adjunct services that are related to the primary procedure and other services that are ordered by other physicians and/or are unrelated to the primary procedure. These commenters were concerned that if CMS assumed that all services reported on the claim are related, it could lead to incorrect ratesetting. Alternatively, these commenters reasoned that if CMS revised billing instructions to allow all unrelated services (not merely labs) to be billed on separate claims, hospitals would need to change their billing systems to bill separately for unrelated services and would experience significant administrative burden separating unrelated from related items and services.

Response: We do not agree with the commenters’ assertions that a significant

amount of unrelated services would be billed on the claim for the primary service. We note that most commenters were concerned about unrelated services reported on claims spanning 30 days. We remind hospitals that we have previously issued manual guidance in the Internet Only Manual at 100–4, Chapter 1, Section 50.2.2 that only recurring services should be billed monthly. Moreover, we have further 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.

Additionally, we have noted that occasionally beneficiaries may, for reasons of convenience or coincidence, receive laboratory services at the hospital that are unrelated to the primary service. When beneficiaries are at the hospital for the non-trivial procedures in comprehensive APCs, we do not expect that unrelated laboratory services would be a common occurrence, but we have nonetheless instructed hospitals that laboratory tests ordered by unrelated providers for unrelated medical conditions may be billed on a 14X bill-type. We refer readers to section II.A.3.c.(3) of this final rule with comment period for more discussion of this final policy.

Beyond these two sets of circumstances, we believe that other services performed at the time of these major procedures can reasonably be considered to be related to the primary service or procedure. We proposed that we would consider all services reported on the claim to be related to the primary service. Under such a presumption, all services delivered to a beneficiary during an encounter for a comprehensive procedure would be included in establishing the payment rate for the comprehensive APC. As we are including all adjunctive services in the comprehensive APC calculation, hospitals would not need to look for unrelated services. We considered all covered costs when calculating the comprehensive APC payment as is done with IPPS DRGs. As previously noted, hospitals would continue to code and bill for these services in the same way that they currently code and bill.

Comment: One commenter asked that CMS modify the proposal by specifically excluding clinical diagnostic laboratory tests and the

facility component of anatomic pathology procedures from comprehensive APC payment for the same reasons that other commenters believed that these services should not be packaged as part of our general packaging proposals.

Response: We do not agree with this commenter that laboratory and the facility component of anatomic pathology procedures should be excluded from the comprehensive APC payment. We are finalizing our other proposed policy to package laboratory tests, as described in section II.A.3.c.(3) of this final rule with comment period. We note that laboratory and anatomic pathology tests are almost always performed as part of the provision of the primary service in the case of these comprehensive services and are, therefore, appropriately considered ancillary and supportive. In summary, we believe that these device-dependent procedures represent archetypal cases of a single comprehensive service and that laboratory and anatomic pathology services are classic examples of adjunctive services that are supportive of the primary procedure.

(5) Inclusion of Devices, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

As part of the comprehensive service packaging policy described above, we proposed to package all devices; implantable durable medical equipment (DME); implantable prosthetics; DME, prosthetics, and orthotics when used as supplies in the delivery of the comprehensive service; and supplies used in support of these items when these items or supplies are provided as part of the delivery of a comprehensive service. 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). Under this proposal, DME, prosthetics, and orthotics, when used as supplies in the delivery of the comprehensive service, would be covered OPD services as provided under section 1833(t)(1)(B)(i) of the Act and § 419.2(b)(4) of the regulations. Under this proposal, we believe that when such items and services are provided as adjunctive components in the delivery of a comprehensive service, such items are appropriate for coverage under the OPPS as covered OPD services, and for payment under the OPPS. We noted that, at other times, such items when not provided as adjunctive components in the delivery of a comprehensive

service would not constitute covered OPD services, and such items would be appropriately provided by suppliers and paid for under the DMEPOS benefit. More specifically, we do not believe that this proposed policy limits a hospital's ability to function as a DMEPOS supplier and bill DMEPOS items to the DME-MAC when those items are unrelated to the outpatient procedure and provided outside of the delivery of the comprehensive service.

In summary, we proposed to consider all DMEPOS items to be covered hospital outpatient department services and to be adjunctive to the primary service when they are delivered during the comprehensive service, as described above and, therefore, proposed to package such items into the applicable comprehensive service. This policy includes any items described by codes that are otherwise covered and paid separately in accordance with the payment rules for DMEPOS items and services, and applies to those items when they are provided as part of the delivery of the comprehensive service. Under this proposal, when such items are provided during the delivery of a comprehensive service, we proposed that they are covered OPD services as provided under sections 1833(t)(1)(B)(i) and (t)(1)(B)(iii) of the Act and §§ 419.2(b)(4), (b)(10), and (b)(11) of the regulations, and payable under the OPPS, as described above.

We did not receive any public comments on our proposal to include these DMEPOS items in the comprehensive APC payment. We did receive public comments on the impact of these new items on budget neutrality, which we discuss below, and comments on how DMEPOS items impact APC 0227 (Implantation of Drug Infusion Device), which we discuss in greater detail later in this section.

(6) Inclusion of OPD Services Reported by Therapy Codes

Generally, section 1833(t)(1)(B)(4) of the Act excludes therapy services from the OPPS. We have previously noted that therapy services are those provided by therapists under a plan of care, and are paid under section 1834(k) of the Act subject to an annual therapy cap, when applied. However, certain other activities similar to therapy services are considered and paid as outpatient services. Although some adjunctive services may be provided by therapists and reported with therapy codes, we do not believe that these services always constitute therapy services. In the case of adjunctive components of a comprehensive service that are described by codes that would, under

other circumstances, be indicative of therapy services, we note that there are a number of factors that would more appropriately identify them as OPD services. These services are not independent services, but are delivered as an integral part of the OPD service on the order of the physician who is providing the service; they are not typically provided under an established plan of care, but on a direct physician order; they may be performed by nontherapists; and they frequently do not contribute to a rehabilitative process. For example, we note that therapists might be asked to provide a detailed documentation of patient weaknesses to be used by the physician to help identify or quantify a possible procedure-associated stroke or help with the mobilization of the patient after surgery in order to prevent blood clots. We note that these nontherapy services furnished by a therapist are limited to the immediate perioperative period, consistent with their inclusion as part of the larger service to deliver the device, and are distinct from subsequent therapy services furnished under a therapy plan of care, which serve to establish rehabilitative needs and begin the process of rehabilitation.

For that reason, when provided within this very limited context of a comprehensive service such as the implantation of an expensive device, in the CY 2014 OPPS/ASC proposed rule (78 FR 43534), we proposed that services reported by therapy HCPCS codes, including costs associated with revenue codes 042X, 043X and 044X would be considered to be adjunctive OPD services in support of the primary service when those services occur within the perioperative period; that is, during the delivery of this comprehensive service that is bracketed by the OPD registration to initiate the service and the OPD discharge at the conclusion of the service. These services do not constitute therapy services provided under a plan of care, are not subject to a therapy cap, if applied, and are not paid separately as therapy services.

Comment: Physical therapy stakeholders commented that they were concerned about the effect this proposal may have on necessary physical therapy services that are provided in conjunction with these proposed 29 APCs and any comprehensive APCs that may be added in the future. The commenter stated that, generally, section 1833(t)(1)(B)(4) of the Act excludes therapy services from the OPPS. The commenter further stated that, instead, the majority of therapy services in the hospital setting are

provided by therapists under a plan of care, and are paid under the physician fee schedule (we refer readers to section 1834(k) of the Act). However, the commenter acknowledged that there is a subset of services designated as “sometimes therapy” services that are paid under the OPPS when they are not furnished as therapy under a certified plan of care in an outpatient hospital or critical access hospital (CAH).

The commenter stated that physical therapy should not be considered to be an adjunctive service because physical therapists are consultative members of the health care team, physical therapy is a separate benefit, and some services provided during the perioperative period, such as a physical therapy evaluation to establish a plan of care, could still be considered to be therapy services. The commenter was also concerned that the comprehensive APC payment would not be adequate to cover the services provided by therapists during this perioperative period, that rehabilitation could be prolonged if the therapist is unable to intervene “to increase the patient’s mobility, function and endurance prior to surgery,” and that it could be difficult to reliably and reproducibly differentiate those perioperative services that are not therapy from those that could be separately billed as therapy services. Another commenter asked if functional reporting requirements would apply in these cases of adjunctive services reported with therapy codes.

Response: We agree with the commenter that physical therapy is a separate benefit that is not part of an OPPS service. However, after consideration of the public comments we received, we continue to believe that services 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 note that adjunctive services are those services provided in support of another service, that is, they are typically performed to facilitate the primary service and are unnecessary or serve a different function if the primary service is not provided. Adjunctive services may be provided by consultative members of the healthcare team. For example, an add-on procedure performed by a cardiac surgeon is nonetheless adjunctive to the primary procedure, as an add-on procedure by definition cannot exist in the absence of the procedure to which it is added.

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 an annual therapy cap, when applied. However, certain other activities similar to therapy services are considered and paid as outpatient services. Specifically, we have said in the Claims Processing Manual IOM 100–4, Chapter 5, Section 20.1 that some services, described as “sometimes therapy services,” may at times be considered therapy, but at other times may be considered to be outpatient department services, such as when those services are provided by non-therapists or provided in the absence of a plan of care. We stated in the proposed rule that we believe services reported with therapy codes, but that are provided as part of a comprehensive service are similar to “sometimes therapy” services in that these services are not properly considered to be therapy services even though they may be reported with therapy HCPCS codes (78 FR 43559 through 43560).

Considering the services that commenters believed should be therapy services, we note that these are outpatient procedures; therefore, the comprehensive procedure includes only the perioperative period, a brief period of time immediately before and immediately following the procedure. We would not expect that an evaluation performed immediately following the surgery would establish the beneficiary’s needs for rehabilitation because the beneficiary is still under the influence of the completed primary surgical procedure. Rather, services reported with therapy codes during that brief time period may represent interventions to promote breathing and ambulation, traditional post-operative nursing services, or may represent assessments to provide the surgeon with specific clinical information relative to the immediate effects of the surgery. We would not expect therapy assessments or rehabilitative therapy until after the patient has recovered from the immediate effects of the procedure and associated anesthesia. With respect to the statement that it may be beneficial to increase the beneficiary’s endurance prior to surgery, we agree with the commenter that this can be a desirable and necessary service, but we would not expect that therapists are routinely increasing “mobility, function and endurance” in the hour or two immediately before the surgery. Therefore, we do not expect that providers and reviewers would struggle to differentiate separately paid therapy

services from appropriately packaged nontherapy services. We believe that therapy services would be separated in time from the comprehensive services, and would not be provided during the span of the comprehensive service, from OPD registration to discharge, because we do not expect that the comprehensive service would extend beyond the immediate perioperative period. We also believe that, for a beneficiary who is already receiving therapy on an ongoing basis, it is very unlikely that a therapist would deliver that service during a comprehensive service. There are rare exceptions, for example, in the case of a beneficiary receiving therapy for a burn or contracture. In that case, we have previously published guidance stating that recurring services may be separated from acute services and billed on a separate claim.

We have stated that the relative cost of these comprehensive services includes all of the estimated costs reported on the claims for these services. Therefore, the total payment for the comprehensive service includes a payment for the services reported with therapy codes that is proportional to the frequency with which these codes are reported on the claims. As the comprehensive payment now reflects costs, we believe that the aggregate comprehensive payment will continue to be adequate to cover the cost of the service provided, and we do not expect that these services would be discontinued when they are medically necessary. We also note that there is no provision in this final rule with comment period that prohibits a hospital from providing any medically necessary service as part of a comprehensive service, regardless of the code with which it is otherwise commonly reported.

With respect to functional reporting, we note that these services reported with therapy codes are outpatient department services not therapy services and, therefore, the requirement for functional reporting does not apply. These changes will be implemented in the claims processing systems prior to the start of CY 2015.

(7) Inclusion of Additional Hospital Room and Board Revenue Cost Centers in the Calculation of Covered Costs

In the CY 2014 OPPS/ASC proposed rule (78 FR 43534), we stated that we believe that the cost of the bed and room occupied by the patient, the cost of nursing services, and the cost of any necessary fluid and nutrition (board) are considered covered costs when incurred during the provision of an OPD service,

that is, during the provision of the comprehensive service. Because we are able to assign all costs reported on the claim to the comprehensive service, we believe that we have an opportunity to better capture costs by including these costs in our calculations even when they appear in certain revenue cost centers not usually used to report OPPS costs. Specifically, we proposed to include costs reported with room, board, and nursing revenue codes 012X, 013X, 015X, 0160, 0169, 0200 through 0204, 0206 through 0209, 0210 through 0212, 0214, 0219, 0230 through 0234, 0239, 0240 through 0243, and 0249 because we believe these revenue cost centers are sometimes associated with the costs of room, nutrition, and nursing care provided during these comprehensive services.

Comment: One commenter supported the specific inclusion of room and board revenue cost centers on outpatient claims, but another commenter believed that reporting may be difficult for hospitals and hospital systems. Commenters were concerned that CMS did not discuss how those charges would be included in the cost calculation for the comprehensive APCs or provide a cost center source for converting those charges to costs in the CY 2014 OPPS Revenue Code to Cost Center Crosswalk released with the proposed rule. Another commenter was concerned that additional funds were not moved into the OPPS system to account for these “new” costs.

Response: We appreciate the commenter’s support for our decision to specifically identify the costs of room and board as being covered costs in certain outpatient stays. We understand the other commenters’ confusion as to why room and board revenue codes would appear on an outpatient claim because our claims processing instructions do not allow payment for these revenue codes on Part B claims as they are reserved exclusively for inpatient use. (For example, we refer readers to our recent contractor instructions under Change Request (CR) 8185, “CMS Administrator’s Ruling: Part A to Part B Rebilling of Denied Hospital Inpatient Claims”, which excludes these revenue codes on rebilled Part B inpatient claims because room and board services are not covered under Medicare Part B). For this reason, we have not included these revenue codes on our revenue code to cost center crosswalk. Although we proposed to include costs estimated from charges for these revenue codes in our estimate of comprehensive APC costs, we did not include any of these costs. We failed to modify our revenue code-to-cost center

crosswalk that we use to estimate costs from charges on claims to include room and board revenue codes. Without revenue codes and associated CCRs from identified cost centers, our model ignored those revenue codes and did not estimate a cost for the room and board revenue codes. We did not include any additional estimated costs in our proposed comprehensive APC payment calculation. We discuss the role of the revenue code-to-cost center crosswalk in section II.A.1.c. of this final rule with comment period.

We now believe that the appearance of these revenue codes on hospital outpatient claims would be improper billing. Charges on ancillary revenue codes for recovery room and observation, for example, should reflect the complete costs of furnishing those services, including the capital cost of the room and nursing labor costs. Further, we would expect that hospitals would allocate these costs, and if appropriate, board costs for services furnished to outpatients, to ancillary cost centers on their Medicare hospital cost report consistent with the matching principles of cost accounting principles. We believe that, as calculated, our estimated costs for comprehensive APCs appropriately includes all costs and charges associated with staying in a room for the duration of the comprehensive service as an outpatient, and we are not finalizing our proposal to include the costs reported with certain inpatient room, board, and nursing revenue codes.

(8) Inclusion of Hospital-Administered Drugs

In the CY 2014 OPPS/ASC proposed rule (78 FR 43534), we also proposed to package all drugs provided to the beneficiary as part of the delivery of the comprehensive service, except for those drugs separately paid through a transitional pass-through payment. Intravenous drugs, for example, are OPPS services that are considered adjunctive to the primary procedure because the correct administration of the drug either promotes a beneficial outcome, such as the use of intravenous pain medications, or prevents possible complications, such as the use of intravenous blood pressure medications to temporarily replace oral blood pressure medications and reduce the risk of a sudden rise in blood pressure when a normal daily medication is stopped. We noted that, in defining these packaged drugs, we were applying both our existing definitions of self-administered drugs (SADs) and our existing definition of drugs as supplies

to the situation where the OPD service is a comprehensive service.

We proposed that all medications provided by the hospital for delivery during a comprehensive service pursuant to a physician order, regardless of the route of administration, would be considered to be adjunctive supplies and, therefore, packaged as part of the comprehensive APC payment. We stated that we believe that the physician order demonstrates that the delivery of the medication by the hospital is necessary to avoid possible complications during the delivery of the comprehensive service, to ensure patient safety, and to ensure that the comprehensive service delivery is not compromised and, therefore, the medication should be considered an adjunctive supply.

Therefore, we proposed to consider all medications to be supplies that are adjunctive to the primary service if the medicines are ordered by the physician and supplied and delivered by the hospital for administration during the comprehensive service.

Comment: Commenters generally supported the inclusion of drugs as supplies in the comprehensive APC payment. For example, one commenter stated that this proposal would be extremely helpful to beneficiaries by reducing their financial burden and would greatly reduce the processing burden on the hospital. Several commenters stated that CMS’ reasoning was sound and the concept should be expanded to all self-administered drugs incident to practitioners’ therapeutic services, not just in comprehensive APCs because the commenters believed that the concept that drugs are integral and adjunctive to the furnishing of a therapeutic service applies to observation and other procedures. For example, one commenter stated that self-administered drugs provided during an ED visit are directly related to the necessary care. The commenter suggested that a requirement to bill for self-administered drugs be established so that these costs could be identified for inclusion in ratesetting.

However, one commenter was concerned that including all hospital-administered drugs, regardless of the route of administration, in the cost calculations of the comprehensive APCs will not accurately account for the significant cost variation in required drugs from beneficiary to beneficiary based on individual beneficiary requirements and that, as a result, the payment rate for a comprehensive APC might not provide adequate payment for the specific drugs and biologicals an individual beneficiary needs, and that

hospitals would be discouraged from providing appropriate drugs during a comprehensive service.

Response: We appreciate the commenters' support for our proposal to consider drugs, regardless of their route of administration, to be adjunctive supplies used in support of the primary comprehensive service when ordered by a physician and delivered during the administration of a comprehensive service.

Self-administered drugs are a special issue because they are excluded from Medicare Part B coverage by section 1861(s)(2)(B) of the Act as implemented in the regulations at 42 CFR 410.27. However, as we have stated in the Benefit Policy Manual IOM 100–2, Chapter 15, Section 50.2, drugs that are integral to a procedure are considered to be supplies used in the delivery of covered hospital outpatient services, and not part of the Part B drug benefit as described under section 1861(s)(2)(B) of the Act and 42 CFR 410.27. We do not view this proposal to include all medications provided by the hospital for delivery during a comprehensive service pursuant to a physician order, regardless of the route of administration, as adjunctive supplies to be an exception to the benefit category exclusion for self-administered drugs, but rather that covered outpatient services include supplies and other ancillary items needed to deliver these comprehensive services. As stated in our discussion above, we have historically instructed hospitals to include charges for self-administered drugs as supplies on submitted claims, and we, therefore, include them in our calculation of APC payments. We also do not view this proposal as an expansion of coverage, but rather as the application of an existing policy to a broader payment bundle.

Although some cost of drugs that are used as supplies have been included in APC payments, we recognize that there are some drugs that previously may not have been considered as supplies because previously they were provided outside of the defined service. We generally address public comments about how costs for newly included adjunctive items will be considered under budget neutrality below.

We do not believe that including these drugs and biologicals in the comprehensive APC payment greatly increases a hospital's financial risk for providing a comprehensive service. Further, we expect that a payment based on geometric mean estimated cost would reflect the relative resources of drugs used as supplies included on comprehensive service claims, along with all other ancillary supplies and services, and that while the cost of any given case will vary, the hospital would receive a payment based on average estimated cost for all cases. We do not believe that comprehensive APC payments that include physician-ordered, hospital-administered drugs delivered during the comprehensive service would be inadequate to cover the cost of providing the service, and we do not believe that the comprehensive APC payment would discourage hospitals from providing appropriate drugs during delivery of these comprehensive services.

Finally, we agree with the commenters that all covered costs related to a service should be included on the claim per our manual instruction in the Claims Processing Manual IOM 100–4, Chapter 4, Section 10.4.A and as discussed in section II.3.a. (Packaging) of this final rule with comment period and that those costs should be reported as precisely as possible using HCPCS codes when available or uncoded revenue cost centers when HCPCS codes

do not exist. Overall, we believe that drug costs, regardless of the route of administration, are accurately accounted for in the APC relative payment weight. We believe that overall payment for the comprehensive service is adequate and will permit access to the specific drugs and biologicals required for an individual beneficiary.

After consideration of all of the public comments we received, we are finalizing our proposal to package all outpatient services, including 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; coded and uncoded services and supplies used during the service; outpatient department services delivered by therapists as part of the comprehensive service; durable medical equipment, as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other outpatient components reported by HCPCS codes that are provided during the comprehensive service, except for certain services including mammography services, ambulance services, brachytherapy seeds, and pass-through drugs and devices. When billed on a claim in conjunction with a primary procedure assigned to status indicator "J1" in CY 2015, we will pay for these services through the OPPTS comprehensive APC payment. We are not finalizing our proposal to include costs reported with room, board, and nursing revenue codes 012X, 013X, 015X, 0160, 0169, 0200 through 0204, 0206 through 0209, 0210 through 0212, 0214, 0219, 0230 through 0234, 0239, 0240 through 0243, and 0249.

The APCs for which we are finalizing this proposal for CY 2015 are identified below in Table 8.

TABLE 8.—CY 2014 COMPREHENSIVE APCs ILLUSTRATION

Clinical Family	CY 2014 APC*	Group Title	Comments	CY 2014 Estimated Geometric Mean Cost*	CY 2014 Proposed APC
NSTIM	0039	Level I Implantation of Neurostimulator	Renamed	\$17,590.47	0039
NSTIM	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes		\$4,714.87	0040
NSTIM	0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes		\$6,567.49	0061
EVASC	0083	Level I Endovascular Procedures	Renamed	\$4,229.68	0083
EPHYS	0085	Level II Electrophysiologic Procedures		\$5,058.62	0085
AICDP	0089	Level III Insertion/Replacement of Permanent Pacemaker	Renamed	\$10,754.87	0089
AICDP	0090	Level I Insertion/Replacement of Permanent Pacemaker		\$7,480.34	0090
EVASC	0104	Level I Endovascular Stents	Renamed	\$8,554.42	0104
AICDP	0106	Insertion/Replacement of Pacemaker Components	Renamed	\$4,946.02	0106
AICDP	0107	Level I Implantation of Cardioverter-Defibrillators (ICDs)		\$25,557.38	0107
AICDP	0108	Level II Implantation of Cardioverter-Defibrillators (ICDs)		\$32,947.68	0108
UROGN	0202	Level VII Female Reproductive Procedures		\$4,595.75	0202
PUMPS	0227	Implantation of Drug Infusion Device		\$15,790.66	0227
EVASC	0229	Level II Endovascular Procedures	Renamed	\$8,769.82	0229
ENTXX	0259	Level VII ENT Procedures		\$30,445.75	0259
EYEXX	0293	Level VI Anterior Segment Eye Procedures		\$8,459.01	0293
NSTIM	0318	Level II Implantation of Neurostimulator	Renamed	\$27,227.27	0318
EVASC	0319	Level IV Endovascular Procedures	Renamed	\$15,891.12	0319
UROGN	0385	Level I Urogenital Procedures	Renamed	\$7,668.56	0385
UROGN	0386	Level II Urogenital Procedures	Renamed	\$13,611.48	0386
ARTHRR	0425	Level II Arthroplasty or Implantation with Prosthesis		\$10,240.36	0425
EPHYS	0444	Level IV Electrophysiologic Procedures	New	\$14,302.41	
EVASC	0445	Level III Endovascular Procedures	New	\$13,375.31	
BREAS	0648	Level IV Breast and Skin Surgery		\$7,262.53	0648
AICDP	0654	Level II Insertion/Replacement of Permanent Pacemaker		\$8,424.63	0654
AICDP	0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode		\$15,425.03	0655
EVASC	0656	Level II Endovascular Stents	Renamed	\$10,061.92	0656
UROGN	0674	Level III Urogenital Procedures	Renamed	\$15,729.54	0674
EVENT	0680	Insertion of Patient Activated Event		\$6,993.24	0680

Clinical Family	CY 2014 APC*	Group Title	Comments	CY 2014 Estimated Geometric Mean Cost*	CY 2014 Proposed APC
		Recorders			
EVASC		(Deleted)	Deleted		0082
NSTIM		(Deleted)	Deleted		0315
EPHYS		(Deleted)	Deleted		8000

* APC and associated geometric mean costs from CY 2012 claims data that we would have implemented for CY 2014; finalizing the comprehensive APC policy for CY 2015. We will recalibrate all of the comprehensive APC relative payment weights for CY 2015 using CY 2013 claims data.

Keys:

AICDP = Implantable Cardiac Defibrillators and Pacemakers

ARTHRO = Arthroplasty

BREAS = Breast Surgery

ENTXX = ENT Procedures

EPHYS = Cardiac Electrophysiology

EYEXX = Ophthalmologic Procedures

EVASC = Endovascular Procedures

EVENT = Event Monitoring

NSTIM = Neurostimulators

UROGN = Urogenital Procedures

(c) Methodology

As we stated in the CY 2014 OPPS/ASC proposed rule (78 FR 43534), we calculated the proposed relative payment weights for these device-dependent comprehensive APCs by using relative costs derived from our standard process as described in section II.A. of the proposed rule and this final rule with comment period. Specifically, after converting charges to costs on the claims, we identified all claims containing 1 of the 136 HCPCS codes that define procedures specified as constituting a comprehensive service. These claims were, by definition, classified as single major procedure claims. Any claims that contained more than one of these HCPCS codes were identified, but were not included in calculating the cost of the procedure that had the greatest cost when traditional HCPCS level accounting was applied. All other costs were summed to calculate the total cost of the comprehensive service, and statistics for those services were calculated in the usual manner. Comprehensive claims for each primary service reported by a HCPCS code were excluded when their comprehensive claim cost exceeded ± 3 standard deviations from the geometric mean comprehensive cost of the primary service HCPCS code.

(d) Payments

As we further stated in the CY 2014 OPPS/ASC proposed rule (78 FR 43534), we used the proposed APC relative payment weights for each of these device-dependent comprehensive services to calculate proposed payments following our standard methodology.

The proposed payments for the HCPCS codes assigned to these proposed comprehensive APCs were included in Addendum B of the proposed rule (which is available via the Internet on the CMS Web site). We proposed to assign a new status indicator, “J1” (OPD services paid through a comprehensive APC), to these device-dependent procedures. The claims processing system would be configured to make a single payment for the device-dependent comprehensive service whenever a HCPCS code reporting one of these primary procedures appears on the claim. From a processing system perspective, all other adjunctive services except mammography, ambulance, and pass-through services would be conditionally packaged when a comprehensive service is identified on a claim. From our data, we determined that multiple primary HCPCS codes are reported together in 24 percent of these device-dependent claims, but rarely represent unrelated services. Having determined that having multiple unrelated device-dependent services reported on a claim is an uncommon event, we proposed to only pay the largest comprehensive payment associated with a claim. However, the costs of all of these more extensive or additional services are included in the calculations of the relative payment weights for the comprehensive service, so the prospective payment includes payment for these occurrences.

Comment: Some commenters suggested that errors and lack of clarity pertaining to some HCPCS codes proposed for comprehensive payment in the proposed rule prevented the public

from being able to respond informatively to the comprehensive APC proposal. One commenter was concerned that CMS stated in the preamble text that there are 136 HCPCS codes that define the device-dependent services to be included in the proposed comprehensive APCs whereas, in Addendum B to the proposed rule, there are 148 HCPCS codes listed. Other commenters identified occasional instances in the proposed rule APC cost statistics data files where the number of single procedures was reported as more than the number of total procedures, and they also identified several inconsistencies in Addendum B where the HCPCS code’s status indicator was listed as “Q2” (conditionally packaged), yet the APC assignment was associated with status indicator “J1” (comprehensive APC, all other items on the claim are packaged).

Response: We discussed 136 primary procedure codes in our proposal for comprehensive APCs (78 FR 43534). Commenters are correct that we also identified 148 primary procedure codes in Addendum B to the proposed rule as corrected (which is available on the CMS Web site at: <http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>). As we discussed in our September 6, 2013 correcting document, we revised the status indicators of several HCPCS codes that appeared in Addendum B from “Q2” to “J1” to reflect their status as a primary procedure code in a comprehensive APC. The remaining difference in these two numbers is that 136 represents the number of CY 2012

device-dependent HCPCS codes reported on the CY 2012 claims that we are using to model CY 2014 geometric mean costs to illustrate the comprehensive APC methodology. We generally discuss our modeling of the CY 2012 claims data to establish CY 2014 payment rates in section II.A.1.c. of this final rule with comment period. However, considering the revisions to specific procedure codes used to report certain procedures, such as the new percutaneous coronary intervention procedure codes (CPT codes 92920 through 92943) beginning in CY 2013, the number of CY 2013 device-dependent HCPCS codes appropriately assigned to comprehensive APCs increased to 148. Upon adoption of the new coding scheme for CY 2014, the number of HCPCS codes assigned to a comprehensive APC for payment in this final rule with comment period as it would have been implemented for CY 2014 is 167. All of these comprehensive HCPCS codes for each year (CY 2012

through 2014) appear below in Table 9. Before we implement this policy in CY 2015, we will assess all active codes for CY 2015 and assign the procedure to status indicator “J1,” as appropriate.

We believe that the corrections to the status indicators assigned to the device-dependent procedure codes that appeared in Addendum B to our correcting document (<http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>) were minor and did not compromise the ability of commenters to analyze and respond to our comprehensive APC proposal. We note that some commenters were able to correctly identify the claims that we used to model the proposed CY 2014 payment rates for comprehensive APCs by identifying the device-related HCPCS codes associated with the 29 comprehensive APCs for CY 2012. Some commenters also were able to correctly identify the HCPCS codes that we

proposed would trigger a comprehensive payment in CY 2014 based on our identification of HCPCS codes in Addendum B. The commenters were able to model relative payments based on our identification of the inclusion of all services reported on the claim except mammography, ambulance, and pass-through services, and were able to determine the impact of the proposal based on our publication of proposed payment rates for those 29 comprehensive APCs. Our proposed payment rate for these comprehensive APCs did not change appreciably with the correcting document. In addition, we are delaying implementation of the finalized comprehensive APC policy until CY 2015, and we are providing a detailed discussion of our final methodology for establishing comprehensive APC relative payment weights through this final rule with comment period.

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TABLE 9.—APC ASSIGNMENTS FOR HCPCS CODES PROPOSED TO BE ASSIGNED TO STATUS INDICATOR “J1” FOR CY 2014 AND DISPLAYED HERE FOR ILLUSTRATION

HCPCS Code	Short Descriptor	Proposed CY 2014 APC	CY 2014 APC *	Comment	Source	APC Single “J1” Geometric Mean Cost*	HCPCS Single “J1” Geometric Mean Modeled Cost*
19296	Place po breast cath for rad	0648	0648	Existing Code	CY 2012 Data	\$6,430	\$5,789
19298	Place breast rad tube/caths	0648	0648	Existing Code	CY 2012 Data	\$6,430	\$5,290
19325	Enlarge breast with implant	0648	0648	Existing Code	CY 2012 Data	\$6,430	\$5,328
19342	Delayed breast prosthesis	0648	0648	Existing Code	CY 2012 Data	\$6,430	\$4,836
19357	Breast reconstruction	0648	0648	Existing Code	CY 2012 Data	\$6,430	\$7,600
23470	Reconstruct shoulder joint	0425	0425	Existing Code	CY 2012 Data	\$10,184	\$9,816
23473	Revis reconst shoulder joint	0425	0425	New For 2013	Model/2013	\$10,184	\$6,169
24361	Reconstruct elbow joint	0425	0425	Existing Code	CY 2012 Data	\$10,184	\$11,921
24363	Replace elbow joint	0425	0425	Existing Code	CY 2012 Data	\$10,184	\$15,496
24366	Reconstruct head of radius	0425	0425	Existing Code	CY 2012 Data	\$10,184	\$8,989
24370	Revise reconst elbow joint	0425	0425	New For 2013	Model/2013	\$10,184	TBD
24371	Revise reconst elbow joint	0425	0425	New For 2013	Model/2013	\$10,184	TBD
25441	Reconstruct wrist joint	0425	0425	Existing Code	CY 2012 Data	\$10,184	\$10,973
25442	Reconstruct wrist joint	0425	0425	Existing Code	CY 2012 Data	\$10,184	\$10,754
25446	Wrist replacement	0425	0425	Existing Code	CY 2012 Data	\$10,184	\$12,987
27446	Revision of knee joint	0425	0425	Existing Code	CY 2012 Data	\$10,184	\$10,640
33206	Insert heart pm atrial	0089	0089	Existing Code	CY 2012 Data	\$10,752	\$10,272

HCPCS Code	Short Descriptor	Proposed CY 2014 APC	CY 2014 APC *	Comment	Source	APC Single "J1" Geometric Mean Cost*	HCPCS Single "J1" Geometric Mean Modeled Cost*
33207	Insert heart pm ventricular	0089	0089	Existing Code	CY 2012 Data	\$10,752	\$9,319
33208	Insrt heart pm atrial & vent	0655	0089	Existing Code	CY 2012 Data	\$10,752	\$11,087
33210	Insert electrd/pm cath sngl	0106	0106	Existing Code	CY 2012 Data	\$4,944	\$4,447
33211	Insert card electrodes dual	0106	0106	Existing Code	CY 2012 Data	\$4,944	\$5,129
33212	Insert pulse gen sngl lead	0090	0090	Existing Code	CY 2012 Data	\$7,479	\$7,212
33213	Insert pulse gen dual leads	0654	0654	Existing Code	CY 2012 Data	\$8,423	\$9,087
33214	Upgrade of pacemaker system	0655	0089	Existing Code	CY 2012 Data	\$10,752	\$11,158
33216	Insert 1 electrode pm-defib	0106	0106	Existing Code	CY 2012 Data	\$4,944	\$5,066
33217	Insert 2 electrode pm-defib	0106	0090	Existing Code	CY 2012 Data	\$7,479	\$7,256
33221	Insert pulse gen mult leads	0654	0089	Existing Code	CY 2012 Data	\$10,752	\$12,539
33224	Insert pacing lead & connect	0655	0089	Existing Code	CY 2012 Data	\$10,752	\$12,176
33227	Remove&replace pm gen singl	0090	0090	Existing Code	CY 2012 Data	\$7,479	\$7,499
33228	Remv&replc pm gen dual lead	0654	0654	Existing Code	CY 2012 Data	\$8,423	\$8,384
33229	Remv&replc pm gen mult leads	0654	0655	Existing Code	CY 2012 Data	\$15,419	\$14,543
33230	Insrt pulse gen w/dual leads	0107	0107	Existing Code	CY 2012 Data	\$25,556	\$26,715
33231	Insrt pulse gen w/mult leads	0107	0108	Existing Code	CY 2012 Data	\$32,946	\$30,149

HCPCS Code	Short Descriptor	Proposed CY 2014 APC	CY 2014 APC *	Comment	Source	APC Single "J1" Geometric Mean Cost*	HCPCS Single "J1" Geometric Mean Modeled Cost*
33240	Insrt pulse gen w/singl lead	0107	0107	Existing Code	CY 2012 Data	\$25,556	\$26,540
33249	Nsert pace-defib w/lead	0108	0108	Existing Code	CY 2012 Data	\$32,946	\$32,938
33262	Remv&replc cvd gen sing lead	0107	0107	Existing Code	CY 2012 Data	\$25,556	\$21,896
33263	Remv&replc cvd gen dual lead	0107	0107	Existing Code	CY 2012 Data	\$25,556	\$23,795
33264	Remv&replc cvd gen mult lead	0107	0107	Existing Code	CY 2012 Data	\$25,556	\$28,165
33282	Implant pat-active ht record	0680	0680	Existing Code	CY 2012 Data	\$6,992	\$6,992
35458	Repair arterial blockage	0083	0083	Existing Code	CY 2012 Data	\$4,229	\$4,824
35460	Repair venous blockage	0083	0083	Existing Code	CY 2012 Data	\$4,229	\$4,670
35471	Repair arterial blockage	0083	0083	Existing Code	CY 2012 Data	\$4,229	\$6,413
35472	Repair arterial blockage	0083	0083	Existing Code	CY 2012 Data	\$4,229	\$5,319
35475	Repair arterial blockage	0083	0083	Existing Code	CY 2012 Data	\$4,229	\$4,411
35476	Repair venous blockage	0083	0083	Existing Code	CY 2012 Data	\$4,229	\$4,000
37183	Remove hepatic shunt (tips)	0229	0229	Existing Code	CY 2012 Data	\$8,767	\$4,953
37204	Transcatheter occlusion	0082	0229	Deleted for 2014	CY 2012 Data	\$8,767	\$8,508
37205	Transcath iv stent percut	0229	0229	Deleted for 2014	CY 2012 Data	\$8,767	\$9,534
37206	Transcath iv stent/perc addl	N/A	N/A	Deleted for 2014	Packaged	N/A	N/A
37207	Transcath iv stent open	0229	0229	Deleted for 2014	CY 2012 Data	\$8,767	\$8,803
37208	Transcath iv stent/open addl	N/A	N/A	Deleted for 2014	Packaged	N/A	N/A

HCPCS Code	Short Descriptor	Proposed CY 2014 APC	CY 2014 APC *	Comment	Source	APC Single "J1" Geometric Mean Cost*	HCPCS Single "J1" Geometric Mean Modeled Cost*
37210	Embolization uterine fibroid	0229	0229	Deleted for 2014	CY 2012 Data	\$8,767	\$6,044
37220	Iliac revasc	0083	0083	Existing Code	CY 2012 Data	\$4,229	\$5,561
37221	Iliac revasc w/stent	0229	0229	Existing Code	CY 2012 Data	\$8,767	\$9,068
37224	Fem/popl revas w/tla	0083	0083	Existing Code	CY 2012 Data	\$4,229	\$5,528
37225	Fem/popl revas w/ather	0229	0229	Existing Code	CY 2012 Data	\$8,767	\$10,489
37226	Fem/popl revasc w/stent	0229	0229	Existing Code	CY 2012 Data	\$8,767	\$10,317
37227	Fem/popl revasc stnt & ather	0319	0319	Existing Code	CY 2012 Data	\$15,857	\$17,239
37228	Tib/per revasc w/tla	0083	0083	Existing Code	CY 2012 Data	\$4,229	\$6,157
37229	Tib/per revasc w/ather	0229	0445	Existing Code	CY 2012 Data	\$13,336	\$12,527
37230	Tib/per revasc w/stent	0229	0445	Existing Code	CY 2012 Data	\$13,336	\$11,318
37231	Tib/per revasc stent & ather	0319	0319	Existing Code	CY 2012 Data	\$15,857	\$17,095
37236	Open/perq place stent 1st	N/A	0229	New For 2014	Model	\$8,767	TBD
37237	Open/perq place stent ea add	N/A	0445	New For 2014	Model	\$13,375	TBD
37238	Open/perq place stent same	N/A	0229	New For 2014	Model	\$8,767	TBD
37239	Open/perq place stent ea add	N/A	0445	New For 2014	Model	\$13,375	TBD
37241	Vasc embolize/occlude venous	N/A	0229	New For 2014	Model	\$8,767	TBD
37242	Vasc embolize/occlude artery	N/A	0229	New For 2014	Model	\$8,767	TBD

HCPCS Code	Short Descriptor	Proposed CY 2014 APC	CY 2014 APC *	Comment	Source	APC Single "J1" Geometric Mean Cost*	HCPCS Single "J1" Geometric Mean Modeled Cost*
37243	Vasc embolize/occlude organ	N/A	0229	New For 2014	Model	\$8,767	TBD
37244	Vasc embolize/occlude bleed	N/A	0229	New For 2014	Model	\$8,767	TBD
43647	Lap impl electrode antrum	0061	0039	Existing Code	CY 2012 Data	\$17,590	\$20,380
51845	Repair bladder neck	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$4,057
53440	Male sling procedure	0385	0385	Existing Code	CY 2012 Data	\$7,666	\$8,252
53444	Insert tandem cuff	0385	0385	Existing Code	CY 2012 Data	\$7,666	\$7,953
53445	Insert uro/ves nck sphincter	0386	0674	Existing Code	CY 2012 Data	\$15,726	\$15,515
53447	Remove/replace ur sphincter	0386	0386	Existing Code	CY 2012 Data	\$13,609	\$12,323
54400	Insert semi-rigid prosthesis	0385	0385	Existing Code	CY 2012 Data	\$7,666	\$9,493
54401	Insert self-contd prosthesis	0386	0386	Existing Code	CY 2012 Data	\$13,609	\$13,420
54405	Insert multi-comp penis pros	0386	0386	Existing Code	CY 2012 Data	\$13,609	\$14,161
54410	Remove/replace penis prosth	0386	0386	Existing Code	CY 2012 Data	\$13,609	\$12,887
54416	Remv/repl penis contain pros	0386	0386	Existing Code	CY 2012 Data	\$13,609	\$12,167
55873	Cryoablate prostate	0674	0385	Existing Code	CY 2012 Data	\$7,666	\$8,188
57220	Revision of urethra	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$3,806
57265	Extensive repair of vagina	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$4,510
57282	Colpopexy extraperitoneal	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$5,437

HCPCS Code	Short Descriptor	Proposed CY 2014 APC	CY 2014 APC *	Comment	Source	APC Single "J1" Geometric Mean Cost*	HCPCS Single "J1" Geometric Mean Modeled Cost*
57283	Colpopexy intraperitoneal	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$5,258
57284	Repair paravag defect open	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$4,580
57285	Repair paravag defect vag	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$5,011
57288	Repair bladder defect	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$4,484
57310	Repair urethrovaginal lesion	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$3,131
57423	Repair paravag defect lap	0202	0385	Existing Code	CY 2012 Data	\$7,666	\$9,672
57556	Remove cervix repair bowel	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$4,568
58290	Vag hyst complex	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$4,643
58291	Vag hyst incl t/o complex	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$4,660
58292	Vag hyst t/o & repair compl	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$4,154
58294	Vag hyst w/enterocele compl	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$6,231
58356	Endometrial cryoablation	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$2,771
58565	Hysteroscopy sterilization	0202	0202	Existing Code	CY 2012 Data	\$4,593	\$3,958
61623	Endovasc tempory vessel occl	0082	0229	Existing Code	CY 2012 Data	\$8,767	\$8,571
61626	Transcath occlusion non-cns	0082	0229	Existing Code	CY 2012 Data	\$8,767	\$9,151
61885	Insrt/redoneurostim 1 array	0039	0039	Existing Code	CY 2012 Data	\$17,590	\$17,828

HCPCS Code	Short Descriptor	Proposed CY 2014 APC	CY 2014 APC *	Comment	Source	APC Single "J1" Geometric Mean Cost*	HCPCS Single "J1" Geometric Mean Modeled Cost*
61886	Implant neurostim arrays	0315	0318	Existing Code	CY 2012 Data	\$27,197	\$23,245
62361	Implant spine infusion pump	0227	0227	Existing Code	CY 2012 Data	\$15,789	\$12,307
62362	Implant spine infusion pump	0227	0227	Existing Code	CY 2012 Data	\$15,789	\$15,854
63650	Implant neuroelectrodes	0040	0040	Existing Code	CY 2012 Data	\$4,754	\$4,640
63655	Implant neuroelectrodes	0061	0039	Existing Code	CY 2012 Data	\$17,590	\$12,339
63663	Revise spine eltrd perq aray	0040	0040	Existing Code	CY 2012 Data	\$4,754	\$5,426
63664	Revise spine eltrd plate	0040	0061	Existing Code	CY 2012 Data	\$6,552	\$6,852
63685	Insrt/redo spine n generator	0039	0039	Existing Code	CY 2012 Data	\$17,590	\$20,143
64553	Implant neuroelectrodes	0040	0061	Existing Code	CY 2012 Data	\$6,552	\$6,860
64555	Implant neuroelectrodes	0040	0040	Existing Code	CY 2012 Data	\$4,754	\$3,959
64561	Implant neuroelectrodes	0040	0040	Existing Code	CY 2012 Data	\$4,754	\$4,875
64565	Implant neuroelectrodes	0040	0040	Existing Code	CY 2012 Data	\$4,754	\$5,575
64568	Inc for vagus n elect impl	0318	0318	Existing Code	CY 2012 Data	\$27,197	\$27,561
64569	Revise/repl vagus n eltrd	0040	0040	Existing Code	CY 2012 Data	\$4,754	\$5,329
64575	Implant neuroelectrodes	0061	0061	Existing Code	CY 2012 Data	\$6,552	\$8,377
64580	Implant neuroelectrodes	0061	0061	Existing Code	CY 2012 Data	\$6,552	\$10,676
64581	Implant neuroelectrodes	0061	0061	Existing Code	CY 2012 Data	\$6,552	\$6,991
64590	Insrt/redo pn/gastr stimul	0039	0039	Existing Code	CY 2012 Data	\$17,590	\$17,254

HCPCS Code	Short Descriptor	Proposed CY 2014 APC	CY 2014 APC *	Comment	Source	APC Single "J1" Geometric Mean Cost*	HCPCS Single "J1" Geometric Mean Modeled Cost*
65770	Revise cornea with implant	0293	0293	Existing Code	CY 2012 Data	\$8,459	\$8,459
69714	Implant temple bone w/stimul	0425	0425	Existing Code	CY 2012 Data	\$10,184	\$9,167
69715	Temple bone implnt w/stimulat	0425	0425	Existing Code	CY 2012 Data	\$10,184	\$10,188
69717	Temple bone implant revision	0425	0425	Existing Code	CY 2012 Data	\$10,184	\$5,907
69718	Revise temple bone implant	0425	0425	Existing Code	CY 2012 Data	\$10,184	\$14,575
69930	Implant cochlear device	0259	0259	Existing Code	CY 2012 Data	\$30,356	\$30,356
75960	Transcath iv stent rs&i	N/A	N/A	Deleted for 2014	Packaged	N/A	N/A
92920	Prq cardiac angioplast 1 art	0083	0083	New For 2013	Model/2013	\$4,229	TBD
92921	Prq cardiac angio addl art	0083	0229	New For 2013	Model/2013	\$8,767	TBD
92924	Prq card angio/athrect 1 art	0082	0229	New For 2013	Model/2013	\$8,767	TBD
92925	Prq card angio/athrect addl	0082	0445	New For 2013	Model/2013	\$13,375	TBD
92928	Prq card stent w/angio 1 vsl	0104	0104	New For 2013	Model/2013	\$8,550	TBD
92929	Prq card stent w/angio addl	0104	0656	New For 2013	Model/2013	\$10,059	TBD
92933	Prq card stent/ath/angio	0104	0656	New For 2013	Model/2013	\$10,059	TBD
92934	Prq card stent/ath/angio	0104	0445	New For 2013	Model/2013	\$13,375	TBD
92937	Prq revasc byp graft 1 vsl	0104	0104	New For 2013	Model/2013	\$8,550	TBD
92938	Prq revasc byp graft addl	0104	0656	New For 2013	Model/2013	\$10,059	TBD

HCPCS Code	Short Descriptor	Proposed CY 2014 APC	CY 2014 APC *	Comment	Source	APC Single "J1" Geometric Mean Cost*	HCPCS Single "J1" Geometric Mean Modeled Cost*
92941	Prq card revasc mi 1 vsl	0104	0104	New For 2013	Model/2013	\$8,550	TBD
92943	Prq card revasc chronic 1vsl	0104	0104	New For 2013	Model/2013	\$8,550	TBD
92944	Prq card revasc chronic addl	0104	0445	New For 2013	Model/2013	\$13,375	TBD
92980	Insert intracoronary stent	N/A	0104	Deleted for 2013	CY 2012 Data	\$8,550	\$8,637
92981	Insert intracoronary stent	N/A	0656	Deleted for 2013	CY 2012 Data	\$10,059	\$12,602
92982	Coronary artery dilation	N/A	0083	Deleted for 2013	CY 2012 Data	\$4,229	\$6,420
92984	Coronary artery dilation	N/A	0104	Deleted for 2013	CY 2012 Data	\$8,550	\$7,616
92986	Revision of aortic valve	0083	0083	Existing Code	CY 2012 Data	\$4,229	\$7,029
92987	Revision of mitral valve	0083	0104	Existing Code	CY 2012 Data	\$8,550	\$8,540
92990	Revision of pulmonary valve	0083	0104	Existing Code	CY 2012 Data	\$8,550	\$8,181
92995	Coronary atherectomy	N/A	0445	Deleted for 2013	CY 2012 Data	\$13,336	\$9,712
92996	Coronary atherectomy add-on	N/A	0229	Deleted for 2013	CY 2012 Data	\$8,767	\$14,966
92997	Pul art balloon repr percut	0083	0104	Existing Code	CY 2012 Data	\$8,550	\$8,405
93619	Electrophysiology evaluation	0085	0085	Existing Code	CY 2012 Data	\$5,056	\$3,616
93620	Electrophysiology evaluation	0085	0085	Existing Code	CY 2012 Data	\$5,056	\$5,160
93624	Electrophysiologic study	0085	0085	Existing Code	CY 2012 Data	\$5,056	\$8,633
93650	Ablate heart dysrhythm focus	0085	0083	Existing Code	CY 2012 Data	\$4,229	\$4,161

HCPCS Code	Short Descriptor	Proposed CY 2014 APC	CY 2014 APC *	Comment	Source	APC Single "J1" Geometric Mean Cost*	HCPCS Single "J1" Geometric Mean Modeled Cost*
93653	Ep & ablate supravent arrhyt	8000	0444	New For 2013	Model/2013	\$14,302	TBD
93654	Ep & ablate ventric tachy	8000	0444	New For 2013	Model/2013	\$14,302	TBD
93656	Tx atrial fib pulm vein isol	8000	0444	New For 2013	Model/2013	\$14,302	TBD
0234T	Trluml perip athrc renal art	0082	0229	Existing Code	CY 2012 Data	\$8,767	\$7,217
0236T	Trluml perip athrc abd aorta	0082	0229	Existing Code	Model	\$8,767	\$9,578
0237T	Trluml perip athrc brchiocph	0082	0229	Existing Code	CY 2012 Data	\$8,767	\$9,601
0238T	Trluml perip athrc iliac art	0082	0229	Existing Code	CY 2012 Data	\$8,767	\$9,621
0268T	Implt/rpl crtd sns dev gen	0039	0040	Existing Code	CY 2012 Data	\$4,754	\$1,588
0282T	Periph field stimul trial	0040	0040	Existing Code	CY 2012 Data	\$4,754	\$5,114
0283T	Periph field stimul perm	0318	0318	Existing Code	CY 2012 Data	\$27,197	\$26,616
0302T	Icar ischm mntrng sys compl	0089	0089	New for 2013	Model/2013	\$10,752	TBD
0303T	Icar ischm mntrng sys eltrd	0106	0106	New for 2013	Model/2013	\$4,944	TBD
0304T	Icar ischm mntrng sys device	0090	0090	New for 2013	Model/2013	\$7,479	TBD
0316T	Replc vagus nerve pls gen	0039	0039	New For 2013	Model/2013	\$17,590	TBD
0319T	Insert subq defib w/eltrd	0107	0107	New For 2013	Model/2013	\$25,556	TBD
0320T	Insert subq defib electrode	0106	0106	New For 2013	Model/2013	\$4,944	TBD
0321T	Insert subq defib pls gen	0107	0107	New For 2013	Model/2013	\$25,556	TBD
0323T	Rmvl & replc subq pls gen	0107	0107	New For 2013	Model/2013	\$25,556	TBD

HCPCS Code	Short Descriptor	Proposed CY 2014 APC	CY 2014 APC *	Comment	Source	APC Single "J1" Geometric Mean Cost*	HCPCS Single "J1" Geometric Mean Modeled Cost*
C9600	Perc drug-el cor stent sing	0656	0656	New For 2013	Model/2013	\$10,059	TBD
C9601	Perc drug-el cor stent bran	0656	0445	New For 2013	Model/2013	\$13,375	TBD
C9602	Perc d-e cor stent ather s	0656	0656	New For 2013	Model/2013	\$10,059	TBD
C9603	Perc d-e cor stent ather br	0656	0445	New For 2013	Model/2013	\$13,375	TBD
C9604	Perc d-e cor revasc t cabg s	0656	0656	New For 2013	Model/2013	\$10,059	TBD
C9605	Perc d-e cor revasc t cabg b	0656	0445	New For 2013	Model/2013	\$13,375	TBD
C9606	Perc d-e cor revasc w AMI s	0656	0445	New For 2013	Model/2013	\$13,375	TBD
C9607	Perc d-e cor revasc chro sin	0656	0656	New For 2013	Model/2013	\$10,059	TBD
C9608	Perc d-e cor revasc chro add	0656	0445	New For 2013	Model/2013	\$13,375	TBD
G0290	Drug-eluting stents, single	N/A	0656	Deleted for 2013	CY 2012 Data	\$10,059	\$9,998
G0291	Drug-eluting stents,each add	N/A	0319	Deleted for 2013	CY 2012 Data	\$15,857	\$11,179

*APC and associated "J1" single claim geometric mean cost for APC and HCPCS derived from CY 2012 claims data that we would have used in cost calculations for CY 2014 instead of finalizing the comprehensive APC policy for CY 2015. We will recalibrate all of the cost information for CY 2015 using CY 2013 claims data. For codes deleted in CY 2013, the CY 2014 APC indicates the primary APC assignment that we used in modeling the presented cost information.

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Comment: Commenters stated that they had difficulty understanding the APC assignment of a specific claim when two or more procedure codes assigned to status indicator "J1" appear on a single claim and indicated that they could not independently replicate the proposed comprehensive APC methodology. Commenters believed that there was ambiguity in whether the primary HCPCS code assignment was based on CY 2012 Medicare payment for the primary procedure or CY 2012 claims cost as determined by reported charges converted to costs in the CY 2012 claims data set using CMS' methodology outlined in section II.A.1.c. of the proposed rule and this final rule with comment period. One

commenter believed that using a ranking based on CY 2012 payments would be inconsistent with setting a prospective payment rate for CY 2014 because prioritizing by payment was potentially more reflective of historical costs than CY 2102 costs and also reflected units in a way that assigned some procedures reporting claims with single units to one APC and other procedures reporting claims with multiple units to a different APC. This latter issue was particularly concerning to commenters because the commenters believed that some claims contributed to the cost of one APC, yet would actually be paid through a different APC.

Response: We disagree with the commenters that we proposed different criteria to assign procedures to

comprehensive APCs for modeling payments and to assign procedures to comprehensive APCs for payment in the claims processing system. However, we recognize that the wording of our proposed methodology for assigning procedures to comprehensive APCs could be interpreted in several ways, and we are receptive to commenters concerns that they better understand the proposed comprehensive APC payment methodology for the treatment of claims reporting multiple device-related procedures. While we are finalizing a comprehensive APC policy, we are delaying the effective date of this policy until CY 2015, and we invite comment on the final methodology discussed in this section.

We stated in the proposed rule that, “Any claims that contained more than one of these procedures were identified but were included in calculating the cost of the procedure that had the greatest cost when traditional HCPCS level accounting was applied.” Using this methodology, we proposed to identify a primary service on claims reporting multiple HCPCS codes assigned to status indicator “J1” by identifying the HCPCS code assigned to status indicator “J1” on the claim that had the highest device-dependent APC geometric mean cost. The primary service is not only the most costly service but also typically represents the most significant or core service that is being provided to the beneficiary. To facilitate claims processing and to ensure that we identified the most costly device-related procedure on each claim, including those billed with multiple units, we envisioned using the CY 2014 device-dependent APC payment amount that would have been made for the service in the absence of a proposal for comprehensive APCs to identify the most costly procedure described by a HCPCS code assigned to status indicator “J1” on the claim. We proposed to assign the procedure described by a HCPCS code assigned to status indicator “J1” with the highest device-dependent APC line-item payment, considering the entire payment when multiple units are billed, as the primary procedure and to make payment for the claim through the associated comprehensive APC. We note that the device-dependent APC payment rates have the same relativity as device-dependent geometric mean costs, as those costs underpin final budget neutral payment rates.

We agree with the commenters that the methodology by which a claim that has at least one procedure described by a HCPCS code that is assigned to status indicator “J1” is assigned to a comprehensive APC is fundamental to understanding final payment under the comprehensive APC policy. If there is only one procedure described by a HCPCS code assigned to status indicator “J1” reported on the claim, the comprehensive APC assignment is straightforward; the claim is paid through the comprehensive APC associated with that procedure. This is true under the proposed methodology as well as under the revised methodology we are finalizing in this final rule with comment period. In the event that more than one procedure described by a HCPCS code assigned to status indicator “J1” was present on the claim, an important goal of our proposed

methodology was to ensure that the costliest procedure, including increased cost due to multiple units, would be identified as the primary procedure on the claim so that the claim would be paid through the most costly potential comprehensive APC and ultimately garner the highest potential comprehensive APC payment. After review of the public comments we received, we are modifying our proposed methodology for assigning a primary procedure described by a HCPCS code assigned to status indicator “J1” reported on a claim to an appropriate comprehensive APC when more than one procedure described by a HCPCS code assigned to status indicator “J1” is reported. First, we will only use current ratesetting estimated cost information and not device-dependent APC payment rates to identify the primary procedure described by the HCPCS code assigned to status indicator “J1” on the claim and the subsequent comprehensive APC through which payment for the service would be made. For CY 2015, we will use estimated costs on CY 2013 claims to calibrate comprehensive APC payment amounts.

Second, we will recognize the greater resources attributable to more complex cases. Commenters suggested addressing variations in cost of comprehensive APCs by recognizing the greater resources attributable to more complex cases with multiple device-dependent procedures in some manner similar to the severity adjustment incorporated into the IPPS MS-DRG system. We agree with the commenters that instituting a higher comprehensive payment for complex cases would both allow us to continue a comprehensive payment methodology where the most costly service reported with status indicator “J1” on the claim determines the comprehensive APC assignment and also recognize relative resource differences associated with multiple device-dependent procedures. In this response, we discuss the first step in this process of identifying a primary HCPCS service assigned to status indicator of “J1” for each claim. We present the methodology for identifying complex subsets of primary services and reassigning claims to higher-level APCs in the following comment and response.

To address concerns presented by some of the commenters that they could not fully model the proposal, we provide all of the information we used to create relative payment weights for CY 2014 using the CY 2012 claims data to illustrate the final methodology below. We believe that this will assist interested parties in replicating our

methodology. We will recalibrate all of the comprehensive APC relative payment weights for CY 2015 using CY 2013 claims data, consistent with our annual recalibration of APC relative payment weights, to reflect the most recently available claims and cost information.

To arrive at the illustrative CY 2014 comprehensive geometric mean cost for the comprehensive APCs in Table 8, we began by first identifying all claims reporting a single procedure described by a HCPCS code with status indicator “J1.” As noted earlier, this is approximately 75 percent of claims with any procedure described by a HCPCS code reported with status indicator “J1.” On claims reporting a single procedure described by a HCPCS code with status indicator “J1,” we considered that procedure to be the primary service that determines the comprehensive APC assignment. We then used these single “J1” claims to calculate a comprehensive APC single “J1” procedure claim geometric mean cost for all comprehensive APCs using the total cost on each claim. These comprehensive APC single “J1” procedure claim geometric mean costs appear in Table 9.

We then began the process of identifying a “primary HCPCS code” that represents the “primary service” or “primary procedure” on a claim reporting multiple procedures described by HCPCS codes with status indicator “J1.” We used the APC geometric mean comprehensive cost based on claims reporting a single “J1” procedure described by a HCPCS code with status indicator “J1” (Table 9) to identify the most costly procedure reported on each claim. Specifically, we selected the primary HCPCS code by determining the comprehensive procedure that is assigned to the APC with the highest geometric mean comprehensive cost based on claims with a single service with status indicator “J1.” We undertook a second step when a comprehensive service claim contained two or more procedures described by a HCPCS code with status indicator “J1” that are assigned to the same APC. Of those procedures described by a HCPCS code with status indicator “J1” that are also assigned to the same APC with the highest comprehensive APC cost from Table 9, we identified the service described by a HCPCS code reported with status indicator “J1” with the highest HCPCS-level geometric mean cost, also derived from the comprehensive cost of claims that contain a single procedure with status indicator “J1,” to be the primary HCPCS code on the claim.

In the event that a HCPCS-level geometric mean comprehensive cost cannot be determined for a particular HCPCS code from the claims data, such as new HCPCS codes that are not represented in the claims data or an add-on code for which there are no claims with only that procedure, we will model a HCPCS-level comprehensive geometric mean cost that we will only use to identify a primary procedure. For procedure codes with missing data, we will include an estimated comprehensive HCPCS code geometric mean cost in each proposed or final rule, as appropriate, using the best information we have available about each code. However, we will not use modeled HCPCS-level comprehensive geometric mean costs to set comprehensive APC payment rates. We will only use modeled HCPCS-level comprehensive geometric mean costs in our claims processing systems to identify a primary HCPCS code reported on a claim with multiple procedures described by HCPCS codes assigned to status indicator “J1” in the same comprehensive APC. Our goal in modeling such a HCPCS-specific geometric mean cost is to identify a primary HCPCS code on a claim with multiple procedures in the same comprehensive APC with sufficient accuracy for a few years until actual claims data become available. This modeled geometric mean cost is not intended in any way to presuppose the actual cost of the service for future ratesetting.

Table 9 contains a list of all HCPCS codes assigned to status indicator “J1” that are assigned to APCs, which are associated with a comprehensive payment. Deleted codes are those codes that were used to estimate geometric mean costs, but are not valid codes for CY 2104 while new codes are those codes that will be valid for payment in CY 2014, but were not present in the CY 2012 claims data. The comprehensive APC assignment that we proposed for each HCPCS code assigned to status indicator “J1” in the proposed rule is shown in Column 3, and the illustrative final CY 2014 comprehensive APC assignment that we would have been established based on public comment on the CY 2014 proposed rule and using CY 2012 claims data is shown in Column 4. Column 7 shows the APC geometric mean cost and Column 8 shows the HCPCS code geometric mean cost; together these two columns allow the determination of the primary service HCPCS code and initial APC assignment for any claims with a combination of HCPCS codes reported with status

indicator “J1.” We have not provided any modeled HCPCS geometric mean costs for CY 2013 or CY 2014 “J1” HCPCS codes for which we do not have claims data as we are finalizing this policy with modification, but delaying implementation until CY 2015. We will make those modeled geometric mean costs available in next year’s proposed rule.

Comment: Commenters expressed concern that CMS’ proposal for a single, comprehensive APC payment would not adequately cover the higher cost of cases where multiple expensive devices are used. Commenters also raised several concerns with paying claims with multiple primary procedures under a single APC payment. The commenters noted that, under comprehensive APCs, hospitals would find simple claims with a single comprehensive HCPCS code and few services to be more profitable on a case basis than complex claims with a greater number of comprehensive HCPCS codes and more ancillary services. Commenters believed that this could be a significant issue for many of the comprehensive APCs because only one primary service is paid and one quarter of all claims have multiple procedures. Many commenters believed that a single, comprehensive APC payment for single and multiple device insertion procedures would create an incentive to not perform complex and multiple procedures where the cost materially exceeds payment and that it also could create an incentive for hospitals to use inappropriately less expensive devices, services, and supplies to offset the financial threat of reduced “packaged” payments, including cases where those substitutions could increase program costs as a whole and carry greater risk for beneficiaries.

Commenters argued that hospitals systematically performing more multiple device insertion procedures may face severe financial hardship because they would not have enough simple, single primary procedure cases to cover the cost of their many multiple device insertion procedures, which may limit their ability to provide these services as they have in the past. While we stated that we believed that the comprehensive APC proposal would encourage hospitals to negotiate better rates on supplies and increase the efficiency of individual procedures, commenters stated that the added cost of additional expensive devices cannot be routinely reduced to approximate the cost of a single device procedure.

Response: We agree with the commenters that there is wide spread variation in the comprehensive costs of

individual claims within each primary procedure, and we further agree with the commenters that we do not want to financially disadvantage hospitals that treat sicker beneficiaries that require more complex and costly procedures. We also agree with the commenters that the presence of certain device-related procedures reported together on a claim can, but does not always, constitute a more complex and resource-intensive subset of a comprehensive procedure.

In calculating the proposed payment rates for comprehensive APCs, we proposed to allocate the costs of all ancillary and adjunctive services to the primary procedure assigned to status indicator “J1,” including the costs of additional procedures identified with status indicator “J1.” A comprehensive approach increases opportunities for hospitals to garner efficiencies in the delivery of these services, but also increases the variation in estimated total claim costs contributing to the comprehensive APC relative payment weight calculation. We agree with the commenters that, in certain instances, cost variation could be too large and could potentially create undue financial risk for hospitals that treat complex patients. We also agree with the commenters that there are some limitations on individual hospitals’ ability to reduce costs associated with complex procedures, especially in the short term. Cost reductions may involve changing suppliers or renegotiating contracts for expensive devices. Further, it may be difficult for hospitals to immediately analyze the effects of changing payment models and rapidly implement the practices that they use to handle cost variations within inpatient DRGs.

Given our interest in establishing a comprehensive APC payment under the OPPI that is comparable to a severity level DRG payment adjustment, we agree with the commenters who recommended assigning combinations of procedures that are reported together which indicate a more complex and resource-intensive version of the primary procedure to higher level comprehensive APCs, not unlike the IPPS policy of assigning procedures with certain conditions to higher paying MS-DRGs. After reviewing significant public comments pointing out common clinical scenarios for combinations of device insertion procedures assigned to status indicator “J1,” we decided to recognize complexity in these device-dependent procedures by reassigning claims for certain forms of the primary procedures to higher level comprehensive APCs as a modification to our proposal. We welcome public

comments on recognizing the cost of more complex forms of primary procedures through our final policy to reassign claims for complex forms of the primary procedures discussed below. We identify the complex forms of primary procedures that we would reassign for CY 2014 using CY 2012 claims data if we were implementing the comprehensive APC policy in CY 2014 in Table 10. We discuss our consideration of code-specific comments by clinical family later in this section.

We took several steps to moderate resource cost variation in comprehensive APC payments. First, we undertook a standard APC recalibration. We specifically evaluated the APC assignment of some primary procedures and moved those procedures from one APC to another to better align resource and clinical homogeneity. In considering the APC assignment of these procedures, we looked at the traditional parameters of geometric mean cost for the primary service and clinical characteristics of the APC. We created, consolidated, or redefined the primary procedures in the comprehensive APCs as necessary to better group services with clinical and resource homogeneity. Second, we identified complex subsets of primary procedures, which consist of the primary HCPCS code reported in combination with other HCPCS codes that together describe a more complex form of the primary service. We reassigned many claims with complex subsets of primary procedures to a higher level comprehensive APC in the same clinical family through this methodology. We define a clinical family of comprehensive APCs to be a set of clinically related comprehensive APCs that represent different resource levels of clinically comparable services.

Reassignment of claims with complex subsets of the primary procedures does not change the primary service identified on a claim. We continue to consider all services reported on the claim, even the additional "J1" HCPCS codes identifying a claim as complex, to be adjunctive and packaged into the primary service. We make a distinction here between the idea of a primary service under comprehensive APCs and the concept of a composite service as discussed in section II.A.2.f. of this final rule with comment period. Both methodologies foster more accurate ratesetting by allowing us to use additional information reported on a claim to establish a geometric mean cost and accompanying relative payment weight. However, under a composite payment approach, we identify certain

procedures that are frequently performed together during a single clinical encounter as a single service and identify that set of services as a complete service. For comprehensive APCs, we assess many combinations of procedure codes for purposes of determining complex forms of a primary service, but the combination of codes is not considered to be separate and distinct service. For comprehensive APCs, the primary service continues to represent the complete furnished service.

For the purpose of evaluating HCPCS code combinations for reassignment to a higher level comprehensive APC after identifying one of the procedures described by a HCPCS code assigned to status indicator "J1" reported on the claim as being the primary service, we recognized a combination of procedure codes as complex and appropriately reassigned to a higher level APC in the same clinical family of services if the complex combination of procedures met all of the following criteria.

- The comprehensive geometric mean cost of the claims with the combination of procedures was more than two times the comprehensive geometric mean cost of claims reporting only a single comprehensive procedure described by a HCPCS code assigned to status indicator "J1."
- There were greater than 100 claims with the specific combination of procedure codes.
- The number of claims reporting the specific combination of procedure codes exceeded 5 percent of the total volume of claims reporting that procedure as the primary service described by a HCPCS code assigned to status indicator "J1", and we did not determine that the combination of procedure codes represented an uncommon clinical or resource extreme value within the entire family of services.

In reviewing the CY 2012 claims data for purposes of illustrating this final methodology, we addressed all of the combinations of procedures reported on claims that met all of these criteria, but also addressed other combinations of procedures reported on claims that did not meet all of these criteria if clinical consistency suggested that additional reassignment was necessary.

Once we determined that a particular procedure code combination for a primary service was complex because it represented a sufficiently costly case and frequent subset within the primary procedure overall, we evaluated alternate APC assignments for those claims reporting a combination of procedure codes. 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. We maintained clinical homogeneity by reassigning claims within the same clinical family of comprehensive APCs. Any combinations of multiple comprehensive HCPCS codes that were not sufficiently frequent or which did not represent sufficiently costly cases relative to the cost of the primary procedure established with simple, single procedure claims were not identified as complex subsets of the primary procedures and were not reassigned. We repeated this process for each APC for which commenters expressed concerns regarding complexity of cases contributing to wide variation in costs. After both reassigning some procedure codes to different comprehensive APCs and reassigning claims for complex cases of primary services, we then calculated the final comprehensive geometric mean cost for the comprehensive APCs. The illustrative comprehensive geometric mean costs that we would have calculated for the comprehensive APCs for CY 2014 appear in Table 8.

Infrequently, we will not have claims data for some procedures described by HCPCS codes that are assigned to status indicator "J1" and, therefore, no claims cost information upon which to base an assessment of volume or costliness. In this case, we will use the best information available to us to prospectively identify a complex version of the primary service, which is indicated by the combination of procedure codes reported on a claim and assign those complex cases to a higher level comprehensive APC. We will reassess the appropriateness of identifying certain combinations of procedure codes as complex subsets of a primary service once cost information becomes available. This is comparable to our policy for assigning new codes or codes without claims data to an APC based on the best information we have available at the time of assignment and reassessing that resource homogeneity of that APC assignment when claims data become available.

Table 10 shows the combinations of procedure codes that we identified within the 136 primary procedure codes assigned to status indicator "J1" in the CY 2012 claims data that we used in our illustration of CY 2014 modeling and the APC to which those combinations of procedures would be reassigned, as well as combinations of CY 2013 and CY 2014 procedure codes that are not represented in our modeling dataset for

which we identified a clinical similarity to existing services and would have identified for reassignment as a complex subset of the primary service for CY 2014. We intend to reassess both procedure code assignments in the comprehensive APCs and our identification and reassignment of complex cases represented by combinations of procedure codes using updated claims and cost report data as we establish relative payment weights each year. We note that we will have CY 2013 claims data for some of the procedure codes listed in Table 10 and we will reassess our identification of combinations of procedures as complex for CY 2015 in light of data and in response to comments received on this final rule with comment period in our CY 2015 OPPS/ASC proposed rule.

In summary, after consideration of the public comments we received, we are finalizing the following methodology for establishing an APC relative payment weight for the comprehensive APC policy, which is our proposed policy with a modification. During ratesetting, single claims reporting a single procedure described by a HCPCS code assigned to status indicator “J1” are used to establish an initial APC assignment for each procedure described by that HCPCS code. The geometric mean of the total estimated costs on each claim is used to establish resource similarity for each procedure code’s APC assignment and is evaluated within the context of clinical similarity, with assignment starting from the APC assignments in effect for the current payment year. Claims reporting multiple procedures described by HCPCS codes assigned to status indicator “J1” are identified and the procedures are then assigned to a comprehensive APC, based on the primary HCPCS code, that has the highest geometric mean estimated 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 comprehensive 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 HCPCS code is then based on the procedure described by the HCPCS code assigned to status indicator “J1” with the highest HCPCS-level

geometric mean cost based on claims with a single HCPCS code assigned to status indicator “J1.” Where we have no claims data upon which to establish a HCPCS-level comprehensive geometric mean cost, we will model a HCPCS-level geometric mean cost for the sole purpose of appropriately assigning the primary HCPCS code reported on a claim. The comprehensive APC assignment of each procedure described by HCPCS codes assigned to status indicator “J1” is then confirmed by verifying that the APC assignment remains appropriate when considering the clinical similarity, as well as the estimated cost of all claims reporting each procedure described by HCPCS codes assigned to status indicator “J1,” including simple and complex claims, with multiple device-related procedures.

We are providing in Table 9 the APC assignments for each procedure described by HCPCS codes assigned to status indicator “J1,” the APC geometric mean estimated cost based on claims reporting single procedures, and the HCPCS geometric mean estimated cost based on the claims reporting single procedures that we used to identify primary HCPCS codes and to assign the procedure to an appropriate comprehensive APC. If we were implementing this policy in CY 2014, Table 9 would contain the same information as the claims processing system and could, therefore, be used to determine the initial APC assignment and APC geometric mean estimated cost for any procedure described by HCPCS codes assigned to status indicator “J1” reported on claims prior to any reassignment of certain costly claims for a primary service that represent a complex form of the primary service to higher level APCs. Table 9 is configured for CY 2104 and will be updated for implementation in CY 2015.

We then considered reassigning complex subsets of claims for each primary service HCPCS code. All claims reporting more than one procedure described by HCPCS codes assigned to status indicator “J1” are evaluated for the existence of commonly occurring combinations 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 HCPCS code. This indicates that the subset of procedures identified by the secondary HCPCS code has increased resource requirements relative to less complex subsets of that procedure. If a combination of procedure codes reported on claims is identified that

meets these requirements, that is, commonly occurring and exhibiting materially greater resource requirements, it is further evaluated to confirm clinical validity as a complex subset of the primary procedure and the combination 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 combination of procedure codes does not meet the requirement for a materially different cost or does not occur commonly, it is not considered to be a complex, and primary service claims with that combination of procedure codes are not reassigned. All combinations of procedures described by HCPCS codes assigned to status indicator “J1” for each primary HCPCS code are similarly evaluated.

Once all combinations 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 comprehensive APC within a clinical family of comprehensive APCs, that is, an APC with greater estimated resource requirements than the initially assigned comprehensive 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.

For new HCPCS codes and codes without data, we will use the best data available to us to identify combinations of procedures that represent a more complex form of the primary procedure and warrant reassignment to a higher level APC. We will reevaluate our APC assignments, and identification and APC placement of complex claims once claims data become available. We then recalculate all APC comprehensive geometric mean costs and ensure clinical and resource homogeneity.

We have provided in Table 10 the combinations of procedures described by HCPCS codes assigned to status indicator “J1” that we used to set payment rates and the additional combinations of procedures described by new HCPCS codes assigned to status indicator “J1” that would be identified for reassignment as a complex form of the primary procedure in CY 2014. If we were implementing this policy in CY 2014, Table 10 would contain the same information as the claims processing system and could, therefore, be used to

determine the final comprehensive APC assignment and comprehensive APC geometric mean estimated cost for any procedure described by HCPCS codes	assigned to status indicator “J1” reported on an individual claims. Table 10 is configured for CY 2104. We will	update this table for implementation in CY 2015. BILLING CODE 4120-01-P
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TABLE 10.—CY 2014 COMPLEXITY REASSIGNMENTS: ILLUSTRATION

Primary HCPCS Assigned to Status Indicator “J1”	Descriptor	Initial APC**	Combination HCPCS Assigned to Status Indicator “J1”	Descriptor	Final APC**	Used in CY 2012 Data	Would be Used in CY 2014 Claim Processing
33206	Insert heart pm atrial	0089	93620	Electrophysiology evaluation	0655	Yes	Yes
33207	Insert heart pm ventricular	0089	33210	Insert electrd/pm cath sngl	0655	Yes	Yes
33207	Insert heart pm ventricular	0089	93620	Electrophysiology evaluation	0655	Yes	Yes
33207	Insert heart pm ventricular	0089	93650	Periph field stimul perm	0655	Yes	Yes
33208	Insrt heart pm atrial & vent	0089	G0290	Drug-eluting stents, single	0655	Yes	Yes
33208	Insrt heart pm atrial & vent	0089	33208	Insrt heart pm atrial & vent	0655	Yes	Yes
33208	Insrt heart pm atrial & vent	0089	33210	Insert electrd/pm cath sngl	0655	Yes	Yes
33208	Insrt heart pm atrial & vent	0089	33217	Insert 2 electrode pm-defib	0655	Yes	Yes
33208	Insrt heart pm atrial & vent	0089	92980	Insert intracoronary stent	0655	Yes	Yes
33208	Insrt heart pm atrial & vent	0089	93619	Electrophysiology evaluation	0655	Yes	Yes
33208	Insrt heart pm atrial & vent	0089	93620	Electrophysiology evaluation	0655	Yes	Yes

Primary HCPCS Assigned to Status Indicator "J1"	Descriptor	Initial APC**	Combination HCPCS Assigned to Status Indicator "J1"	Descriptor	Final APC**	Used in CY 2012 Data	Would be Used in CY 2014 Claim Processing
33208	Insrt heart pm atrial & vent	0089	93650	Periph field stimul perm	0655	Yes	Yes
33210	Insert electrd/pm cath sngl	0106	92982	Coronary artery dilation	0090	Yes	Yes
33212	Insert pulse gen sngl lead	0090	33210	Insert electrd/pm cath sngl	0654	Yes	Yes
33213	Insert pulse gen dual leads	0654	33210	Insert electrd/pm cath sngl	0089	Yes	Yes
33216	Insert 1 electrode pm-defib	0106	33210	Insert electrd/pm cath sngl	0089	Yes	Yes
33216	Insert 1 electrode pm-defib	0106	33216	Insert 1 electrode pm-defib	0089	Yes	Yes
33216	Insert 1 electrode pm-defib	0106	35476	Repair venous blockage	0089	Yes	Yes
33224	Insert pacing lead & connect	0089	33208	Insrt heart pm atrial & vent	0655	Yes	Yes
33224	Insert pacing lead & connect	0089	33216	Insert 1 electrode pm-defib	0655	Yes	Yes
33224	Insert pacing lead & connect	0089	33217	Insert 2 electrode pm-defib	0655	Yes	Yes
33224	Insert pacing lead & connect	0089	93650	Periph field stimul perm	0655	Yes	Yes
33227	Remove&rep lace pm gen sngl	0090	33210	Insert electrd/pm cath sngl	0654	Yes	Yes

Primary HCPCS Assigned to Status Indicator "J1"	Descriptor	Initial APC**	Combination HCPCS Assigned to Status Indicator "J1"	Descriptor	Final APC**	Used in CY 2012 Data	Would be Used in CY 2014 Claim Processing
33227	Remove&replace pm gen singl	0090	35475	Repair arterial blockage	0654	Yes	Yes
33228	Remv&replc pm gen dual lead	0654	33210	Insert electrd/pm cath singl	0089	Yes	Yes
33228	Remv&replc pm gen dual lead	0654	33211	Insert card electrodes dual	0089	Yes	Yes
33228	Remv&replc pm gen dual lead	0654	33228	Remv&repl c pm gen dual lead	0089	Yes	Yes
33228	Remv&replc pm gen dual lead	0654	93620	Electrophysiology evaluation	0089	Yes	Yes
33230	Insrt pulse gen w/dual leads	0107	33216	Insert 1 electrode pm-defib	0108	Yes	Yes
33240	Insrt pulse gen w/singl lead	0107	33216	Insert 1 electrode pm-defib	0108	Yes	Yes
33240	Insrt pulse gen w/singl lead	0107	33217	Insert 2 electrode pm-defib	0108	Yes	Yes
33263	Remv&replc cvd gen dual lead	0107	33263	Remv&repl c cvd gen dual lead	0108	Yes	Yes
33264	Remv&replc cvd gen mult lead	0107	33210	Insert electrd/pm cath singl	0108	Yes	Yes
33264	Remv&replc cvd gen mult lead	0107	33216	Insert 1 electrode pm-defib	0108	Yes	Yes
33264	Remv&replc cvd gen mult lead	0107	33217	Insert 2 electrode pm-defib	0108	Yes	Yes

Primary HCPCS Assigned to Status Indicator "J1"	Descriptor	Initial APC**	Combination HCPCS Assigned to Status Indicator "J1"	Descriptor	Final APC**	Used in CY 2012 Data	Would be Used in CY 2014 Claim Processing
33264	Remv&replc cvd gen mult lead	0107	33224	Insert pacing lead & connect	0108	Yes	Yes
33264	Remv&replc cvd gen mult lead	0107	35476	Repair venous blockage	0108	Yes	Yes
33264	Remv&replc cvd gen mult lead	0107	93620	Electrophysiology evaluation	0108	Yes	Yes
33264	Remv&replc cvd gen mult lead	0107	93650	Periph field stimul perm	0108	Yes	Yes
35471	Repair arterial blockage	0083	35471	Repair arterial blockage	0229	Yes	Yes
35471	Repair arterial blockage	0083	35476	Repair venous blockage	0229	Yes	Yes
35471	Repair arterial blockage	0083	37220	Iliac revasc	0229	Yes	Yes
35471	Repair arterial blockage	0083	37224	Fem/popl revas w/tla	0229	Yes	Yes
35475	Repair arterial blockage	0083	35476	Repair venous blockage	0229	Yes	Yes
35476	Repair venous blockage	0083	35476	Repair venous blockage	0229	Yes	Yes
37204	Transcatheter occlusion	0229	37204	Transcatheter occlusion	0445	Yes	Yes
37205	Transcath iv stent percut	0229	G0290	Drug-eluting stents, single	0445	Yes	Yes

Primary HCPCS Assigned to Status Indicator "J1"	Descriptor	Initial APC**	Combination HCPCS Assigned to Status Indicator "J1"	Descriptor	Final APC**	Used in CY 2012 Data	Would be Used in CY 2014 Claim Processing
37205	Transcath iv stent percut	0229	37204	Transcatheter occlusion	0445	Yes	Yes
37205	Transcath iv stent percut	0229	37205	Transcath iv stent percut	0445	Yes	Yes
37220	Iliac revasc	0083	37220	Iliac revasc	0104	Yes	Yes
37221	Iliac revasc w/stent	0229	37205	Transcath iv stent percut	0445	Yes	Yes
37221	Iliac revasc w/stent	0229	37220	Iliac revasc	0445	Yes	Yes
37221	Iliac revasc w/stent	0229	37221	Iliac revasc w/stent	0445	Yes	Yes
37224	Fem/popl revas w/tla	0083	35475	Repair arterial blockage	0104	Yes	Yes
37224	Fem/popl revas w/tla	0083	37220	Iliac revasc	0104	Yes	Yes
37224	Fem/popl revas w/tla	0083	37224	Fem/popl revas w/tla	0104	Yes	Yes
37225	Fem/popl revas w/ather	0229	35476	Repair venous blockage	0445	Yes	Yes
37225	Fem/popl revas w/ather	0229	37205	Transcath iv stent percut	0445	Yes	Yes
37225	Fem/popl revas w/ather	0229	37220	Iliac revasc	0445	Yes	Yes
37225	Fem/popl revas w/ather	0229	37221	Iliac revasc w/stent	0445	Yes	Yes

Primary HCPCS Assigned to Status Indicator "J1"	Descriptor	Initial APC**	Combination HCPCS Assigned to Status Indicator "J1"	Descriptor	Final APC**	Used in CY 2012 Data	Would be Used in CY 2014 Claim Processing
37225	Fem/popl revas w/ather	0229	37225	Fem/popl revas w/ather	0445	Yes	Yes
37225	Fem/popl revas w/ather	0229	37226	Fem/popl revasc w/stent	0445	Yes	Yes
37225	Fem/popl revas w/ather	0229	37228	Tib/per revasc w/tla	0445	Yes	Yes
37226	Fem/popl revasc w/stent	0229	G0290	Drug-eluting stents, single	0445	Yes	Yes
37226	Fem/popl revasc w/stent	0229	35471	Repair arterial blockage	0445	Yes	Yes
37226	Fem/popl revasc w/stent	0229	37204	Transcatheter occlusion	0445	Yes	Yes
37226	Fem/popl revasc w/stent	0229	37205	Transcath iv stent percut	0445	Yes	Yes
37226	Fem/popl revasc w/stent	0229	37220	Iliac revasc	0445	Yes	Yes
37226	Fem/popl revasc w/stent	0229	37221	Iliac revasc w/stent	0445	Yes	Yes
37226	Fem/popl revasc w/stent	0229	37226	Fem/popl revasc w/stent	0445	Yes	Yes
37226	Fem/popl revasc w/stent	0229	37228	Tib/per revasc w/tla	0445	Yes	Yes
37228	Tib/per revasc w/tla	0083	35476	Repair venous blockage	0104	Yes	Yes

Primary HCPCS Assigned to Status Indicator "J1"	Descriptor	Initial APC**	Combination HCPCS Assigned to Status Indicator "J1"	Descriptor	Final APC**	Used in CY 2012 Data	Would be Used in CY 2014 Claim Processing
37228	Tib/per revasc w/tla	0083	37220	Iliac revasc	0104	Yes	Yes
37228	Tib/per revasc w/tla	0083	37224	Fem/popl revas w/tla	0104	Yes	Yes
37228	Tib/per revasc w/tla	0083	37228	Tib/per revasc w/tla	0104	Yes	Yes
37229	Tib/per revasc w/ather	0445	37221	Iliac revasc w/stent	0319	Yes	Yes
37229	Tib/per revasc w/ather	0445	37226	Fem/popl revasc w/stent	0319	Yes	Yes
37229	Tib/per revasc w/ather	0445	37229	Tib/per revasc w/ather	0319	Yes	Yes
37230	Tib/per revasc w/stent	0445	37221	Iliac revasc w/stent	0319	Yes	Yes
37230	Tib/per revasc w/stent	0445	37226	Fem/popl revasc w/stent	0319	Yes	Yes
37230	Tib/per revasc w/stent	0445	37228	Tib/per revasc w/tla	0319	Yes	Yes
54405	Insert multi-comp penis pros	0386	53440	Male sling procedure	0674	Yes	Yes
54405	Insert multi-comp penis pros	0386	53447	Remove/re place ur sphincter	0674	Yes	Yes
54405	Insert multi-comp penis pros	0386	54410	Remove/re place penis prosth	0674	Yes	Yes
57265	Extensive repair of vagina	0202	57288	Repair bladder defect	0385	Yes	Yes

Primary HCPCS Assigned to Status Indicator "J1"	Descriptor	Initial APC**	Combination HCPCS Assigned to Status Indicator "J1"	Descriptor	Final APC**	Used in CY 2012 Data	Would be Used in CY 2014 Claim Processing
57282	Colpopexy extraperitoneal	0202	57285	Repair paravag defect vag	0385	Yes	Yes
57282	Colpopexy extraperitoneal	0202	57288	Repair bladder defect	0385	Yes	Yes
57283	Colpopexy intraperitoneal	0202	57285	Repair paravag defect vag	0385	Yes	Yes
57283	Colpopexy intraperitoneal	0202	57288	Repair bladder defect	0385	Yes	Yes
57285	Repair paravag defect vag	0202	57288	Repair bladder defect	0385	Yes	Yes
61885	Insrt/redo neurostim 1 array	0039	61885	Insrt/redo neurostim 1 array	0318	Yes	Yes
61885	Insrt/redo neurostim 1 array	0039	64553	Implant neuroelectrodes	0318	Yes	Yes
61885	Insrt/redo neurostim 1 array	0039	64569	Revise/repl vagus n eltrd	0318	Yes	Yes
63650	Implant neuroelectrodes	0040	63650	Implant neuroelectrodes	0061	Yes	Yes
63650	Implant neuroelectrodes	0040	64555	Implant neuroelectrodes	0061	Yes	Yes
63663	Revise spine eltrd perq array	0040	63663	Revise spine eltrd perq array	0061	Yes	Yes
63663	Revise spine eltrd perq array	0040	64555	Implant neuroelectrodes	0061	Yes	Yes
63685	Insrt/redo spine n generator	0039	63650	Implant neuroelectrodes	0318	Yes	Yes

Primary HCPCS Assigned to Status Indicator "J1"	Descriptor	Initial APC**	Combination HCPCS Assigned to Status Indicator "J1"	Descriptor	Final APC**	Used in CY 2012 Data	Would be Used in CY 2014 Claim Processing
63685	Insrt/redo spine n generator	0039	63655	Implant neuroelectr odes	0318	Yes	Yes
63685	Insrt/redo spine n generator	0039	63663	Revise spine eltrd perq aray	0318	Yes	Yes
63685	Insrt/redo spine n generator	0039	63664	Revise spine eltrd plate	0318	Yes	Yes
63685	Insrt/redo spine n generator	0039	63685	Insrt/redo spine n generator	0318	Yes	Yes
63685	Insrt/redo spine n generator	0039	64555	Implant neuroelectr odes	0318	Yes	Yes
63685	Insrt/redo spine n generator	0039	64565	Implant neuroelectr odes	0318	Yes	Yes
63685	Insrt/redo spine n generator	0039	64575	Implant neuroelectr odes	0318	Yes	Yes
64555	Implant neuroelectro des	0040	64555	Implant neuroelectr odes	0061	Yes	Yes
64590	Insrt/redo pn/gastr stimul	0039	63650	Implant neuroelectr odes	0318	Yes	Yes
64590	Insrt/redo pn/gastr stimul	0039	63664	Revise spine eltrd plate	0318	Yes	Yes
64590	Insrt/redo pn/gastr stimul	0039	64555	Implant neuroelectr odes	0318	Yes	Yes
64590	Insrt/redo pn/gastr stimul	0039	64575	Implant neuroelectr odes	0318	Yes	Yes
64590	Insrt/redo pn/gastr stimul	0039	64590	Insrt/redo pn/gastr stimul	0318	Yes	Yes

Primary HCPCS Assigned to Status Indicator "J1"	Descriptor	Initial APC**	Combination HCPCS Assigned to Status Indicator "J1"	Descriptor	Final APC**	Used in CY 2012 Data	Would be Used in CY 2014 Claim Processing
92920	Prq cardiac angioplast 1 art	0083	92920	Prq cardiac angioplast 1 art	0229	No	Yes
92928	Prq card stent w/angio 1 vsl	0104	92928	Prq card stent w/angio 1 vsl	0656	No	Yes
92928	Prq card stent w/angio 1 vsl	0104	92928	Prq card stent w/angio 1 vsl	0656	No	Yes
92928	Prq card stent w/angio 1 vsl	0104	92937	Prq revasc byp graft 1 vsl	0656	No	Yes
92933	Prq card stent/ath/angio	0656	92933	Prq card stent/ath/angio	0445	No	Yes
92941	Prq card revasc mi 1 vsl	0104	92941	Prq card revasc mi 1 vsl	0656	No	Yes
92943	Prq card revasc chronic 1vsl	0104	92943	Prq card revasc chronic 1vsl	0656	No	Yes
92980	Insert intracoronary stent	0104	33210	Insert electrd/pm cath sngl	0656	Yes	Yes
92980	Insert intracoronary stent	0104	92980	Insert intracoronary stent	0656	Yes	Yes
92981	Insert intracoronary stent	0656	92981	Insert intracoronary stent	0319	Yes	Yes
92982	Coronary artery dilation	0083	92982	Coronary artery dilation	0229	Yes	Yes
92995	Coronary atherectomy	0445	G0290	Drug-eluting stents, single	0319	Yes	Yes

Primary HCPCS Assigned to Status Indicator "J1"	Descriptor	Initial APC**	Combination HCPCS Assigned to Status Indicator "J1"	Descriptor	Final APC**	Used in CY 2012 Data	Would be Used in CY 2014 Claim Processing
93619	Electrophysiology evaluation	0085	93650	Ablate heart dysrhythm focus	0444	Yes	Yes
93619	Electrophysiology evaluation	0085	93651	Ablate heart dysrhythm focus	0444	Yes	No
93619	Electrophysiology evaluation	0085	93652	Ablate heart dysrhythm focus	0444	Yes	No
93620	Electrophysiology evaluation	0085	93650	Ablate heart dysrhythm focus	0444	Yes	Yes
93620	Electrophysiology evaluation	0085	93651	Ablate heart dysrhythm focus	0444	Yes	No
93620	Electrophysiology evaluation	0085	93652	Ablate heart dysrhythm focus	0444	Yes	No
0238T	Trluminal peripathric iliac artery	0229	37220	Iliac revascularization	0445	Yes	Yes
0282T	Peripheral field stimulation trial	0040	0282T	Peripheral field stimulation trial	0039	Yes	Yes
0282T	Peripheral field stimulation trial	0040	63650	Implantable neuroelectrodes	0039	Yes	Yes
C9600	Pericatheter drug-eluting coronary stent	0656	C9600	Pericatheter drug-eluting coronary stent	0445	No	Yes
C9602	Pericatheter drug-eluting coronary stent with antithrombotic coating	0656	C9602	Pericatheter drug-eluting coronary stent with antithrombotic coating	0445	No	Yes
C9602	Pericatheter drug-eluting coronary stent with antithrombotic coating	0656	C9600	Pericatheter drug-eluting coronary stent	0445	No	Yes

Primary HCPCS Assigned to Status Indicator "J1"	Descriptor	Initial APC**	Combination HCPCS Assigned to Status Indicator "J1"	Descriptor	Final APC**	Used in CY 2012 Data	Would be Used in CY 2014 Claim Processing
C9604	Perc d-e cor revasc t cabg s	0656	C9604	Perc d-e cor revasc t cabg s	0445	No	Yes
C9604	Perc d-e cor revasc t cabg s	0656	C9600	Perc drug-el cor stent sing	0445	No	Yes
C9606	Perc d-e cor revasc w AMI s	0656	C9606	Perc d-e cor revasc w AMI s	0445	No	Yes
C9606	Perc d-e cor revasc w AMI s	0656	C9600	Perc drug-el cor stent sing	0445	No	Yes
C9607	Perc d-e cor revasc chro sin	0656	C9600	Perc drug-el cor stent sing	0445	No	Yes
C9608	Perc d-e cor revasc chro add	0656	C9608	Perc d-e cor revasc chro add	0445	No	Yes
G0290	Drug-eluting stents, single	0656	G0290	Drug-eluting stents, single	0445	Yes	No
G0290	Drug-eluting stents, single	0656	33210	Insert electrd/pm cath sngl	0445	Yes	No
G0290	Drug-eluting stents, single	0656	37224	Fem/popl revas w/tla	0445	Yes	No
G0290	Drug-eluting stents, single	0656	37228	Tib/per revasc w/tla	0445	Yes	No
G0290	Drug-eluting stents, single	0656	93620	Electrophysiology evaluation	0445	Yes	No
G0291	Drug-eluting stents,each add	0319	G0290	Drug-eluting stents, single	0319	Yes	No
G0291	Drug-eluting stents,each add	0319	G0291	Drug-eluting stents,each add	0319	Yes	No

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(e) Impact of Proposed Comprehensive APCs for Device-Dependent Procedures

• Impact on Medicare Payments

In our proposed rule, we stated that because these device-dependent comprehensive APCs are entirely derived from existing services currently reported on Medicare claims, the policy is effectively budget neutral in its impact on Medicare payments. We noted that room, board, and nursing services have been covered costs in the delivery of outpatient services that require the patient to receive nursing services, occupy a bed for outpatient care, and maintain a controlled metabolic intake during a prolonged outpatient stay. Although we proposed to include new revenue center costs for room and board when reported on these claims, we emphasized that we were proposing to include them to increase the accuracy of reporting and not because they represent a new cost.

Comment: One commenter opined that CMS is correct to include the costs of all component services and supplies that would be packaged under the proposal for CY 2014; all adjunctive services, including laboratory tests, diagnostic tests and evaluation and management services; DMEPOS for which payment would be made under the OPPS; services reported by therapy codes that would be payable under the OPPS; room and board as reported in room and board revenue cost centers; and cost of hospital-administered drugs (regardless of the route of administration) to ensure that the geometric mean cost upon which the payment for these comprehensive APCs would be based would include all necessary costs of the services. However, several commenters were concerned that CMS did not account for the payments for services proposed to contribute to the comprehensive APC geometric mean costs into the CY 2013 current year payment estimates in budget neutrality calculations, but included these costs in the CY 2014 OPPS payment rate calculations. The commenters pointed out that CMS proposed to include the CLFS payments for laboratory services proposed for packaging in the OPPS current year (CY 2013) total payment amount when calculating budget neutrality adjustments for the prospective payment year (CY 2014), but that CMS apparently did not add payments to the OPPS current year total payment estimate for the adjunctive items and services that would be newly paid under the OPPS through the 29 comprehensive APCs. In short, payment

for newly added services should be added to the total CY 2013 payment level against which CY 2014 payments would be held budget neutral. These commenters defined the additional services that would be newly paid under the OPPS to include durable medical equipment, therapy services, inpatient nursing services, and inpatient room and board for overnight outpatient stays. The commenters further stated that the proposed rule provides no information concerning how this calculation was made and data was not provided to allow the public to review and validate the determination of budget neutrality.

Response: We appreciate the acknowledgement that we correctly identified and included the costs of adjunctive services contributing to these comprehensive OPD services, with the exception of charges on inpatient revenue codes, including room and board revenue codes. We agree with the commenters that we should have included payments for adjunctive services proposed for payment through the OPPS for the first time in the current year budget neutrality calculations as well as in the relative payment weights for the proposed year calculation. In calculating budget neutrality adjustments for CY 2015 we will incorporate modeled payments for services that will be newly included in the comprehensive APCs on both sides of the budget neutrality calculation as we did for those laboratory services that we are packaging for CY 2014.

Comment: Several commenters stated that, although they recognized that changes in assignments in a prospective (average) payment system cause some payments to increase and others to decrease, the commenters were concerned that payment amounts have not been set to appropriately encompass the additional services that will be packaged. Another commenter noted that the shift from limited to comprehensive APCs would be accompanied by wide shifts in payment and questioned whether the changes with the expanded bundles, including occasional decreases, accurately reflected the costs of the additional packaged services. They requested that CMS delay proposed payments for the comprehensive APCs to ensure payment amounts have been set appropriately to include the additional packaged services.

Response: We agree with commenters that, for some services, there was considerable variation in the payment change from an isolated payment for the primary service, a device-related procedure, to a comprehensive payment

for the complete service. There were a number of reasons for this variation. First, services varied considerably with respect to the number and estimated cost of adjunctive services that were typically provided during the same encounter. Some services were almost completely described by the primary HCPCS code with status indicator “J1” with few additional adjunctive services reported in the claims data. Proposed comprehensive payment for these services did not change significantly. Other services, however, appear with many adjunctive services reported in the claims data that became packaged into the comprehensive payment, so the comprehensive payment for those primary HCPCS codes was considerably greater than the payment for the primary service alone.

Second, comprehensive payments allow us to use almost all of the claims for the primary service, rather than using a smaller subset of claims that have a single major procedure and no other significant procedures. We believe that this methodology provides much more accurate cost estimates for these comprehensive services, including incorporating the cost of all adjunctive services proportional to their presence on claims reporting comprehensive services into our final APC relative payment weight calculation. Our adoption of the geometric mean-based methodology rather than the median-based methodology to establish relative payment weights finalized in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68229 through 68233) ensures that the final APC relative payment weight captures the complete spectrum of estimated geometric mean costs of procedures reported on claims and assigned to that APC. We recognize that the magnitude and direction of the change in payment from current OPPS payment structure for more granular payment for individual services to the proposed single comprehensive APC payment for the primary service and its adjunctive services varied from primary service to primary service. In a few instances, the relative geometric mean cost of the entire comprehensive service was less than the geometric mean cost of the primary service alone. We believe that this is largely attributable to the improved accuracy of our ratesetting process. Under our traditional ratesetting methodology, we attempt to identify a cost for each separately payable service from our claims data. We use many strategies to use as much claims data as possible, but we cannot use all claims to estimate the APC

geometric mean cost underpinning the relative payment weight. Comprehensive APCs allow us to use almost all of the claims for the primary service to calculate the geometric mean cost and the comprehensive APC to which the primary service is assigned.

Finally, we note that we reassigned some procedures described by HCPCS codes assigned to status indicator “J1” to different comprehensive APCs based on public comments that we received. Also in response to public comments that we received, we are finalizing a methodology for identifying complex subsets of the procedures reported in combination with the primary service that contain multiple device-dependent procedures and require greater resources, and we are reassigning these complex cases to a higher level comprehensive APC. We believe that reassigning claims for complex forms of the primary procedure to a higher level APC within the same clinical family directly addresses commenters’ concerns regarding recognizing the additional cost of ancillary services in complex procedures and improves the relative accuracy of the final OPPS payment for the primary service.

Comment: Several commenters questioned whether outlier payments would be adequate under the OPPS as the new comprehensive APCs are formed and packaging is expanded. The commenters noted that under the IPPS outlier payments are set at 5.1 percent of total payments, compared to 1 percent under the OPPS, and costs reported above the outlier threshold under the IPPS are paid at 80 percent compared to 50 percent under the OPPS. One commenter suggested that CMS increase outlier payments for comprehensive APCs, while another commenter suggested that outlier payments are an issue that CMS should examine and perhaps should have examined prior to advancing new packaging policies.

Response: Although we did not propose a change in outlier payments, we will consider whether we should expand our current outlier payment policy. Section 1833(t)(5)(C) of the Act specifies that the estimated total of additional payments for outliers cannot exceed 3 percent of estimated total program payments in that year. Currently, we allocate 1 percent of total program payments to outlier payments each year. Overall, we believe that the current structure of the OPPS, which continues to make separate payment for most services, does not create the same financial risk for individually costly cases as IPPS payment through MS-DRGs, for example. Further, we are not

sure an expansion to our outlier payment policy is necessary because we believe that our final policy to reassign claims for complex forms of primary services to higher level APCs reduces financial risk associated with comprehensive APC payment.

• Impact on APCs

Impact on Composite APCs. There is currently one device-dependent composite service under the OPPS, cardiac resynchronization therapy, which is assigned to APC 0108. Because a comprehensive APC will treat all individually reported codes as representing components of the comprehensive service, all of the elements of the composite service are included in the new comprehensive service. Therefore, cardiac resynchronization therapy will no longer be identified as a composite service, but will be identified as a comprehensive service. All services currently assigned to APC 0108, including cardiac resynchronization therapy services, were assigned to the new comprehensive APC in our CY 2014 proposal.

Comment: Several commenters noted that, whereas we proposed making APC 0085 (Level II Electrophysiologic Procedures) a comprehensive APC, we did not discuss composite APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite), which also would be absorbed by the new comprehensive APC policy. The commenters also noted that they believed that CMS calculated an APC geometric mean cost and payment rate based on the same set of claims for both APCs.

Response: We stated that cardiac resynchronization therapy services (assigned to APC 0108 Cardiac Resynchronization Therapy) would no longer be identified as a composite service because it would be incorporated into a comprehensive service. However, we did not state in the proposed rule that the same situation existed in terms of APC 8000. Commenters are correct that the same principle applies. Because one of the components of the composite service is assigned a procedure assigned to status indicator “J1,” all of those claims reporting these services would trigger the comprehensive payment policy that we are finalizing with modification in this final rule with comment period. Commenters also are correct that in the proposed rule, we incorrectly assigned procedures to both APCs and calculated geometric mean costs and relative payment weights based on the same set of claims. We will reassign the previous

status indicators for procedures assigned to APC 8000 from “S” and “T” to status indicator “J1” for CY 2015, and we will make a comprehensive APC payment for cardiac electrophysiologic evaluation and ablation services.

Impact on Claims Used to Calculate Other APCs. Some of the costs reported on claims for device-dependent procedures may no longer be available to contribute to the calculations for other services through the pseudo-single process described in section II.A. of this final rule with comment period. However, the loss of usable cost data for these services will not create a significant impact on other APCs because most of these services currently cannot be isolated as the “single services” that can be used in the cost calculation process. The exceptions are services such as EKGs and chest x-rays that occur in very high frequency across all types of encounters, and laboratory services and drugs, neither of which are calculated based on average cost. Finally, it is also important to note that the impact associated with the loss in usable claims data is lessened when assessing the benefit of more accurate cost calculations and ratesetting that will be achieved from the use of 400,000 new claims that can now be used for these purposes because of the establishment of the comprehensive APCs.

Impact on Device-Dependent APCs. The impact on current device-dependent APCs is described above in section II.A.2.d.(1) of this final rule with comment period. Comprehensive APC geometric mean costs generally exceed the device-dependent procedure geometric mean costs by an average of 11 percent, less than \$1,000 per claim. The direct cost contribution of other adjunctive OPPS services accounts for most of this increase, with laboratory tests contributing approximately \$18 per claim (a 0.1 percent increase) and other adjunctive covered outpatient services (not currently paid under the OPPS) contributing an additional \$18 per claim. There is significant variation across comprehensive APCs, however, not only because the distribution of adjunctive services varies, but also because the larger bundles allow a more complete incorporation of packaged costs. Finally, the use of comprehensive APCs would allow the number of claims used to estimate costs for these services to almost triple from 233,000 to 649,000, increasing the accuracy of our relative cost estimates.

Comment: Several commenters were concerned about hospitals’ willingness to consider new technologies, which can be costly. The commenters

expressed concern that this proposal would impact device pass-through payment, New Technology APC provisions, and payments for device-dependent APCs. The commenters also were concerned that packaging is likely to limit the data available for future OPPS updates because the commenters believed that hospital reporting would be less accurate if there were no payment consequences for omitting a device on the claim and that the sunset of device edits would reduce the reliability of the data provided for payment calculations for the same reason. The commenters also were concerned that future potential pass-through device categories may be disadvantaged because pass-through eligibility includes demonstrating costliness relative to several thresholds based on APC payment. Specifically, the commenters were concerned that fewer device categories would be eligible for pass-through payment because fewer device categories would exceed a new higher threshold as a percent of the APC payment amount as payment increases with expanded packaging. Some commenters requested that CMS continue to apply the procedure-to-device and device-to-procedure edits. One commenter asserted that hospitals do not find these edits to be burdensome, that the edits are a useful flag for accurate charging and that, if it is eliminated, providers could fail to report device charges completely.

Response: We do not agree with commenters that comprehensive APC payment will inhibit adoption of new technology. We have not proposed any changes to the New Technology APCs or device pass-through payment provisions and we discuss these payment policies in sections II.A.2.d.(1) and I.B. of this final rule with comment period. These processes for supporting new technologies will continue. New Technology APCs are reserved for new services that are not eligible for transitional pass-through payments for a device, drug, or biological, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group. Our proposed policy does not impact our New Technology APC policy, and our determination of new technology eligibility is not dependent on a particular cost threshold.

With regard to pass-through payment eligibility, we agree with the commenters that comprehensive APCs will create expanded bundles and generally higher payment from which the dollar value of the various cost thresholds that are part of the pass-through eligibility process will be

determined. The specific cost thresholds used in determining eligibility of a new device pass-through category are listed in 42 CFR 419.66(d). For CY 2015, payment for device-dependent procedures through comprehensive APC payment will create a higher costliness threshold against which new device categories interested in pass-through status must demonstrate costliness. We believe that the statutory construction of the OPPS envisions the relative cost of services to vary over time as services are redefined, recoded, and reassigned among APCs, and as new claims and cost report data become available, which would raise or lower the cost threshold for pass-through payment eligibility under section 1833(t)(6)(A)(iv)(II) of the Act. We estimate that, for CY 2014, the inclusion of additional adjunctive packaged services, in aggregate, account for approximately 11 percent of the cost of these device-intensive services. Relative payment weights for device-related procedures can change by this amount each year due to annual recalibration. As we implement the comprehensive APC payment policy in CY 2015, we will monitor the impact of eligibility for device pass-through payments for a change in the percent of potential device categories failing to clear the current cost threshold criteria.

We also believe that that expanded payment bundles encourage adoption of new technologies by giving hospitals more flexibility over how they deliver a particular service and creating more opportunities for hospitals to make tradeoffs to absorb the cost of improved devices. As we discuss in section II.A.2.d.(1) of this final rule with comment period, we plan to continue our historical device editing in CY 2014. Also as indicated in that section, we are further assessing whether we need to continue claims processing edits requiring a device HCPCS code to be reported on the claim when we implement the comprehensive APCs policy in CY 2015.

• Impact on Beneficiary Payments

Under the comprehensive service APCs, instead of paying copayments for a number of separate services that are generally, individually subject to the copayment liability cap at section 1833(t)(8)(C)(i) of the Act, beneficiaries can expect to only pay a single copayment that is subject to the cap. This will likely reduce beneficiary overall liability for most of these claims.

Comment: Several commenters agreed with CMS that, due to the inpatient deductible cap on beneficiary copayments, net beneficiary

coinsurance would decrease under the proposed change. One commenter was concerned that beneficiary out-of-pocket costs may still be higher for any individual beneficiary. The commenter was particularly concerned that new cost-sharing with beneficiaries for laboratory services would be contrary to statute and congressional intent. The commenter objected to a proposal that would impose new beneficiary cost-sharing requirements in order to cut total projected Medicare spending for outpatient services.

Response: We believe that this proposal decreases the liability for almost all beneficiaries receiving primary procedures assigned to comprehensive APCs in CY 2015 because the inpatient deductible cap, mandated by statute to apply to single services, will now apply to the entire hospital claim, as it is now considered a single service or procedure. We agree with the commenters that there may be some isolated beneficiaries who may have a higher beneficiary liability than they would have had we not proposed comprehensive APCs. In many instances, and for these device-related procedures in particular, beneficiaries will no longer make copayments for individual ancillary services. Because the device insertion procedures that we have proposed as comprehensive services are universally very expensive, the cap will apply to the majority of claims reporting services assigned to comprehensive APC. We received many public comments on our proposal to package laboratory services and address those comments and concerns in our discussion of that final policy in section II.A.3.c.(3) of this final rule with comment period.

• Impact on Specific APCs

In conjunction with our proposed rule, we published Addendum B, which identified specific proposed comprehensive payments associated with HCPCS codes proposed for assignment to status indicator “J1” under the proposed comprehensive APC payment policy. We identified the 29 device-dependent APCs proposed for comprehensive APCs and assigned HCPCS codes based on their prior APC assignment. Most of the public comments that we received were specific to certain HCPCS codes, certain APCs, or certain families of services.

Although we are not implementing this final comprehensive APC payment policy until CY 2015, to address concerns by some commenters that they could not fully model the proposal, we provide all of the information we would use to create a relative payment weight

for CY 2014 using the CY 2012 claims data in order to illustrate the final comprehensive APC methodology. We summarize and respond to the public comments on individual services in this section, as if we were implementing this policy for CY 2014, grouped by those families of services below. We will recalibrate all of the comprehensive APC relative payment weights for CY 2015 using CY 2013 claims data, consistent with our annual recalibration of APC relative payment weights, to reflect the most recently available claims and cost information in next year's rulemaking cycle.

Comment: With reference to the neurostimulator family of APCs, APCs 0039, 0041, 0061, and 0318, one commenter was concerned that the CY 2014 proposal would broadly decrease payments for neurostimulator insertions. Other commenters believed that total payments would remain approximately the same, but also believed that the spread of costs within a given APC was too great when certain combinations of devices were used. Commenters argued that there is a vast difference in supply (device) costs between a battery or generator replacement and a paddle lead implant or even a percutaneous lead implant. Commenters argued that bundling all of the different variations of neurostimulator implants into one comprehensive payment could create an unintended incentive to use less effective single leads and to increase the number of device replacements and revisions, which could potentially limit the therapeutic effectiveness for patients with complex pain syndromes.

With respect to leads, commenters stated that payment for dual lead trials would be decreased by nearly 40 percent, while single lead trials would be increased by 25 percent, encouraging single lead trials. Similarly, the payment for the initial dual lead implant would decrease by 16 percent. The commenter asserted that this policy may reverse the common clinical practice of dual lead trials for the majority of patients and create a financial incentive to reduce the number of leads used for permanent implants, increasing the need for additional lead placements at a later time, which would result in an increase in readmissions and possible increase in adverse events and complications.

Additionally, commenters believed that this proposal could create incentives to use shorter life devices such as non-rechargeable devices, requiring more frequent replacement procedures in future years. The commenters stated that on the one hand, providers would have a financial

incentive to use less expensive devices initially. However, the commenter further stated that on the other hand because CMS is proposing to increase the generator replacement payment rate by 29 percent, providers could be encouraged to use shorter life devices that may require more frequent replacements with a consequent increase in Medicare spending and beneficiary cost sharing.

Commenters proposed a number of modifications to address these issues, including the creation of composite APCs to pay appropriately for the combination of devices provided to an individual patient. The commenters recommended that CMS retain the existing single component APCs for use when only one component (that is, a generator or an array) is implanted or replaced, and create two new composite APCs that reflect different combinations of components—pulse generator and one array and pulse generator and two or more arrays. Alternatively, the commenters recommended Comprehensive APC 0318 (Implantation of Neurostimulator Pulse Generator and Electrode) as the appropriate assignment for most complete neurostimulator systems procedures because it is already used to describe complete cranial nerve and vagus nerve systems procedures. Several commenters recommended maintaining a differentiation between laminectomy lead implants and percutaneous implants, and between spinal systems and sacral systems.

Response: We do not agree with the commenters who are concerned that we are underestimating payments for neurostimulators. We believe that by using all claims for these services, instead of the much smaller subsets of single claims that we used for our device-dependent methodology, any adjustments in the payments for specific services represent a more accurate estimation of relative resources required for the primary service than past estimates. We also note that by estimating the total cost of the procedure by packaging all charges reported on the claim, we ensure that all of the estimated costs of all of these services contribute to the cost estimation for the neurostimulator procedure. Our methodology for identifying single claims, which is designed to isolate the unique costs associated with a specific service, makes some assumptions about assigning packaged costs to individual services. However, we agree with the commenters who were concerned that complex procedures such as those characterized by multiple units and multiple comprehensive components have a wide

variation in comprehensive costs and that the geometric mean cost of these subsets is often materially greater than the geometric mean cost of all claims that include both simple and complex versions of the procedure. We agree with the commenters that delivery of these complex services could potentially be impacted under our proposed comprehensive APC payment policy.

Specifically, we agree with the commenters that procedures that implant individual elements of device systems, such as a generator without leads, may have significantly different costs than procedures that implant entire systems. We also agree with the commenters that there may be significant resource differences between individual elements of neurostimulator systems, such as transcutaneous leads and implanted paddles, and between different systems, such as epidural systems and sacral systems. These differences may then be reflected in the variation in the estimated geometric mean costs of the comprehensive service due to different combinations of component services. Therefore, we are accepting the commenters' suggestions and we would reconfigure these APCs to better separate procedures for individual elements of neurostimulator systems from procedures in which the entire system is implanted, and to more closely align relative resource requirements of complex subsets of the service with the corresponding payment for that subset if we were implementing this comprehensive APC policy in CY 2014.

Once we reassign complex claims for a primary service to a higher level APC, as we discuss below, we believe that many of the concerns raised by the commenters would be directly addressed, and therefore, we do not believe that we should not consider these procedures for a comprehensive APC assignment in CY 2015. We believe that hospitals understand that under a prospective payment system the cost of providing care to individual patients may vary relative to the payment amount, which is one hallmark of a prospective payment system. We are comfortable implementing comprehensive APCs for neurostimulators in CY 2015 with variance in the geometric mean costs of individual services that are comparable to the variance we see in estimated hospital costs for traditional, discrete, noncomprehensive services.

To implement the commenters' suggestions we would use the four techniques described above to reassign claims for complex forms of the primary

service to higher level APCs. We have analyzed the claims in which multiple units or multiple HCPCS codes assigned to status indicator “J1” are present and have divided individual services into simple and complex services, with complex services characterized by complete systems, multiple components or other associations that correlate with high resource requirements (high cost). We are adopting the basic suggestion of differentiating between partial systems and complete systems, and we plan to use the claims data to group clinically similar, high-volume, complex procedures into APCs with similar costs in CY 2015. In this final rule with comment period, we invite commenters to apply the analysis, methodology, and the payment estimation techniques presented here to specific neurostimulator services and to provide comment on these illustrative CY 2014 reassignments of complex neurostimulator claims.

Changes to implement the commenters’ suggestions and concerns for CY 2014, if we were implementing this policy for CY 2014, for this neurostimulator family of APCs are as follows:

- **APC Redesignations:** We would eliminate APC 0315, and we would rename APC 0039 and APC 0318.
- **APC Reassignments:** We would reassign CPT codes 43647 and 63655 from APC 0061 to APC 0039; CPT code 0268T from APC 0039 to APC 0040; CPT codes 63664 and 64553 from APC 0040 to APC 0061; and CPT code 61886 from APC 0315 to APC 0318.
- **Complexity Reassignment:** We would reassign certain HCPCS code combinations that occur with CPT codes 0282T, 61885, 63650, 63663, 63685, 64555, and 64590 as complex forms of the primary service. We summarize all of the codes that we would reassign as complex forms of their primary procedure in Table 10 as if we were implementing this policy in CY 2014.

We request comment on these specific HCPCS code movements and complex claim reassignments. We will reassess the application of this policy to this neurostimulator family of APCs with CY 2013 claims data for CY 2015 implementation, and we will update them based on new claim and cost report data and any relevant new CY 2015 codes through next year’s rulemaking cycle.

Comment: With reference to the endovascular family of APCs, APCs 0082, 0083, 0104, 0229, 0319, and 0656, one commenter was supportive of the approach to further integrate the payment methodologies for the inpatient and outpatient systems in this

case and agreed that patients who receive the major services contained within the 29 comprehensive APCs are unlikely to be receiving unrelated services on the same day. The commenter urged CMS to monitor the effects of this new system to ensure that patients continue to receive access to the most appropriate care. Other commenters were generally supportive of the approach, but believed that there were specific reasons for not applying comprehensive status to the endovascular family APCs, for delaying the implementation for these comprehensive APCs, or for modifying payments within the family. One commenter specifically was concerned about a substantial decline in payment for APC 0083 (Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization of the Lower Extremity).

Commenters noted that for CY 2011, 16 new HCPCS codes were implemented to create comprehensive codes for endovascular treatment in the lower extremity arterial territories; for CY 2013, new base and add-on codes were created for coronary artery interventions; and four new comprehensive endovascular codes will be added for CY 2014. Several commenters objected to the creation of any comprehensive APCs using any CPT codes that are less than 3 years old, as they believe the data is not yet reliable.

Several commenters noted that the existing OPPS payment structure for coronary and peripheral revascularization procedures (angioplasty and stent placement) is component-based, providing separate but often reduced APC payments for each clinical aspect of the revascularization service, which are frequently assigned a status indicator of “T” (multiple reduction applies). Commenters argued that the clinical scenarios for revascularization procedures are based on each beneficiary’s unique clinical needs, making them incredibly complex with required resources varying significantly from patient to patient. Given this complexity, one commenter opined that coronary and peripheral revascularization procedures are ill-suited for comprehensive APCs because this type of payment structure is unable to capture the differences in hospital resources associated with the differences in revascularization services offered to patients. A few commenters believed that the proposal will inevitably give hospitals an incentive to use less expensive items and less extensive procedures even if those items will increase program costs as a whole

and carry greater risk for beneficiaries. In a specific example, one commenter was concerned that all cardiac magnetic resonance imaging and other imaging studies within a 30-day period would be bundled into payment for the comprehensive APC, discourage the use of appropriate imaging modalities, and result in cost as the driving factor in patient access to needed medical imaging services.

Finally, another commenter believed that comprehensive APCs for stent placement procedures would allow a few patients receiving all the possible components of the bundle to experience a lesser hospital outpatient copayment amount, but would cause many beneficiaries to pay for services that they have not received and do not need.

Response: We appreciate the commenters’ support for our conclusion that beneficiaries receiving these major services are unlikely to be receiving unrelated services on the same day, and we appreciate commenters who were generally supportive of our intent to create comprehensive packages. We recognize that there has been recent change in the coding and billing of many of these endovascular procedures, but we believe that hospitals prepare to adopt new codes each year and establish a charge relative to the best cost information available to them. We use estimated costs from claims data as soon as it becomes available to establish APC relative payment weights generally, and we have no reason to believe that continuing that practice for comprehensive APCs is not appropriate. With respect to the comments concerning APC 0083, for example, we note that the estimated hospital costs for the procedure alone did not change significantly between CY 2011 and CY 2012, and that the proposed comprehensive service geometric mean cost was approximately 10 percent higher than the single procedure geometric mean cost, a ratio that is comparable to the average aggregate increase in cost for the additional ancillary services observed across all proposed comprehensive services, indicating continued stability in the relative cost estimations despite changes to a methodology that now aggregates all estimated costs reported on each claim before calculating a geometric mean cost.

However, we agree with the commenters that endovascular procedure coding has historically been component based. In general, commenters argued that multi-vessel endovascular procedures have different resource requirements than single-vessel procedures. We agree with the

commenters that there is a correlation between the number of vessels treated and hospital costs. However, we also observe that there are a variety of endovascular procedures where the geometric mean costs of some single-vessel procedures are similar to the geometric mean costs of other multi-vessel procedures. Nonetheless, we generally agree with the commenters that the range of estimated costs for any individual HCPCS code or HCPCS code combination is wide, with considerable overlap occurring across primary service codes and code combinations. We agree that, in general, payments for multiple vessel services should be adjusted to account for higher complexity and resources when those higher resources are reflected in our claims data.

To model commenters' suggestions for illustration purposes in CY 2014, we have used the techniques described above to reassign claims for certain high-cost, complex versions of the primary service, primarily multiple vessel endovascular procedures. We analyzed the claims in which multiple units of a primary service or multiple HCPCS codes assigned to status indicator "J1," including the primary service, are present. We divided individual services into simple and complex services, with complex services characterized by multiple components, multiple vessels, or other associations that correlate with high resource requirements (high cost). For our CY 2014 illustration, we are adopting the basic suggestion of differentiating between single vessel and multiple vessel procedures, and we are using the claims data to group clinically similar, high-volume, complex procedures into APCs with similar costs. In this final rule with comment period, we invite commenters to apply the analysis, methodology, and the payment estimation techniques presented here to specific endovascular services and to provide comment on these illustrative CY 2014 reassignments of complex claims for endovascular services.

Changes to implement the commenters' suggestions and concerns for CY 2014, if we were implementing this policy for CY 2014 for this endovascular family of APCs are as follows:

- **APC Redesignations:** We would delete APC 0082 and reassign its services to other APCs. We would create a new APC, APC 0445 (Level III Endovascular Procedures). We would rename APCs 0083, 0104, 0229, 0319, and 0656.
- **APC Reassignments:** We would reassign CPT codes 37229, 37230 and

92995 from APC 0082 to APC 0445; CPT codes 92984, 92987, 92990, and 92997 from APC 0083 to APC 0104; and HCPCS code G0291 from APC 0656 to APC 0319 (for the purpose of estimating geometric mean costs from CY 2012 claims data used for CY 2014 ratesetting).

- **New HCPCS Codes:** The comprehensive APC assignments that we would make for new HCPCS codes for this family are listed in Table 9. The new codes in this family would include CPT codes 37236, 37237, 37238, 37239, 37241, 37242, 37243, 37244, 92920, 92921, 92924, 92925, 92928, 92933, 92934, 92937, 92938, 92941, 92943, 92944, and HCPCS codes C9600, C9601, C9602, C9603, C9604, C9605, C9606, C9607, and C9608.

- **Complexity Reassignments:** We would reassign certain HCPCS code combinations that occur with HCPCS and CPT codes 0238T, 35471, 35475, 35476, 37204, 37205, 37220, 37221, 37224, 37225, 92920, 92928, 92933, 92941, 92943, 92980, 92981, 92982, 92995, C9600, C9602, C9604, C9606, C9608, G0290, and G0291. We summarize all of the codes that we would reassign as complex forms of their primary service in Table 10 as if we were implementing this policy in CY 2014.

We request comment on these specific HCPCS movements and complex claim reassignments. We will reassess the application of this policy to this endovascular services family of APCs with CY 2013 claims data for CY 2015 implementation, and we will update them based on new claims data and any relevant new CY 2015 codes through next year's rulemaking cycle.

Comment: Commenters generally did not object to the creation of comprehensive APCs for cardiac electrophysiology (EP) studies and one commenter specifically supported the proposal. However, commenters were confused and concerned about the impact of comprehensive APCs on payment for certain ablation procedures when performed in conjunction with EP studies. In the proposed rule, we discussed the creation of comprehensive APCs for EP studies, applying our proposed methodology in which all adjunctive services, with a few exceptions already discussed, reported on the claim are packaged into the payment for the primary service, which is based on the average comprehensive cost of those claims. However, we also inadvertently included a discussion of the continued existence of composite APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation), a composite payment based on the performance of an

ablation procedure with an EP service. Claims containing HCPCS codes for both an ablation and an EP study would, therefore, meet the criteria for the composite, but would also meet the criteria for comprehensive APC 0085 (Level II Electrophysiologic Procedures), understandably generating reader confusion and causing commenters to ask how any services would be paid as composite APC 8000 services when they would all be subsumed under comprehensive APC 0085. We also believe that we added to this confusion by initially including some claims and estimated costs in the cost calculation of both APC 8000 and APC 0085, duplicating the reporting of composite APC 8000 claims and causing some statistics for the two APCs to be incorrect. Moreover, we also were not consistent in our application of status indicators or in our treatment of EP-ablation composites that for CY 2013 were reported with new CPT codes.

Commenters proposed several alternatives to our proposed treatment of EP studies and ablations but all of the alternatives involved differentially paying for ablation procedures when those procedures were performed in conjunction with EP procedures. One commenter recommended retaining one of the remaining ablation codes, CPT code 93650 (Ablate heart dysrhythm focus), as a status indicator "Q3" codes that may be paid through a composite APC when not conditionally packaged. Noting that a status indicator of "Q3" would have the same packaging effect as including it in the comprehensive package as proposed, we believe this commenter intended to recommend a higher payment for EP procedures performed with an ablation, such as would occur when the two codes would determine a composite APC assignment. Another commenter expressed concerns that CPT code 93620 (Electrophysiology evaluation) was also listed with a status indicator of "Q3" but assigned to comprehensive APC 0085. Commenters requested that we clarify the intended treatment of EP and ablation services, differentially pay for the lower costs of EP studies performed alone relative to the higher costs of EP-ablation procedures, and create a consistent treatment of services within these sets of codes.

Response: We agree with the commenters that our proposed rule provisions were not consistent in regard to our treatment of the electrophysiology-ablation procedures as composite services and as comprehensive services. We also agree with the commenters that there are significant differences between

estimated costs of EP studies and estimated costs of EP-ablation procedures, and that the costs of services reported with EP-ablation combination codes are similar to the costs of single EP-ablation services assigned to composite APC 8000. For CY 2015, we intend to modify our proposal to create a separate comprehensive APC for new CY 2013 HCPCS codes that represent an EP study procedure with ablation, and we also intend to identify combined EP-ablation services reported with multiple HCPCS codes as a complex form of EP services and reassign them to a higher level APC. Finally, we also intend to delete composite APC 8000 as we move payment for these services under the comprehensive APC payment policy. In this final rule with comment period, we invite commenters to apply the analysis, methodology, and the payment estimation techniques presented here to specific EP services and to provide comment on these illustrative CY 2014 reassignments of complex claims for EP services.

Changes to implement the commenters' suggestions and concerns for CY 2014, as if we were implementing this policy for CY 2014, for this set of electrophysiologic evaluation and ablation APCs are as follows:

- **APC Redesignations:** We would redesignate composite APC 8000 as comprehensive APC 0444 (Level III Electrophysiologic Procedures).
- **New codes:** We would reassign CPT codes 93653, 93654 and 93656 from APC 8000 to APC 0444.
- **Complexity Reassignments:** We would reassign HCPCS codes 93619 and 93620, in combination with CPT code 93650, as complex forms of the primary EP service, and we would reassign those claims to APC 0444. For purposes of modeling the policy for CY 2014, we treated claims previously assigned to composite APC 8000 as complex forms of the primary service. We summarize all of the codes that we would reassign as complex forms of their primary procedures in Table 10 as if we were implementing this policy in CY 2014.

We request public comment on these specific HCPCS movements and complex claim reassignments. We will reassess the application of this policy to this set of electrophysiologic evaluation and ablation APCs with CY 2013 claims data for CY 2015 implementation, and we will update them based on new claims data and any relevant new CY 2015 codes through next year's rulemaking cycle.

Comment: In addition to the general comment that CMS should ensure that

complex (multiple device) procedures are not inappropriately grouped with single device insertions, there were several public comments regarding the pacemaker-defibrillator family of services, APCs 0089, 0090, 0106, 0107, 0108, 0654, 0655, and 0674. With the exception of public comments on cardiac resynchronization therapy (CRT), these comments dealt with general issues such as the difficulty in modeling the impacts of payment changes based on the information provided in the proposed rule and are discussed elsewhere in this final rule with comment period. Currently, we pay for CRT services through composite APC 0108 (Level II Implantation of Cardioverter-Defibrillators (ICDs)) based on the geometric mean costs of procedures reported on claims with a specific set of codes describing the parts of this composite service (77 FR 68258). Our proposal for comprehensive payment would have subsumed the need for a composite APC in CY 2014. One commenter requested that CRT services continue to be paid based on the geometric mean cost of the composite service rather than based on the geometric mean cost of all services furnished with multiple lead pacemakers or defibrillators that would occur with both our proposal to package procedures described by add-on codes and the comprehensive APC policy.

Response: We agree with the commenters that complex forms of certain services, generally characterized by combinations of codes in which components were separately reported in order to describe the delivery of an entire pacemaker or defibrillator system, have different resource profiles from simple procedures that implant system components or certain simple devices. We agree that CRT services are one of the most costly subsets of pacemaker implantation services but that other complex combinations of codes also exist. However, as part of the process of converting these APCs to comprehensive APCs, we noted that the comprehensive geometric mean cost of these services differed considerably, in some cases, from our estimates of the primary service calculated through our traditional single bill methodology and these new cost estimates suggested reassigning codes among the family of pacemaker APCs in order to increase resource homogeneity. These reassignments also suggested renaming or restructuring APCs as necessary. We found these reassignments would reduce much of the cost to payment variance.

Therefore, in response to public comments we received, we would

modify our proposal to establish comprehensive payments for pacemaker related services. We would realign the APCs by moving primary services subject to our standard 2 times rule methodology. In addition, we have identified a number of HCPCS combinations that represent high volume, high cost, more complex subsets of the primary service, and we would reassign those claims to a higher level APC. We note that our decision to finalize this proposed comprehensive APC policy with modification in this final rule with comment period, but to delay implementation of the policy until CY 2015 creates the opportunity for the public to further review the illustrative reconfigurations of comprehensive APCs that we would make in response to comment. In this final rule with comment period, we invite commenters to apply the analysis, methodology, and the payment estimation techniques presented here to specific pacemaker services and to provide comment on these illustrative CY 2014 APC configurations, APC assignments, and complexity reassignments.

Changes to implement commenters' suggestions and concerns for CY 2014, if we were implementing this policy for CY 2014, for this pacemaker-defibrillator family of APCs are as follows:

- **APC Redesignations:** We would rename APC 0089 "Level III Insertion/Replacement of Permanent Pacemaker," and we would rename APC 0106 "Insertion/Replacement of Pacemaker Components."
- **APC Reassignments:** We would reassign CPT code 33217 from APC 0106 to APC 0090; CPT code 33229 from APC 0645 to APC 0655; CPT code 33231 from APC 0107 to APC 0108; CPT codes 33208, 33214, and 33224 from APC 0655 to APC 0089; and CPT code 33221 from APC 0654 to APC 0089.
- **Complexity Reassignments:** We would reassign certain combinations of the following CPT codes 33206, 33207, 33208, 33210, 33212, 33213, 33216, 33224, 33227, 33228, 33230, 33240, 33263, and 33264 as complex forms of the primary pacemaker-defibrillator service. We summarize all of the codes that we would reassign as complex forms of their primary procedures in Table 10 as if we were implementing this policy in CY 2014.

We request comment on these specific HCPCS movements and complex claim reassignments. We will reassess the application of this policy to this pacemaker-defibrillator family of APCs with CY 2013 claims data for CY 2015 implementation, and we will update them based on new claims data and any

relevant new CY 2015 codes through next year's rulemaking cycle.

Comment: Several commenters requested that CMS not designate APC 0202 (Level VII Female Reproductive Procedures) as a comprehensive APC. The commenters opined that, as opposed to the stated description of comprehensive APCs, APC 0202 does not contain a single major procedure with relatively small cost contributions from adjunctive services but contains independent services that are frequently performed in combination with each other. Commenters also noted that CMS is currently achieving payment efficiencies for these concomitant procedures by reducing the payment for any second procedure to 50 percent even when that second procedure contains an additional medical device. The commenters stated that when multiple services are performed together under a comprehensive payment, the averaged payment assigned to the APC may be significantly less than the cost of the individual services performed. The commenters believed that this may encourage some hospitals to delay or stage procedures inappropriately, increasing overall Medicare costs and potentially threatening patient access to certain devices.

One commenter believed that APCs 0385 (Level I Prosthetic Urological Procedures) and 0386 (Level II Prosthetic Urological Procedures) similarly would have sizable reductions in Medicare payments that could create significant disincentives for hospitals to perform certain procedures that utilize medical devices. Another commenter believed that this result also applied to APC 0674 (Prostate Cryoablation).

Response: We do not agree with the commenters that these APCs represent a different class of services. All of the services described by the HCPCS codes in these APCs represent major surgical procedures where the encounter can be viewed as a single primary service and where a beneficiary would view the encounter globally. What commenters are describing as unrelated procedures are individual components of a single surgical procedure, which is, in turn, the primary reason for the encounter. CPT codes are designed by physicians to facilitate reporting of variation in physician work and, as a result, often describe individual components of services that can be grouped in various ways. However, from a hospital payment perspective, many of those component codes are ancillary to or supportive of a primary service. For example, during a procedure to repair the urogenital tract the surgeon may report CPT code 57265 (Extensive repair

of vagina) along with CPT code 57288 (Repair bladder defect), but these individual physician services are both part of the comprehensive surgical repair procedure. In the proposed rule, we proposed defining the most costly component of a comprehensive service as the primary service that determines the APC assignment and final payment of the service, and we believe that this methodology remains appropriate for these services.

We agree with the commenters generally and that, with respect to these reproductive surgery APCs specifically, there are some instances of commonly performed clinically coherent combinations of HCPCS codes assigned to status indicator "J1" that are associated with high estimated cost and sufficient volume, and we would designate these procedures as complex subsets of these primary services eligible for reassignment to a higher level APC if we were implementing this policy in CY 2014. We would have applied this methodology along with other techniques described above for CY 2014 in order to facilitate the transition from discrete incremental payments to a single comprehensive payment for the entire service. For APCs 0385, 0386, and 0674, as well as APC 0202, we also identified several combinations of HCPCS codes that represented common, costly subsets of services and we would reassign several HCPCS codes to different APCs to reduce the variance between the geometric mean estimated cost of the complex services and geometric mean cost of the APC to which the services would be assigned. In this final rule with comment period, we are inviting commenters to apply the analysis, methodology, and the payment estimation techniques presented here to specific reproductive services and to provide comment on these illustrative CY 2014 reassignment of complex reproductive services claims.

Changes to implement the commenters' suggestions and concerns for CY 2014, if we were implementing the policy for CY 2014, for this urogenital procedures family of APCs are as follows:

- **APC Redesignations:** We would rename APC 0385 "Level I Urogenital Procedures"; APC 0386 "Level II Urogenital Procedures"; and APC 0674 "Level III Urogenital Procedures".
- **APC Reassignments:** We would reassign CPT code 53445 from APC 0386 to APC 0674; CPT code 55873 from APC 0674 to APC 0385; and CPT code 57423 from APC 0202 to APC 0385.
- **Complexity Reassignments:** We would reassign certain combinations of CPT codes 54405, 57265, 57282, and

57285 as complex forms of the primary service. We summarize all of the codes that we would reassign as complex forms of their primary procedures in Table 10 as if we were implementing this policy in CY 2014.

We request comment on these specific HCPCS movements and complex claim reassignments. We will reassess the application of this policy to this urogenital procedures family of APCs with CY 2013 claims data for CY 2015 implementation, and we will update them based on new claims data and any relevant new CY 2015 codes through next year's rulemaking cycle.

Comment: One commenter noted that APC 0082, a cardiovascular APC, includes CPT code 37204 (Transcatheter occlusion), which is occasionally used to report brachytherapy for liver therapy. The commenter believed that packaging yttrium in the cost of APC 0082 would be in conflict with section 1833(t)(2)(H) of the Act, which requires separate payment for brachytherapy.

Response: We agree with the commenters that the statute specifies that brachytherapy devices (seeds) shall be classified separately under the OPPS from other services. Because brachytherapy devices could be used during some encounters to deliver comprehensive services, we will modify our proposal to state that brachytherapy devices, like mammography and ambulance services, will not be included in the comprehensive payments beginning in CY 2015 and will continue to receive separate payment.

Comment: One commenter stated that CMS should not consider APC 0227 (Implantation of Drug Infusion Device) to be a comprehensive APC because the drug that is used to fill the reservoir is not part of the comprehensive service. The commenter stated that the drug that is used to fill the pump should not be considered adjunctive because the drug itself is therapeutic and separate and apart from the implantation of the primary (pump) service. This commenter believed that therapeutic drugs in general should be excluded from a comprehensive APC payment and expressed concern that packaging may decrease hospital use of costly drugs, such as PRIALT, which is a non-narcotic alternative. Another commenter stated that CMS should provide greater data transparency if it decides to move ahead with the inclusion of DME items within a comprehensive APC. The commenter was concerned that there will be a decrease in the payment rate for APC 0227 relative to the CY 2013 payment rate, which will render the

payment inadequate to cover the cost of the services in question.

Response: We do not agree with the commenters 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. Drugs supplied to fill the pump during implantation of the pump are adjunctive to the procedure. As we have noted above, 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. Certainly, the greater the cost variance of a particular component and the less frequently that exceptional component is used, the less the relative payment weight, based on a geometric mean of estimated cost, will reflect those less frequent, costly cases. Hospitals are also aware that the costs of extremely costly cases are partially mitigated by outlier payments, which would continue to apply in this case upon implementation of the comprehensive APC policy in CY 2015. Finally, with respect to APC 0227, we note that the comprehensive estimated geometric mean costs are in fact approximately 10 percent higher than the individual procedure estimated geometric mean costs, consistent with the relative contribution of adjunctive services across all comprehensive APCs.

Therefore, we are confirming that drugs used to fill in pumps at the time of a comprehensive pump insertion procedure are considered to be ancillary and supportive to the primary procedure and packaged as part of the comprehensive APC payment regardless of whether the drug was previously packaged within the OPPS payment, was previously separately paid under the OPPS, or was previously paid according to a DMEPOS fee schedule.

(f) Summary of Creation of Comprehensive APCs for High-Cost Device Dependent Procedures for Implementation in CY 2015

In summary, in response to public comments we received, we have decided to finalize the comprehensive APCs with modification and to delay the implementation or effective date of the policy until CY 2015. We acknowledge commenters' concerns that this is a complex new payment structure under the OPPS. We agree that hospitals should have time to prepare for this comprehensive payment structure, and we also agree with the commenters that a delay in implementation will allow us

(and them) more time to operationalize changes necessary to process comprehensive payments.

In response to public commenters' request for additional detail on our calculation of the comprehensive APC relative payment weights, we have provided a granular discussion of our methodology for constructing the comprehensive APC payment rates as well as the specific APC configurations we would implement for CY 2014 if we were not delaying implementation to CY 2015. We also believe that the delay in implementation will give hospitals more time to study the final methodology for calculating relative payment weights that we discuss in this section, and specifically how the methodology recognizes resource differences in complex and simple versions of the same primary service. We are taking advantage of the delay in implementation and requesting additional comment on this methodology.

For CY 2015, we will recalibrate comprehensive APCs and final reassignment of complex claims in light of any comments on the illustrative CY 2014 assignments that we present and updated CY 2013 claims and cost report data next year. For CY 2014, we will continue our payment for device-dependent APCs and composite payment for both CRT and cardiac electrophysiologic evaluation and ablation as discussed elsewhere in this final rule with comment period.

Effective for CY 2015, we will include all integral, ancillary, supportive, dependent, and adjunctive outpatient services into the comprehensive APC payment, excluding certain services such as ambulance services; mammography services; brachytherapy sources; and drugs, biologicals, and devices receiving pass-through payment. We will not include charges reported with inpatient room and board revenue codes as we do not believe outpatient costs are correctly reported in those revenue codes. Adjunctive items and services that will be unconditionally packaged into the comprehensive APC payment for CY 2015 include the following.

- All packaged services that were packaged in CY 2013.
- All services finalized for unconditional or conditional packaging for CY 2014.
- All adjunctive services and supplies provided during the delivery of the comprehensive service, which includes all other cover OPPS items and services appearing on a claim, including those with a HCPCS with status indicator "J1"; implantable DMEPOS supplies

provided during the comprehensive OPPS service; services performed by therapists provided during the OPPS service; and all other covered outpatient items and services appearing on the claim.

- All packaged hospital-administered drugs pursuant to a physician order, excluding pass-through drugs that are required to be separately paid by statute.

We are finalizing a modification to our proposed methodology for identifying a primary service, assigned to status indicator "J1" on a claim reporting multiple procedures described by HCPCS codes assigned to status indicator "J1" in order to effectuate an appropriate comprehensive APC payment. We are finalizing a multiple step process to include an evaluation of costliness based on the comprehensive geometric mean cost of single procedures assigned to status indicator "J1" reported on claims. We also have determined that there are certain subsets of outpatient cases for a primary service that should be more appropriately paid when stratified according to the complexity of the service. Therefore, we have identified a number of complexity reassignments for certain high-volume, costly, complex versions of a primary service, and we have reassigned these subsets of procedures representing a complex version of the primary service to higher-level APCs in the same clinical family.

In response to public comments we received, we discuss how we would have revised some comprehensive APC definitions and reassigned HCPCS codes to specific APCs in order to better align the comprehensive geometric mean cost of primary services with APCs that better capture the resource and clinical aspects of the service if we were implementing this policy for CY 2014. We discuss the methodology that we followed for all of those modifications to our proposal in detail earlier in this section. We display the final APC revisions that we would make and final comprehensive geometric mean cost for those APCs, if we were implementing this policy for CY 2014 in Table 8. We display final HCPCS assignments in Table 9 and complexity reassignments in Table 10 that we would make if we were implementing this policy for CY 2014.

We have reconciled the inconsistency in our proposal to pay for cardiac electrophysiology-ablation procedures under both composite and comprehensive methodologies. For CY 2015, we are reassigning the codes assigned to composite APC 8000 into a new composite APC 0444, along with complex services from APC 0085 that

are characterized by composite EP-ablation procedures described by HCPCS code combinations.

Therefore, for CY 2015, we are creating 29 comprehensive APCs to prospectively pay for services associated with 167 CY 2014 HCPCS codes, which is the most recent code set available. We note that the list of HCPCS codes represent the procedures that would be assigned to a comprehensive APC if we implemented this policy for CY 2014. We will update this list as indicated in our proposed and final OPPS rules for CY 2015.

For CY 2015, we are treating all individually reported procedures that are assigned to status indicator “J1,” which will appear in the CY 2015 Addendum B to the proposed rule, as representing components of a comprehensive service characterized by a primary service, and we will make a single payment for the comprehensive service. We will be making a single all-inclusive payment for each comprehensive service reported on a claim with that payment subject to a single beneficiary copayment, up to the cap set at the level of the inpatient hospital deductible, as provided at section 1833(t)(8)(C)(i) of the Act.

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 2014 OPPS/ASC proposed rule (78 FR 43561), for CY 2014, we proposed to continue our composite policies for extended assessment and management services, LDR prostate brachytherapy services, cardiac electrophysiologic evaluation and ablation services, mental health services, and multiple imaging services, as discussed below. We proposed to discontinue and supersede the cardiac resynchronization therapy composite APC with our proposed comprehensive APC 0108, as discussed in section II.A.2.e. of the proposed rule (78 FR 43561). Comments on cardiac resynchronization therapy relating to comprehensive APCs are discussed in section II.A.2.e. of this final rule with comment period.

(1) Extended Assessment and Management Composite APCs (APCs 8002 and 8003)

(a) Background

Beginning in CY 2008, we included composite APC 8002 (Level I Extended Assessment and Management Composite) and composite APC 8003 (Level II Extended Assessment and Management 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 supportive and ancillary to the other services provided to a patient. From CY 2008 through CY 2013, in the circumstances when observation care is provided in conjunction with a high level visit, critical care, or direct referral and is an integral part of a patient's extended encounter of care, payment is made for the entire care encounter 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 proposed rule (78 FR 43562 through 43563), for CY 2014, we proposed to modify our longstanding policy to provide payment to hospitals in certain circumstances when extended assessment and

management of a patient occur. We proposed to create 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. We proposed to allow any visit furnished by a hospital in conjunction with observation services of substantial duration to qualify for payment through EAM composite APC 8009. These policies are discussed in greater detail below.

(b) Payment for Extended Assessment and Management Services

As we discussed in section VII. of the CY 2014 OPPS/ASC proposed rule (78 FR 43614 through 43617), we proposed to no longer recognize five distinct visit levels for clinic visits and emergency department visits based on the existing HCPCS E/M codes, and instead recognize three new alphanumeric HCPCS codes for each visit type. Currently, the payment criteria for the EAM composite APCs 8002 and 8003 include a high level visit represented by HCPCS code 99205, 99215, 99284, 99285, or G0304; critical care represented by CPT code 99281; or direct referral represented by HCPCS code G0379 provided in conjunction with observation care represented by HCPCS code G0378. We stated that in light of the proposal to no longer differentiate visit payment levels, and the fact that the current high level visit codes (HCPCS codes 99205, 99215, 99284, 99285 and G0304) would no longer be recognized under the OPPS, it would no longer be feasible to continue with our current payment criteria for the EAM composite APCs 8002 and 8003 for CY 2014. Therefore, to ensure that we continue to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur, for CY 2014, we proposed to provide payment for the entire care encounter through proposed new EAM Composite APC 8009 when observation care is provided in conjunction with a visit, critical care, or direct referral and is an integral part of a patient's extended encounter of care. Specifically, for CY 2014, we proposed to provide EAM composite APC payment through a newly created composite APC in circumstances when a clinic or ED visit, identified by one of the three new alphanumeric HCPCS codes proposed in section VII. of the proposed rule, is accompanied by observation care of substantial duration on a claim. We would no longer recognize composite APC 8002 or APC

8003. The specific criteria we proposed to be met for the proposed new EAM composite APC to be paid is provided below in the description of the claims that we proposed to select for the calculation of the proposed CY 2016 geometric mean costs for this composite APC.

We proposed to calculate the geometric mean costs for the proposed new EAM composite APC (APC 8009) for CY 2014 using CY 2012 single and “pseudo” single procedure claims that meet each of the following criteria:

- The claim does 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 contains 8 or more units of HCPCS code G0378 (Observation services, per hour); and

- The claim contains one of the following codes: HCPCS code G0379 (Direct referral of patient for hospital observation care) on the same date of service as 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 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency

department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)); or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); 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 2014 geometric means cost resulting from this methodology for the proposed new EAM composite APC (APC 8009) was approximately \$1,357, which was calculated from 318,265 single and “pseudo” single claims that met the required criteria.

We stated in the proposed rule that when hospital claims data for the CY 2014 proposed clinic and ED visit codes becomes available, we proposed to calculate the geometric mean cost for the proposed new EAM composite APC (APC 8009) for CY 2016 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 HCPCS code G0378 (Observation services, per hour); and

- 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; or CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or newly proposed alphanumeric Level II HCPCS code GXXXXA (Type A ED visit); newly proposed alphanumeric Level II HCPCS code GXXXXB (Type B ED visit); or newly proposed alphanumeric Level II HCPCS code GXXXXC (Clinic visit) provided on the same date of service or

1 day before the date of service for HCPCS code G0378.

Comment: One commenter supported CMS’ proposal to delete composite APCs 8002 and 8003 and to pay for extended assessment and management services through newly created composite APC 8009. Another commenter, who did not support the proposal, stated that the proposed policy did not accurately account for the cost of providing an extended assessment and management service and urged CMS to carefully assess the potential impact of this proposal upon different types of facilities and patients before moving forward.

Response: We appreciate the commenter’s support of our proposal. We disagree with the one commenter’s argument that our proposal does not accurately account for the cost of providing an extended assessment and management service. 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.

After consideration of the public comments we received, we are finalizing our proposal to create a 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 recognizing two levels of EAM Composite APCs. In light of our CY 2014 final visit payment policy, which is discussed in detail in section VII. of this final rule with comment period, we are modifying our proposal to allow any clinic and certain high level ED visits furnished by a hospital in conjunction with observation services of substantial duration to qualify for payment through the newly created Extended Assessment and Management (EAM) Composite APC (APC 8009). Specifically, we are allowing a clinic visit (for CY 2014, there will be one code to describe all clinic visits), a Level 4 or Level 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 composite APC 8009. This modification of the proposed EAM composite APC criteria is due to our decision not to finalize any changes to the Type A or Type B ED visit codes for CY 2014. Because we are not changing the ED visit codes for CY 2014, we also are not changing for CY 2014 the particular ED visit codes that qualify for the EAM composite APC.

We also are modifying our proposal to calculate the payment rate for the new EAM composite APC (APC 8009). Specifically, we calculated the geometric mean cost for procedures assigned to APC 8009 for CY 2014 using CY 2012 single and “pseudo” single procedure claims that met each of the following criteria:

- The claim does 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 contains 8 or more units of HCPCS code G0378 (Observation services, per hour); and

- The claim contains 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)); or 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 final CY 2014 payment rate for composite APC 8009 is approximately \$1,199.

(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 OPSS 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 based 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 OPSS/ASC final rule with comment period (72 FR 66652 through 66655) for a full history of OPSS payment for LDR prostate brachytherapy services and a detailed description of how we developed the LDR prostate brachytherapy composite APC.

In the CY 2014 OPSS/ASC proposed rule (78 FR 43563), for CY 2014, we proposed to continue to pay for LDR prostate brachytherapy services using the composite APC methodology proposed and implemented for CY 2008 through CY 2013. That is, we proposed to use CY 2012 claims on which both CPT codes 55875 and 77778 were billed on the same date of service with no other separately paid procedure codes (other than those on the bypass list) to

calculate the payment rate for composite APC 8001. Consistent with our CY 2008 through CY 2013 practice, 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 stated that we 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 composite APC payment rate.

Using a partial year of CY 2012 claims data available for the CY 2014 OPSS/ASC proposed rule, we were able to use 1,487 claims that contained both CPT codes 55875 and 77778 to calculate the geometric mean cost of these procedures upon which the proposed CY 2014 payment rate for composite APC 8001 was based. The proposed payment rate for composite APC 8001 for CY 2014 was approximately \$4,340.

Comment: A few commenters asserted that the existing methodology to create “pseudo” single claims from multiple procedure claims is not yielding a significant number of claims to be used to calculate adequate payment rates for APC 8001, APC 0312 (Radioelement Applications), and APC 0313 (Brachytherapy). The commenters believed that use of this methodology and its insignificant results is a continuing trend.

Response: For CY 2014, we have 591 final rule claims available for APC 8001 geometric mean cost calculation, while for CY 2013 we were able to use 677 claims that contained both CPT codes 55875 and 77778 to calculate the geometric mean cost of these procedures upon which the final CY 2013 payment rate for composite APC 8001 was based. For CY 2014, we have 52 single claims available for geometric mean cost calculation for APC 0312, compared to 74 claims available for CY 2013. For APC 0313, we have 17,810 single claims available for CY 2014 for geometric mean cost calculation compared to 17,743 single claims available for CY

2013. Therefore, there is approximately the same number of “pseudo” single claims available for APCs 8001 and 0313 geometric mean cost calculation compared to CY 2013. With regard to APC 0312 geometric mean cost calculation, the number of single claims available for ratesetting for CY 2014 compared to CY 2013 is somewhat low for both years. We agree with the commenter that it would be preferable if we had a larger volume of single claims on which to base the payment rate for APC 0312. We will continue to evaluate additional refinements and improvements to our ratesetting methodologies in order to maximize our use of claims data. In addition, we will continue to study means by which we can use a larger volume of claims data to establish the payment rate for APC 0312 specifically.

Comment: One commenter supported CMS’ proposal to continue paying for LDR prostate brachytherapy services using composite APC 8001 and noted recognition of the proposed increase in payment.

Response: We appreciate the commenter’s support for this proposal.

After consideration of the public comments we received, we are finalizing our policy to continue paying for LDR prostate brachytherapy services using composite APC 8001 for CY 2014, with a final CY 2014 geometric mean cost for APC 8001 of approximately \$3,858.

(3) Cardiac Electrophysiologic Evaluation and Ablation Composite APC (APC 8000)

Effective January 1, 2008, we established APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite) to pay for a composite service made up of at least one specified electrophysiologic evaluation service and one specified electrophysiologic ablation service. Correctly coded claims for these services often include multiple codes for component services that are reported with different CPT codes and that, prior to CY 2008, were always paid separately through different APCs (specifically, APC 0085 (Level II Electrophysiologic Evaluation), APC 0086 (Ablate Heart Dysrhythm Focus), and APC 0087 (Cardiac Electrophysiologic Recording/Mapping)). Calculating a composite APC for these services allowed us to utilize many more claims than were available to establish the individual APC geometric mean costs for these services, and advanced our stated goal of promoting hospital efficiency through larger payment bundles. In order to calculate the geometric mean cost upon

which the payment rate for composite APC 8000 is based, we used multiple procedure claims that contained at least one CPT code from Group A for evaluation services and at least one CPT code from Group B for ablation services reported on the same date of service on an individual claim. Table 9 in the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66656) identified the CPT codes that are assigned to Groups A and B. For a full discussion of how we identified the Group A and Group B procedures and established the payment rate for the cardiac electrophysiologic evaluation and ablation composite APC, we refer readers to the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66655 through 66659). Where a service in Group A is furnished on a date of service that is different from the date of service for a CPT code in Group B for the same beneficiary, payments are made under the appropriate single procedure APCs and the composite APC does not apply.

Subsequent to the publication of the CY 2013 OPPTS/ASC proposed rule, the AMA’s CPT Editorial Panel created five new CPT codes describing cardiac electrophysiologic evaluation and ablation services, effective January 1, 2013. These five new codes are:

- CPT code 93653 (Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry);
- CPT code 93654 (Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of ventricular tachycardia or focus of ventricular ectopy including intracardiac electrophysiologic 3D mapping, when performed, and left ventricular pacing and recording, when performed);
- CPT code 93655 (Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic

maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure));

- CPT code 93656 (Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with atrial recording and pacing, when possible, right ventricular pacing and recording, His bundle recording with intracardiac catheter ablation of arrhythmogenic focus, with treatment of atrial fibrillation by ablation by pulmonary vein isolation); and

- CPT code 93657 (Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)).

The CPT Editorial Panel also deleted two electrophysiologic ablation codes, CPT code 93651 (Intracardiac catheter ablation of arrhythmogenic focus; for treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathways, accessory atrioventricular connections or other atrial foci, singly or in combination) and CPT code 93652 (Intracardiac catheter ablation of arrhythmogenic focus; for treatment of ventricular tachycardia), effective January 1, 2013.

As we described in the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68425), new CPT codes 93653, 93654, and 93656 are primary electrophysiologic services that encompass evaluation as well as ablation, while new CPT codes 93655 and 93657 are add-on codes. Because CPT codes 93653, 93654, and 93656 already encompass both evaluation and ablation services, we assigned them to composite APC 8000 with no further requirement to have another electrophysiologic service from either Group A or Group B furnished on the same date of service, and we assigned them interim status indicator “Q3” (paid through a composite APC) in Addendum B to the CY 2013 OPPTS/ASC final rule with comment period. To facilitate implementing this policy, we assigned CPT codes 93653, 93654, and 93656 to a new Group C, which is paid at the composite APC 8000 payment rate. (We noted that we will use single and pseudo single claims for CPT codes 93653, 93654, and 93656 when they become available for calculating the geometric mean costs upon which the payment rate for APC 8000 will be based in future ratesetting.) Because CPT codes 93655 and 93657 are

dependent services that may only be performed as ancillary services to the primary CPT codes 93653, 93654, and 93656, we believed that packaging CPT codes 93655 and 93657 with the primary procedures is appropriate, and we assigned them interim status indicator “N.” Because the CPT Editorial Panel deleted CPT codes 93651 and 93652, effective January 1, 2013, we deleted them from the Group B code list, leaving only CPT code 93650 (Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement) in Group B.

As is our usual practice for new CPT codes that were not available at the time of the proposed rule, our treatment of new CPT codes 93653, 93654, 93655, 93656, and 93657 was open to public comment for a period of 60 days following the publication of the CY 2013 OPPS/ASC final rule with comment period.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43564), for CY 2014, we proposed to continue to pay for cardiac electrophysiologic evaluation and ablation services using the composite APC methodology proposed and implemented for CY 2008 through CY 2013. We also proposed to continue the new Group C methodology we first established for CY 2013, described above, in response to the CPT Editorial Panel’s creation of primary CPT codes 93653, 93654, and 93656. We stated that we continue to believe that the geometric mean cost for cardiac electrophysiologic evaluation and ablation services calculated from a high volume of correctly coded multiple procedure claims would result in an accurate and appropriate proposed payment for these services when at least one evaluation service is furnished during the same clinical encounter as at least one ablation service. Consistent with our practice since CY 2008, we proposed not to use the claims that met the composite payment criteria in the calculation of the geometric mean costs for APC 0085, to which the CPT codes in both Groups A and B for composite APC 8000 are otherwise assigned. We proposed that the geometric mean costs for APC 0085 would continue to be calculated using single procedure claims. For CY 2014, using a partial year of CY 2012 claims data available for the CY 2014 OPPS/ASC proposed rule, we were able to use 15,817 claims containing a combination of Group A and Group B CPT codes (Group C was not effective until January 1, 2013) to calculate a proposed geometric mean

cost of approximately \$13,402 for composite APC 8000.

Table 6 of the proposed rule listed the groups of procedures upon which we proposed to base composite APC 8000 for CY 2014 (78 FR 43565).

Comment: One commenter on the CY 2013 OPPS/ASC final rule with comment period expressed concern with CMS’ treatment of CPT codes 93653, 93654, and 93656, which are assigned to new Group C and paid at the composite APC 8000 payment rate. Specifically, the commenter stated that CMS considers CPT code 93462 (Left heart catheterization by transseptal puncture through intact septum or by transapical puncture (List separately in addition to code for primary procedure)) as separately payable. However, the commenter believed that when CPT code 93462 appears on the claim in combination with CPT code 93656 CMS should treat the claims as single procedures for building composite APC 8000 in regard to cases where CPT code 93462 was used to describe services to treat atrial fibrillation (AF). The commenter contended that CMS did not do so for CY 2013, which resulted in an underpayment for cases assigned to composite APC 8000. The commenter noted that when the CPT Editorial Panel created CPT code 93656, it specifically listed CPT code 93462 as one of the codes that should not be reported in combination with CPT code 93656. The commenter asserted that CMS’ treatment of CPT code 93462 had several ratesetting consequences. According to the commenter, when CPT code 93462 appeared on any electrophysiology (EP) claim, it prevented that claim from becoming a “single procedure” claim for composite APC 8000 ratesetting purposes. Because CPT code 93462 occurs most frequently for EP treatment of AF, preventing EP claims with CPT code 93462 from becoming “single procedure” claims disproportionately excludes AF claims from composite APC 8000 cost calculation. In addition, the commenter stated, because those claims are more expensive than the average EP claim, this result also reduces both the frequency and average cost of claims used to calculate the geometric mean cost of composite APC 8000. The commenter stated that separate payment of CPT code 93462 prevents packaging CPT code 93462 costs on claims for EP involved with AF, which is contrary to the CPT instructions regarding CPT code 93656.

In response to the CY 2014 OPPS/ASC proposed rule, this same commenter and one other commenter expressed appreciation for CMS’ proposal to package the cost of CPT code 93462

within the APC payment rates of other services, and recommended that CMS finalize the proposed method of calculating the cost of APC 8000 for CY 2014.

Response: We assigned CPT code 93462 to APC 0080 for CY 2013, with a payment rate of \$2,649.52. CPT code 93462 is an add-on code. For CY 2014, we proposed to package most add-on codes, including CPT code 93462. As a result of our packaging proposal, the geometric mean cost and frequency for composite APC 8000 have increased. Based on CY 2014 final cost data, the geometric mean cost of composite APC 8000 is approximately \$13,161 based on 16,937 claims available for cost calculation of composite APC 8000. We believe that packaging the cost of CPT code 93462 within the APC payment rates of other services as a result of the add-on code packaging policy addresses the commenters’ concerns.

Comment: One commenter who agreed with CMS’ proposed methodology not to use claims that meet the composite APC 8000 criteria for geometric mean cost calculation purposes for APC 0085, expressed concern regarding the proposed payment rate for APC 0085. The commenter noted that the proposed payment rate for APC 0085 for CY 2014 is \$11,517 (the corrected proposed rate included in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site is approximately \$11,345), which is significantly higher than the CY 2013 payment rate of \$4,035. However, the commenter believed that this variation is a result of unintended reuse of claims used to calculate the composite APC 8000 payment rate. The commenter further believed that excluding the composite APC 8000 claims from APC 0085 cost calculation will lower the geometric mean cost of APC 0085 significantly, and urged CMS to correct this error.

Response: We acknowledge that the proposed payment rate for APC 0085 was incorrectly initially published as approximately \$11,517, as well as the corrected payment rate (which was posted on the CMS Web site) of \$11,345. The proposed rule payment rate for APC 0085 was based on our comprehensive APC methodology, which packaged the cost of ancillary and other services. However, our comprehensive APC methodology will not be effective until CY 2015. The final geometric mean cost for APC 0085 is approximately \$4,248, based on 6,362 claims available for ratesetting.

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

payment for composite APC 8000 for CY 2014. Based on a full year of CY 2012 claims data, the final geometric mean cost of composite APC 8000 is approximately \$13,162, based on 16,935

claims available for ratesetting. We also are finalizing the payment for APC 0085, based on a geometric mean cost of approximately \$4,248.

Table 11 below lists the groups of procedures upon which we based composite APC 8000 for CY 2014

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**TABLE 11.—GROUPS OF CARDIAC ELECTROPHYSIOLOGIC
EVALUATION AND ABLATION PROCEDURES UPON WHICH COMPOSITE
APC 8000 IS BASED FOR CY 2014**

Codes Used in Combinations: At Least One in Group A and One in Group B, or At Least One in Group C	CY 2014 CPT Code	Single Code CY 2014 APC	CY 2014 SI (Composite)
Group A			
Comprehensive electrophysiologic evaluation with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording, including insertion and repositioning of multiple electrode catheters, without induction or attempted induction of arrhythmia	93619	0085	Q3
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording	93620	0085	Q3
Group B			
Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement	93650	0085	Q3

Group C			
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	93653	8000	Q3
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of ventricular tachycardia or focus of ventricular ectopy including intracardiac electrophysiologic 3D mapping, when performed, and left ventricular pacing and recording, when performed	93654	8000	Q3
Comprehensive electrophysiologic evaluation including transeptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with atrial recording and pacing, when possible, right ventricular pacing and recording, His bundle recording with intracardiac catheter ablation of arrhythmogenic focus, with treatment of atrial fibrillation by ablation by pulmonary vein isolation	93656	8000	Q3

BILLING CODE 4120-01-C**(4) Mental Health Services Composite APC (APC 0034)**

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43565), for CY 2104, 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 treatments. We refer readers to the April 7, 2000 OPPTS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPTS/ASC final rule

with comment period (76 FR 74168) for more recent background.

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). Specifically, we 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 proposed that the hospital would continue to be paid one unit of APC 0034. 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 stated that 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 treatments. Therefore, we do not believe that we should pay more for mental health services under the OPPTS 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 2014 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 by a hospital to the payment for APC 0176, which is the maximum partial hospitalization per diem payment for a hospital for CY 2014.

(5) 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 6 of the CY

2013 OPPTS/ASC final rule with comment period (77 FR 68253 through 68257).

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 OPPTS 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 OPPTS/ASC final rule with comment period (73 FR 68559 through 68569).

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43566), for CY 2014, 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. We continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session. The proposed CY 2014 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 2012 claims available for the CY 2014 OPPTS/ASC 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 2012 and CY 2013 geometric mean costs for these composite APCs, as described in the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74169). 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 (76 FR 74169), were identified by asterisks in Addendum N to the proposed rule (which is available via the Internet on the CMS Web site) and were discussed in more detail in section II.A.1.b. of the proposed rule.

For the CY 2014 proposed rule, we were able to identify approximately 0.8 million “single session” claims out of an estimated 1.5 million potential composite cases from our ratesetting claims data, more than half of all eligible claims, to calculate the proposed CY 2014 geometric mean costs for the multiple imaging composite APCs.

Table 7 of the proposed rule listed the proposed HCPCS codes that would be subject to the multiple imaging composite policy and their respective families and approximate composite APC geometric mean costs for CY 2014 (78 FR 43567). We noted that the proposed geometric mean costs calculated for many imaging APCs, including the multiple imaging composite APCs, have changed significantly from the geometric mean costs calculated for the CY 2013 OPPTS/ASC final rule with comment period for these APCs as a result of the proposed adoption of the new MRI and CT cost centers, as discussed in section II.A.1.c. of the proposed rule.

Comment: Some commenters supported CMS’ decision not to propose any new multiple imaging composite APCs. Other commenters urged CMS to restore separate payment for each imaging procedure, regardless of the date of service because of the decreases in payment for imaging services over several years, which according to the commenters may create disincentives to performing multiple imaging services on the same date. Some commenters stated

that other CMS proposals such as the CY 2014 proposed new CCRs for CT and MRI services have further decreased payment rates for imaging services for CY 2014, and the use of the new cost centers is directly responsible for the substantial decreases in payment for multiple imaging APCs, including composite APCs. Some commenters suggested that CMS provide an analysis of the impacts from decreases in payments for imaging services.

Response: As explained earlier in this section, 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. We have a total of 1.6 million composite cases in our claims data for CY 2014 ratesetting, which we believe is a sufficiently robust number of multiple imaging cases performed for ratesetting purposes. We address the concern that the new cost centers may be responsible for substantial decreases in payment for multiple imaging APCs in section II.A.1.c. of this final rule with comment period.

After consideration of the public comments we received, for this CY 2014 final rule with comment period, we

were able to identify approximately 0.7 million “single session” claims out of an estimated 1.6 million potential composite cases from our ratesetting claims data, approximately 45 percent of all eligible claims, to calculate the final CY 2014 geometric mean costs for the multiple imaging composite APCs.

Table 12 below lists the HCPCS codes that will be subject to the multiple imaging composite policy and their respective families and approximate composite APC geometric mean costs for CY 2014.

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**TABLE 12.—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING
PROCEDURE COMPOSITE APCs**

Family 1 – Ultrasound	
CY 2014 APC 8004 (Ultrasound Composite)	CY 2014 Approximate APC Geometric Mean Cost = \$287
76604	Us exam, chest
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76775	Us exam abdo back wall, lim
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76870	Us exam, scrotum
76857	Us exam, pelvic, limited
Family 2 - CT and CTA with and without Contrast	
CY 2014 APC 8005 (CT and CTA without Contrast Composite)*	CY 2014 Approximate APC Geometric Mean Cost = \$307
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 2014 APC 8006 (CT and CTA with Contrast Composite)	CY 2014 Approximate APC Geometric Mean Cost = \$550
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 will assign APC 8006 rather than APC 8005.

Family 3 - MRI and MRA with and without Contrast

CY 2014 APC 8007 (MRI and MRA without Contrast Composite)*	CY 2014 Approximate APC Geometric Mean Cost = \$623
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
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 2014 APC 8008 (MRI and MRA with Contrast Composite)	CY 2014 Approximate APC Geometric Mean Cost = \$931
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 will assign APC 8008 rather than APC 8007.	

BILLING CODE 4120-01-C**(6) Cardiac Resynchronization Therapy Composite APC (APC 0108)**

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. CRT utilizing a pacing electrode implanted in combination with an implantable cardioverter defibrillator (ICD) is known as CRT-D. Hospitals commonly report the implantation of a CRT-D system using 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 (including upgrade to dual chamber system) (List separately in addition to code for primary procedure)) and 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator). As described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74176), over the past several years, stakeholders have pointed out significant fluctuations in the payment rate for CPT code 33225 and that, because the definition of CPT code 33225 specifies that the pacing electrode is inserted at the same time as an ICD or pacemaker, CMS would not have many valid claims upon which to calculate an accurate cost. In response to these concerns, we established a policy beginning in CY 2012 to recognize CPT codes 33225 and 33249 as a single, composite service when the procedures are performed on the same day and to assign them to APC 0108 (Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes) when they appear together on a claim with the same date of service. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74176 through 74182) for a full

description of how we developed this policy.

As described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74182), hospitals continue to use the same CPT codes to report CRT-D implantation services, and the I/OCE will identify when the combination of CPT codes 33225 and 33249 on the same day qualify for composite service payment. We make a single composite payment for such cases. When not performed on the same day as the procedure described by CPT code 33225, the procedure described by CPT code 33249 is also assigned to APC 0108. When not performed on the same day as the procedure described by CPT code 33249, the procedure described by CPT code 33225 is assigned to APC 0655 (Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker).

In order to ensure that hospitals correctly code for CRT services, we also finalized a policy in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74182) to implement claims processing edits that will return to providers incorrectly coded claims on which a pacing electrode insertion (the procedure described by CPT code 33225) is billed without one of the following procedures to insert an ICD or pacemaker, as specified by the AMA in the CPT codebook:

- 33206 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial);
- 33207 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); ventricular);
- 33208 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular);
- 33212 (Insertion or replacement of pacemaker pulse generator only; single chamber, atrial or ventricular);

- 33213 (Insertion or replacement of pacemaker pulse generator only; dual chamber, atrial or ventricular);

- 33214 (Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator));

- 33216 (Insertion of a single transvenous electrode, permanent pacemaker or cardioverter-defibrillator);

- 33217 (Insertion of 2 transvenous electrodes, permanent pacemaker or cardioverter-defibrillator);

- 33222 (Revision or relocation of skin pocket for pacemaker);

- 33233 (Removal of permanent pacemaker pulse generator);

- 33234 (Removal of transvenous pacemaker electrode(s); single lead system, atrial or ventricular);

- 33235 (Removal of transvenous pacemaker electrode(s); dual lead system, atrial or ventricular);

- 33240 (Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator); or

- 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator).

We continued for CY 2013 to recognize CRT-D as a single, composite service as described above and finalized in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259). By continuing to recognize these procedures as a single, composite service, we are able to use a higher volume of correctly coded claims for CPT code 33225, which, because of its add-on code status, is always performed in conjunction with another procedure. We also noted that this policy is consistent with the principles of a prospective payment system, specifically to place similar services that

utilize technologies with varying costs in the same APC in order to promote efficiency and decision-making based on individual patient's clinical needs rather than financial considerations. Because CPT codes 33225 and 33249 may be treated as a composite service for payment purposes, we continued to assign them status indicator "Q3" (Codes that may be paid through a composite APC) in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site). The assignment of CPT codes 33225 and 33249 to APC 0108 when treated as a composite service was also reflected in Addendum M to the proposed rule (which is available via the Internet on the CMS Web site).

In addition, for CY 2013, we revised the claims processing edits in place for CPT code 33225 due to revised guidance from the AMA in the CPT codebook specifying the codes that should be used in conjunction with CPT code 33225. Specifically, on February 27, 2012, the AMA posted a correction as errata to the CY 2012 CPT codebook on the AMA Web site at: <http://www.ama-assn.org/resources/doc/cpt/cpt-corrections.pdf>. This correction removed CPT code 33222 (Revision or relocation of skin pocket for pacemaker) as a service that should be provided in conjunction with CPT code 33225, and added CPT codes 33228 (Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; dual lead system), 33229 (Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; multiple lead system), 33263 (Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; dual lead system), and 33264 (Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; multiple lead system). In accordance with this revised guidance, we deleted CPT code 33222 as a code that can satisfy the claims processing edit for CPT code 33225, and added CPT codes 33228, 33229, 33263, and 33264 as codes that can satisfy this edit beginning in CY 2012 (77 FR 68259).

For CY 2014, we proposed to discontinue and supersede the cardiac resynchronization therapy composite APC with our proposed comprehensive APC 0108, as discussed in section II.A.2.e. of the proposed rule (78 FR 43561). The public comments that we received on cardiac resynchronization therapy that relate to proposed comprehensive APCs are discussed in

section II.A.2.e. of this final rule with comment period.

As discussed in section II.A.2.e. of this final rule with comment period, comprehensive APCs will not be effective until CY 2015. Therefore, for CY 2014, we are finalizing the continuation of our current CRT-D composite policy, without modification and finalizing payment for CRT services using the composite APC 0108 payment methodology that we used for CYs 2012 and 2013, as discussed above. That is, for CY 2014, CRT-D will be recognized as a single, composite service as described above and finalized in the CY 2012 and CY 2013 OPPTS/ASC final rules with comment period. In calculating the costs upon which the final payment rate for APC 0108 is based for CY 2014, for this final rule with comment period, we included single procedure claims for the individual services assigned to APC 0108, as well as single procedure claims that contain the composite CRT-D service, defined as the combination of CPT codes 33225 and 33249 with the same date of service. We were able to use 15,454 single bills from the CY 2014 final rule claims data to calculate a final geometric mean cost of approximately \$32,257 for APC 0108. Because CPT codes 33225 and 33249 may be treated as a composite service for payment purposes, we are continuing to assign them status indicator "Q3" (Codes that may be paid through a composite APC) in Addendum B to this final rule with comment period.

3. Changes to Packaged Items and Services

a. Summary of CY 2014 Final Packaging Policies

Beginning in CY 2014, we are unconditionally or conditionally packaging the following items and services and adding them to the list of OPPTS packaged items and services in 42 CFR 419.2(b):

- (1) Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure;
- (2) Drugs and biologicals that function as supplies when used in a surgical procedure;
- (3) Certain clinical diagnostic laboratory tests;
- (4) Certain procedures described by add-on codes; and
- (5) Device removal procedures.

The HCPCS codes that we are packaging for CY 2014 are displayed in both Addendum P and Addendum B of this final rule with comment period. The supporting documents for this final rule with comment period, including

but not limited to these Addenda, are available at the CMS Web site at: <http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. Further details including comments and responses on the particular packaging proposals are discussed below.

b. Background

Like other prospective payment systems, the OPPTS 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 OPPTS 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 to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, supplies, etc. 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. Most, but not necessarily all, items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). 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 proposed rule (72 FR 42628) and the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580).

Over the last 15 years, we have refined our understanding and implementation of the OPPS and have packaged numerous services that we originally paid as primary services. As we continue to consider the development of larger payment groups that more broadly reflect services provided in an encounter or episode of care, we may propose to expand these packaging policies as they apply to services that we currently separately pay as primary services. We use the term “primary service” to refer to the HCPCS codes that represent the primary therapeutic or diagnostic modality into which we package payment for a dependent service.

Hospitals include HCPCS codes and charges for packaged services on their claims, and the estimated costs associated with those packaged services are then added to the costs of separately payable procedures on the same claims to establish prospective payment rates for the combination of the separately payable services and any associated packaged services. We emphasize that hospitals should report all HCPCS codes for provided services, including those for packaged services, unless the CPT Editorial Panel or CMS provides other specific guidance. The appropriateness 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.

In addition to the packaged items and services listed in 42 CFR 419.2(b), in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66610 through 66659), we adopted the packaging of payment for items and services in seven categories with the primary diagnostic or therapeutic modality to which we believe these items and services are typically ancillary and supportive. The seven categories are: (1) Guidance services; (2) image processing services; (3) intraoperative services; (4) imaging supervision and interpretation services; (5) diagnostic radiopharmaceuticals; (6) contrast media; and (7) observation services. We specifically chose these categories of HCPCS codes for packaging

because we believe that the items and services described by the codes in these categories 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. In addition, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68634), we packaged products described as implantable biologicals. As discussed below, in the CY 2014 OPPS/ASC proposed rule (78 FR 43575), we proposed to add each of these categories of packaged items and services that were packaged beginning in CYs 2008 and 2009, along with newly proposed packaged items and services for CY 2014 as described below to the OPPS packaging regulation at 42 CFR 419.2(b). Composite APCs under the OPPS, which are described in section II.A.2.f. of this final rule with comment period, and comprehensive APCs, which are described in section II.A.2.e. of this final rule with comment period, also include packaging.

c. Basis for New Packaging Policies for CY 2014

As discussed above, the OPPS is a prospective payment system. It is not intended to be a fee schedule, in which separate payment is made for each coded line item. However, the OPPS is currently a prospective payment system that packages some items and services but not others. Payment for some items and services in the OPPS is according to the principles of a prospective payment system, while the payment for other items and services is more like that of a fee schedule. 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.

Therefore, as we did in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66610 through 66659), 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 see 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 2014 OPPS/ASC proposed rule, 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 2014. In several cases, we proposed that services be conditionally packaged so that if they are provided without other services, there will be a separate payment for the service. The proposed policies detailed below are not exhaustive, and we expect to continue to review the OPPS and consider additional packaging policies in the future.

d. New Packaging Policies for CY 2014

In the CY 2014 OPPS/ASC proposed rule (78 FR 43570 through 43575), we proposed to package the following categories of items and services beginning in 2014:

- (1) Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure;
- (2) Drugs and biologicals that function as supplies when used in a surgical procedure;
- (3) Certain clinical diagnostic laboratory tests;
- (4) Procedures described by add-on codes;
- (5) Ancillary services (status indicator “X”);
- (6) Diagnostic tests on the bypass list; and
- (7) Device removal procedures.

Category (2) listed above was described in the proposed rule as “drugs and biologicals that function as supplies or devices when used in a surgical procedure.” In this final rule with comment period, we are deleting the words “or devices” from the name of this category because the words are redundant of “supplies.” In this context, devices are a type of supply (78 FR 43571), so it is not necessary to include the words “or devices” after supplies in the name of this category of packaged items.

Comment: Many commenters requested that CMS postpone finalizing all of the packaging proposals because of the commenters’ inability to replicate

the CY 2014 proposed OPPS payment rates, which the commenters asserted limited their ability to fully evaluate and, therefore, meaningfully comment on the packaging proposals. Many commenters also stated that, given the significance and scope of the proposals, CMS should delay implementation of these policies to allow stakeholders more time to evaluate these packaging proposals. In addition, the Advisory Panel on Hospital Outpatient Payment recommended that CMS delay implementation of the CY 2014 packaging proposals until data can be reviewed by the Panel at its spring 2014 meeting regarding interactions between the proposals and their potential cumulative impact.

Response: We appreciate that it requires time and effort to examine proposed policies. We discovered some limited methodological errors concentrated in a handful of APCs during the comment period. In response, we issued corrected data files on August 28, 2013, and published a correcting document in the **Federal Register** on September 6, 2013 (78 FR 54842) to address these technical errors. We also afforded the public a 10-day extension of the comment period on those topics affected by the corrected proposed rates. We believe that our standard 60-day comment period afforded commenters an adequate amount of time to meaningfully comment on the proposed policies. While we acknowledge that the OPPS is one of the more complicated Medicare payment systems to simulate, we make extensive data files and descriptions publicly available, in addition to proposed payment rates, in an effort to assist commenters in their review. Furthermore, the isolated technical errors that were corrected in the correcting document had limited interaction with the packaging proposals, and we believe the relativity (the relative magnitude of the difference between payment rates for different procedures) of the proposed payment rates for almost all APCs was sufficient for meaningful comment. Finally, we received numerous substantive, thoughtful, and helpful comments on our packaging proposals, which suggested that the public had sufficient time to meaningfully comment on the seven CY 2014 proposed packaging policies, and therefore, we do not believe a delay in implementation is necessary. We will review additional information regarding the impacts of the packaging policies with the Panel at future Panel meetings.

Below we discuss our proposals and summarize and respond to the

numerous substantive public comments we received on each packaging proposal.

(1) Drugs, Biologicals, and Radiopharmaceuticals That Function as Supplies When Used in a Diagnostic Test or Procedure

As we discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 43570), in the OPPS, we currently unconditionally package the following six categories of drugs, biologicals, and radiopharmaceuticals (unless temporary pass-through status applies): (1) those with per day costs at or below the packaging threshold (discussed further in section V.B.2. of the proposed rule and this final rule with comment period); (2) diagnostic radiopharmaceuticals; (3) contrast agents; (4) anesthesia drugs; (5) drugs used as supplies according to § 419.2(b)(4); and (6) implantable biologicals. For CY 2014, we reviewed all of the drugs, biologicals, and radiopharmaceuticals administered in the hospital outpatient setting to identify categories or classes of drugs, biologicals, and radiopharmaceuticals that either should be packaged according to existing packaging policies or should be packaged as a logical expansion of existing OPPS packaging policies for drugs, biologicals, and radiopharmaceuticals.

Currently, two of the categories of drugs, biologicals, and radiopharmaceuticals that are packaged in the OPPS (contrast agents and diagnostic radiopharmaceuticals) have a common characteristic—they both describe products that function as supplies when used in a diagnostic test or procedure. Although in the past we identified these specific categories of drugs, biologicals, and radiopharmaceuticals as packaged unless pass-through status applied, we recognize that they actually represent subcategories of a broader category of drugs, biologicals, and radiopharmaceuticals that should be packaged in the OPPS according to OPPS packaging principles: drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure. In particular, we are referring to drugs, biologicals, and radiopharmaceuticals that function as supplies as a part of a larger, more encompassing service or procedure, namely, the diagnostic test or procedure in which the drug, biological, or radiopharmaceutical is employed. Because diagnostic radiopharmaceuticals and contrast agents represent specific examples of a broader category of drugs, biologicals, or

radiopharmaceuticals that function as supplies that are integral and supportive to a diagnostic test or procedure, we proposed to unconditionally package drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, except when the drug, biological, or radiopharmaceutical has pass-through payment status.

A diagnostic test or procedure is defined as any kind of test or procedure performed to aid in the diagnosis, detection, monitoring, or evaluation of a disease or condition. A diagnostic test or procedure also includes tests or procedures performed to determine which treatment option is optimal. A diagnostic test or procedure can have multiple purposes, but at least one purpose must be diagnostic. We proposed to revise the regulations at 42 CFR 419.2(b) to specify that any drugs, biologicals, and radiopharmaceuticals that function as supplies when used in diagnostic tests or procedures will be packaged as supplies in the OPPS, except when pass-through status applies. This proposed broader category of packaged drugs, biologicals, and radiopharmaceuticals includes the currently packaged categories of contrast agents and diagnostic radiopharmaceuticals.

In the proposed rule, we identified one new class of drugs (stress agents) and one specific drug (Cysview) that we believe also fit within this new category of packaged items, that is, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure. We discuss the application of this policy to these specific drugs and the associated comments below.

(a) Stress Agents

Our review of OPPS drugs identified pharmacologic stress agents (“stress agents”) as a class of drugs that is described by the proposed packaged category of drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure. Stress agents are a class of drugs that are used in diagnostic tests to evaluate certain aspects of cardiac function. In many cases, these agents are used in patients who are unable to perform an exercise stress test, which typically precedes additional diagnostic imaging. The primary diagnostic test in which these agents are used is myocardial perfusion imaging (MPI), which is primarily reported with CPT code 78452 and is the highest cost nuclear medicine procedure in the OPPS, with total payments exceeding \$800 million in CY 2012. In the

proposed rule, we reported that approximately 96 percent of MPI is billed with CPT code 78452. Stress agents include the following drugs described by these HCPCS codes: HCPCS codes J0152 (Injection, adenosine for diagnostic use, 30 mg); J1245 (Injection, dipyridamole, per 10 mg); J1250 (Injection, dobutamine hydrochloride, per 250 mg); and J2785 (Injection, regadenoson, 0.1 mg). For CY 2013, HCPCS codes J1245 and J1250 are packaged in the OPPS, and J0152 and J2785 are separately paid. OPPS payments for the two separately payable stress agents totaled approximately \$111 million in CY 2012.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43570), we proposed to package all stress agents that function as supplies into the diagnostic tests or procedures in which they are employed, consistent with the policy proposed above. The primary service in which stress agents are employed is MPI. MPI with stress encompasses the imaging service, the stress test, and either exercise to induce stress or the administration of a pharmacologic stress agent. In the proposed rule, we included Table 8 which showed the CY 2013 separate payment versus the proposed CY 2014 packaged payment for MPI (78 FR 43571). We note that some of the payment rates for MPI in Table 8 were corrected in the correcting document published in the **Federal Register** on September 6, 2013 (78 FR 54842).

Comment: Some commenters supported packaging stress agents into MPI because they believed that it supports CMS' goal to make OPPS payments more consistent with those of a prospective payment system.

Response: We appreciate the commenters' support.

Comment: Several commenters objected to this proposal. Some commenters stated that CMS should not expand packaging to any new categories of drugs, biologicals, and radiopharmaceuticals, including stress agents. One commenter objected to the proposed policy for the following reasons and suggested changes or alternatives to the proposed policy:

- Packaging stress agents into MPI could adversely affect patient access to stress agents;
- Because a stress agent is not used with 100 percent of MPI tests, CMS should only package drugs that are used at least 80 percent of the time with the primary procedure, to ensure that the packaged payment reflects the full cost of the packaged drug;
- Hospitals would have a financial incentive not to use a stress agent with

MPI, because stress can be induced with exercise instead of a stress agent;

- To avoid incurring the cost of a stress agent, hospitals will encourage patients to exercise, and this could be dangerous for the patient;
- As a consequence of packaging stress agents, hospitals may perform inadequate MPI tests (without proper stress), resulting in misdiagnoses;
- CMS should require hospitals to code stress agents on MPI claims to ensure that costs are adequately captured; and
- CMS should create separate APCs for MPI with and without use of a stress agent.

Response: We disagree with the commenter that packaging stress agents will limit beneficiary access to MPI tests with a stress agent when it is not clinically appropriate for the patient to induce stress through exercise. Rather, as we discuss below, we believe that a single payment for MPI establishes better incentives to ensure clinically appropriate patient care.

We are not adopting the commenter's recommendation that we adopt a minimum utilization requirement of 80 percent for drug packaging. We package services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service, irrespective of the frequency with which this packaged service is used in any given primary procedure. This policy has been a fundamental part of the OPPS since its implementation in August 2000. In some cases, a packaged item may be associated with a primary service 100 percent of the time and in other cases a packaged item may be rarely used with the procedure or service with which it is packaged. Using the geometric mean cost for an APC ensures that minor changes in the total for items and services from low volume packaged services will impact the APC payment rate. Receiving some incremental amount for packaged items allows the hospital to best determine the most efficient and clinically appropriate delivery of a service. An 80 percent utilization threshold for packaging is more reflective of a fee schedule than a prospective payment system, creating payment for a single service of MPI and stress agent that would not encourage the efficient delivery of MPI. We believe a minimum utilization threshold would be unduly restrictive in the context of a prospective payment system because such a threshold would exclude services or items from packaging that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service.

Regarding the commenter's concern that hospitals will have a financial incentive not to use a stress agent with MPI, again we note that the established payment rate is based on the geometric mean cost of claims with and without a stress agent and that hospitals will now receive incrementally more payment for each MPI, proportional to included costs for stress agents on the claims, even when they do not use a stress agent. We believe that knowing the full amount of payment for the MPI, with or without the stress agent, will allow the hospital to make the most efficient decision that is clinically appropriate. As we state above, like other prospective payment systems, the OPPS relies on the concept of averaging, where 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. Finally, the recent availability of certain generic stress agents should further mitigate any financial incentive not to use a stress agent with MPI.

With regard to clinical concerns that hospitals may encourage physicians to order exercise rather than an MPI with stress agent, we disagree that hospitals and physicians are likely to settle for inadequate stress-MPI tests rather than incur the cost of the stress agent because a truly inadequate stress test would not provide the physician with sufficient information to arrive at a diagnosis and would require repeat testing. We believe that hospitals and physicians choose the most clinically appropriate diagnostic testing approach for their patients and that they will use a stress agent when necessary.

With regard to the suggestion that we require hospitals to code stress agents in MPI claims, we have repeatedly stated that hospitals should report all codes and associated charges on the claim for the item and services provided to the patient, so that we will be able to monitor trends in stress agent utilization over time.

Finally, we are not accepting the suggestion that we assign MPI tests with and without the use of a stress agent to different APCs. As with the minimum utilization threshold, we believe that establishing separate APCs would result in unnecessary differentiation between stress MPI with stress induced through exercise and stress MPI with stress induced through a stress agent, and that such a difference could discourage the efficient delivery of MPI. Further, the MPI CPT code descriptors include stress or rest, and stress can be induced either through exercise or use of a stress agent.

After consideration of the public comments we received, we are

finalizing our proposed policy to package stress agents under our policy that packages all drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure. We are assigning HCPCS codes J0151 (which replaces HCPCS code J0152 in CY 2014) and J2785 the status indicator of “N,” indicating unconditional packaging in the OPPS for CY 2014.

(b) Hexaminolevulinate Hydrochloride (Cysview®)—HCPCS Code C9275

Cysview is a drug for which pass-through status expired on December 31, 2012. Beginning in CY 2013, Cysview was unconditionally packaged in the OPPS as a contrast agent (77 FR 68364). The indications and usage of Cysview as listed in the FDA-approved label are as follows: “Cysview is an optical imaging agent indicated for use in the cystoscopic detection of non-muscle invasive papillary cancer of the bladder among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy. Cysview is used with the Karl Storz D-Light C Photodynamic Diagnostic (PDD) system to perform cystoscopy with the blue light setting (Mode 2) as an adjunct to the white light setting (Mode 1).”

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 42672), we described contrast agents as follows: “Contrast agents are generally considered to be those substances introduced into or around a structure that, because of the differential absorption of x-rays, alteration of magnetic fields, or other effects of the contrast medium in comparison with surrounding tissues, permit visualization of the structure through an imaging modality. The use of certain contrast agents is generally associated with specific imaging modalities, including x-ray, computed tomography (CT), ultrasound, and magnetic resonance imaging (MRI), for purposes of diagnostic testing or treatment.”

Upon reexamining this description of contrast agents and considering our prior application of this description to specific compounds, we believe that contrast agents should include those compounds that are used with the imaging modalities x-ray, computed tomography (CT), ultrasound, magnetic resonance imaging (MRI), and other related modalities that could represent advancements of these modalities. Based on the indications and usage described above for Cysview, we do not believe that Cysview is best described as a contrast agent. Rather, we believe Cysview is more appropriately

described as a drug used in a procedure to diagnose bladder cancer.

As discussed above, in the CY 2014 OPPS/ASC proposed rule, we proposed a new policy to package all drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure. Cysview is a drug that functions as a supply when used in a diagnostic test or procedure for the purpose of the “detection of non-muscle invasive papillary cancer of the bladder.” Therefore, as a drug that functions as a supply when used in a diagnostic test or procedure, we proposed to package Cysview for CY 2014 under the OPPS (78 FR 43571). Cysview is currently assigned to status indicator “N” for CY 2013, and under this proposal, the status indicator assignment of “N” would continue for CY 2014.

Comment: Many of the commenters on CMS’ proposal to package Cysview were urologists who consider Cysview to be valuable in the care of bladder cancer patients and who expressed concern that CMS’ proposed packaging policy will restrict access to blue light cystoscopy, which is the service in which Cysview is employed. One commenter stated that:

- Packaging Cysview limits patient access to the drug;
- Cystoscopy procedures that employ Cysview are not clinically comparable to other procedures assigned to the same APCs;
- CMS does not have the authority to package drugs, biologicals, and radiopharmaceuticals used in a diagnostic test or procedure;
- Packaging Cysview results in an inequitable payment for Cysview;
- Cysview does not function as a supply and therefore should not be packaged;
- Cysview is a treatment and is not used in a diagnostic test and therefore should not be packaged under the policy that packages drugs, biologicals, and radiopharmaceuticals used as a supply in a diagnostic test or procedure.
- CMS must create a separate APC for Cysview as it has done for procedures that use contrast agents.

Response: We disagree with the commenters that packaging will limit patient access to Cysview. As we state above, like other prospective payment systems, the OPPS relies on the concept of averaging, where 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. There are many items and services in the OPPS in which use of the item or service may increase the cost per case above that of the average or typical case,

and there are cases where no additional items or services are necessary and the cost of a typical case is much less than the average. This is a fundamental aspect of a prospective payment system. Overall, we believe that OPPS payments reflect average estimated costs for both situations and encourage the hospital to assess the appropriate use of those additional items and services in diagnosing bladder cancer and other diseases.

Cysview is used in blue light cystoscopy, which is an optional adjunct to white light cystoscopy. The various CPT codes for cystoscopy include white light cystoscopy with or without blue light cystoscopy. Cysview is packaged into the cystoscopy procedures. We believe that the current structure of the APCs that include the various cystoscopy procedures sufficiently reflects clinical and resource homogeneity as required by section 1833(t)(2)(B) of the Act because most of the codes in these APCs are cystoscopy procedures or other urological endoscopy procedures that, like cystoscopy, employ an endoscope. We also do not believe that packaging Cysview in the OPPS is inequitable. We package all drugs that function as supplies when used in a diagnostic test or procedure, and we will continue to review drugs used in the OPPS to assess whether they function as supplies or are otherwise integral, ancillary, and supportive to a diagnostic test or procedure, and therefore appropriately packaged into the procedure.

We disagree with the commenters who suggested that we do not have the authority to package drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure. We discussed our authority to package drugs, biologicals, and radiopharmaceuticals extensively in 2008, when we packaged diagnostic radiopharmaceuticals and contrast agents, and refer readers to that discussion in the CY 2008 OPPS final rule (72 FR 66610).

We disagree with the commenter’s view that Cysview should not be packaged because it does not function as a supply when used in a diagnostic test. We believe that the commenter misunderstands the term “supply” as it is used in the OPPS. Supply is a very broad term that describes many types of products in the OPPS. As discussed elsewhere in this section and in the CY 2014 OPPS/ASC proposed rule (78 FR 43571 through 43575), supplies is a large category of items that typically are either for single patient use or have a shorter life span in use than equipment. A supply in the OPPS can be anything

that is not equipment, and supplies can be either expensive or inexpensive and either commonly or uncommonly used. According to OPPS policy, drugs, biologicals, radiopharmaceuticals, medical devices, and other items and products that are not equipment can be supplies in the OPPS (78 FR 43571 and 43575). Since the inception of the OPPS, implantable medical devices have been considered supplies in the OPPS (65 FR 18443). Many implantable medical devices are very technologically sophisticated, costly, and tailored to specific medical needs but they are nonetheless supplies in the OPPS. Cysview facilitates diagnosis through blue light cystoscopy, and therefore we consider it to be a drug that functions as a supply in a diagnostic test in the OPPS.

We do not believe that Cysview and blue light cystoscopy are therapeutic. The FDA-approved label for Cysview states that Cysview is used for “cystoscopic detection of non-muscle invasive papillary cancer of the bladder,” which is a diagnostic purpose according to our definition of a diagnostic test described above and in the proposed rule (78 FR 43570). Also, Cysview itself does not eliminate bladder cancer cells. It enables better localization of the bladder cancer cells as compared to white light cystoscopy alone, which then requires a therapeutic procedure such as resection.

Finally, we disagree with the commenter’s suggestion that we must create a separate APC according to section 1833(t)(2)(G) of the Act for procedures that use Cysview. Cysview is not being packaged as a contrast agent. Instead, it is being packaged into the service in which it is used under the policy of packaging drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, which also currently includes diagnostic radiopharmaceuticals, contrast agents, and stress agents.

Comment: One commenter requested clarification regarding CMS’ definition of the term “contrast agent,” and requested that CMS recognize these products as drugs and that CMS refrain from calling these products supplies.

Response: The purpose of the clarification of the term “contrast agent” in the proposed rule (78 FR 43571), which is repeated above, was to explain that we believe that contrast agents are products used in certain types of imaging techniques (or advancements of those techniques), namely x-ray, computed tomography (CT), ultrasound, and magnetic resonance imaging (MRI). Contrast agents are typically drugs and

are eligible for pass-through as drugs in the OPPS. However, as mentioned above, drugs can also function as supplies, and be paid as such, when used in a diagnostic test or procedure in the OPPS. Contrast agents function as supplies when used in an imaging test and are packaged in the OPPS, unless pass-through status applies. This is a well-established OPPS packaging policy, and this policy makes no fundamental changes to the policy of unconditionally packaging contrast agents. We consider packaging of contrast agents under the more general packaging category of drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and this packaging category is being codified at 42 CFR 419.2(b)(15).

After consideration of the public comments we received, we are finalizing our proposed policy to package Cysview as a drug under our policy that packages drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure. Therefore, HCPCS code C9275 (Cysview) will be assigned status indicator “N” (unconditionally packaged) in CY 2014.

Comment: One commenter requested that radiopharmaceuticals used for dosimetry not be considered diagnostic radiopharmaceuticals but instead be treated as therapeutic radiopharmaceuticals.

Response: Radiopharmaceuticals used for dosimetry are packaged supplies in the OPPS according to established OPPS policy (68 FR 63443). In addition, the purpose of dosimetry is to establish the treatment dose or the optimal treatment for the patient. As stated in the proposed rule (78 FR 43570) and again above, diagnostic items “include tests or procedures performed to determine which treatment option is optimal.” Therefore, because dosimetry is performed to determine the optimal treatment dose of a therapeutic radiopharmaceutical, we believe, according to our definition of a diagnostic item, test, or procedure, that it is diagnostic and not therapeutic. Therefore, radiopharmaceuticals used for dosimetry are packaged in the OPPS.

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

Since the inception of the OPPS we have packaged medical devices, medical and surgical supplies, and surgical dressings into the related procedure under § 419.2(b)(4). Medical and surgical supplies are a broad category of items used in the hospital outpatient

setting. Supplies is a large category of items that typically are either for single patient use or have a shorter life span in use than equipment. Supplies include not only minor, inexpensive, or commodity-type items but also include a wide range of products used in the hospital outpatient setting, including certain implantable medical devices. We consider implantable medical devices to be integral to, dependent on, and supportive to a surgical implantation procedure. For further discussion, we refer readers to the CY 2000 OPPS final rule (65 FR 18443). Packaged supplies can include certain drugs, biologicals, and radiopharmaceuticals. Packaged supplies in the OPPS also include implantable biologicals, which are packaged because they function as implantable devices which, as noted above, are considered to be a type of supply in the OPPS. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68634) for a more detailed discussion of implantable biologicals. We believe that the existing packaging policy for implantable biologicals represents an example of a broader category of drugs and biologicals that should be packaged in the OPPS according to longstanding regulations and existing policies: drugs and biologicals that function as supplies when used in a surgical procedure. Therefore, in the CY 2014 OPPS/ASC proposed rule (78 FR 43571), beginning in the CY 2014 OPPS, we proposed to unconditionally package all drugs and biologicals that function as supplies in a surgical procedure, following the current packaging policy for implantable biologicals.

Skin substitutes are a class of products that we treat as biologicals that fit within the proposed packaging category of drugs and biologicals that function as supplies in a surgical procedure. The term “skin substitutes” refers to a category of products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers. Although the term “skin substitute” has been adopted to refer to this category of products in certain contexts, these products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue. We refer readers to the “Skin Substitutes for Treating Chronic Wounds Technology Assessment Report at ES–2” which is available on the AHRQ Web site at:

http://www.ahrq.gov/research/findings/ta/skinsubs/HCPR0610_skinsubst-final.pdf. Skin substitutes are regulated by the FDA as either medical devices (and classified as wound dressings) or as human cell, tissue, and cellular and tissue-based products (HCT/Ps) under section 361 of the Public Health Service Act. Most of the various skin substitutes are applied to a wound during a surgical procedure described by CPT codes under the heading in the 2013 CPT codebook “Skin Replacement Surgery” and the subheading “Skin Substitute Grafts” in the CPT code range 15271 through 15278. To be properly performed, every surgical procedure in this CPT code range requires the use of at least one skin substitute product. These surgical procedures include preparation of the wound and application of the skin substitute product through suturing or various other techniques. Currently skin substitutes are separately paid in the OPSPS as if they are biologicals according to the ASP methodology and are subject to the drug and biological packaging threshold.

Because a skin substitute must be used to perform any of the procedures described by a CPT code in the range 15271 through 15278, and conversely because it is the surgical procedure of treating the wound and applying a covering to the wound that is the independent service, skin substitute products serve as a necessary supply for these surgical repair procedures. In addition, the FDA classifies many skin substitutes as wound dressings, which make them in many cases similar to surgical dressings that are packaged under § 419.2(b)(4). Finally, implantable biological products are very similar to (and in some instances the same as) skin substitute products, except that the clinical applications for implantable biologicals are typically an internal surgery versus the application to a wound for a skin substitute. Some products that are used as skin substitutes have dual uses as both skin substitutes and implantable biologicals, which underscores the similarity of these overlapping classes of products. Some products that function as skin substitutes can also function as implantable biologicals. Implantable biologicals and skin substitutes both function as supplies that are used in surgical procedures and, therefore, we believe that they should be packaged with the surgical procedure in which the products are used. Since CY 2009, we have packaged implantable biologicals. We see no reason to distinguish skin substitutes from

implantable biologicals for OPSPS packaging purposes based on the clinical application of individual products. Therefore, in the CY 2014 OPSPS/ASC proposed rule (78 FR 43572), we proposed to unconditionally package skin substitutes into their associated surgical procedures. Packaging payment for these skin substitutes into the APC payment for the related surgical procedures would result in a total prospective payment that is more reflective of the average resource costs of the procedures because prices for these products vary significantly from product to product. Packaging these products also would promote more efficient resource use by hospitals and would be more consistent with the treatment of similar products under the OPSPS. Pass-through payment status would still be available to new skin substitutes that meet the pass-through payment criteria.

Comment: Many commenters supported CMS’ proposal to package skin substitutes, and believed that packaging will result in greater access to the full range of skin substitute products, that patients will benefit, and that Medicare will also benefit through cost savings from this proposed change in payment policy.

Response: We appreciate the commenters’ support.

Comment: Many commenters opposed CMS’ proposal to package skin substitutes and argued that because all skin substitutes or two skin substitutes in particular, Apligraf and Dermagraft, are specified covered outpatient drugs (SCODs) under section 1833(t)(14)(B) of the Act, CMS cannot package these products and instead must pay separately for them in the OPSPS.

Response: We disagree with the commenters’ assertion that skin substitutes generally or Apligraf and Dermagraft specifically are SCODs. Section 1833(t)(14)(B) of the Act defines a SCOD as a “covered outpatient drug (as defined in section 1927(k)(2))” Covered outpatient drugs under section 1927(k)(2) of the Act are generally limited to products approved as drugs by the FDA, biologicals licensed under section 351 of the Public Health Service Act, and insulin. Skin substitutes, including Apligraf and Dermagraft, are not within any of these categories of products because they were approved by the FDA as either medical devices or as human cell, tissue, and cellular and tissue-based products (HCT/Ps) under section 361 of the Public Health Service Act. Therefore, none of these products are covered outpatient drugs under section 1927(k)(2) of the Act, and therefore no skin substitutes are SCODs

according to section 1833(t)(14)(B) of the Act. Furthermore, we explained in finalizing our policies of packaging diagnostic radiopharmaceuticals and contrast agents in the CY 2008 OPSPS final rule (72 FR 66766) that CMS has the authority to package the payment of SCODs in the OPSPS and that we may consider additional packaging options for SCODs and other separately payable drugs in the future.

Comment: Many commenters believed that skin substitutes should continue to be separately paid and not packaged because, according to these commenters, they are neither supplies, nor comparable to implantable biologicals, nor wound dressings, and because they have a therapeutic purpose. Some commenters requested that CMS begin referring to these products as “cellular and/or tissue based products for wounds (CTPs)” instead of using the term “skin substitutes” to describe the products that are applied in the procedures described by the CPT codes 15271 through 15278. Commenters also expressed concern about CMS’ use of the term “wound dressing” to describe skin substitutes.

Response: We disagree with the commenters that we should not describe skin substitutes as a type of supply used in a surgical procedure. As explained in the proposed rule (78 FR 43571 and 43575) and elsewhere in this final rule with comment period, supplies are a large category of items that typically are either for single patient use or have a shorter life span in use than equipment. Supplies can be anything that is not equipment and include not only minor, inexpensive, or commodity-type items but also include a wide range of products used in the hospital outpatient setting, including certain implantable medical devices, which we have considered supplies since the inception of the OPSPS (65 FR 18443). Supplies can also be drugs, biologicals, or radiopharmaceuticals. We consider implantable medical devices to be integral to, dependent on, and supportive to a surgical implantation procedure. We consider implantable biologicals to be supplies used in a surgical procedure because, as a part of a surgical procedure, they reinforce and aid the healing of various internal structures, which makes them integral to, dependent on, and supportive to a surgical procedure. Similarly, we believe that skin substitutes are supplies used in a surgical procedure because, as a part of a surgical repair procedure, they reinforce and aid the healing of tissue like implantable biologicals, but with skin substitutes, the tissue is skin instead of internal connective tissues.

Like implantable biologicals, skin substitutes are integral to, dependent on, and supportive to the surgical procedures in which they are used. Therefore, we believe it is appropriate to describe skin substitutes as supplies, and it is consistent with OPPS policy to consider skin substitutes as a type of supply (like an implantable biological or medical device) used in a surgical repair procedure.

We disagree with the commenters who stated that skin substitutes are unlike packaged implantable biologicals and therefore should not be packaged. Our proposal to package skin substitutes relies on our determination that these products act as supplies that are integral to, dependent on, and supportive to a surgical procedure. We also believe that a reasonable analogy can be made that skin substitutes are similar to and operate as implantable biologicals in terms of composition, clinical use, role in hospital outpatient care, and product function in healing and repair such that packaging skin substitutes represents a logical expansion of our current packaging policy that packages implantable biologicals as surgical supplies. For example, implantable biologicals are used in internal surgeries for healing and to improve the structural integrity of joints, soft tissues and nerves, among others, and skin substitutes do the same for external surgical repairs of the integumentary system. In fact, several of the skin substitute products that are described by HCPCS Q-codes in the Q4100 series are used both as implantable biologicals and skin substitutes.

With regard to the comments relating to our use of the term “wound dressing” to describe skin substitutes, we discussed surgical dressings in the proposed rule as an example of packaged surgical supplies that have some similarities to skin substitutes, many of which FDA classifies as “wound dressings.” We believe that commenters may have misunderstood our description of skin substitutes in the proposed rule as wound dressings and assumed that we were conflating skin substitutes with products in the Medicare benefit category of surgical dressings described in section 1861(s)(5) of the Act. We are not conflating these two product categories. We note that the FDA uses the term “wound dressing” to classify many of the skin substitutes. For example, the skin substitutes Apligraf and Dermagraft are classified by the FDA as “dressing, wound and burn, interactive,” and the skin substitute Oasis is classified by the FDA as “dressing, wound, collagen.” Further, we assign HCPCS A-codes to surgical

dressings; HCPCS Q-codes are typically assigned to drugs and biologicals and are used to describe skin substitutes, unless a HCPCS C-code has been assigned to a skin substitute with pass-through payment status.

Regarding the comment that skin substitutes should not be packaged because they have a therapeutic purpose, we proposed for CY 2014 the packaging of drugs and biologicals that function as supplies when used in a surgical procedure, and surgical procedures typically have a therapeutic purpose. This CY 2014 packaging proposal for drugs and biologicals that function as supplies does not exclude items with a therapeutic purpose.

We use the term “skin substitute” to describe the products that are used in the surgical procedures described by CPT codes 15271 through 15278 because the CPT code descriptors for these codes include the term “skin substitute graft” for the products that are applied in these procedures. For example, the descriptor for CPT code 15271 is “Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area.” While we acknowledge that the term “skin substitutes” may be more or less appropriate for specific products, we believe that this term is currently the best term for these products in order to avoid ambiguity. The term “skin substitutes” is conventional in the medical vernacular for these products and it is also used in the CPT code descriptor for the surgical procedures that apply these products. In addition, we do not believe that we should adopt the term “cellular and/or tissue based products for wounds (CTPs) to describe skin substitutes,” because “CTP” is too close to the abbreviation HCT/P that the FDA uses to refer to human cell, tissue, and cellular and tissue-based products (HCT/Ps) under section 361 of the Public Health Service Act, which is the regulatory pathway for only some skin substitutes.

We acknowledge that there are differences in composition among the various skin substitute products and that is why each is assigned a distinct HCPCS Q-code (or HCPCS C-code in some cases). If all of the products were identical, we would only need one code to describe all of them. Skin substitutes are those products that are used in wound healing procedures and that are typically assigned a HCPCS Q-code in the Q4100 series (or assigned a HCPCS C-code if OPPS pass-through payment status applies). We understand that some of the products described by HCPCS Q-codes in the HCPCS code

Q4100 series function both as skin substitutes and implantable biologicals.

Comment: Many commenters opposed packaging skin substitutes, but also requested that, if CMS does package skin substitutes, CMS exclude from the packaging policy any products that are approved by the FDA through the premarket approval (PMA) process, the biologic license application (BLA) process, or the new drug application (NDA) process. Some commenters believed that products that achieve marketability through one of these processes are clinically superior to the other skin substitutes that are regulated by FDA as either 510(k) medical devices or as HCT/Ps because the PMA, NDA, or BLA-approval routes are more rigorous. As a consequence, they believe that PMA, NDA, or BLA-approved products deserve special recognition under the OPPS versus other skin substitutes that are regulated by FDA through another process. However, other commenters stated that the FDA regulatory pathway does not necessarily establish the clinical utility of the product. Other commenters argued that the various skin substitutes should not be packaged because they are different products each with different characteristics; for example, some skin substitutes are constructed of living cells while others are not.

Commenters also stated that among the range of skin substitutes, some products, including those approved through the PMA process, have higher costs than other skin substitutes that are used in the skin substitute surgical procedures. They argued that surgical procedures using these higher cost skin substitutes should not receive the same payment rate as those surgical procedures using less costly skin substitutes. These commenters were concerned that hospitals would have a financial incentive to use the least expensive skin substitute. Other commenters suggested different approaches to payment based on differential skin substitute cost or other skin substitute properties.

Response: Payment under the OPPS is established based on an assessment of resource and clinical homogeneity. We disagree that certain products with FDA regulatory approval should be exempt from packaging. With notable regulatory and statutory exceptions, clinical superiority, utility, and efficacy are not aspects of a service or product that we consider in developing a payment rate under the OPPS. However, we are persuaded by numerous public comments that there is a significant difference in resource costs among the numerous skin substitute products and

that multiple codes based on resource differences may be more appropriate.

We do not believe that the FDA approval process should exempt products from this packaging proposal or factor into the level of Medicare payment. While some skin substitutes have been approved by FDA as medical devices through the PMA process, including Apligraf, Dermagraft, and the Integra skin substitutes, all of the other current skin substitutes are regulated as either 510(k) medical devices or HCT/PS under section 361 of the Public Health Service Act. Proponents of some of the products approved through the PMA process request that we make an exception to packaging for these products (or any products approved through a PMA, NDA, or BLA). We believe that this request is based on the presumption that, because these FDA approval routes typically require clinical trials, these products have stronger evidence that supports their clinical performance as compared to the non-PMA approved products, and therefore PMA approval can be used as a proxy for evidence of clinical superiority relative to non-PMA-approved skin substitutes. However, we consider factors such as clinical and resource homogeneity for OPPS payment. As previously stated in regard to implantable biologicals, “We do not believe that it is necessary to make our OPPS payment policies regarding implantable biologicals dependent on categories of FDA approval, the intent of

which is to ensure safety and efficacy . . .” (74 FR 60476), but rather according to our established criteria of clinical and resource homogeneity. Therefore, as in the case of implantable biologicals, we also believe that the FDA regulatory pathway should not determine OPPS skin substitute payment policy. Generally, once a service is covered, clinical and resource homogeneity, as well as other considerations, determines APC placement and packaging status. Determinations related to the clinical merits of a product are outside the scope of this rule. We proposed to apply the packaging policy to all skin substitutes recognized by CMS, regardless of the FDA regulatory pathway.

However, we agree with commenters that, among the range of skin substitutes, there is sufficient resource heterogeneity such that all of the skin substitutes should not be packaged into the same application procedures and placed in the same APC. As noted above, factors in APC assignment in the OPPS include clinical homogeneity and resource homogeneity. While the procedures described by CPT codes 15271 through 15278 are clearly clinically homogeneous, there is significant resource heterogeneity in the payment amount for the various skin substitutes from approximately \$6.95 per sq cm for the least expensive to approximately \$200 per sq cm for the most expensive. In order to ensure adequate resource homogeneity among

APC assignments, in this final rule with comment period, we are dividing the skin substitutes into two groups for packaging purposes: high cost skin substitutes and low cost skin substitutes. Assignments to the high cost or low cost groups depended upon a comparison of the July 2013 payment amount for the skin substitute in OPPS Addendum B to the weighted average payment per unit of all skin substitutes using the skin substitute utilization from the CY 2012 claims data and the July 2013 payment amounts in OPPS Addendum B; this weighted average is \$32 per sq cm. Skin substitutes with a payment amount above \$32 per sq cm are classified in the high cost group and those at or below \$32 are classified in the low cost group. Table 13 below lists the skin substitutes and their assignment as either a high cost or low cost skin substitute. We also note that a few skin substitute products are applied as either liquids or powders per milliliter or per milligram and are employed in procedures outside of CPT codes 15271 through 15278. These products will not be classified as either high cost or low cost but will be packaged into the surgical procedure in which they are used. These products are not listed below in Table 13 but appear in Addendum B to this final rule with comment period (which is available via Internet on the CMS Web site).

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TABLE 13.—SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS

CY 2014 HCPCS Code	CY 2014 Short Descriptor	CY 2014 SI	Low/High Cost Skin Substitute
C9358	SurgiMend, fetal	N	Low
C9360	SurgiMend, neonatal	N	Low
C9363	Integra Meshed Bil Wound Mat	N	Low
Q4100	Skin substitute, NOS	N	Low
Q4101	Apligraf	N	High
Q4102	Oasis wound matrix	N	Low
Q4103	Oasis burn matrix	N	Low
Q4104	Integra BMWD	N	Low
Q4105	Integra DRT	N	Low
Q4106	Dermagraft	N	High
Q4107	Graftjacket	N	High
Q4108	Integra matrix	N	Low
Q4110	Primatrix	N	High
Q4111	Gammagraft	N	Low
Q4115	Alloskin	N	Low
Q4116	Alloderm	N	High
Q4117	Hyalomatrix	N	Low
Q4119	Matristem wound matrix	N	Low
Q4120	Matristem burn matrix	N	Low
Q4121	Theraskin	N	Low
Q4122	Dermacell	G	n/a
Q4123	Alloskin	N	Low
Q4124	Oasis tri-layer wound matrix	N	Low
Q4125	Arthroflex	N	High
Q4126	Memoderm/derma/tranz/integup	N	High
Q4127	Talymed	G	n/a
Q4128	Flexhd/Allopatchhd/matrixhd	N	Low
Q4129	Unite biomatrix	N	Low
Q4131	Epifix	G	n/a
Q4132	Grafix core	G	n/a
Q4133	Grafix prime	G	n/a
Q4134	HMatrix	N	High
Q4135	Mediskin	N	Low
Q4136	EZderm	N	Low
Q4137	Amnioexcel or biodexcel, 1cm	N	Low

CY 2014 HCPCS Code	CY 2014 Short Descriptor	CY 2014 SI	Low/High Cost Skin Substitute
Q4138	BioDfence DryFlex, 1cm	N	Low
Q4140	Biodfence 1cm	N	Low
Q4141	Alloskin ac, 1 cm	N	Low
Q4142	Xcm biologic tiss matrix 1cm	N	Low
Q4143	Repriza, 1cm	N	Low
Q4146	Tensix, 1cm	N	Low
Q4147	Architect ecm, 1cm	N	Low
Q4148	Neox 1k, 1cm	N	Low

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We will update the groupings of high cost and low cost skin substitutes annually through rulemaking for existing skin substitutes according to the current skin substitute prices. We also will initially assign new skin substitutes that do not qualify for pass-through payment status to either the high cost or low cost category on a quarterly basis using the weighted average per square centimeter number defining high and low cost identified in each final rule. For any new skin substitute products approved for payment during CY 2014, we will use \$32 per square centimeter to determine mapping to the high or low cost skin substitute category. We expect manufacturers to continue reporting ASP to facilitate cost category assignment. Any new skin substitutes without pricing information will be assigned to the low cost category until pricing information is available.

High cost skin substitutes will continue to be billed using the existing

skin substitute application CPT codes 15271 through 15278. We are creating a new set of HCPCS C-codes that parallel the current set of skin substitute application CPT codes (15271 through 15278) for application of low cost skin substitutes beginning in CY 2014 (HCPCS codes C5271, C5272, C5273, C5274, C5275, C5276, C5277, and C5278). We are establishing code edits in our claims processing system that require that the high cost skin substitutes be reported with the CPT codes and the low cost skin substitutes be reported with the new HCPCS C-codes. Geometric mean costs for the various procedures were calculated using only claims for the skin substitutes that are assigned to each class; that is, claims for services described by CPT codes 15271, 15273, 15275, and 15277, including only high cost skin substitutes, were used to calculate the geometric mean costs for these procedures and claims for HCPCS codes C5271, C5273, C5275, and C5277,

including only low cost skin substitutes, were used to calculate the geometric mean costs for these procedures. The add-on CPT skin substitute application codes (CPT codes 15272, 15274, 15276, and 15278) and the add-on HCPCS C-codes for skin substitute application (HCPCS codes C5272, C5274, C5276, and C5278) are packaged in the OPPS under the add-on code packaging policy described in section II.B.3.d.(4) of this final rule with comment period. CPT codes 15271, 15273, 15275, and 15277 and HCPCS C-codes C5271, C5273, C5275, and C5277 were assigned to one of the following four skin repair APCs according to the geometric mean cost for the code: APC 0326 (Level I Skin Repair); APC 0327 (Level II Skin Repair); APC 0328 (Level III Skin Repair); and APC 0329 (Level IV Skin Repair). These procedure codes and the CY 2014 APC assignments and status indicator for each of the procedure codes are listed in the Table 14 below.

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TABLE 14.—CY 2014 SKIN REPAIR PROCEDURE CODES, APC ASSIGNMENTS, AND STATUS INDICATORS

CY 2014 HCPCS Code	CY 2014 Long Descriptor	CY 2014 SI	CY 2014 APC
Skin Substitute Application Procedures for High Cost Skin Substitute Products			
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area	T	0328
15272	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	N	n/a
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	T	0329
15274	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)	N	n/a
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area	T	0328
15276	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	N	n/a
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	T	0328
15278	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)	N	n/a
Skin Substitute Application Procedures for Low Cost Skin Substitute Products			
C5271	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area	T	0327

CY 2014 HCPCS Code	CY 2014 Long Descriptor	CY 2014 SI	CY 2014 APC
C5272	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	N	n/a
C5273	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	T	0327
C5274	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)	N	n/a
C5275	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area	T	0327
C5276	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	N	n/a
C5277	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	T	0327
C5278	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)	N	n/a

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Skin substitutes with pass-through payment status should be reported with CPT codes 15271 through 15278. We will apply an offset to the payment for pass-through skin substitutes according to the offset policy described in section V.A.4.d of this final rule with comment period.

Comment: A few commenters stated that CMS should not package skin substitutes because the claims data used for modeling the cost does not accurately represent the actual cost of the skin substitutes used in the HOPD. They suggested that inaccurate coding and reporting by hospitals, and charge

compression, result in packaged costs that are lower than the actual costs of the skin substitutes used in the surgical procedures in which skin substitutes are employed.

Response: It is our longstanding policy to use the claims and cost report data available to us, without significant editing or modification, to model the prospective payment year OPPS payment rates. We have stated previously that: “[b]eyond 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 do not believe that a problem exists with skin substitute reporting or with the associated data used in modeling the packaged payments for the procedures that includes the cost of the skin substitute. Currently, there is an incentive to code properly for skin substitute application services as the significant majority of the overall payment for these services stems from the separately paid and reported skin substitute, which we believe provides sufficient motivation for the hospitals to

accurately report the amount of skin substitute used. We do not have any evidence of systemic underreporting of these products. We have estimated costs for skin substitutes as we have for all other services in our claims data using our standard methodology outlined in section II.A.2.c. of this final rule with comment period, and we believe these costs to be sufficient for establishing payment for skin substitute application procedures as they are for all other services paid under the OPPS and ASC payment systems. Regarding charge compression, we have addressed charge compression in the OPPS through new cost centers. We refer readers to section II.A.1.c. of this final rule with comment period for a discussion of this topic.

Comment: A few commenters requested that CMS not package implantable biologicals that are used for various surgical procedures in which the implantable biological product is implanted into the body as a part of surgical procedure.

Response: Implantable biologicals have been packaged in the OPPS since 2009. We did not propose to reconsider this packaging policy for CY 2014. In fact, part of the rationale for extending packaging in the OPPS to include skin substitutes that function as surgical supplies is that we already package several products that are the same as or similar to skin substitutes in the OPPS that are described by the term “implantable biological” due to their particular clinical use. Several of the products in the HCPCS code Q4100 series are dual use or multi-use products in that they serve as both skin substitutes and implantable biologicals. We believe that both implantable biologicals and skin substitutes should be packaged into the surgical procedures that employ these products when they function as supplies.

Comment: Some commenters expressed concern that packaging skin substitutes in the OPPS will inhibit the development of biotechnology products and that this proposed policy will result in less investment in such technology.

Response: We do not believe that this policy will result in less investment in biotechnology. New skin substitutes remain eligible for pass-through payment status for at least 2 years, but not more than 3 years. Pass-through payments are intended to facilitate the adoption of certain new products. In addition, we believe that the packaged payments for the associated surgical procedures, including payment for the skin substitute are adequate and will not discourage use of the skin substitute products used in these procedures. Furthermore, the final policy that

distinguishes high cost from low cost skin substitutes addresses the issue of differential cost among the range of skin substitute products. Finally, this packaging policy applies to skin substitutes and other drugs and biologicals used in surgical procedures. It does not apply broadly to all biotechnology.

Comment: Some commenters mentioned that the skin substitute packaging policy will result in a site-of-service shift to the physician office setting where separate payment for skin substitutes will be made in CY 2014.

Response: The physician, in consultation with his or her patient, decides the site of service for treatment and many factors are considered as a part of that decision. We believe that we have adequately addressed concerns about heterogeneous resource costs resulting in payment inadequacy and that these procedures will continue to be performed in the HOPD.

We received a few additional public comments regarding a single product that we also proposed to package because it is a drug that functions as a supply in a surgical procedure. We summarize and respond to these comments below.

Comment: A few commenters objected to the packaging of the drug Mitosol (HCPCS code J7315) when used as a supply in a surgical procedure, which was the interim assignment for new HCPCS code J7315 in the CY 2013 OPPS/ASC final rule with comment period. We refer readers to Addendum B.—Final OPPS Payment by HCPCS Code for CY 2013 available on the Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1589-FC.html?DLPage=1&DLSort=2&DLSortDir=descending>. One commenter in particular complained that, although Mitosol is indicated as “an adjunct for ab externo glaucoma surgery,” OPPS packaging requires that an item be integral to the procedure. The commenter stated that because the use of Mitosol is optional in some cases of glaucoma surgery, it should not be packaged in the OPPS. The commenter stated that “up to 20% of glaucoma surgeries do not include an anti-fibrotic [including Mitosol].” The commenter further stated that Mitosol serves a separate clinical purpose from glaucoma surgery. The commenter emphasized CMS’ threshold packaging policy for drugs, biologicals, and radiopharmaceuticals, and suggested that drugs with per day costs above the threshold should not be packaged. Finally, the commenter stated that the

clinical benefits and orphan drug designation are reasons to not package Mitosol.

Response: Mitosol is an anti-fibrotic drug (meaning that it inhibits wound healing) that is used in glaucoma surgery. Since this comment was filed, we granted Mitosol pass-through payment status. We address the commenter’s specific points as follows. First, we want to dispel the notion that packaged drugs must be used in the associated procedure 100 percent of the time that the procedure is performed. That is not our OPPS packaging policy. As stated above and throughout the proposed rule, we believe packaging is appropriate for items and services that are integral or ancillary or supportive or dependent or adjunctive to the primary procedure. Therefore, items and services that fall within any of these categories may be properly packaged in the OPPS. Mitosol, as an adjunct to trabeculectomy, would therefore be appropriately packaged as a surgical supply if pass-through payment status were not in effect because it functions as a supply in a surgical procedure, and supplies are integral to, dependent on, and supportive of a primary service, as noted above.

We also disagree with the commenter’s assertion that Mitosol serves a different clinical purpose than trabeculectomy, which is to create a functioning filtering bleb for control of intraocular pressure. Mitosol prevents the bleb from scarring, which helps to maintain a functioning filtering bleb, which is the purpose of the glaucoma surgery. Determinations related to the clinical merit of a product are outside the scope of this rule. As noted above, relative clinical value or effectiveness was not proposed as a criterion for OPPS packaging determinations. Finally, while FDA orphan drug designation results in additional exclusivity according to the Federal Food Drug, and Cosmetic Act, it does not exempt a drug from packaging in the OPPS. Upon expiration of pass-through payment status for Mitosol, it is our intent to package it as a supply with glaucoma surgery in the OPPS.

After consideration of the public comments we received, we are packaging all skin substitutes according to the scheme described above, which assigns skin substitutes to either the high cost category or the low cost category unless pass-through payment status applies. Skin substitutes assigned to the high cost category will be reported with CPT codes 15271 through 15278 and the applicable skin substitute HCPCS Q-code, while skin substitutes assigned to the low cost category will be

reported with HCPCS codes C5271 through C5278 and the applicable skin substitute HCPCS Q-code. In addition, the few skin substitute products that are applied as either liquids or powders per milliliter or per milligram and are currently employed in procedures outside of the CPT code range of 15271 through 15278 will not be classified as either high cost or low cost, but will be packaged into the surgical procedure in which they are used.

The skin substitute products that are unconditionally packaged under this final policy and assigned to status indicator "N" for CY 2014 are listed in Addendum P to this CY 2014 OPPS/ASC final rule with comment period. The payment for CPT codes 15271 through 15278 for surgical application of high cost skin substitutes (payment rate per square centimeter over \$32 for CY 2014) and HCPCS codes C5271 through C5278 for surgical application of low cost skin substitutes (payment rate per square centimeter \$32 and under for CY 2014), including the cost of the packaged skin substitutes, for CY 2014, are listed in Addendum B to this final rule with comment period. The OPPS addenda are available on the CMS Web site at: <http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

(3) Clinical Diagnostic Laboratory Tests

Since the beginning of the OPPS, clinical diagnostic laboratory tests (laboratory tests) provided in the hospital outpatient setting have been separately paid to hospitals at Clinical Laboratory Fee Schedule (CLFS) rates (65 FR 18442). Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. Under this authority, the Secretary excluded from the OPPS those services that are paid under fee schedules or other payment systems. As stated in the April 17, 2000 OPPS final rule with comment period: "Rather than duplicate existing payment systems that are effectively achieving consistency of payments across different service delivery sites, we proposed to exclude from the outpatient PPS those services furnished in a hospital outpatient setting that were already subject to an existing fee schedule or other prospectively determined payment rate" (65 FR 18442). Because payment rates for laboratory tests were based on the CLFS, laboratory tests are among the services excluded from the OPPS. We codified this policy at 42 CFR 419.22(l).

As discussed above, it is our intent to revise the structure of the OPPS to adopt

greater aspects of a prospective payment system and retain less of a fee schedule structure, which makes separate payment for each separately coded item. We have examined the services performed in the hospital outpatient setting to determine those services that we believe should be packaged in order to make the OPPS a more complete and robust prospective payment system. We were guided by our longstanding OPPS packaging principle of packaging the payment of items or services when they are provided along with primary services they support. Based on this approach, we believe that laboratory tests (other than molecular pathology tests, as discussed below) that are integral, ancillary, supportive, dependent, or adjunctive to the primary services provided in the hospital outpatient setting are services that should be packaged. Laboratory tests and their results support clinical decision making for a broad spectrum of primary services provided in the hospital outpatient setting, including surgery and diagnostic evaluations. Therefore, except as discussed below for molecular pathology tests, in the CY 2014 OPPS/ASC proposed rule (78 FR 43572), we proposed to package laboratory tests when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting. Specifically, we proposed that laboratory tests would be integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting and appropriate for packaging into the payment of the primary service when they are provided on the same date of service as the primary service and when they are ordered by the same practitioner who ordered the primary service. We stated that the laboratory test codes that we were proposing to be packaged and assigned status indicator "N" for CY 2014 were listed in Addendum P to the proposed rule (which is available via the Internet on the CMS Web site). We also proposed to revise the regulation text at § 419.2(b) and § 419.22(l) to reflect this laboratory test packaging proposal.

We stated that we would consider a laboratory test to be unrelated to a primary service and, therefore, not part of the proposed packaging policy when the laboratory test is the only service provided on a date of service or when the laboratory test is provided on the same date of service as the primary service but is ordered for a different purpose than the primary service by a

practitioner different than the practitioner who ordered the primary service provided in the hospital outpatient setting. We stated that laboratory tests not included in the packaging proposal would continue to be paid separately at CLFS rates when billed on a 14X bill type. We note that hospitals already use the 14X bill type to bill for referred specimens or any situation where the beneficiary receives laboratory tests but is not a registered outpatient of the hospital.

We also proposed an exception to our proposal to package laboratory tests for molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479. We did not propose that these services be packaged because we believe that these relatively new tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we proposed to package. As we gain more experience with molecular pathology tests, we stated that we will consider if packaging them in the OPPS in the future would be appropriate. These services would continue to be billed on a 13x claim and be assigned status indicator "A."

In addition to the laboratory packaging policy proposals described above, we considered proposing an alternative laboratory packaging policy that would package those laboratory tests meeting the proposed policies above, but exclude laboratory tests with costs greater than some dollar threshold similar to the approach we use for separately paid drugs and biologicals in the OPPS so that only laboratory tests (meeting the proposed standards above) with CLFS payment rates below a certain dollar threshold amount would be packaged. Under this alternative policy, tests meeting the proposed standards above, but for which the CLFS payment rates are above the threshold amount, would continue to be separately paid. We decided not to propose this alternative policy because, as discussed above in the background section, our packaging policies generally do not consider the cost of the individual items and services that are packaged, meaning that we package both inexpensive and expensive items according to OPPS packaging principles.

We recognize that the Medicare Part B deductible and coinsurance generally do not apply for laboratory tests paid to hospitals at CLFS rates and that the deductible and coinsurance would apply to laboratory tests packaged into other services in the OPPS. The purpose

of the laboratory packaging proposal was not to shift program costs onto beneficiaries. It is to encourage greater efficiency by hospitals and the most economical delivery of medically necessary laboratory tests which would contain unnecessary growth in hospital outpatient spending over the long run, which benefits all stakeholders. We stated that we estimate that the combination of packaging laboratory tests into a wide array of primary services provided in the hospital outpatient setting combined with our longstanding methodology to adjust the copayment percentages to 20 percent as provided in section 1833(t)(3)(B)(ii) of the Act and as discussed in section II.I. of the proposed rule (78 FR 43586 through 43587), and the limitation on the copayment amount for a procedure to the inpatient hospital deductible as set forth at section 1833(t)(8)(C)(i) of the Act would fully offset the financial impact on Medicare beneficiaries receiving laboratory tests that would be subject to the proposed packaging policy.

Further, we stated that we believe that creating these larger bundles will result in a more efficient use of laboratory tests when they are adjunctive to an outpatient service. In addition, to the extent that the coinsurance and deductible do not apply under the CLFS, they would continue not to apply for tests that are ordered, provided, and billed independently from a primary service as discussed above, or for molecular pathology tests. We invited public comments on the effect of packaging laboratory tests on beneficiary coinsurance.

Comment: Some commenters supported the proposal to package laboratory tests because they believed that packaging laboratory tests is consistent with CMS' goal to move the structure of the OPPTS closer to a prospective payment system and away from a fee schedule construction.

Response: We appreciate the commenters' support.

Comment: A few commenters opposed the proposal to package laboratory tests because they believed that it could harm beneficiary access to these laboratory tests.

Response: We disagree. We believe that beneficiaries will continue to receive laboratory tests that are medically necessary. We are continuing to pay for these laboratory tests and have included the cost of the associated laboratory tests with the estimated cost of primary hospital outpatient services when establishing payment for these services. We believe that packaged payment will allow hospitals to better

assess when and which laboratory tests are appropriate and provide these services more efficiently, but that this policy will not affect beneficiaries' access to reasonable and appropriate care.

Comment: A few commenters opposed the proposal to package laboratory tests because they believed that it would not achieve CMS' objective of greater cost efficiency in hospitals.

Response: We disagree. 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 OPPTS since its implementation in August 2000. We believe that packaging encourages hospitals to furnish services in the most efficient way by enabling hospitals to manage their resources with the maximum flexibility, thereby encouraging long-term cost containment. Therefore, our packaging policies support our strategic goal of incentivizing hospitals to provide appropriate care in the most efficient manner.

Comment: One commenter suggested that CMS does not have the legislative authority to package laboratory tests in the OPPTS. The commenter states that section 1833(h)(1)(A) of the Act requires that CMS pay for laboratory tests (except inpatient laboratory tests) in all settings according to the CLFS.

Response: We disagree. Although section 1833(h)(1)(A) of the Act established the CLFS, it does not prohibit outpatient laboratory tests from being paid either separately or as part of a packaged payment under the OPPTS. Section 1833(t) of the Act gives the Secretary discretion to designate which services are covered OPD services, with the exception of those listed in section 1833(t)(1)(B)(iv) of the Act, and laboratory tests are not among the services listed in section 1833(t)(1)(B)(iv) of the Act. Laboratory tests provided in the hospital outpatient department have always been considered hospital outpatient services. However, until this proposal, we have since the inception of the OPPTS elected to separately pay for laboratory tests in the hospital outpatient setting at the CLFS payment rates. For CY 2014, we proposed to include certain laboratory tests as covered OPD services under the OPPTS, and we proposed to package payment for certain tests, similar to other covered outpatient services that are typically integral, ancillary, supportive, dependent, or adjunctive to

a primary hospital outpatient services under the OPPTS.

Comment: A few commenters expressed concern about increased beneficiary liability associated with laboratory tests being paid under the OPPTS, which has a coinsurance obligation, unlike payment for laboratory tests under the CLFS, which does not have an associated coinsurance obligation by statute. One commenter also requested that, if CMS does finalize the laboratory test packaging policy for CY 2014, it exclude laboratory tests from the services into which they are packaged for the purpose of determining the coinsurance amount.

Response: We appreciate the commenters' concern about the welfare of Medicare beneficiaries. We assessed the financial impact of packaging laboratory tests on beneficiaries for the proposed rule and reassessed the impact for this final rule with comment period. We estimated in the proposed rule that the combination of packaging laboratory tests into a wide array of primary services provided in the hospital outpatient setting combined with our longstanding methodology to adjust the copayment percentages to 20 percent, as provided in section 1833(t)(3)(B)(ii) of the Act and as discussed in section II.I. of the proposed rule (78 FR 43573, 43586 through 43587), and the limitation on the copayment amount for a procedure to the inpatient hospital deductible as set forth at section 1833(t)(8)(C)(i) of the Act, would offset the financial impact on Medicare beneficiaries receiving laboratory tests that will be subject to the finalized packaging policy.

In this final rule with comment period, we are not finalizing our proposed policy to package ancillary services with a CY 2013 status indicator of "X" and diagnostic tests on the bypass list in response to public comments. We estimate that, in aggregate, the percentage of beneficiary liability for OPPTS payments for CY 2014, including payment for certain clinical diagnostic laboratory tests, will be 21.7 percent in CY 2014, consistent with aggregate beneficiary liability under the OPPTS in recent years. We believe that our final policy to create 29 comprehensive APCs for CY 2015 will reduce the aggregate beneficiary liability in CY 2015.

In addition, we believe that creating larger payment bundles will result in a more efficient use of clinical diagnostic laboratory tests when they are integral or supportive of an outpatient service. Furthermore, to the extent that the coinsurance and deductible do not apply under the CLFS, they would

continue not to apply for tests that are ordered, provided, and billed independently from a primary service as discussed above, or for molecular pathology tests, which will continue to be paid under the CLFS.

Regarding the commenter's request that CMS exclude laboratory tests from the services into which they are packaged for the purpose of determining the coinsurance amount, we do not have the authority under section 1833(t)(8) of the Act to exclude laboratory tests from the services into which they are packaged for the purpose of determining the coinsurance amount.

Comment: Some commenters expressed concern about CMS' proposed exception to packaging for laboratory tests provided on the same date of service as another hospital outpatient service or services, but that are ordered by a different practitioner than the practitioner who ordered the primary hospital outpatient service or services and where the ordered laboratory test also is for a different purpose than the primary service. Commenters were concerned about hospitals' administrative burden associated with billing for separately paid laboratory tests. Commenters suggested that CMS implement claims processing changes and instructions in advance of adopting the laboratory packaging policy to ease hospitals' transition to this policy and the exceptions to this policy.

Response: We believe that these commenters may have misunderstood the nature of the proposed laboratory packaging policy. We proposed to package laboratory tests when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting; that is, when they are provided on the same date of service as the primary service and when they are ordered by the same practitioner who ordered the primary service. One exception to our proposal to package laboratory tests is to exempt molecular pathology tests, which would continue to be separately paid when billed on a 13x claim.

A laboratory test can be separately paid when (1) the laboratory test is the only service provided to that beneficiary on that date of service; or (2) the laboratory test is on the same date of service as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service. When a laboratory test is the only service provided to a beneficiary at the hospital, the hospital can receive separate payment for those laboratory tests by

billing for these services on a 14x claim; we would pay hospitals for these laboratory tests based on the CLFS payment rate. To illustrate the second scenario, a beneficiary has eye surgery scheduled with physician A, an ophthalmologist, but also has an order from physician B, a cardiologist, for unrelated laboratory tests. The beneficiary goes to the hospital for the eye procedure and decides to have the laboratory tests that have been ordered by physician B for a different purpose than the eye procedure on the same date of service. While the laboratory test is on the same date of service as the eye procedure, the laboratory tests are ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the eye procedure. In this situation, the hospital can bill Medicare for the unrelated laboratory tests on a 14x claim and receive separate payment under the CLFS, similar to when the laboratory tests are the only service performed in the hospital outpatient department on a given date of service. However, if, in this example, physician A also ordered some laboratory tests as a part of a preoperative evaluation for the eye procedure and the beneficiary had the tests on the same date of service as the eye procedure, then the hospital would report those laboratory tests on a 13x claim along with the eye surgery. Payment for those preoperative laboratory tests would be packaged into the payment for the surgery, which is the primary procedure that would be paid separately. It will be the hospital's responsibility to determine when to separately bill laboratory tests on the 14x claim according to this description of these limited exceptions. We plan to issue revised contractor instructions for billing for these laboratory tests on a 14x bill type in January 2014, and we also will install claims processing edits.

Comment: A few commenters suggested that CMS adopt the alternative laboratory packaging policy discussed briefly above and in the proposed rule (78 FR 43573) to package only those laboratory tests with payment rates below some dollar threshold, similar to the approach that CMS uses for most drugs, biologicals, and therapeutic radiopharmaceuticals in the OPPS. Commenters stated that such a policy would enable hospital specialty clinics to perform more complex, expensive, and esoteric laboratory tests.

Response: We appreciate the commenters' thoughts on this alternative. We continue to believe that a dollar packaging threshold is not appropriate for laboratory tests because almost all laboratory tests are

inexpensive (97 percent of all laboratory tests have CLFS national limitation amounts of less than \$100) relative to other services that are provided in the hospital outpatient department. This is unlike many of the drugs and biologicals that are used in the hospital outpatient department that not uncommonly cost thousands of dollars per dose. Therefore, we continue to believe that it is not necessary to adopt a payment threshold policy for packaging laboratory tests similar to the threshold policy for packaging drugs and biologicals.

Comment: A few commenters requested additional exceptions to the proposal to package specific laboratory tests, including, for example, tests for in situ hybridization and cardiovascular screening. These commenters stated that, like molecular pathology tests for which CMS proposed an exception to the proposal to conditionally package laboratory tests, these tests have a different pattern of clinical use than most other laboratory tests and, therefore, should continue to be separately paid in the hospital outpatient setting.

Response: After considering the various requests for exceptions for specific laboratory tests that we received, we do not believe that additional exceptions to the laboratory packaging policy are necessary. We understand that there are laboratory tests that are less common and frequent than a standard panel, such as new tests. We do not believe that the tests described by the commenters or other laboratory tests that were proposed to be packaged are similar to the tests in the molecular pathology test series such that additional exceptions are warranted. We proposed to exclude the molecular pathology tests from our packaging proposal because, as a class of laboratory tests, their overall pattern of clinical use has not yet developed and we believe that these tests are less tied to a primary service than other laboratory tests. Once their pattern of use develops, we will assess whether we believe these laboratory tests also should be conditionally packaged. We do not believe that in situ hybridization and cardiovascular screening or other types of laboratory tests are a developing class of laboratory tests for which we do not know the pattern of use. For example, in situ hybridization may be a part of a comprehensive evaluation for a suspected malignancy. In response to commenter requests for additional exceptions, we also reviewed all of the laboratory tests listed in Addendum P to the proposed rule and do not believe that further exceptions to

our proposal to conditionally package laboratory tests are necessary.

After consideration of the public comments we received, for CY 2014, we are finalizing our proposal without modification to package laboratory tests in the OPPS when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting; that is, when they are provided on the same date of service as the primary service and when they are ordered by the same practitioner who ordered the primary service. This means that a laboratory test will not be packaged when (1) a laboratory test is the only service provided to that beneficiary on that date of service; or (2) a laboratory test is conducted on the same date of service as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service. We also are finalizing our proposal without modification to except molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 from this packaging proposal. In addition, we are finalizing our proposal without modification to revise the regulation text at § 419.2(b) and § 419.22(l) to reflect this conditional laboratory test packaging policy.

The laboratory test codes subject to this packaging policy will be assigned status indicator “N” because any laboratory tests reported on a 13x bill type will be packaged for CY 2014. These codes are listed in Addendum P to this final rule with comment period (which is available via the Internet on the CMS Web site).

(4) Procedures Described by Add-On Codes

Add-on codes describe procedures that are always performed in addition to a primary procedure. CPT defines add-on codes as codes that describe “procedures [that] are commonly carried out in addition to the primary procedure performed,” and also states that “[a]dd-on codes are always performed in addition to the primary service or procedure and must never be reported as a stand-alone code” (2013 CPT Codebook Professional Edition, page xi). CPT add-on codes are listed in Appendix D of the CPT codebook. Add-on codes can also be Level II HCPCS codes. For example, the procedure described by CPT code 11001 is “Debridement of extensive eczematous or infected skin; each additional 10% of the body surface, or part thereof (list separately in addition to code for

primary procedure).” This code is used for additional debridement beyond that described by the primary procedure code. Historically, the OPPS has generally paid separately for add-on codes based on an APC assignment with status indicator “T” indicating that the multiple procedure payment reduction for surgeries applies.

Procedures described by add-on codes represent an extension or continuation of a primary procedure, which means that they are typically supportive, dependent, or adjunctive to a primary service, which is usually a surgical procedure. The primary code defines the purpose and typical scope of the patient encounter and the add-on code describes incremental work, when the extent of the procedure encompasses a range rather than a single defined endpoint applicable to all patients. The CPT codebook states that an add-on code describes “additional intra-service work associated with the primary procedure” (2013 CPT Codebook Professional Edition, page xi). For example, add-on CPT code 11001 is used for each additional 10 percent of debridement beyond that described by the primary code. Given the dependent nature and adjunctive characteristics of procedures described by add-on codes and in light of longstanding OPPS packaging principles described above, we believe add-on procedures should be packaged with the primary procedure. In the CY 2014 OPPS/ASC proposed rule (78 FR 43573), we proposed to unconditionally package all procedures described by add-on codes in the OPPS.

Aside from advancing the OPPS as a prospective payment system by packaging add-on codes, an additional benefit to packaging add-on codes is more accurate OPPS payment for procedures described by add-on codes. Currently, calculating geometric mean costs for procedures described by add-on codes is problematic in the OPPS because, as with many claims with multiple procedures, we cannot determine which costs on a claim are attributable to the primary procedure and which costs are attributable to the add-on procedure. Furthermore, because we use single claims and pseudo single procedure claims for ratesetting, we generally must rely on incorrectly coded claims containing only the add-on code to determine payment rates for add-on procedures. Claims containing only an add-on code are incorrectly coded because they should be reported with (or “added-on” to) a primary procedure. Packaging the line item costs associated with an add-on code into the cost of the primary procedure will help address this ratesetting problem because the

costs of the add-on code would be packaged into the primary procedure, and we would no longer have to use miscoded claims to calculate estimated costs for add-on codes. Packaging add-on codes also would increase the number of single bills available for ratesetting for the primary procedures. We discuss how we model claims to establish relative payment weights, including definitions of multiple, single, and pseudo single claims in section II.A.2. of this final rule with comment period.

We proposed to revise the regulations at § 419.2(b) to include the packaging of add-on codes. The specific add-on codes that we proposed to be unconditionally packaged and assigned status indicator “N” for CY 2014 are listed in Addendum P to the proposed rule, which is available via the Internet on the CMS Web site.

Comment: Some commenters supported the proposal to package add-on codes, and agreed with CMS that packaging add-on codes is consistent with a prospective payment system and will improve OPPS ratesetting.

Response: We appreciate the commenters’ support.

Comment: Several commenters objected to the proposal to package add-on codes for the following reasons:

- According to the commenters, procedures described by add-on codes are not necessarily integral, ancillary, supportive, dependent, or adjunctive to the primary service into which they would be packaged.

- Some procedures described by add-on codes include expensive implantable medical devices, and although they are integral to the primary procedure, commenters note that packaging these procedures into the primary procedure risks significant underpayment for the overall procedure that includes additional medical devices, which could negatively affect patient access to these devices.

- Add-on code packaging should not apply to infrequently performed add-on codes as the cost of these infrequent services will not be sufficiently reflected in the payment for the primary procedure.

- Some add-on codes are not related to the primary procedure but represent incremental additional physician work, and for this reason should not be packaged.

To insure continued patient access to these procedures, commenters requested that CMS establish exceptions to its proposal to package add-on codes for specific services that commenters believed would be underpaid under the policy, including, but not limited to,

kyphoplasty add-on procedure, endoscopic retrograde cholangiopancreatography add-on procedure, pelvic reconstruction add-on procedures, neurolysis, and pathology services.

Response: We disagree with commenters that add-on services are not integral, ancillary, supportive, dependent, or adjunctive to the primary service. 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 very definition of an add-on code is that it is an extension of a primary, base service. CPT states that “add-on codes describe additional intra-service work *associated with the primary procedure*” (emphasis

added) (2013 CPT Codebook Professional Edition, page xi). Therefore, we believe that add-on code procedures 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. For the same reasons, we also do not agree 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.

Regarding the packaging of add-on procedures that use expensive medical devices, we note that the most expensive medical devices used in procedures to insert or implant devices in the outpatient setting are included in

procedures we proposed to be assigned to comprehensive APCs. In section II.A.2.e. of this final rule with comment period, we discuss this policy, which we are adopting, but delaying the implementation until CY 2015. We will continue to separately pay for procedures described by add-on codes that are currently assigned to device-dependent APCs. We note that almost all such codes will be included in a comprehensive APC for CY 2015. Therefore, until the comprehensive APC policy is implemented, we will continue to pay separately for procedures described by add-on codes that are assigned to device-dependent APCs. The device-dependent add-on codes that will continue to be separately paid in CY 2014 are listed below in Table 15.

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**TABLE 15.—ADD-ON CODES ASSIGNED TO DEVICE-DEPENDENT APCS
FOR CY 2014**

CY 2014 Add-on Code	Short Descriptor	CY 2014 APC
19297	Place breast cath for rad	0648
33225	L ventric pacing lead add-on	0655
37222	Iliac revasc add-on	0083
37223	Iliac revasc w/stent add-on	0083
37232	Tib/per revasc add-on	0083
37233	Tibper revasc w/ather add-on	0229
37234	Revsc opn/prq tib/pero stent	0083
37235	Tib/per revasc stnt & ather	0083
37237	Open/perq place stent ea add	0083
37239	Open/perq place stent ea add	0083
49435	Insert subq exten to ip cath	0427
92921	Prq cardiac angio addl art	0083
92925	Prq card angio/athrect addl	0082
92929	Prq card stent w/angio addl	0104
92934	Prq card stent/ath/angio	0104
92938	Prq revasc byp graft addl	0104
92944	Prq card revasc chronic addl	0104
92998	Pul art balloon repr percut	0083
C9601	Perc drug-el cor stent bran	0656
C9603	Perc d-e cor stent ather br	0656
C9605	Perc d-e cor revasc t cabg b	0656
C9608	Perc d-e cor revasc chro add	0656

BILLING CODE 4120-01-C

However, in general the cost of all medical devices used along with all of the other costs associated with the add-on code procedures are a part of the costs used to calculate the payment for

a primary procedure when add-on codes are packaged. Most important, a prospective payment system pays an average amount for a unit of service, which may be more or less costly on a case-by-case basis. Unless an ancillary

service is always performed with a primary procedure or service, a prospective payment will not reflect the full estimated cost of the packaged procedure or service. Payment for the primary procedure rather would reflect

some payment for the ancillary procedure, but each time the primary procedure is performed, the hospital receives additional payment, even when the ancillary service is not provided. Unless an add-on code is always performed with a primary procedure, we would not expect the relative payment weight to reflect the full costs associated with performing the primary procedure and certain add-on procedures, especially if the add-on procedures are performed relatively infrequently as compared to the primary procedure. Our experience with packaging services under the OPPS, where we continue to see packaged services furnished with the primary procedure, leads us to believe that hospitals will continue to provide the full range of medically necessary care to beneficiaries under overall prospective payment for the primary procedure and any add-on procedures. Therefore, we do not believe that it is necessary to create additional exceptions to the add-on code policy for select infrequently performed services that may cost more (in addition to the cost of the primary procedure) to pay more than the prospective payment for the primary service with add-on code procedures packaged into them.

However, we acknowledge that, under certain circumstances, certain primary code and add-on code combinations could be more likely to result in a relatively highly costly case as compared to the packaged payment for the primary code. Therefore, in light of this new policy to unconditionally package most add-on codes, we will examine our estimated OPPS outlier percentage in light of all final packaging policies contained in this final rule with comment period and consider increasing it in the future to accommodate greater potential risk from high cost outlier cases that would result from packaging of certain add-on codes. An increase in the outlier percentage would accommodate more relatively high cost cases.

Comment: Some commenters objected to packaging drug administration add-on codes, which typically describe each additional hour of infusion or each additional intravenous push, etc. in addition to the initial drug administration service. The commenters believed that such a policy could disadvantage providers of longer drug administration services, which are often protocol driven and are not necessarily dictated by the hospital but by the characteristics of the specific drug or biological being administered to the patient.

Response: We believe that, given the frequency of drug administration services in the hospital outpatient department and their use in such a wide variety of different drug treatment protocols for various diseases in all types of hospitals, further study of the payment methodology for these services is warranted at this time. Therefore, we are not finalizing our proposal to package the drug administration add-on codes in CY 2014. However, we may continue to explore other payment options, including packaging and variations on packaging, in future years.

After consideration of the public comments we received, we are finalizing our proposal to unconditionally package procedures described by add-on codes, with the exception of add-on codes for drug administration services and for CY 2014 add-on codes assigned to device-dependent APCs. In addition, for CY 2014 only, we will continue to separately pay for procedures described by add-on codes that are currently assigned to device-dependent APCs. We also are revising § 419.2(b) to include add-on code procedures among the services that are packaged in the OPPS. The specific add-on codes that we are unconditionally packaging and assigning status indicator “N” for CY 2014 are listed in Addendum P and Addendum B to this final rule with comment period (which are available via the Internet on the CMS Web site).

(5) Ancillary Services (Status Indicator “X”)

Under the OPPS, we currently pay separately for certain ancillary services that are assigned to status indicator “X,” defined as “ancillary services.” Those ancillary services assigned status indicator “X” in the OPPS and paid separately are, by definition, ancillary to primary services provided in the OPPS and include many minor diagnostic tests and procedures that are typically performed with a primary service, although there are instances where hospitals provide such services alone and without another primary service on the same date.

As mentioned above, our intent is that the OPPS be more of a prospective payment system through expanded packaging. 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 proposed rule (78 FR 43573) that we believe that these ancillary services, which are assigned status indicator “X,” 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 § 419.2(b) that packages ancillary services into primary services while preserving separate payment for those instances in which one of these services is provided alone (not with a separate primary service) to a hospital outpatient.

In summary, in the proposed rule, we proposed to conditionally package all ancillary services that were previously assigned a status indicator of “X” and assign these services to status indicator “Q1” (packaged when provided with a service assigned a status indicator of “S,” “T,” or “V”). Status indicator “X” would be discontinued. To encourage maximum flexibility to beneficiaries across different sites of service, we did not propose to conditionally package preventive services assigned to status indicator “X” and instead proposed to change the status indicator for preventive services from the currently assigned status indicator “X” to status indicator “S.” The specific codes for procedures assigned to status indicator “X” that were proposed to be conditionally packaged and assigned to status indicator “Q1” for CY 2014 were listed in Addendum P to the proposed rule (which is available via the Internet on the CMS Web site).

Comment: A few commenters agreed with CMS’ proposal to package services assigned the status indicator “X” (ancillary services) because they believed that this proposal was consistent with CMS’ policy of packaging services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary HOPD service.

Response: We appreciate the commenters’ support.

Comment: Many commenters opposed the proposal to conditionally package services currently assigned status indicator “X.” These commenters stated that this category of services is too varied and that the services in this category are not always ancillary to the services into which they would be packaged. The commenters specifically mentioned radiation oncology planning services and pathology services as examples of services that, under the proposal, could be packaged into a visit but would not be ancillary to that visit. They also objected because, in some cases, relatively costly services could be packaged into services with a low payment, especially a visit code because there is so much volume in visit codes that high cost, low volume ancillary

services would not measurably impact visit payments.

Response: We believe that the commenters have raised some valid points regarding whether all of the services currently assigned status indicator “X” are in all cases ancillary to the services into which their payment would be packaged. We believe that a reexamination of this group of services is warranted to determine which services are best described as ancillary services and packaged on that basis and which services should either be packaged under a different policy or separately paid in the OPPS.

However, we will finalize the conditional packaging of one ancillary service described by CPT code 93017 (Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; tracing only, without interpretation and report). Stress testing is often performed as a part of myocardial perfusion imaging (MPI). MPI is most commonly reported with CPT code 78452 (Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction, by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection). As indicated by the code descriptor, MPI includes stress testing as described by CPT code 93017, and approximately 96 percent of MPI is performed under stress. Therefore, we believe that, because stress testing is both integral and ancillary to MPI, it should be packaged into MPI when a stress test accompanies MPI.

After consideration of the public comments we received, we are not finalizing our proposal to conditionally package codes currently assigned the ancillary service status indicator “X” for CY 2014 when performed with another service, with the exception that CPT code 93017 will be conditionally packaged. We may review the services assigned status indicator “X” (ancillary services) to determine which may be appropriate for packaging as ancillary services in the OPPS in future years.

(6) Diagnostic Tests on the Bypass List

For the CY 2013 OPPS, we continued our policy to use a bypass list to convert lines from multiple procedure claims into “pseudo” single procedure claims. In the CY 2014 OPPS/ASC proposed rule (78 FR 43574), we proposed to continue developing “pseudo” single

procedure claims using a bypass list for the CY 2014 OPPS, as discussed in section II.A.1.b. of the proposed rule. The bypass list of separately paid services is used to convert claims with multiple separately payable procedures, which are generally not used for ratesetting purposes, into claims with the isolated costs of a single separately paid procedure that can be used for ratesetting. Services on the bypass list have limited associated packaged costs so they can be bypassed when assigning packaged costs on a claim to a separately paid procedure on the same claim.

As noted above, beginning in CY 2008, we packaged several diagnostic items and services including guidance services, image processing services, intraoperative services, imaging supervision and interpretation services, diagnostic radiopharmaceuticals, and contrast agents. In the CY 2014 OPPS/ASC proposed rule (78 FR 43570), we also proposed to conditionally package several diagnostic items and services, including drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, ancillary services (many of which are diagnostic tests), and certain clinical laboratory tests. We stated that we believe that the diagnostic tests on the bypass list share many of the characteristics with these other conditionally or unconditionally packaged or proposed packaged categories of items and services in that they are diagnostic and are integral, ancillary, supportive, dependent, or adjunctive to a primary service. Examples include a barium swallow test (CPT code 74220) and a visual field examination (CPT code 92081). Given the nature of these services, we proposed to conditionally package these procedures. We recognize that some of these services are sometimes provided without other services and, therefore, they will continue to be separately paid in those circumstances.

We proposed to conditionally package codes on the bypass list and to assign them the appropriate status indicator “Q1” beginning in the CY 2014 OPPS. Some of these diagnostic tests on the bypass list are currently assigned to status indicator “X” and, therefore, would be conditionally packaged under the proposed policy to conditionally package ancillary services currently assigned status indicator “X.” The only diagnostic codes on the bypass list affected by this proposal are currently assigned to status indicator “S.” The specific codes for the diagnostic tests on the bypass list that we proposed to be conditionally packaged and assigned to

status indicator “Q1” for CY 2014 were listed in Addendum P to the proposed rule (which is available via the Internet on the CMS Web site). Similar to our conditional packaging proposal for services previously assigned to status indicator “X,” we did not propose to conditionally package preventive services that are diagnostic tests on the bypass list.

Comment: Some commenters supported CMS’ proposal to package diagnostic codes on the bypass list because they believed that they are generally ancillary and supportive to other HOPD services.

Response: We appreciate the commenters’ support.

Comment: Some commenters opposed packaging diagnostic tests on the bypass list for the following reasons:

- Some of the tests, for example, echocardiography, included in this category are not typically integral, ancillary, supportive, dependent, or adjunctive to the service into which they would be packaged.
- Some of the procedures on the bypass list would be packaged into significantly lower paying procedures, including visits.
- The interaction between conditional packaging of these diagnostic tests and other status indicator logic sometimes produces anomalous payments.
- Hospitals have an incentive to schedule procedures on different days to avoid packaging.
- Access to some of these tests may be negatively impacted by packaging.

Response: We believe that the commenters have raised some valid points regarding whether all of the services included in the category “diagnostic codes on the bypass list” are integral, ancillary, supportive, dependent, or adjunctive to the service into which their payment is packaged. We believe that a reexamination of this group of services is warranted to determine which services are best described as integral, ancillary, supportive, dependent, or adjunctive services to the service into which it would be packaged to determine which services should either be packaged under a different policy or separately paid in the OPPS.

Therefore, after consideration of the public comments we received, we are not finalizing our proposal to conditionally package diagnostic tests on the bypass list for CY 2014, or our proposal to assign these codes a status indicator of “Q1.” We will review the services currently listed in Addendum P under “diagnostic tests on the bypass list” to determine which tests may be

appropriate for packaging in the OPPS in future years. Codes that would have been affected by the CY 2014 packaging proposal for this category of services will remain on the bypass list for the CY 2014 OPPS, as discussed in section II.A.1.b. of this final rule with comment period.

(7) Device Removal Procedures

Implantable devices frequently require a procedure to remove or replace the device due to wear, failure, recall, and infection, among other reasons. Since the beginning of the OPPS, implantable devices have been packaged (either as supplies, implantable prosthetics, or implantable DME) into their associated procedures. A device removal procedure is sometimes described by a code that may include repair or replacement. In other cases, a device removal procedure is described by a separate code that only describes the surgical procedure to remove a device. Device removal procedures are frequently performed with procedures to repair or replace devices, although it is possible that a device removal procedure may occur without repair or replacement if the clinical indication for the device that was removed no longer exists. When a separately coded device removal procedure is performed with a separately coded device repair or replacement procedure, the device removal procedure should be considered as one part of an overall procedure for removing a device with repair or replacement of the device.

Given that a separately coded device removal procedure that accompanies a device repair or replacement procedure represents a service that is integral and supportive to a primary service, in the CY 2014 OPPS/ASC proposed rule (78 FR 73574), we proposed to conditionally package device removal codes when they are billed with other surgical procedures involving repair or replacement and assign a status indicator of "Q2." We stated that we believe that this conditional packaging policy is appropriate under longstanding OPPS packaging principles because these device removal procedures are an integral and supportive step in a more comprehensive overall procedure. Furthermore, conditionally packaging these device removal procedures with the replacement or revision codes would be consistent with our packaging policies for other dependent services. The specific codes for the device removal procedures that we proposed to be conditionally packaged and assigned to status indicator "Q2" for CY 2014 were listed in Addendum P to the

proposed rule (which is available via the Internet on the CMS Web site).

Comment: Some commenters agreed with CMS' proposal to conditionally package device removal procedures in the OPPS because they are often part of a larger procedure to revise or replace a device.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our policy to conditionally package device removal procedures in the OPPS when performed together with a repair or replacement of a device and to assign a status indicator of "Q2." The specific device removal procedure codes that we are conditionally packaging and assigning to status indicator "Q2" for CY 2014 are listed in Addendum P to this final rule with comment period (which is available via the Internet on the CMS Web site).

e. Clarification Regarding Supplies That Are Packaged in the OPPS

Under the regulations at § 419.2(b)(4), medical and surgical supplies and equipment are unconditionally packaged in the OPPS and have been since the beginning of the payment system. Supplies is a large category of items that typically are either for single patient use or have a shorter life span in use than equipment. Packaged supplies can include certain drugs, biologicals, and radiopharmaceuticals. The only supplies that are sometimes paid separately in the hospital outpatient setting are prosthetic supplies under § 419.22(j), and if paid separately, they are paid according to the DMEPOS fee schedule. As we discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 43575), in our annual review of the OPPS for CY 2014, we discovered many supplies that should be packaged in the OPPS according to § 419.2(b)(4), but that are currently assigned to status indicator "A" and are separately paid in the hospital outpatient setting according to the DMEPOS fee schedule. For CY 2014, we proposed to revise the status indicator for all supplies described by Level II HCPCS A-codes (except for prosthetic supplies) from status indicator "A" to "N," so that these supplies would be unconditionally packaged as required by § 419.2(b)(4).

Comment: A few commenters supported CMS' proposed change in the status indicators for these supplies from "A" to "N." One commenter urged CMS not to finalize this proposal because the commenter believed that hospitals should be separately paid for supplies given to the patient to take home.

Response: Our longstanding regulations at § 419.2(b)(4) require that we package all supplies in the OPPS except prosthetic supplies.

After consideration of the public comments we received, we are updating the status indicators for all supplies (except prosthetic supplies) to "N." The specific Level II HCPCS A-codes whose status indicator are revised from "A" to "N" are listed in Addendum P to this CY 2014 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

f. Revision and Clarification of the Regulations at 42 CFR 419.2(b) and 42 CFR 419.22

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68272), after consideration of public comments we received on the proposed rule, we clarified the regulatory language at § 419.2(b) to make explicit that the OPPS payments for the included costs of the nonexclusive list of items and services covered under the OPPS referred to in this paragraph are packaged into the payments for the related procedures or services with which such items and services are provided. In the CY 2014 OPPS/ASC proposed rule (78 FR 43575), we proposed to further revise this regulation to add the packaging categories that were adopted in CYs 2008 and 2009 in addition to the new proposed policies described above. We also proposed to make some further minor revisions and editorial clarifications to the existing language of § 419.2(b) to make it more clearly reflect current packaging policy. Finally, we proposed to revise the list of services excluded from the OPPS at § 419.22.

Comment: Some commenters urged CMS not to revise the regulations at 42 CFR 419.2(b) as a part of their request that CMS not adopt any of the packaging proposals.

Response: We believe that codifying the new policies will promote clarity regarding OPPS packaging policy, and therefore we are finalizing our revision of the regulations.

After consideration of the public comments received, we are finalizing our revision of the regulations at 42 CFR 419.2(b) and 419.22 to reflect the new packaging policies.

g. Comment Solicitation on Increased Packaging for Imaging Services

We currently package several kinds of imaging services in the OPPS, including image guidance services, image processing services, intraoperative imaging, and imaging supervision and interpretation services. In addition to

these imaging services that are either packaged or proposed to be packaged, we stated in the CY 2014 OPPS/ASC proposed rule (78 FR 43575) that we are considering a proposal for CY 2015 that would conditionally package all imaging services with any associated surgical procedures. We stated that imaging services not provided with a surgical procedure would continue to either be separately paid according to a standard clinical APC or a composite APC. We requested public comments on this potential CY 2015 proposal.

Comment: Some commenters objected to this potential future proposal on the grounds that such a packaging policy could result in less access to imaging in the HOPD. One commenter asked about the claims logic hierarchy for packaging imaging into surgery as it relates to the imaging composites.

Response: We appreciate these thoughtful comments, and we will consider them as we further consider packaging imaging services in the OPPS.

4. Calculation of OPPS Scaled Payment Weights

In the CY 2014 OPPS/ASC proposed rule (78 FR 43576), for CY 2014, we proposed to calculate the relative payment weights for each APC for CY 2014 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. For this CY 2014 final rule with comment period, we are continuing to use this methodology to calculate the relative payment weights for each APC for CY 2014. In years 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 for 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 APC 0606 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 to calculate relative payment weights. For the CY 2014 OPPS, we proposed to

continue basing the relative payment weights on which OPPS payments will be made by using geometric mean costs (78 FR 43576). As we discuss in section VII. of the proposed rule and this final rule with comment period, we proposed to reconfigure the CY 2014 visit APCs so that they would include a single level for each visit type. However, in an effort to maintain consistency in calculating unscaled weights that represent the cost of some of the most frequently provided services, we proposed to use the cost of the clinic visit APC in calculating unscaled weights, which for CY 2014 was proposed APC 0634. While we have previously used APC 0606 as the base from which to develop the OPPS budget neutral weight scaler, under our proposal to reconfigure the visit APCs, we proposed to have a single APC for each visit type. The proposal to reconfigure the visit APCs is discussed in more detail in section VII. of the proposed rule and this final rule with comment period. Following our general methodology for establishing relative payment weights derived from APC costs, but using the proposed CY 2014 geometric mean cost for APC 0634, for CY 2014, 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 for all other APCs does not affect the 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 2014 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, as we proposed, we compare the estimated aggregate weight using the CY 2013 scaled relative payment weights to the estimated aggregate weight using the CY 2014 unscaled relative payment weights.

For CY 2013, we multiplied the CY 2013 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2012 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 2014, we are applying the same process using the CY 2014 unscaled relative payment weights rather than scaled relative payment weights. We calculate the weight scaler by dividing the CY 2013 estimated aggregate weight by the CY 2014 estimated aggregate weight. 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, as a result of the CY 2014 OPPS packaging policy for laboratory tests described in section II.A.3.b.(3) of this final rule with comment period, we need to incorporate the estimated relative payment weights from those services. Therefore, the CY 2013 estimated OPPS aggregate weight include payments for outpatient laboratory tests paid at the 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>.

We include estimated payments to CMHCs in our comparison of the estimated unscaled relative payment weights in CY 2014 to the estimated total relative payment weights in CY 2013 using CY 2012 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we adjusted the CY 2014 unscaled relative payment weights for purposes of budget neutrality. The CY 2014 unscaled relative payment weights were adjusted by multiplying them by a weight scaler of 1.2732 to ensure that the CY 2014 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 2014 OPPS.

Comment: One commenter expressed the concern that CMS may have underfunded the OPPS in developing the budget neutral weight scaler for the additional costs associated with laboratory tests for CY 2014.

Response: We appreciate the commenter's concern. We discussed the calculation of the proposed CY 2014 budget neutral weight scaler in the CY 2014 OPPS/ASC proposed rule (78 FR 43576) as well as the claims accounting narrative that we make available via the Internet on the CMS Web site. In calculating the CY 2014 OPPS budget neutral weight scaler, we calculated the CY 2013 aggregate payment weight associated with the laboratory tests paid at CLFS rates by applying the CY 2013 CLFS payment rates to the laboratory tests performed in the hospital setting. We note that this is the standard process we use to develop relative payment weights for budget neutrality for items and services that have predetermined payment rates, such as separately paid OPPS drugs and New Technology APCs. We note that we released corrected data files on August 28, 2013, and extended the comment period to September 16, 2013, on the technical corrections noted in the correcting document published in the **Federal Register** on September 6, 2013 (78 FR 54842). However, there were no corrections associated with the amount of the estimated payment weight being budget neutralized from these clinical diagnostic laboratory tests.

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 1.2732 for this final rule with comment period. The CY 2014 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 2014 IPPS/LTCH PPS final rule (78 FR

50607), consistent with current law, based on IHS Global Insight, Inc.'s second quarter 2013 forecast of the FY 2014 market basket increase, the final FY 2014 IPPS market basket update is 2.5 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(iii) 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 2014.

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 2014 IPPS/LTCH PPS proposed rule (78 FR 27572), we discussed the calculation of the proposed MFP adjustment for FY 2014, which was 0.4 percentage point.

We proposed that if more recent data became subsequently available after the publication of the proposed rule (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such data, if appropriate, to determine the CY 2014 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 2014 OPPS/ASC final rule with comment period. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50607), we discussed the calculation of the final MFP adjustment for FY 2014, which is 0.5 percentage point.

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 2014, section 1833(t)(3)(G)(iii) of the Act provides a 0.3 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)(iii) of the Act, in the CY 2014 OPPS/ASC proposed rule (78 FR 43577), we proposed to apply a 0.3 percentage point reduction to the OPD fee schedule increase factor for CY 2014.

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 for a year, and may result in payment rates under the OPPS for a year being less than such payment rates for the preceding year. As described in further detail below, using the final methodology and more recent data results in an OPD fee schedule increase factor of 1.7 percent for the CY 2014 OPPS (which is 2.5 percent, the final estimate of the hospital inpatient market basket percentage increase, less the final 0.5 percentage point MFP adjustment, and less the 0.3 percentage point additional adjustment).

We note that 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. As a result, using the final methodology and more recent data, those hospitals failing to meet the Hospital OQR Program reporting requirements will receive an OPD fee schedule increase factor of –0.3 percent (which is 2.5 percent, the final estimate of the hospital inpatient market basket percentage increase, less the final 0.5 percentage point MFP adjustment, less the 0.3 percentage point additional adjustment, and less 2.0 percentage points for the Hospital OQR Program reduction). For further discussion of the Hospital OQR Program, we refer readers to section XIII. of this final rule with comment period.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43577), we proposed to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (5) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2014, 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)(iii) 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 0.3 percentage point for CY 2014.

We did not receive any public comments on our proposed adjustments to the OPD fee schedule increase factor or on the proposed changes to § 419.32(b)(1)(iv)(B) to add a new paragraph (5). For the reasons discussed above, we are adjusting the OPD fee schedule increase factor and adopting, as final, the amendment to § 419.32(b)(1)(iv)(B), as proposed.

We did not receive any public comments on our proposed methodology for calculating the CY 2014 conversion factor. Therefore, we are finalizing our proposed methodology for calculating the budget neutrality adjustment factors, as described in the following discussion.

As we proposed, to set the OPPS conversion factor for CY 2014, we are increasing the CY 2013 conversion factor of \$71.313 by 1.7 percent. In accordance with section 1833(t)(9)(B) of the Act, we are further adjusting the conversion factor for CY 2014 to ensure that any revisions made to the updates for a revised wage index and rural adjustment are made on a budget neutral basis. We are calculating an overall budget neutrality factor of 1.0002 for wage index changes by comparing total estimated payments from our simulation model using the final FY 2014 IPPS wage indices to those payments using the FY 2013 IPPS wage indices, as adopted on a calendar year basis for the OPPS.

For CY 2014, we did not propose to make a change to our rural adjustment policy, and as discussed in section II.E. of this final rule with comment period, we are not making any changes to the rural adjustment policy. Therefore, the budget neutrality factor for the rural adjustment is 1.0000.

For CY 2014, 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. We are calculating a CY 2014 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing the estimated total CY 2014 payments under section 1833(t) of the Act, including the CY 2014 cancer hospital payment adjustment, to the estimated CY 2014 total payments using the CY 2013 final cancer hospital payment adjustment as required under section 1833(t)(18)(B) of the Act. The difference in the CY 2014 estimated payments as a result of applying the CY 2014 cancer hospital payment adjustment relative to the CY 2013 final cancer hospital payment adjustment has a limited impact on the budget neutrality calculation. Therefore,

we are applying a budget neutrality adjustment factor of 1.0005 to the conversion factor to ensure that the cancer hospital payment adjustment is budget neutral.

For this final rule with comment period, we estimate that pass-through spending for both drugs and biologicals and devices for CY 2014 will equal approximately \$12.3 million, which represents 0.02 percent of total projected CY 2014 OPPS spending. Therefore, the conversion factor is also adjusted by the difference between the 0.15 percent estimate of pass-through spending for CY 2013 and the 0.02 percent estimate of CY 2014 pass-through spending, resulting in an adjustment for CY 2014 of 0.13 percent. Finally, estimated payments for outliers remain at 1.0 percent of total OPPS payments for CY 2014.

The final OPD fee schedule increase factor of 1.7 percent for CY 2014 (that is, the estimate of the hospital inpatient market basket percentage increase of 2.5 percent less the final 0.5 percentage point MFP adjustment and less the 0.3 percentage point required under section 1833(t)(3)(F)(ii) of the Act), the required wage index budget neutrality adjustment of approximately 1.0002, the cancer hospital payment adjustment of 1.0005, 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 2014 of \$72.672.

As we stated in the proposed rule (78 FR 43578), hospitals that fail to meet the reporting requirements of the Hospital OQR Program will continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates made for their services as required by section 1833(t)(17) of the Act. For a complete discussion of the Hospital OQR Program requirements and the payment reduction for hospitals that fail to meet those requirements, we refer readers to section XIII.G. of this final rule with comment period. To calculate the CY 2014 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the Hospital OQR Program for the full CY 2014 payment update, we are making all other adjustments discussed above, but using a reduced OPD fee schedule update factor of – 0.3 percent (that is, the OPD fee schedule increase factor of 1.7 percent further reduced by 2.0 percentage points as required by section 1833(t)(17)(A)(i) of the Act for failure to comply with the Hospital OQR requirements). This results in a reduced

conversion factor for CY 2014 of \$71.219 for those hospitals that fail to meet the Hospital OQR requirements (a difference of – \$1.453 in the conversion factor relative to those hospitals that met the Hospital OQR requirements).

In summary, for CY 2014, we are using a final conversion factor of \$72.672 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs. We are finalizing our proposed amendment to § 419.32(b)(1)(iv)(B) by adding a new paragraph (5) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2014 in order to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(iii) of the Act. We also are using a reduced conversion factor of \$71.219 in the calculation of payments for hospitals that fail to comply with the Hospital OQR Program requirements to reflect the reduction to the OPD fee schedule increase factor that is required by section 1833(t)(17) of the Act.

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, we did not propose to revise this policy for the CY 2014 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 the 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 2014 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 the 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. Thus, 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 believed 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 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 “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 2014 OPPS/ASC proposed rule, we stated that, for the CY 2014 OPPS, we will implement this provision in the same manner as we have since CY 2011. That is, frontier State hospitals will 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, the HOPD will 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 will also apply for the affiliated HOPD. We refer readers to the following

sections in the FY 2011 through FY 2014 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: FY 2011 (75 FR 50160 through 50161), FY 2012 (76 FR 51793, 51795, and 51825), FY 2013 (77 FR 53369 through 53370), and FY 2014 (78 FR 50590 through 50591).

In addition to the changes required by the Affordable Care Act, we note that the final FY 2014 IPPS wage indices 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 2014 IPPS/LTCH PPS final rule (78 FR 50585 through 50596) for a detailed discussion of all changes to the FY 2014 IPPS wage indices. 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.

For purposes of the OPPS, we proposed to continue our policy for CY 2014 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 noted that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage adjustment. Table 4J from the FY 2014 IPPS/LTCH PPS final rule as corrected (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 hospitals that will receive the adjustment for FY 2014. We also noted that, beginning with FY 2012, under the IPPS, an eligible hospital that waives its Luger status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, including being considered rural for the disproportionate share hospital (DSH) payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment.

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50592) for a more detailed discussion on the Luger redesignation waiver for the out-migration adjustment. As we have done in prior years, we are including Table 4J from the FY 2014 IPPS/LTCH PPS final rule as corrected as Addendum L to this final rule with comment period with the addition of non-IPPS hospitals that will receive the section 505 out-migration adjustment under the CY 2014 OPPS. Addendum L is available via the Internet on the CMS Web site.

As discussed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50586), the Office of Management and Budget (OMB) issued revisions to the current geographic area designations on February 28, 2013, that included a number of significant changes such as new CBSAs, urban counties that become rural, rural counties that become urban, and splitting existing CBSAs (OMB Bulletin 13–01). This bulletin can be found at: <http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b13-01.pdf>. All of these designations have corresponding effects on the wage index system and its adjustments. In order to allow for sufficient time to assess the new revisions and their ramifications, we intend to propose changes to the IPPS wage index based on the newest CBSA designations in the FY 2015 IPPS/LTCH PPS proposed rule. Similarly, in the OPPS, which uses the IPPS wage index, we intend to propose changes based on the new OMB revisions in the CY 2015 OPPS/ASC proposed rule, consistent with any proposals in the FY 2015 IPPS/LTCH PPS proposed rule.

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 current regulations which require that we use the FY 2014 IPPS wage indices for calculating OPPS payments in CY 2014.

We did not receive any public comments on our proposals. Therefore, we are finalizing our proposals without modification and are adopting the FY 2014 IPPS wage index for the CY 2014 OPPS in its entirety, including the rural floor, geographic reclassifications, and all other wage index adjustments. 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 are using the final FY 2014 IPPS wage indices for calculating OPPS payments in CY 2014. 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 final FY 2014 IPPS wage indices 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 2014 IPPS wage index tables.

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. Medicare contractors 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 Medicare contractor 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 2014 OPPS/ASC proposed rule (78 FR 43579), we proposed to update the default ratios for CY 2014 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 2014, 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 proposed CY 2014 OPPS relative payment weights. Table 9 published in the proposed rule (78 FR 43580 through 43581) listed the proposed CY 2014 default urban and rural CCRs by State and compared them to last year's 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 2014 proposal. We are finalizing our proposal 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 2014 OPPS relative payment weights. We used this methodology to calculate the statewide average default CCRs listed in Table 16 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 2013 and CY 2014 are modest and the few significant changes are associated with areas that have a small number of hospitals.

Table 16 below lists the finalized statewide average default CCRs for OPPS services furnished on or after January 1, 2014.

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TABLE 16.—CY 2014 STATEWIDE AVERAGE CCRs

State	Urban/Rural	CY 2014 Default CCR	Previous Default CCR (CY 2013 OPPS Final Rule)
ALASKA	RURAL	0.473	0.489
ALASKA	URBAN	0.302	0.307
ALABAMA	RURAL	0.229	0.209
ALABAMA	URBAN	0.188	0.193
ARKANSAS	RURAL	0.244	0.219
ARKANSAS	URBAN	0.220	0.234
ARIZONA	RURAL	0.254	0.238
ARIZONA	URBAN	0.182	0.190
CALIFORNIA	RURAL	0.190	0.192
CALIFORNIA	URBAN	0.206	0.202
COLORADO	RURAL	0.393	0.331
COLORADO	URBAN	0.221	0.226
CONNECTICUT	RURAL	0.343	0.364
CONNECTICUT	URBAN	0.276	0.287
DISTRICT OF COLUMBIA	URBAN	0.279	0.302
DELAWARE	RURAL	0.246	0.282
DELAWARE	URBAN	0.356	0.353
FLORIDA	RURAL	0.160	0.182
FLORIDA	URBAN	0.160	0.167
GEORGIA	RURAL	0.260	0.237
GEORGIA	URBAN	0.205	0.214
HAWAII	RURAL	0.345	0.323
HAWAII	URBAN	0.298	0.306
IOWA	RURAL	0.308	0.296
IOWA	URBAN	0.266	0.269
IDAHO	RURAL	0.359	0.417
IDAHO	URBAN	0.478	0.357
ILLINOIS	RURAL	0.252	0.240
ILLINOIS	URBAN	0.222	0.230
INDIANA	RURAL	0.326	0.285
INDIANA	URBAN	0.288	0.256
KANSAS	RURAL	0.313	0.290
KANSAS	URBAN	0.239	0.210
KENTUCKY	RURAL	0.221	0.217
KENTUCKY	URBAN	0.225	0.241

State	Urban/Rural	CY 2014 Default CCR	Previous Default CCR (CY 2013 OPPS Final Rule)
LOUISIANA	RURAL	0.257	0.242
LOUISIANA	URBAN	0.222	0.225
MARYLAND	RURAL	0.283	0.275
MARYLAND	URBAN	0.248	0.246
MASSACHUSETTS	RURAL	0.395	0.427
MASSACHUSETTS	URBAN	0.336	0.323
MAINE	RURAL	0.452	0.445
MAINE	URBAN	0.438	0.449
MICHIGAN	RURAL	0.341	0.303
MICHIGAN	URBAN	0.322	0.303
MINNESOTA	RURAL	0.462	0.469
MINNESOTA	URBAN	0.349	0.321
MISSOURI	RURAL	0.263	0.241
MISSOURI	URBAN	0.280	0.262
MISSISSIPPI	RURAL	0.233	0.226
MISSISSIPPI	URBAN	0.200	0.182
MONTANA	RURAL	0.481	0.431
MONTANA	URBAN	0.384	0.384
NORTH CAROLINA	RURAL	0.258	0.253
NORTH CAROLINA	URBAN	0.256	0.254
NORTH DAKOTA	RURAL	0.661	0.322
NORTH DAKOTA	URBAN	0.400	0.414
NEBRASKA	RURAL	0.323	0.318
NEBRASKA	URBAN	0.243	0.254
NEW HAMPSHIRE	RURAL	0.326	0.317
NEW HAMPSHIRE	URBAN	0.287	0.292
NEW JERSEY	URBAN	0.213	0.207
NEW MEXICO	RURAL	0.291	0.256
NEW MEXICO	URBAN	0.304	0.279
NEVADA	RURAL	0.220	0.234
NEVADA	URBAN	0.154	0.162
NEW YORK	RURAL	0.345	0.420
NEW YORK	URBAN	0.351	0.369
OHIO	RURAL	0.327	0.321
OHIO	URBAN	0.232	0.237

State	Urban/Rural	CY 2014 Default CCR	Previous Default CCR (CY 2013 OPPS Final Rule)
OKLAHOMA	RURAL	0.258	0.239
OKLAHOMA	URBAN	0.205	0.212
OREGON	RURAL	0.311	0.314
OREGON	URBAN	0.357	0.335
PENNSYLVANIA	RURAL	0.257	0.267
PENNSYLVANIA	URBAN	0.198	0.200
PUERTO RICO	URBAN	0.614	0.504
RHODE ISLAND	URBAN	0.295	0.264
SOUTH CAROLINA	RURAL	0.190	0.211
SOUTH CAROLINA	URBAN	0.203	0.214
SOUTH DAKOTA	RURAL	0.287	0.307
SOUTH DAKOTA	URBAN	0.219	0.218
TENNESSEE	RURAL	0.207	0.209
TENNESSEE	URBAN	0.190	0.195
TEXAS	RURAL	0.235	0.235
TEXAS	URBAN	0.197	0.206
UTAH	RURAL	0.474	0.374
UTAH	URBAN	0.334	0.359
VIRGINIA	RURAL	0.226	0.227
VIRGINIA	URBAN	0.238	0.237
VERMONT	RURAL	0.456	0.408
VERMONT	URBAN	0.397	0.384
WASHINGTON	RURAL	0.330	0.366
WASHINGTON	URBAN	0.360	0.301
WISCONSIN	RURAL	0.344	0.345
WISCONSIN	URBAN	0.291	0.307
WEST VIRGINIA	RURAL	0.283	0.277
WEST VIRGINIA	URBAN	0.319	0.338
WYOMING	RURAL	0.400	0.379
WYOMING	URBAN	0.269	0.301

BILLING CODE 4120-01-C*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 OPSS, 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 CY 2007, we became aware that we did not specifically address whether the adjustment applies to EACHs, which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act. Thus, under the statute, EACHs are treated as SCHs. Therefore, in the CY 2007 OPSS/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, three 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 OPSS 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 2013. Further, in the CY 2009 OPSS/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 2014 OPSS/ASC proposed rule (78 FR 43582), 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 OPSS, 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. One commenter also recommended that CMS update the analysis in the near future to assess if the 7.1 percent payment adjustment remains a valid figure. One commenter recommended that any potential future changes to the rural adjustment be implemented 12

months after the changes are finalized, to address concerns about budgeting.

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 2014. As we indicated in the proposed rule (78 FR 43582), 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. We recognize the concerns that commenters present regarding budgeting concerns and will take into consideration these concerns for any review and revision of the adjustment in the future.

After consideration of the public comments we received, we are finalizing our CY 2014 proposal, without modification, to apply the 7.1 percent payment adjustment to rural SCHs, including EACHs, for all services and procedures paid under the OPSS in CY 2014, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

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

1. Background

Since the inception of the OPSS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPSS for covered outpatient hospital services. There are 11 cancer hospitals that meet the classification criteria in section 1886(d)(1)(B)(v) of the Act that are exempted from payment under the IPSS. 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 hold harmless cancer hospitals and children’s hospitals based on their pre-BBA amount under the OPSS. 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 OPSS 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 OPSS than the payment they would have received before implementation of the OPSS, as set forth in section 1833(t)(7)(F) of the Act. The “pre-BBA amount” is an amount equal to the product of the reasonable cost of the hospital for covered outpatient services for the portions of the hospital’s cost reporting period (or periods) 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 and Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, 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 of 2010 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 OPSS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed the costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. In addition, section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by such hospitals when studying cancer hospital costliness. Further, section 1833(t)(18)(B) of the Act provides that if the Secretary determines that costs by these cancer hospitals with respect to APC groups are determined to be greater than the costs of other hospitals furnishing services under section 1833(t) of the Act, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. After conducting the study required by section 1833(t)(18)(A) of the Act, we determined in 2011 that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPSS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPSS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on our findings that costs incurred by cancer hospitals were greater than the costs incurred by other OPSS hospitals, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects the 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 each of the 11 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.

2. Payment Adjustment for Certain Cancer Hospitals for CY 2014

In the CY 2014 OPPS/ASC proposed rule (78 FR 43582), 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 2014 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 2014 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 estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 90 percent of reasonable cost (weighted average PCR of 0.90). Based on these data, we proposed a target PCR of 0.90 that would be used to determine the CY 2014 cancer hospital payment adjustment that would be paid at cost report settlement. 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 0.90 for each cancer hospital.

Comment: Similar to public comments received in response to the CY 2013 OPPS/ASC proposed rule that we addressed in the CY 2013 OPPS/ASC final rule with comment period, commenters representing the cancer hospitals again stated that the PCR is only one component of the adjustment needed to account for the differences in providing cancer care. The commenters suggested that CMS utilize a methodology that they stated would ensure that the 11 cancer hospitals' losses (on a per unit PCR basis) equal the losses (on a per unit PCR basis) of the other PPS hospitals. The commenters provided details of this "equivalent loss per unit" methodology which they indicated would result in a target PCR equal to 0.94 for CY 2014.

Response: As we indicated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68293), section 3138 of the Affordable Care Act provides that if the Secretary determines under section 1833(t)(18)(A) of the Act that costs incurred by cancer hospitals exceed those costs of other hospitals furnishing services under section 1833(t) of the Act, the Secretary shall provide for an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect the higher costs. Because the statute requires that we provide a cancer hospital payment adjustment to reflect the higher costs, not losses, incurred at cancer hospitals, we believe that it would be inappropriate to revise our cancer hospital payment adjustment policy so that the target PCR is calculated based on the cancer hospitals' losses per unit PCR compared to the other OPPS hospitals' losses per unit PCR.

Comment: Commenters stated that CMS should not recalculate the target PCR annually because the cancer hospitals require payment stability and predictability in order to provide services to Medicare beneficiaries.

Response: As we stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68294) in response to this same comment, we believe that annual recalculation of the target PCR will provide a timely assessment of the changes in OPPS payments relative to costs and, therefore, will enable us to provide payment adjustments to cancer hospitals that are accurate and equitable. In addition, because the target PCR is set in advance of each calendar year, cancer hospitals can easily predict the amount of their hospital-specific payment adjustment associated with the

target PCR for the following year and budget accordingly.

After consideration of the public comments we received, we are finalizing our proposal 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 for the other OPPS hospitals using the most recent submitted or settled cost report data that were available at the time of this final rule with comment period. To calculate the final CY 2014 target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A. of this final rule with comment period, used to estimate costs for the CY 2014 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 2012 claims data that we used to model the impact of the final CY 2014 APC relative payment weights (4,044 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2014 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2011 to 2012. We then removed the cost report data of the 48 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 116 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 an analytic file of 3,880 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). Based on these data, we used a target PCR of 0.89 to determine the CY 2014 cancer hospital payment adjustment to be paid at cost report settlement. Therefore, the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement will be the additional payment needed to result in a PCR equal to 0.89 for each cancer hospital.

Table 17 below indicates the estimated percentage increase in OPPS payments to each cancer hospital for CY 2014 due to the cancer hospital payment adjustment policy. The actual amount of the CY 2014 cancer hospital payment adjustment for each cancer hospital will

be determined at cost report settlement and will depend on each hospital's CY 2014 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.

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TABLE 17.—ESTIMATED CY 2014 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2014
050146	City of Hope Comprehensive Cancer Center	13.7%
050660	USC Norris Cancer Hospital	27.5%
100079	Sylvester Comprehensive Cancer Center	15.4%
100271	H. Lee Moffitt Cancer Center & Research Institute	22.3%
220162	Dana-Farber Cancer Institute	46.5%
330154	Memorial Sloan-Kettering Cancer Center	45.7%
330354	Roswell Park Cancer Institute	33.7%
360242	James Cancer Hospital & Solove Research Institute	34.1%
390196	Fox Chase Cancer Center	15.4%
450076	M.D. Anderson Cancer Center	57.1%
500138	Seattle Cancer Care Alliance	53.3%

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G. Hospital Outpatient Outlier Payments

1. Background

Currently, the OPPS provides outlier payments on a service-by-service basis. In CY 2012, the outlier threshold was determined to be met when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a \$2,025 fixed-dollar threshold. We introduced a fixed-dollar threshold in CY 2005, in addition to the traditional multiple threshold, in order to better target outlier payments to those high-cost and complex procedures where a very costly service could present a hospital with significant financial loss. If the cost of a service meets both of these conditions, the multiple 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 rate. Before CY 2009, this outlier payment had historically been considered a final payment by longstanding OPPS policy. However, we implemented a reconciliation process similar to the IPPS outlier reconciliation process for cost reports with cost reporting periods beginning on or after January 1, 2009, in our CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy for the past several years to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the proposed OPPS. Our current estimate of total outlier payments as a percent of total CY 2012 OPPS payment, using available CY 2012 claims and the revised OPPS expenditure estimate for the 2013 Trustee's Report, is

approximately 1.2 percent of the total aggregated OPPS payments. Therefore, for CY 2012, we estimate that we paid 0.2 percent above the CY 2012 outlier target of 1.0 percent of total aggregated OPPS payments.

As explained in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68295 through 68297), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for CY 2013. The outlier thresholds were set so that estimated CY 2013 aggregate outlier payments would equal 1.0 percent of the total estimated aggregate payments under the OPPS. Using CY 2012 claims data and CY 2013 payment rates, we currently estimate that the aggregate outlier payments for CY 2013 will be approximately 1.1 percent of the total CY 2013 OPPS payments. The difference between 1.1 percent and 1.0 percent is reflected in

the regulatory impact analysis in section XXIII. of this final rule with comment period. We note that we provide estimated CY 2014 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital-Specific Impacts—Provider-Specific Data file on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

2. Proposed Outlier Calculation

In the CY 2014 OPPS/ASC proposed rule (78 FR 43584), we proposed to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. We proposed that a portion of that 1.0 percent, an amount equal to 0.18 percent of outlier payments (or 0.0018 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 CY 2014 OPPS/ASC proposed rule (78 FR 43622), 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 this final rule with comment period.

To ensure that the estimated CY 2014 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 the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a \$2,775 fixed-dollar threshold.

We calculated the proposed fixed-dollar threshold using largely the standard methodology, most recently used for CY 2013 (77 FR 68295 through 68297). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2013 update to the Outpatient Provider-

Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCR, which are maintained by the Medicare contractors 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 2014 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2012 claims using the same inflation factor of 1.0993 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27767). We used an inflation factor of 1.0485 to estimate CY 2013 charges from the CY 2012 charges reported on CY 2012 claims. The methodology for determining this charge inflation factor is discussed in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27767) as well as the FY 2014 IPPS/LTCH PPS final rule (78 FR 50982). 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, in the CY 2014 OPPS/ASC proposed rule, we proposed to apply the same CCR inflation adjustment factor that we apply for the FY 2014 IPPS outlier calculation to the CCRs used to simulate the CY 2014 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2014, we proposed to apply an adjustment factor of 0.9732 to the CCRs that were in the April 2013 OPSF to trend them forward from CY 2013 to CY 2014. The methodology for calculating this proposed adjustment was discussed in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27766 through 27768) as well as the FY 2014 IPPS/LTCH PPS final rule (78 FR 50978 through 50982).

Therefore, to model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2013 OPSF file after adjustment (using the proposed CCR inflation adjustment factor of 0.9732 to approximate CY 2014 CCRs) to charges on CY 2012 claims that were adjusted (using the charge inflation factor of 1.0993 to approximate CY 2014 charges). We simulated aggregated CY 2014 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 2014 OPPS payments. We estimated that a proposed fixed-dollar threshold of \$2,775, 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. We proposed to continue to make an outlier payment that equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the proposed fixed-dollar threshold of \$2,775 were met. 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: Several commenters urged CMS to reconsider the increase in the CY 2014 OPPS outlier threshold. The commenters believed that the thresholds were being set higher than was

necessary to achieve the OPPS outlier spending target, based on their analysis of the thresholds and aggregate outlier spending in prior years. Commenters also desired transparency about why an outlier threshold increase was necessary, when historical evidence suggested that such a change is unwarranted. One commenter recommended that the OPPS outlier percentage spending target be reduced to 0.5 percent of the system because patients who develop complications requiring complex care are highly likely to be admitted to inpatient care.

Response: Many of the commenters who recommended changes to the OPPS fixed-dollar outlier threshold relied on direct comparisons between aggregate spending and the OPPS outlier thresholds. As discussed earlier in this section, OPPS outliers are paid and modeled based on comparisons between APC payment and estimated cost. As a result, changing the OPPS fixed-dollar outlier threshold by any increment does not result in an evenly distributed change in OPPS outlier spending as well as services that receive OPPS outlier payments.

There are a variety of factors that may affect the OPPS fixed-dollar outlier threshold, including data changes such as hospital charging practices and fluctuations in the overall ancillary CCRs as well as changes in OPPS payment policy such as those involving packaging and compositing. Those changes can influence the individual comparisons between APC service payment and estimated costs. While the OPPS outlier threshold has been relatively stable in the past several years, historically the OPPS fixed-dollar outlier threshold has fluctuated from year to year as identified in the Annual Policy Files which are available via the Internet on the CMS Web site. In the CY 2014 OPPS/ASC proposed rule, we proposed to update several OPPS packaging policies which would have a corresponding effect on the OPPS fixed-dollar outlier threshold by potentially increasing APC payment for certain paid service lines while moving affected services from previously being on the payment portion of the OPPS outlier payment comparison into the cost portion. In particular, by conditionally packaging certain clinical diagnostic laboratory tests previously paid at CLFS rates, the CY 2014 fixed-dollar OPPS outlier threshold would have to account for significant changes to both the APC payment and estimated cost portions of the OPPS outlier payment comparison.

We appreciate the recommendation regarding revisiting the correct OPPS outlier spending target and will

continue to consider whether a 1.0 percent OPPS outlier percentage spending target continues to remain appropriate.

3. Final Outlier Calculation

Consistent with historical practice, we use updated data for this final rule with comment period for our outlier calculation. For CY 2014, we are applying the overall CCRs from the October 2013 OPSF with a CCR adjustment factor of 0.9645 to approximate CY 2014 CCRs to charges on the final CY 2012 claims that were adjusted to approximate CY 2014 charges (using the final 2-year charge inflation factor of 1.0969). These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed dollar threshold for the FY 2014 IPPS/LTCH PPS final rule (78 FR 50982). We simulated aggregated CY 2014 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payment 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 2014 OPPS payments. We estimate that a fixed-dollar threshold of \$2,900, combined with the multiple threshold of 1.75 times the APC payment rate, will allocate 1.0 percent of estimated aggregated total OPPS payments to outlier payments.

In summary, for CY 2014, we will continue to make an outlier payment that equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the final fixed-dollar threshold of \$2,900 are met. 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 is calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. We estimate that this threshold will allocate 0.16 percent of outlier payments to CMHCs for PHP outlier payments.

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

2014 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 2014 scaled weight for the APC by the CY 2014 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.

We demonstrate in the steps below 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: "P," "Q1," "Q2," "Q3," "R," "S," "T," "U," "V," or "X" (as defined in Addendum D1 to this final rule with comment period), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of "Q1" and "Q2") qualify for separate payment. We note that,

although blood and blood products with status indicator “R” and brachytherapy sources with status indicator “U” are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements. We note that we had proposed to create status indicator “J1” to reflect the comprehensive APCs discussed in section II.A.2.e. of this final rule with comment period. However, the comprehensive APCs will not be implemented in the CY 2014 OPPS, and therefore status indicator “J1” will not apply. We also note that we had proposed to delete status indicator “X” as part of the CY 2014 packaging proposal for ancillary services, discussed in section II.A.4. of this final rule with comment period. We are not finalizing the ancillary services packaging policy, and therefore status indicator “X” will continue to be active in the CY 2014 OPPS.

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 2014 OPPS fee schedule increase factor of 1.7 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.

$X = .60 * (\text{national unadjusted payment rate})$

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. 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 2014 under the IPPS, reclassifications through the MGCRB, section 1886(d)(8)(B) “Lugar” hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in § 412.103 of the regulations, and hospitals designated as urban under section 601(g) of Pub. L. 98–21. (For further discussion of the changes to the FY 2014 IPPS wage indices, as applied to the CY 2014 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 Pub. L. 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 2014 IPPS and listed as Table 4J in the FY 2014 IPPS/LTCH PPS final rule and available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>. This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

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

The formula below is a mathematical representation of Step 4 and adjusts the

labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

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

$X_a = .60 * (\text{national unadjusted payment rate}) * \text{applicable wage index}$

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.

$Y = .40 * (\text{national unadjusted payment rate})$

Adjusted Medicare Payment = $Y + X_a$

Step 6. If a provider is an SCH, 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 have provided 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 35644. This provider bills one service that is assigned to APC 0019 (Level I Excision/Biopsy). The CY 2014 full national unadjusted payment rate for APC 0019 is approximately \$318.79. The reduced national unadjusted payment rate for APC 0019 for a hospital that fails to meet the Hospital OQR Program requirements is approximately \$312.41. This reduced rate is calculated by multiplying the reporting ratio of 0.980 by the full unadjusted payment rate for APC 0019.

The FY 2014 wage index for a provider located in CBSA 35644 in New York is 1.3129. The labor-related portion of the full national unadjusted payment is approximately \$251.12 (.60 * \$318.79 * 1.3129). The labor-related portion of the reduced national unadjusted payment is approximately \$246.10 (.60 * \$312.41 * 1.3129). The nonlabor-related portion of the full national unadjusted payment is approximately \$127.52 (.40 * 318.79). The nonlabor-related portion of the reduced national unadjusted payment is approximately \$124.96 (.40 * \$312.41). The sum of the labor-related and nonlabor-related portions of the full national adjusted payment is approximately \$378.64 (\$251.12 + \$127.52). The sum of the reduced national adjusted payment is approximately \$371.06 (\$246.10 + \$124.96).

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 OPPTS/ASC final rule with comment period (75 FR 72013).

2. OPPTS Copayment Policy

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43586), for CY 2014, 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 OPPTS 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 OPPTS/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 OPPTS that would be effective January 1, 2014, 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 XIII.G. of the proposed rule, for CY 2014, the proposed Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We noted that OPPTS 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 OPPTS cost modeling process. However, as described in the CY 2004 OPPTS/ASC final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPTS APC payments (68 FR 63458 through 63459).

We did not receive any public comments regarding the proposed methodology for calculating copayments for CY 2014. Therefore, for the reasons

set forth in this final rule with comment period, we are finalizing our CY 2014 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 \$63.76 is 20 percent of the full national unadjusted payment rate of approximately \$318.79. 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.

$B = \text{National unadjusted copayment for APC} / \text{national unadjusted payment rate for APC}.$

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, 2014, 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 2014 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. 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. As we proposed in the CY 2014 OPPS/ASC proposed rule (78 FR 43587), in Table 18 below (Table 11 of the proposed rule), we summarized our process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing their treatment under the OPPS. We note that because the payment rates associated with codes effective July 1 were not available to us in time for incorporation into the Addenda of the proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2013 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 2013 OPPS quarterly update were included in Addendum B. Nevertheless, we requested public comments on the codes included in the July 2013 OPPS quarterly update and included these codes in the preamble of the proposed rule.

TABLE 18.—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 1, 2013	Level II HCPCS Codes	April 1, 2013	CY 2014 OPPS/ASC proposed rule	CY 2014 OPPS/ASC final rule with comment period
July 1, 2013	Level II HCPCS Codes	July 1, 2013	CY 2014 OPPS/ASC proposed rule	CY 2014 OPPS/ASC final rule with comment period
	Category I (certain vaccine codes) and III CPT codes	July 1, 2013	CY 2014 OPPS/ASC proposed rule	CY 2014 OPPS/ASC final rule with comment period
October 1, 2013	Level II HCPCS Codes	October 1, 2013	CY 2014 OPPS/ASC final rule with comment period	CY 2015 OPPS/ASC final rule with comment period
January 1, 2014	Level II HCPCS Codes	January 1, 2014	CY 2014 OPPS/ASC final rule with comment period	CY 2015 OPPS/ASC final rule with comment period
	Category I and III CPT Codes	January 1, 2014	CY 2014 OPPS/ASC final rule with comment period	CY 2015 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 2014 OPPS/ASC proposed rule or whether we are soliciting public comments in this CY 2014 OPPS/ASC final rule with comment period. We note that we sought public comments in the CY 2013 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2013. We also sought public comments in the CY 2013 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2012. These new codes, with an effective date of October 1, 2012, or

January 1, 2013, 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 2013 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, which were subject to public comment following publication of the CY 2013 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 2014 OPPS/ASC final rule with comment period.

We received public comments on several new codes that were assigned to comment indicator “NI” in Addendum B of the CY 2013 OPPS/ASC final rule with comment period. We respond to those comments in sections II.A.2., III.C., V.A., and V.B. of this CY 2014 OPPS/ASC final rule with comment period. Table 19 below lists the long descriptors for the CPT and Level II HCPCS codes that were assigned to comment indicator “NI” for which we received public comments on the CY 2013 OPPS/ASC final rule with comment period and the specific sections where the comments are addressed.

**TABLE 19.—COMMENTS TO THE CY 2013 OPPS/ASC FINAL RULE WITH
COMMENT PERIOD ON NEW HCPCS CODES ASSIGNED TO COMMENT
INDICATOR “NI”**

CY 2013 CPT/HCPCS Code	CY 2013 Long Descriptor	Section in This CY 2014 OPPS/ASC Final Rule With Comment Period Where Comments Are Addressed
0319T	Insertion or replacement of subcutaneous implantable defibrillator system with subcutaneous electrode	III.C.1.b. (Subcutaneous Defibrillator)
37211	Transcatheter therapy, arterial infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, initial treatment day	III.C.1.c. (Thrombolytic Therapy)
37212	Transcatheter therapy, venous infusion for thrombolysis, any method, including radiological supervision and interpretation, initial treatment day	III.C.1.c. (Thrombolytic Therapy)
52287	Cystourethroscopy, with injection(s) for chemodenervation of the bladder	III.C.5.a. (Chemodenervation)
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)	III.C.5.a. (Chemodenervation)
93653	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, his recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	II.A.2.f.(3) (Cardiac Electrophysiologic Evaluation and Ablation Composite)

CY 2013 CPT/HCPSC Code	CY 2013 Long Descriptor	Section in This CY 2014 OPPS/ASC Final Rule With Comment Period Where Comments Are Addressed
93654	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, his recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of ventricular tachycardia or focus of ventricular ectopy including intracardiac electrophysiologic 3d mapping, when performed, and left ventricular pacing and recording, when performed	II.A.2.f.(3) (Cardiac Electrophysiologic Evaluation and Ablation Composite)
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (list separately in addition to code for primary procedure)	II.A.2.f.(3) (Cardiac Electrophysiologic Evaluation and Ablation Composite)
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with atrial recording and pacing, when possible, right ventricular pacing and recording, his bundle recording with intracardiac catheter ablation of arrhythmogenic focus, with treatment of atrial fibrillation by ablation by pulmonary vein isolation	II.A.2.f.(3) (Cardiac Electrophysiologic Evaluation and Ablation Composite)
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (list separately in addition to code for primary procedure)	II.A.2.f.(3) (Cardiac Electrophysiologic Evaluation and Ablation Composite)
95907	Nerve conduction studies; 1-2 studies	III.C.5.b. (Nerve Conduction Studies)
95908	Nerve conduction studies; 3-4 studies	III.C.5.b. (Nerve Conduction Studies)
95909	Nerve conduction studies; 5-6 studies	III.C.5.b. (Nerve Conduction Studies)

CY 2013 CPT/HCPCS Code	CY 2013 Long Descriptor	Section in This CY 2014 OPPS/ASC Final Rule With Comment Period Where Comments Are Addressed
95910	Nerve conduction studies; 7-8 studies	III.C.5.b. (Nerve Conduction Studies)
95911	Nerve conduction studies; 9-10 studies	III.C.5.b. (Nerve Conduction Studies)
95912	Nerve conduction studies; 11-12 studies	III.C.5.b. (Nerve Conduction Studies)
95913	Nerve conduction studies; 13 or more studies	III.C.5.b. (Nerve Conduction Studies)
95943	Simultaneous, independent, quantitative measures of both parasympathetic function and sympathetic function, based on time-frequency analysis of heart rate variability concurrent with time-frequency analysis of continuous respiratory activity, with mean heart rate and blood pressure measures, during rest, paced (deep) breathing, valsalva maneuvers, and head-up postural change	III.C.5.c. (Parasympathetic Function and Sympathetic Function)
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	III.C.10.g. (Negative Pressure Wound Therapy)
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	III.C.10.g. (Negative Pressure Wound Therapy)
J7315	Mitomycin, ophthalmic, 0.2 mg	V. (OPPS Drugs, Biologicals, and Radiopharmaceuticals)

CY 2013 CPT/HCPCS Code	CY 2013 Long Descriptor	Section in This CY 2014 OPPS/ASC Final Rule With Comment Period Where Comments Are Addressed
Q9969	Tc-99m from non-highly enriched uranium source, full cost recovery add-on, per study dose	III.C.10.i. (Payment for Radioisotopes Derived From Non-HEU-)

1. Treatment of New CY 2013 Level II HCPCS and CPT Codes Effective April 1, 2013 and July 1, 2013 for Which We Solicited Public Comments in the CY 2014 OPPS/ASC Proposed Rule

Through the April 2013 OPPS quarterly update CR (Transmittal 2664, Change Request 8228, dated March 1, 2013), and the July 2013 OPPS quarterly update CR (Transmittal 2718, Change Request 8338, dated June 7, 2013), we recognized several new HCPCS codes for separate payment under the OPPS. Effective April 1 and July 1 of CY 2013, we made effective 18 new Level II

HCPCS codes and 6 Category III CPT codes. Specifically, 8 new Level II HCPCS codes were effective for the April 2013 quarterly update and another 10 new Level II HCPCS codes were effective for the July 2013 quarterly update for a total of 18. In addition, six new Category III CPT codes were effective for the July 2013 quarterly update. Of the 24 new HCPCS and CPT codes, we recognized for separate payment under the OPPS 14 new codes from the April and July 2013 OPPS quarterly updates.

Through the April 2013 OPPS quarterly update CR, we allowed

separate payment for five new Level II HCPCS codes. Specifically, as displayed in Table 12 of the proposed rule, we provided separate payment for HCPCS codes C9130, C9297, C9298, C9734, and C9735. HCPCS codes Q0507, Q0508, and Q0509 were assigned to OPPS status indicator "A" to indicate that they are paid through another Medicare payment system other than the OPPS. Although HCPCS codes Q0507, Q0508, and Q0509 were effective April 1, 2013, they were previously described by HCPCS code Q0505, which was deleted on March 31, 2013.

TABLE 20.—NEW LEVEL II HCPCS CODES IMPLEMENTED IN APRIL 2013

CY 2013 HCPCS Code	CY 2013 Long Descriptor	April 2013 Status Indicator	April 2013 APC
C9130*	Injection, immune globulin (Bivigam), 500 mg	G	9130
C9297*	Injection, omacetaxine mepesuccinate, 0.01 mg	G	9297
C9298*	Injection, ocriplasmin, 0.125 mg	G	9298
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance	S	0067
C9735	Anoscopy; with directed submucosal injection(s), any substance	T	0150
Q0507	Miscellaneous supply or accessory for use with an external ventricular assist device	A	N/A
Q0508	Miscellaneous supply or accessory for use with an implanted ventricular assist device	A	N/A
Q0509	Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A	A	N/A

*The payment rate for HCPCS codes C9130, C9297, and C9298 are based on ASP+6 percent.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43588), we solicited public comments on the proposed status indicators and APC assignments for Level II HCPCS codes C9130, C9297,

C9298, C9734, C9735, Q0507, Q0508, and Q0509, which were listed in Table 12 of the proposed rule (78 FR 43588) and now appear in Table 20 of this final rule with comment period.

We did not receive any public comments on the proposed APC assignments and status indicators for HCPCS codes C9130, C9297, C9298, Q0507, Q0508, and Q0509. However, we

received several public comments on HCPCS codes C9734 and C9735, which are addressed in sections III.C.10.c. and III.C.3.b., respectively, of this final rule with comment period.

For CY 2014, the HCPCS Workgroup replaced HCPCS codes C9130, C9297, and C9298 with permanent HCPCS J-codes. Table 21 below lists the

replacement HCPCS J-codes for the temporary HCPCS C-codes. Consistent with our general policy of using permanent HCPCS codes rather than using temporary HCPCS codes for the reporting of drugs under the OPPI in order to streamline coding, we are showing the replacement HCPCS codes

for HCPCS codes C9130, C9297, and C9298, which are effective January 1, 2014, in Table 21.

In this final rule with comment period, we are assigning the Level II HCPCS codes listed in Table 21 below to the specified APCs and status indicators for CY 2014.

TABLE 21.—FINAL CY 2014 STATUS INDICATORS AND APC ASSIGNMENTS FOR THE LEVEL II HCPCS CODES THAT WERE NEWLY IMPLEMENTED IN APRIL 2013

CY 2013 HCPCS Code	CY 2014 HCPCS Code	CY 2014 Long Descriptor	Final CY 2014 Status Indicator	Final CY 2014 APC
C9130	J1556	Injection, immune globulin (Bivigam), 500 mg	G	9130
C9297	J9262	Injection, omacetaxine mepesuccinate, 0.01 mg	G	9297
C9298	J7316	Injection, ocriplasmin, 0.125mg	G	9298
C9734	C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance	S	0065
C9735	C9735	Anoscopy; with directed submucosal injection(s), any substance	T	0150
Q0507	Q0507	Miscellaneous supply or accessory for use with an external ventricular assist device	N	N/A
Q0508	Q0508	Miscellaneous supply or accessory for use with an implanted ventricular assist device	N	N/A
Q0509	Q0509	Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A	N	N/A

For CY 2014, we note that we are not making any changes to the status indicator and APC assignment for HCPCS code C9735. Specifically, HCPCS code C9735 will continue to be assigned to APC 0150 for CY 2014 with a status indicator of “T.” However, we are reassigning HCPCS code C9734 from APC 0067 (Level II Stereotactic Radiosurgery) to APC 0065 (IORT, MRgFUS, and MEG), as discussed in section III.C.10.c. of this final rule with comment period. In addition, we are reassigning HCPCS codes Q0507, Q0508, and Q0509 from status indicator

“A” to “N” to indicate that they are now packaged under the hospital OPPI, consistent with our packaging guidelines, which are discussed in section II.A.3. of this final rule with comment period.

Furthermore, because HCPCS codes J1556, J9262, and J7316 describe the same drug and the same dosage currently described by HCPCS codes C9130, C9297, and C9298, respectively, these drugs will continue their pass-through status in CY 2014. Therefore, we are assigning HCPCS codes J1556, J9262, and J7316 to the same APCs and

the same status indicators as their predecessor HCPCS codes, as shown in Table 21.

As discussed in the CY 2014 OPPI/ASC proposed rule (78 FR 43589), through the July 2013 OPPI quarterly update CR, which included HCPCS codes that were made effective July 1, 2013, we allowed separate payment for 5 of the 10 new Level II HCPCS codes. Specifically, as displayed in Table 22 below (also Table 13 of the proposed rule), we provided separate OPPI payment for HCPCS codes C9131, C9736, G0460, Q2050, and Q2051.

TABLE 22.—NEW LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2013

CY 2013 HCPCS Code	CY 2013 Long Descriptor	July 2013 SI	July 2013 APC
C9131*	Injection, ado-trastuzumab emtansine, 1 mg	G	9131
C9736	Laparoscopy, surgical, radiofrequency ablation of uterine fibroid(s), including intraoperative guidance and monitoring, when performed	T	0131
G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment	T	0013
K0008	Custom Manual Wheelchair Base	Y	N/A
K0013	Custom Motorized/Power Wheelchair Base	Y	N/A
K0900	Customized Durable Medical Equipment, Other Than Wheelchair	Y	N/A
Q0090	Levonorgestrel-Releasing Intrauterine Contraceptive System (SKYLA), 13.5 mg	E	N/A
Q2033	Influenza Vaccine, Recombinant Hemagglutinin Antigens, For Intramuscular Use (Flublok)	L	N/A
Q2050**	Injection, Doxorubicin Hydrochloride, Liposomal, Not Otherwise Specified, 10mg	K	7046
Q2051***	Injection, Zoledronic Acid, Not Otherwise Specified, 1mg	K	1356

*The payment rate for HCPCS code C9131 is based on ASP+6 percent.

**HCPCS code Q2050 replaced HCPCS code J9002, effective July 1, 2013. The status indicator for HCPCS code J9002 was changed to “E” (Not Payable by Medicare), effective July 1, 2013. The payment rate for HCPCS code Q2050 is based on ASP+6 percent.

***HCPCS code Q2051 replaced HCPCS codes J3487 and J3488 effective July 1, 2013. The status indicator for HCPCS codes J3487 and J3488 was changed to “E” (Not Payable by Medicare), effective July 1, 2013. The payment rate for HCPCS code Q2051 is based on ASP+6 percent.

We note that two of the Level II HCPCS Q-codes that were made effective July 1, 2013, were previously described by HCPCS J-codes that were separately payable under the hospital OPPS. First, the HCPCS Workgroup replaced HCPCS code J9002 (Injection, doxorubicin hydrochloride, liposomal, Doxil, 10 mg) with new HCPCS code Q2050, effective July 1, 2013, to appropriately identify and pay for both the brand and generic forms of doxorubicin hydrochloride liposome. Consequently, the status indicator for HCPCS code J9002 was changed to “E” (Not Payable by Medicare), effective July 1, 2013. Because HCPCS code Q2050 describes the same product as HCPCS

code J9002, we continued its separate payment status and assigned HCPCS code Q2050 to status indicator “K” (Nonpass-through drugs and nonimplantable biologicals, including therapeutic radiopharmaceuticals; paid under OPPS; separate APC payment). We also assigned HCPCS code Q2050 to the same APC as HCPCS code J9002, specifically APC 7046 (Doxil injection), effective July 1, 2013.

Secondly, the HCPCS Workgroup replaced HCPCS codes J3487 (Injection, zoledronic acid (Zometa), 1 mg) and J3488 (Injection, zoledronic acid (Reclast), 1 mg) with one new HCPCS code, specifically Q2051, effective July 1, 2013, to appropriately identify and

pay for both the brand and generic forms of zoledronic acid. Consequently, the status indicators for HCPCS codes J3487 and J3488 were changed to “E,” effective July 1, 2013, to indicate that the codes were not separately payable by Medicare. Because HCPCS code Q2051 described the same product as HCPCS codes J3487 and J3488, we assigned HCPCS code Q2051 to separate payment status indicator “K,” effective July 1, 2013. Because HCPCS codes J3487 and J3488, which were assigned to two separate APCs, were replaced with only one code, we assigned HCPCS code Q2051 to a new APC to maintain data consistency for future rulemaking. Specifically, HCPCS code Q2051 was

assigned to APC 1356 (Zoledronic acid 1 mg), effective July 1, 2013.

Of the 10 Level II HCPCS codes that were made effective July 1, 2013, we did not recognize for separate payment the following 5 HCPCS codes: HCPCS codes K0008, K0013, and K0900, which were assigned to status indicator "Y" (Non-implantable durable medical equipment; not paid under OPPS); HCPCS code Q2033, which was assigned to status indicator "L" (Not paid under OPPS; paid at reasonable cost); and HCPCS code Q0090, which was assigned to status indicator "E"

(Not payable/Non-covered by Medicare; not paid under OPPS).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43589), we solicited public comments on the proposed status indicators and APC assignments for the HCPCS codes that were listed in Table 13 of the proposed rule and now appear in Tables 22 and 23 of this final rule with comment period.

We did not receive any public comments on the proposed APC assignments and status indicators for HCPCS codes C9131, K0008, K0013, K0900, Q0090, Q2033, Q2050, and

Q2051. Therefore, we are adopting as final, without modification, our proposal to assign these eight Level II HCPCS codes to the APCs and status indicators as proposed for CY 2014.

We received several public comments on HCPCS codes C9736 and G0460, which are addressed in section III.C. of this final rule with comment period.

Table 23 below includes a complete list of the Level II HCPCS codes that were made effective July 1, 2013, with their final status indicators and APC assignments for CY 2014.

TABLE 23.—FINAL CY 2014 STATUS INDICATORS AND APC ASSIGNMENTS FOR THE LEVEL II HCPCS CODES THAT WERE NEWLY IMPLEMENTED IN JULY 2013

CY 2013 HCPCS Code	CY 2014 HCPCS Code	CY 2014 Long Descriptor	Final CY 2014 Status Indicator	Final CY 2014 APC
C9131	J9354	Injection, ado-trastuzumab emtansine, 1 mg	G	9131
C9736	0336T	Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency	T	0174
G0460	G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment	T	0327
K0008	K0008	Custom Manual Wheelchair Base	Y	N/A
K0013	K0013	Custom Motorized/Power Wheelchair Base	Y	N/A
K0900	K0900	Customized Durable Medical Equipment, Other Than Wheelchair	Y	N/A
Q0090	J7301	Levonorgestrel-Releasing Intrauterine Contraceptive System (Skyla), 13.5 mg	E	N/A
Q2033	90673	Influenza virus vaccine, trivalent, derived from recombinant DNA (RIV3), hemagglutinin (HA) protein only, preservative and antibiotic free, for intramuscular use	L	N/A
Q2050	Q2050	Injection, Doxorubicin Hydrochloride, Liposomal, Not Otherwise Specified, 10mg	K	7046
Q2051	J3489	Injection, Zoledronic Acid, 1mg	K	1356

We note that the HCPCS Workgroup replaced HCPCS codes C9131, Q0090, and Q2051 with HCPCS codes J9354, J7301, and J3489, respectively, effective January 1, 2014. Because HCPCS code J9354 describes the same drug currently described by HCPCS code C9131, this drug will continue its pass-through status in CY 2014. Therefore, we are assigning HCPCS code J9354 to the same APC and status indicator as its predecessor HCPCS code, which shares the same dosage descriptor, as shown in Table 23. We note that because HCPCS code Q2051 is assigned to status indicator “K” (Nonpass-Through Drugs; Paid under OPPS; Separate APC payment), its replacement HCPCS code J3489, which describes the same item as its predecessor code, will also continue its nonpass-through status and APC assignment in CY 2014. In addition, because HCPCS code Q0090 is assigned to status indicator “E” to indicate that this drug is not covered by Medicare, its replacement HCPCS code J7301 will also continue its noncovered status in CY 2014. We note that two HCPCS codes, specifically, HCPCS codes C9736 and Q2033, will be replaced with CPT codes 0336T and 90673, respectively, effective January 1, 2014. As noted in Table 23, CPT code 90673, which is the replacement code for HCPCS code Q2033, will be assigned to status

indicator “L.” However, CPT code 0336T, which replaces HCPCS code C9736, will be assigned to APC 0174. We refer readers to section III.C.10.b. of this final rule with comment period for further discussion of the APC assignment of CPT code 0336T, which replaced HCPCS code C9736.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43589), 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 2013 quarterly update, there were no new Category I CPT vaccine codes. However, we note that Level II HCPCS code Q2033, which is listed in Tables 22 and 23, describes a flu vaccine that was effective July 1, 2013, and is separately payable by Medicare at reasonable cost.

Through the July 2013 OPPS quarterly update CR (Transmittal 2718, Change Request 8338, dated June 7, 2013), we

allowed separate payment for four of the six new Category III CPT codes effective July 1, 2013. Specifically, as displayed in Table 24 (also shown in Table 14 of the CY 2014 OPPS/ASC proposed rule), we allowed separate payment for Category III CPT codes 0330T, 0331T, 0332T, and 0334T. We did not recognize for separate payment Category III CPT code 0329T because the device associated with this procedure has not received FDA approval. In addition, we did not recognize for separate payment Category III CPT code 0333T because this procedure is not covered by Medicare. As listed in Table 24, both CPT codes 0329T and 0333T were assigned to status indicator “E” (Not payable/Non-covered by Medicare; not paid under OPPS).

We received public comments on several of the Category III CPT codes that were implemented in July 2013, specifically on CPT codes 0330T, 0331T, 0332T, and 0334T, which are addressed in section III.C. of this final rule with comment period. Table 24 below lists the Category III CPT codes that were implemented in July 2013, along with their final status indicators, APC assignments, and payment rates for CY 2014.

**TABLE 24.—NEW CATEGORY III CPT CODES IMPLEMENTED
IN JULY 2013**

CY 2013 CPT Code	CY 2013 Long Descriptor	Final CY 2014 Status Indicator	Final CY 2014 APC	Final CY 2014 Payment Rate
0329T	Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report	E	N/A	N/A
0330T	Tear film imaging, unilateral or bilateral, with interpretation and report	S	0230	\$51.55
0331T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment;	S	0377	\$1,153.62
0332T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment; with tomographic SPECT	S	0377	\$1,153.62
0333T	Visual evoked potential, screening of visual acuity, automated	E	N/A	N/A
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)	T	0052	\$6,506.96

In the CY 2014 OPPS/ASC proposed rule (78 FR 43588 through 43590), we proposed to continue our process of soliciting public comments on our status indicators and APC assignments for the CPT/HCPCS codes effective April 1 and July 1. For the CY 2014 update, we solicited public comments on the CY 2014 proposed status indicators and the proposed APC assignments and payment rates for the Level II HCPCS codes and the Category III CPT codes that were effective April 1, 2013, and July 1, 2013, through the respective OPPS quarterly update CRs. These codes were listed in Tables 12, 13, and 14 of the proposed rule. We proposed to finalize their status indicators and their APC assignments and payment rates, if applicable, in this CY 2014 OPPS/ASC final rule with comment period. Because the new Category III CPT and Level II HCPCS codes that become effective for July are not available to us in time for incorporation into the Addenda to the OPPS/ASC proposed rule, our policy is

to include the codes, their 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 13 and 14, respectively, of the proposed rule. We proposed to incorporate these codes into Addendum B to this CY 2014 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 2013 OPPS update CR and displayed in Table 12 were included in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site), where their proposed CY 2014 payment rates were also shown.

We did not receive any additional public comments on this process. The final status indicators, APC 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 2013 or July 2013 OPPS update CR can be found in Tables 21, 23, and 24, 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 Were Effective October 1, 2013 and New CPT and Level II HCPCS Codes That Will Be Effective January 1, 2014 for Which We Are Soliciting Public Comments in This CY 2014 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 Workgroup Web site (for Level II HCPCS codes) and the AMA Web site (for CPT codes), and also through the January OPPS quarterly update CRs. In the past, we also have released new Level II

HCPSC codes that are effective October 1 through the October OPSC quarterly update CRs and incorporated these new codes in the final rule with comment period updating the OPSC for the following calendar year. For CY 2014, these codes are flagged with comment indicator “NI” in Addendum B to this 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 HCPSC codes that will be effective January 1, 2014, are flagged with comment indicator “NI” in Addendum B to this 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 the final rule with comment period, and we respond to these comments in the final rule with comment period for the next calendar year’s OPSC/ASC update. In the CY 2014 OPSC/ASC proposed rule (78 FR 43590), we proposed to continue this process for CY 2014. Specifically, for CY 2014, we proposed to include in Addendum B to this CY 2014 OPSC/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2014 (including the Category III CPT codes that were released by the AMA in July 2013) that would be incorporated in the January 2014 OPSC quarterly update CR and the new Level II HCPSC codes, effective October 1, 2013, or January 1, 2014, that would be released by CMS in its October 2013 and January 2014 OPSC quarterly update CRs. As proposed, in this final rule with comment period, the October 1, 2013 and January 1, 2014 codes are flagged with comment indicator “NI” in Addendum B to this CY 2014 OPSC/ASC final rule with comment period to indicate that we have assigned them an interim OPSC payment status for CY 2014. As proposed, in this final rule with comment period, their status indicators and their APC assignments and payment rates, if applicable, are open to public comment and will be finalized in the CY 2015 OPSC/ASC final rule with comment period.

For the CY 2014 update, we are finalizing our proposal to flag new Level II HCPSC codes that become effective October 1, 2013, and new CPT and Level II HCPSC codes that become effective January 1, 2014 with comment indicator “NI” in Addendum B to this CY 2014 OPSC/ASC final rule with comment period to indicate that these codes have been assigned an interim OPSC payment status for CY 2014. In

addition, because these codes have been assigned to comment indicator “NI,” their status indicators and their APC assignments and payment rates, if applicable, are open to public comment and will be finalized in the CY 2015 OPSC/ASC final rule with comment period.

B. OPSC 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 HCPSC 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.

We have packaged into payment for each procedure or service within an APC group the costs associated with those items or services that are directly related to, and supportive of, performing the main independent procedures or furnishing the primary and complete services. Therefore, we do not make separate payment for these packaged items or services. In general, according to the regulations at § 419.2(b), packaged items and services include, but are not limited to:

- (1) Use of an operating suite, procedure room, or treatment room;
- (2) Use of recovery room;
- (3) Use of an observation bed;
- (4) Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations;
- (5) Supplies and equipment for administering and monitoring anesthesia or sedation;
- (6) Intraocular lenses (IOLs);

(7) Incidental services such as venipuncture;

(8) Capital-related costs;

(9) Implantable items used in connection with diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests;

(10) Durable medical equipment that is implantable;

(11) Implantable prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of these devices;

(12) Costs incurred to procure donor tissue other than corneal tissue.

Significant revisions to the regulations at § 419.2(b) were proposed. Further discussion of our packaging proposals was included in section II.A.3. of the proposed rule (78 FR 43568 through 43575).

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). Under the CY 2013 OPSC (77 FR 68243 through 68258), we provided composite APC payments for 10 categories of services:

- (1) Mental Health Services (APC 0034);
- (2) Cardiac Electrophysiologic Evaluation and Ablation (APC 8000);
- (3) Low Dose Rate (LDR) Prostate Brachytherapy (APC 8001);
- (4) Level I Extended Assessment & Management Composite (APC 8002);
- (5) Level II Extended Assessment & Management Composite (APC 8003);
- (6) Ultrasound (APC 8004);
- (7) CT and CTA without Contrast (APC 8005);
- (8) CT and CTA with Contrast (APC 8006);
- (9) MRI and MRA without Contrast Composite (APC 8007); and
- (10) MRI and MRA with Contrast Composite (APC 8008).

Further discussion of composite APCs is included in section II.A.2.f. of this final rule with comment period.

Under the OPSC, we generally pay for hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPSC 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 new proposed APC 0634 (Hospital Clinic Visits). The APC relative payment weights are scaled to

new APC 0634 because it is the hospital clinic visit APC and because clinic visits are among the most frequently furnished services in the hospital outpatient setting. We refer readers to section VII. of the proposed rule and this final rule with comment period for further discussion of the establishment of new APC 0634.

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. 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 2014 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 HCPCS codes for examination of 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 cost to be significant (75 FR 71832). This longstanding criterion to determine when a HCPCS code is significant for purposes of the 2 times rule was established 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 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 cost. In the CY 2014 OPPS/ASC proposed rule (78 FR 43592), 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, for CY 2014.

In the CY 2014 OPPS/ASC proposed rule, we identified APCs with 2 times rule violations, for which we proposed changes to their HCPCS codes' APC assignments in Addendum B to the proposed rule. We note that Addendum B did not appear in the printed version of the **Federal Register** as part of the CY 2014 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 2 times rule violation or to improve clinical and resource homogeneity, we proposed to reassign the HCPCS codes to APCs that contain services that are similar with regard to both their clinical and resource characteristics. We also proposed to rename existing APCs or create new clinical APCs to accommodate proposed HCPCS code reassignments. In many cases, the proposed HCPCS code reassignments and associated APC reconfigurations for CY 2014 included in the proposed rule are related to changes in costs of services that were observed in the CY 2012 claims data newly available for CY 2014 ratesetting. We also proposed changes to the status indicators for some HCPCS codes that were not specifically and separately discussed in the CY 2014 OPPS/ASC proposed rule. In these cases, we proposed to change the status indicators for some HCPCS 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 2014. Addendum B to the CY 2014 OPPS/ASC proposed rule identified with comment indicator “CH” those HCPCS codes for which we proposed a change to the APC assignment or status indicator, or both, that were initially assigned in the April 2013 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 2014 changes compared to the HCPCS codes' status as reflected in the October 2013 Addendum B update.

3. Exceptions to the 2 Times Rule

As discussed earlier, we may make exceptions to the 2 times 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 2014, we reviewed all the APCs to determine which APCs would not satisfy the 2 times rule. Then we used the following criteria to decide 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.

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).

For the CY 2014 OPPS/ASC proposed rule, the list of 10 APCs that appeared in Table 15 of the CY 2014 OPPS/ASC proposed rule (78 FR 43592) that were excepted from the 2 times rule were based on claims data for dates of service between January 1, 2012, and December 31, 2012, that were processed before January 1, 2013. For this final rule with comment period, we used claims data for dates of service between January 1, 2012, and December 31, 2012, that were processed on or before June 30, 2013 and updated CCRs, if available. Therefore, after considering the public comments we received on the CY 2014 OPPS/ASC proposed rule and making changes to APC assignments based on those comments, we analyzed the CY 2012 claims data used for this final rule with comment period to identify the APCs with 2 times rule violations. Based on the final CY 2012 claims data, we found 10 APCs with 2 times rule

violations, which is the same number of APCs that violated the 2 times rule 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 2014, and identified six 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 six new APCs violated the 2 times rule: APC 0066 (Level I Stereotactic Radiosurgery); APC 0067 (Level II Stereotactic Radiosurgery); APC 0193 (Level V Female Reproductive Procedures); APC 0342 (Level I Pathology); APC 0370 (Multiple Allergy Tests); and APC 0634 (Hospital Clinic Visits).

After consideration of the public comments we received and our review of the CY 2012 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 4 of the proposed 10 original APCs from the 2 times rule for CY 2014, specifically, APCs 0057, 0272, 0330, and 0690. In contrast, we are not finalizing our proposal to except 6 of the proposed 10 original APCs from the 2 times rule, specifically, APCs 0060 (Manipulation Therapy), 0075 (Level V Endoscopy Upper Airway), 0105 (Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices), 0148 (Level I Anal/Rectal Procedures), 0278 (Diagnostic Urography), and 0402 (Level II Nervous System Imaging). Our data analysis for this final rule with comment period revealed that these six APCs no longer violate the 2 times rule. Table 25 below lists 10 APCs that we are excepting from

the 2 times rule for CY 2014 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 25.—FINAL APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2014

Final CY 2014 APC	Description
0057	Bunion Procedures
0066	Level I Stereotactic Radiosurgery
0067	Level II Stereotactic Radiosurgery
0193	Level V Female Reproductive Procedures
0272	Fluoroscopy
0330	Dental Procedures
0342	Level I Pathology
0370	Multiple Allergy Tests
0634	Hospital Clinic Visits
0690	Level I Electronic Analysis of Devices

C. OPPIs APC-Specific Policies

1. Cardiovascular and Vascular Services

a. Non-Ophthalmic Fluorescent Vascular Angiography (APC 0263)

We created HCPCS code C9733 (Non-ophthalmic fluorescent vascular angiography (FVA)), effective April 1, 2012, for a service that became known to us through the new technology APC application process. We assigned HCPCS code C9733 to APC 0397 (Vascular Imaging), which had a CY 2012 payment rate of \$154.87 and a status indicator of “Q2.” The “Q2” status indicator shows that payment for the service will be packaged in the APC payment if billed on the same date of service as a HCPCS code assigned status indicator “T”; and in all other

circumstances, a separate APC payment for the service will be made. We maintained the assignment of HCPCS code C9733 to APC 0397 for CY 2013, which has a payment rate of \$330.97, and continued the assignment of status indicator “Q2.”

Comment: One commenter objected to the continued assignment of status indicator “Q2” to the service described by HCPCS code C9733, as well as packaging payment for the service as a result of the breast reconstruction surgery primary code being included in a comprehensive APC, because the commenter believed that both of these proposed policies would result in packaging the payment for the service described by HCPCS code C9733. The commenter stated that packaging payment for a service or item is only

appropriate when the cost of the service or item can be taken into account in establishing the payment rate for the separately paid services. The commenter pointed out that there were no single claims reporting HCPCS code C9733 in the claims data used for the proposed rule ratesetting, and asserted that, because HCPCS code C9733 described a new service with no single claims, payment should not be packaged until several years after the code's creation, when there will be sufficient claims data. The commenter further asserted that the proposed packaging payment for the service described by HCPCS code C9733 with payment for CPT code 19357 (Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion) does not comport with CMS'

principle that packaging payment for services should reflect how the service is reported. The commenter stated that its disagreement with the packaging proposals is supported by CMS' acknowledgement that none of the 10 claims reporting HCPCS code C9733 were identified as single claims and, according to an analysis that the commenter conducted, HCPCS code C9733 was reported in combination with CPT code 19357 approximately 90 percent of the time. The commenter also believed that packaging payment for HCPCS code C9733 contradicts the principle that CMS should be able to map the costs of the packaged service to the separately payable services with which it is performed.

Response: We disagree with the commenter that payment for the service described by HCPCS code C9733 should not be packaged when it is used intraoperatively on the same date of service as the primary procedure. While it is true that HCPCS code C9733 is a relatively new service, the commenter stated that its own data analysis shows that the service is being reported in combination with CPT code 19357 approximately 90 percent of the time. Therefore, payment for the service described by HCPCS code C9733 is being taken into account in establishing the payment rate for the separately paid services with which it is performed. In addition, we believe that packaging payment for the service described by HCPCS code C9733 does reflect how the service is furnished and how it is being reported on a claim in combination with CPT code 19357. Although none of the 10 claims available for the proposed rule ratesetting were single claims, the services reported on the 10 claims appear to have been mapped to appropriate separately paid procedures. The procedure described by HCPCS code C9733 is often performed intraoperatively in combination with a number of primary procedures, including facial reconstruction and reanimation, muscle flaps, trauma reconstruction, and digital and limb reattachment and, as the commenter stated, breast reconstruction, which appears to be the focus of the commenter's concern. In other words, there are a number of plastic and reconstructive surgical procedures with which the imaging procedure described by HCPCS code C9733 can be used, not just breast reconstruction surgery.

While we proposed to maintain the assignment of HCPCS code C9733 to APC 0397, in this final rule with comment period, we are deleting APC 0397 because of multiple 2 times rule violations in APC 0397 based on the

final rule claims data. Once we removed the high-cost services from APC 0397, only several low-volume services remained in this APC, including HCPCS code C9733, which we reassigned to another APC. We have reassigned HCPCS code C9733 to APC 0263 (Level I Miscellaneous Radiology Procedures) for CY 2014, with a final rule geometric mean cost of approximately \$319.

After consideration of the public comment we received, we are finalizing our proposal to maintain the assignment of "Q2" status indicator to HCPCS code C9733. However, we are reassigning HCPCS code C9733 to APC 0263 when the service described by HCPCS code C9733 is performed and reported separately. Further discussion of comprehensive APCs is included in section II.A.2.e. of this final rule with comment period. However, we note that we are not implementing our comprehensive APC policy until CY 2015.

b. Subcutaneous Defibrillator (APC 0107)

For CY 2014, we proposed to continue to assign CPT code 0319T (Insertion or replacement of subcutaneous implantable defibrillator system with subcutaneous electrode) to APC 0107 (Level I Implantation of Cardioverter-Defibrillators (ICDs)), for which we proposed a CY 2014 geometric mean cost of approximately \$25,447. (The proposed payment rate reflects the corrected proposed rate included in the September 6, 2013 OPPTS Addendum B, which was posted on the CMS Web site.)

Comment: Commenters objected to the proposed assignment of CPT code 0319T to APC 0107 and requested that CMS reassign CPT code 0319T to APC 0108 (Level II Implantation of Cardioverter-Defibrillators (ICDs)), for which we proposed a CY 2014 geometric mean cost of approximately \$31,911. The commenters believed that CPT code 0319T is similar in clinical application and resource use to CPT code 33249 (Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber), which is currently assigned to APC 0108.

Response: We believe that the procedure described by CPT code 0319T is sufficiently clinically similar to the other procedures assigned to APC 0107. In addition, because we do not have CY 2012 claims data for CPT code 0319T for the CY 2014 ratesetting cycle, we cannot determine the resource costs for this procedure at this time. We expect to have claims data for CPT code 0319T in preparation for the CY 2015 rulemaking

cycle and will reevaluate the APC assignment of CPT code 0319T at that time.

After consideration of the public comments we received, we are finalizing our CY 2014 proposal, without modification, to continue to assign CPT code 0319T to APC 0107, which has a final CY 2014 APC geometric mean cost of approximately \$25,106.

c. Thrombolytic Therapy (APC 0621)

For CY 2014, we proposed to continue to assign CPT code 37211 (Transcatheter therapy, arterial infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, initial treatment day) and CPT code 37212 (Transcatheter therapy, venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, initial treatment day) to APC 0621 (Level I Vascular Access Procedures), for which we proposed a CY 2014 geometric mean cost of approximately \$866. (The proposed payment rate reflects the corrected proposed rate included in the September 6, 2013 OPPTS Addendum B, which was posted on the CMS Web site.)

Comment: One commenter objected to the proposed continued assignment of CPT codes 37211 and 37212 to APC 0621. The commenter stated that CPT codes 37211 and 37212, which both are assigned status indicator "T," are often times performed in conjunction with CPT code 75710 (Angiography, spinal selective, radiological supervision and interpretation) which is assigned status indicator "Q2" and is assigned to APC 0279 (Level II Angiography and Venography), for which we proposed a CY 2014 geometric mean cost of approximately \$2,700. The commenter stated that, because CPT code 75710 is not separately paid when it appears on a claim in combination with other services assigned to status indicator "T" (such as CPT codes 37211 and 37212), providers receive significantly lower payment for CPT code 75710 when performed and reported in conjunction with CPT code 37211 or CPT code 37212, compared to payment for the services when performed and reported separately, although significantly more resources are used. The commenter stated that payment for CPT codes 37211 and 37212 should not be packaged with payment for CPT code 75710 when the services described by CPT codes 37211 and 37212 are performed on the same date as CPT code 75710.

Response: We believe that the procedure described by CPT codes 37211 and 37212 are sufficiently clinically similar to the other procedures assigned to APC 0621. In addition, CPT codes 37211 and 37212 are new codes for CY 2013, and because we do not have claims data available for these two new CPT codes for CY 2013 resetting, we do not have a way to validate or substantiate the claims made by commenters. We expect to have claims data for CPT codes 37211 and 37212 in preparation for the CY 2015 rulemaking cycle and will reevaluate the APC assignment of CPT codes 37211 and 37212 at that time.

After consideration of the public comments we received, we are finalizing our CY 2014 proposal, without modification, to continue to assign CPT codes 37211 and 37212 to APC 0621, which has a final CY 2014 APC geometric mean cost of approximately \$853.

d. Vascular Ligation (APCs 0091 and 0092)

For CY 2014, we proposed to continue to assign CPT codes 36475 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated) and 37191 (Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed) to APC 0091 (Level II Vascular Ligation), which had a proposed payment rate of approximately \$2,882.

In addition, we proposed to continue to assign CPT code 36478 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated) to APC 0092 (Level I Vascular Ligation), which had a proposed payment rate of approximately \$2,047.

(The proposed payment rates reflect the corrected proposed rates included in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

Comment: One commenter stated that the CPT codes assigned to APCs 0091 and 0092 do not meet the CMS requirement of clinical and cost homogeneity, and requested that CMS consider restructuring APCs 0091 and 0092. The commenter requested that CMS review the clinical and cost characteristics of all the procedures assigned to these APCs and consider

either combining APCs 0091 and 0092 or reassigning specific procedures to more appropriate APCs in order to establish clinical homogeneity. In particular, the commenter requested that CMS review the APC assignments for CPT codes 37191 and 36475 (assigned to APC 0091) and CPT code 36478 (assigned to APC 0092). The commenter stated that CPT code 37191 is not similar to the other procedures assigned to APC 0091 because it is not a ligation procedure, and is the only procedure assigned to APC 0091 that requires an expensive implanted device. The commenter further stated that the cost associated with CPT code 37191 is significantly higher than the cost of most of the other procedures assigned to APC 0091. The commenter also recommended that CPT codes 36475 and 36478 be assigned to the same APC because they are nearly identical procedures. The commenter stated that the CPT clinical vignettes for CPT code 36475 (radiofrequency) and CPT code 36478 (laser) show similarities between these two procedures, which further support the clinical homogeneity of these two procedures. The commenter believed that assigning both of these procedures to two different APCs, and maintaining a payment differential between CPT code 36475 and CPT code 36478, incentivizes providers to choose radiofrequency instead of laser, which is a clinically comparable procedure. The commenter believed that assigning the two procedures to the same APC would encourage providers to make treatment decisions based solely on clinical characteristics.

Response: We appreciate the commenter's suggestions. We agree with the commenter's recommendations for reassignment of CPT codes 36475, 36478, and 37191. With respect to CPT codes 36475 and 36478, we have further analyzed updated hospital outpatient claims data and determined that both procedures are comparable in terms of clinical homogeneity and resource costs and should be assigned to the same APC. Analysis of updated CY 2012 hospital outpatient claims data for the CY 2014 final rule shows a geometric mean cost of approximately \$1,966 for CPT code 36478, which is comparable to the geometric mean cost of approximately \$2,382 for CPT code 36475. We also agree with the commenter that CPT code 37191 should be reassigned to another APC that is more appropriate based on the nature of the procedure. Based on our review of the existing vascular-related APCs and input from our medical advisors, we believe that CPT code 37191 would be

more appropriately reassigned to APC 0093 (Vascular Reconstruction/Fistula Repair) because of the clinical homogeneity and similar resource costs of other procedures assigned to APC 0093.

By accepting the commenter's recommendation to reassign CPT code 37191 from APC 0091 to APC 0093, and after taking into consideration all of the procedures in APCs 0091 and 0092, we have determined that combining APCs 0091 and 0092 into one APC is appropriate. To accomplish this reconfiguration, we are establishing new APC 0219 (Vascular Ligation), which has a geometric mean cost of approximately \$2,147. The geometric mean cost of new APC 0219 is based on the costs of all of the 22 procedures assigned to APCs 0091 and 0092; the most significant cost among these 22 procedures ranged between \$1,455 (for CPT code 37765) and \$2,382 (for CPT code 36475). In addition, because of the reassignment of CPT code 37191 to APC 0093, we are modifying the title of APC 0093 to read: "Vascular Reconstruction/Fistula Repair" to appropriately describe all the procedures assigned to this APC.

After further consideration of the public comment that we received, we are revising the APC assignment for CPT codes 36475, 36478, and 37191. Specifically, we are reassigning CPT codes 36475 and 36478 to new APC 0219, reassigning CPT code 37191 to APC 0093, and modifying the title of APC 0093 to read: "Vascular Reconstruction/Fistula Repair". The final CY 2014 geometric mean cost of APC 0219 is approximately \$2,147, and approximately \$2,857 for APC 0093. The final CY 2014 payment rates for CPT codes 36475, 36478, and 37191 can be found in Addendum B to this CY 2014 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

2. Gastrointestinal Services

a. Fecal Microbiota Transplantation (APC 0340)

For CY 2014, we proposed to continue to assign HCPCS code G0455 (Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen) to APC 0340 (Level I Minor Procedures), which had a proposed payment rate of approximately \$74. Although the CPT Editorial Panel established CPT code 44705 (Preparation of fecal microbiota for instillation, including assessment of donor specimen), effective January 1, 2013, to describe a fecal microbiota procedure, we did not recognize the

CPT code for payment under the OPPS. As we stated in the CY 2013 MPFS final rule with comment period (77 FR 69052), by policy, Medicare's payment for the preparation of the donor specimen would only be made if the specimen is ultimately used for the treatment of a beneficiary. Because of this policy, we believe that it was appropriate to bundle the preparation and instillation of fecal microbiota into one payable HCPCS code. Consequently, we established HCPCS code G0455, effective January 1, 2013, for Medicare reporting of the fecal microbiota procedure.

Comment: One commenter stated that the CY 2013 payment rate of approximately \$50 for HCPCS code G0455 is insufficient. The commenter further stated that this payment rate does not appear to recognize the patient preparation for the implantation or the instillation of the donor microbes, the supplies, or the overall work involved in providing this procedure. The commenter stated that if the microbiota instillation is performed via colonoscopy or esophagogastroduodenoscopy (EGD), the CY 2013 payment rate for the procedure does not include the cost of the endoscopic portion of the procedure. To pay appropriately for this procedure, the commenter recommended that CMS delete existing HCPCS code G0455 and replace it with three new HCPCS G-codes. The commenter suggested that the three recommended HCPCS G-codes differentiate the various preparation methods used in performing the procedure and be assigned accordingly to appropriate APCs. Specifically, the commenter recommended that one HCPCS G-code describe instillation by oronasogastric tube or enema, the second HCPCS G-code describe instillation by upper endoscopy, and the third HCPCS G-code describe instillation by colonoscopy.

Response: We appreciate the commenter's suggestions. However, we believe that the existing HCPCS code G0455 appropriately describes the procedure for which Medicare should pay. Under Medicare, payment for the preparation of the donor specimen would only be made if the specimen is ultimately used for the treatment of a beneficiary because Medicare is not authorized to pay for the costs of any services not directly related to the diagnosis and treatment of a beneficiary. Because of this policy, we believe that it is appropriate to bundle the preparation and instillation of fecal microbiota under HCPCS code G0455.

Based on our understanding of the procedure, we believe that HCPCS code G0455 is appropriately assigned to APC 0340 for CY 2014. Because this code was new for CY 2013, we expect to have claims data for HCPCS code G0455 for the CY 2015 ratesetting process. 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, for any 2 times rule violations. 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 status indicator and APC assignment for HCPCS code G0455 for the CY 2015 OPPS rulemaking cycle.

After consideration of the public comment that we received, we are finalizing our CY 2014 proposal, without modification, to continue to assign HCPCS code G0455 to APC 0340. The final CY 2014 geometric mean cost of HCPCS code G0455 is approximately \$54. The final CY 2014 payment rate for HCPCS code G0455 can be found in Addendum B to this CY 2014 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

b. Transoral Incisionless Fundoplication (APC 0422)

For CY 2014, we proposed to continue to assign CPT code C9724 (Endoscopic full-thickness plication of the stomach using endoscopic plication system (eps); includes endoscopy) to APC 0422 (Level III Upper GI Procedures), which had a proposed payment rate of approximately \$1,967. (The proposed payment rate reflects the corrected proposed rate included in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

HCPCS code C9724, which was established by CMS effective April 1, 2005, describes an endoscopic full-thickness plication procedure for the treatment of gastroesophageal reflux disease (GERD). Since April 2005, HCPCS code C9724 has been assigned to APC 0422. Of the three existing upper GI APCs, APC 0422 is the highest paying APC.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68333), we stated that a presenter at the August 2012 HOP Panel meeting requested that CMS either reassign HCPCS code C9724 from APC 0422 to New Technology APC 1565 (New Technology—Level XXVIII (\$5000–\$5500)) or create a new APC with a descriptor of “Level IV Upper GI

Procedures.” We also stated that, based on the Panel's review and discussion of the claims data, we accepted the Panel's recommendation to continue to assign HCPCS code C9724 to APC 0422 for the CY 2013 update.

Furthermore, because of concerns related to the descriptor of HCPCS code C9724, in that same final rule with comment period, we revised the long descriptor of HCPCS code C9724 to read “Endoscopic full-thickness plication of the stomach using endoscopic plication system (eps); includes endoscopy,” effective January 1, 2013, to accurately describe how the procedure is currently performed.

At the August 2013 HOP Panel meeting, the same presenter at the August 2012 HOP Panel meeting requested that the Panel recommend that CMS reassign HCPCS code C9724 from APC 0422 to a new APC with a descriptor of “Level IV Upper GI Procedures.” The Panel did not make this recommendation at the meeting.

Comment: Several commenters disagreed with the proposal to continue to assign HCPCS code C9724 to APC 0422. The commenters stated that the proposed payment rate for APC 0422 does not adequately pay for the cost of performing the procedure. These commenters urged CMS to establish a new APC with a descriptor of “Level IV Upper GI Procedures” or “Level IV Upper GI Transoral Procedures,” with a payment rate of between \$3,000 and \$5,000, and reassign HCPCS code C9724 and CPT code 43257 to this newly created APC.

Response: Because HCPCS code C9724 became effective April 1, 2005, we have several years of claims data. We examined the latest hospital outpatient claims data for HCPCS code C9724, based on claims data for dates of service between January 1, 2012, and December 31, 2012, that were processed on or before June 30, 2013. Our analysis of these latest claims data shows a geometric mean cost of approximately \$6,801 based on 12 single claims (out of 73 total claims) for HCPCS code C9724. Overall, APC 0422 has a geometric mean cost of approximately \$1,976, which is based on the seven procedures assigned to this APC. Of the seven procedures assigned to APC 0422, three procedures have geometric mean cost ranging between approximately \$1,431 (for CPT code 43830) and approximately \$2,042 (for CPT code 43228).

APC 0422 consists of other procedures that manipulate the natural or an artificial entrance to the stomach, similar to the procedure described by TIF. We believe that maintaining the assignment of HCPCS code C9724 to

APC 0422 continues to be appropriate because several other procedures assigned to this APC are highly clinically similar to the procedure described by HCPCS code C9724 in that they are upper gastrointestinal endoscopy procedures. In particular, CPT code 43257 describes an upper gastrointestinal endoscopy procedure for the treatment of GERD, which is also the method and purpose of HCPCS code C9724. Consistent with our longstanding policy since the implementation of OPSS in 2000, we will reevaluate the APC assignment for every code during our annual rulemaking cycle.

After consideration of the public comments that we received, we are finalizing our CY 2014 proposal, without modification, to maintain the assignment of HCPCS code C9724 to APC 0422. The final CY 2014 geometric mean costs for APC 0422 is approximately \$1,976. The final CY 2014 payment rate for HCPCS code C9724 can be found in Addendum B to this CY 2014 OPSS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

3. Genitourinary Services

a. Percutaneous Renal Cryoablation (APC 0423)

For CY 2014, we proposed to continue to assign CPT code 50593 (Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy) to APC 0423 (Level II Percutaneous Abdominal and Biliary Procedures), with a proposed payment rate of approximately \$4,114. (The proposed payment rate reflects the corrected proposed rate included in the September 6, 2013 OPSS Addendum B, which was posted on the CMS Web site.) CPT code 50593 became effective in CY 2008; however, the same service was previously described by CPT code 0135T (Ablation renal tumor(s), unilateral, percutaneous, cryotherapy). We note that, for CY 2007, based upon the APC Panel's recommendation made at its March 2006 meeting, we reassigned CPT code 0135T (now CPT code 50593) from APC 0163 (Level IV Cystourethroscopy and Other Genitourinary Procedures) to APC 0423, effective January 1, 2007.

Comment: One commenter expressed concern that the proposed payment rate of approximately \$4,114 for APC 0423, the APC to which CPT code 50593 is assigned, is inadequate because the proposed payment rate does not accurately account for the costs incurred by hospitals in performing the procedure described by CPT code 50593. Further, the commenter

indicated that hospitals are hesitant to perform this procedure because of the inadequate APC payment rate assigned to the procedure. The commenter asked CMS to designate CPT code 50593 as a "device-dependent" procedure and require hospitals to submit claims with the appropriate device C-code, specifically, HCPCS code C2618 (Probe, cryoablation). The commenter believed that the inadequacy of the proposed payment rate for APC 0423 is attributable to claims data that do not accurately capture the full costs of the procedure described by CPT code 50593. The commenter stated that approximately half of the single claims reporting CPT code 50593 do not contain the associated charge for the required device used in performing the service, specifically HCPCS code C2618 (Probe, cryoablation). The commenter stated that designating CPT code 50593 as a device-dependent procedure would result in a more accurate payment for the procedure and continued Medicare beneficiary access to percutaneous renal cryoablation in the HOPD.

Response: We continue to believe that CPT code 50593 is appropriately assigned to APC 0423 based on clinical and resource similarities compared to other procedures also proposed for assignment to APC 0423 for CY 2014. As we stated in the CY 2007 OPSS final rule with comment period (71 FR 68049 through 68050), the CY 2008 OPSS/ASC final rule with comment period (72 FR 66709), the CY 2009 OPSS/ASC final rule with comment period (73 FR 68611), the CY 2010 OPSS/ASC final rule with comment period (74 FR 60444), and the CY 2011 OPSS/ASC final rule with comment period (75 FR 71910), we initially revised the APC assignment for the percutaneous renal cryoablation procedure from APC 0163 to APC 0423 in CY 2007 based on the APC Panel's recommendation. In addition, based on our CY 2012 claims data, the resource use associated with CPT code 50593 is comparable to the other procedures assigned to APC 0423. Specifically, our latest hospital outpatient claims data shows that the geometric mean cost for CPT code 50593, based on 667 single claims (out of 1,357 total claims), is approximately \$5,047. Overall, APC 0423 has a geometric mean cost of approximately \$4,121, which is based on claims data for the eight procedures assigned to this APC. Of the eight procedures, six procedures have the most significant geometric mean cost, ranging between approximately \$3,117 (for CPT code 47511) and approximately \$5,047 (for CPT code 50593). Based on our latest

claims data, and the clinical homogeneity and resource similarity of the procedure described by CPT code 50593 to the other procedures assigned to APC 0423, we believe that CPT code 50593 is appropriately assigned to APC 0423.

Moreover, we disagree with the commenter's assertion that hospitals are reluctant to perform this procedure because of the inadequate payment rate. We believe that the payment rate for APC 0423, the APC to which CPT code 50593 is assigned, is sufficient to ensure Medicare beneficiary access to this service.

With regard to the commenter's request to designate CPT code 50593 as a device-dependent procedure in an APC, we do not agree that CPT code 50593 should be designated as a device-dependent procedure. We do not identify individual HCPCS codes as device-dependent HCPCS codes under the OPSS. Rather, we first consider the clinical and resource characteristics of a procedure and determine the most appropriate APC assignment. When we determine that we should assign a procedure to an APC that is device-dependent, based on whether that APC has been historically identified under the OPSS as having very high device costs, we then consider the implementation of device edits, as appropriate. We again note that the identification of device-dependent APCs was particularly important in the early years of the OPSS when separate pass-through payment for many implantable devices expired. At that time, a variety of methodologies to package the costs of those devices into procedural APCs was utilized over several years to ensure appropriate incorporation of the device costs into the procedure payments. At this point in time, hospitals have significantly more experience reporting HCPCS codes for packaged and separately payable items and services under the OPSS and the payment groups are more mature. We believe that our standard ratesetting methodology typically results in appropriate payment rates for new procedures that utilize devices, as well as those that do not use high-cost devices. In recent years, we have not encountered circumstances whereby we have had to establish new device-dependent APCs because we were not able to accommodate the clinical and resource characteristics of a procedure by assigning it to an existing APC (whether device-dependent or non-device-dependent), and the procedure described by CPT code 50593 is no exception.

While all of the procedures assigned to APC 0423 require the use of

implantable devices, for many of the procedures, there are no Level II HCPCS codes that describe all of the technologies that may be used in the procedures. Therefore, it would not be possible for us to develop procedure-to-device edits for all of the CPT codes assigned to APC 0423. Under the OPPS, there are many other procedures that require the use of implantable devices that, because they are assigned to OPPS APCs that are not device-dependent, do not have procedure-to-device edits applied, even if those claims processing edits would be feasible. We continue to believe that our payments for procedures that utilize high-cost devices are appropriate for those services, even when those services are grouped with other procedures that either do not require the use of implantable devices or which utilize devices that are not described by specific Level II HCPCS codes. When reporting CPT code 50593, we expect hospitals to also report the device HCPCS code C2618, which is associated with this procedure. We also remind hospitals that they must report all of the HCPCS codes that appropriately describe the items used to provide services, regardless of whether the HCPCS codes are packaged or paid separately. If hospitals use more than one probe in performing the procedure described by CPT code 50593, we expect hospitals to report this information on the claim and adjust their charges accordingly. Hospitals should report the number of cryoablation probes used to perform the procedure described by CPT code 50593 as the number of units of HCPCS code C2618, which describes these devices, with their charges for the probes. Since CY 2005, we have required hospitals to report device HCPCS codes for all devices used in procedures if there are appropriate HCPCS codes available. In this way, we can be confident that hospitals have included charges on their claims for costly devices used in procedures when they submit claims for those procedures. For further discussion of device-dependent edits, we refer readers to section II.A.2.d. of this CY 2014 OPPS/ASC final rule with comment period.

Comment: One commenter requested that CMS revise the code descriptor for device HCPCS code C2618 consistent with how cryoablation probes are now classified by the medical industry. The commenter stated that since the implementation of the OPPS and the development of device descriptions, cryoablation probes have improved and these devices are now referred to as cryoablation needles. The commenter

believed that modifying the description of HCPCS code C2618 will enable hospitals to appropriately report the use of the device when submitting claims to CMS and other payers.

Response: Based on input from our medical advisors, we agree that a change in the description of HCPCS code C2618 is appropriate. Therefore, for the CY 2014 update, we are revising the description for HCPCS code C2618 from "Probe, cryoablation" to "Probe/needle, cryoablation" effective January 1, 2014.

After consideration of the public comments we received, we are finalizing our CY 2014 proposal, without modification, to continue to assign CPT code 50593 to APC 0423, which has a final CY 2014 geometric mean cost of approximately \$4,121. In addition, we are revising the code descriptor for HCPCS code C2618 to read: "Probe/needle, cryoablation" effective January 1, 2014. The final CY 2014 payment rate for CPT code 50593 can be found in Addendum B to this CY 2014 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

b. Anoscopy With Directed Submucosal Injection (APC 0150)

We created HCPCS code C9735 (Anoscopy; with directed submucosal injection(s), any substance) effective April 1, 2013, and assigned the code to APC 0150 (Level IV Anal/Rectal Procedures) for CY 2013, which has a payment rate of \$2,365.97. The procedure described by 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). For CY 2014, we proposed to maintain the assignment of HCPCS code C9735 to APC 0150, with a proposed payment rate of approximately \$2,520. (The proposed payment rate reflects the corrected proposed rate included in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

Comment: One commenter believed that the proposed assignment of HCPCS code C9735 to APC 0150 is inappropriate. The commenter stated that the bulking agent used in the performance of the procedure described by HCPCS code C9735 costs \$4,900 for the 4 mL required for the injections, and that the total cost of the procedure described by HCPCS code C9735 is more than the proposed payment rate of approximately \$2,519 for APC 0150. The commenter recommended creating a new Level V Anal/Rectal Procedures APC, composed of HCPCS code C9735,

and two other procedures, CPT code 46762 (Sphincteroplasty, anal, for incontinence, adult; implantation artificial sphincter), and CPT code 0184T (Excision of rectal tumor, transanal endoscopic microsurgical approach (ie, TEMS), including muscularis propria (ie, full thickness)). The commenter stated that the procedure described by CPT code 46762 is clinically similar to the procedure described by HCPCS code C9735 because both procedures involve implantation of a product to treat fecal incontinence, and that the procedure described by HCPCS code C9735 is similar to the procedure described by CPT code 0184T because both procedures involve new technology with significant procedure costs.

Alternatively, the commenter recommended assigning HCPCS code C9735 to New Technology APC 1526, with a CY 2014 proposed payment rate of approximately \$4,250.

Response: HCPCS code C9735 was created effective April 1, 2013. Therefore, we do not have claims data on this procedure at this time. Our longstanding policy is to wait until claims data are available on a new procedure before reassigning the procedure to another clinical APC. We do not agree with the commenter that creating a Level V Anal/Rectal Procedures APC is warranted at this time. The three codes recommended for assignment to such an APC, all of which are currently assigned to the Level IV Anal/Rectal Procedures APC, are low volume or no volume services. According to our CY 2012 claims data, CPT code 0184T has 104 single frequency claims, CPT code 46762 has 8 single claims, and HCPCS code C9735 has no claims volume. The low volume of claims for such an APC would contribute to APC cost and payment volatility. Regarding the commenter's recommendation to assign HCPCS code C9735 to a New Technology APC, we believe that HCPCS code C9735 is clinically similar to the other services assigned to APC 0150, which includes another anoscopy service, and, therefore, APC 0150 is an appropriate APC assignment for HCPCS code C9735. Based on our established OPPS ratesetting methodology, we will review the APC assignment for HCPCS code C9735 once we have OPPS claims data for this service during our annual OPPS update process. Therefore, we are finalizing our proposal to maintain the assignment of HCPCS code C9735 to APC 0150 for CY 2014. The final CY 2014 geometric mean cost for APC 0150 is approximately \$2,510.

4. Musculoskeletal Services

a. Arthroplasty (APC 0425)

APC 0425 (Level II Arthroplasty or Implantation with Prosthesis) contains arthroplasty procedures as well as osseointegrated implant procedures. For CY 2014, we proposed to convert APC 0425 to a comprehensive APC, with a proposed geometric mean cost of approximately \$9,939. (The proposed payment rate reflects the corrected proposed rate included in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

Comment: One commenter requested that CMS review the current composition of APC 0425 for clinical homogeneity and resource cost cohesion, including the newly added adjunctive costs that would result from converting APC 0425 to a comprehensive APC. The commenter recommended that CMS remove the following osseointegrated implant procedure codes from APC 0425 and assign them to a more clinically appropriate APC: CPT code 69714 (Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy); CPT code 69715 (Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy); CPT code 69717 (Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy); and CPT code 69718 (Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy).

Response: In response to the commenter's request, we have again reviewed the composition of APC 0425 for clinical and resource homogeneity. Although we are not making comprehensive APCs effective until CY 2015, the proposed procedural composition of APC 0425 is the same whether this APC is a comprehensive APC or not. We found in our review that the clinical and resource composition of proposed APC 0425 is appropriate because all of the procedures assigned to the APC involve surgical procedures that use high-cost devices, including the osseointegrated device procedures represented by CPT codes 69714, 69715, 69717, and 69718. Therefore, we do not

believe that it is necessary to reconfigure the proposed APC 0425.

After consideration of the public comment we received, we are finalizing the proposed composition of APC 0425 for CY 2014 with the modification that APC 0425 will not be made a comprehensive APC until CY 2015. The final CY 2014 geometric mean cost of APC 0425 is approximately \$9,766.

b. Joint Stabilization (APC 0052)

The CPT Editorial Panel created CPT 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)), effective July 1, 2013. For CY 2013, we assigned CPT code 0334T to APC 0208 (Laminotomies and Laminectomies) with a payment rate of \$3,758.59. For CY 2014, we proposed to maintain the assignment of CPT code 0334T to APC 0208, with a proposed payment rate of approximately \$4,109. (The proposed payment rate reflects the corrected proposed rate included in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

Comment: A few commenters objected to our proposed assignment of CPT code 0334T to APC 0208, and stated that APC 0208 is not an appropriate assignment for CPT code 0334T either in terms of resources or clinical homogeneity. The commenters stated that the proposed payment rate for APC 0208 is insufficient to cover the approximately \$10,500 in implant costs. The commenters further stated that the other procedures assigned to APC 0208 do not have appreciable device costs. One commenter performed a cost analysis on claims reporting CPT code 27280 (Arthrodesis, sacroiliac joint (including obtaining graft)), the CPT code that would have been used for minimally invasive Sacroiliac (SI) fusion procedures in CY 2012, the year used for the CY 2014 ratesetting. Based on the commenter's analysis, 38 hospitals submitted outpatient claims reporting CPT code 27280. However, no claims were used for CY 2014 Medicare ratesetting because CPT code 27280 was included on the OPPS inpatient only list for CY 2012 (and currently remains on this list). The commenter calculated a geometric mean cost of \$14,733 based on these 38 claims. The commenter believed that these 38 claims represented migration of the procedure described by CPT code 27280, which uses minimally invasive techniques and

implants, to the hospital outpatient setting. Some commenters also stated that other procedures assigned to APC 0208 are primarily used for decompressing the disc and neural structures, which differ in location and purpose from the procedure described by CPT code 0334T. The commenters recommended that CMS consider assigning CPT code 0334T to a New Technology APC with a payment rate range between \$14,500 and \$15,000, based on the commenter's analysis of the claims reporting CPT code 27280; or creating a new clinical APC and assigning CPT code 0334T to that APC based on the cost estimate for performing the procedure described by CPT code 27280 because there are no other clinical APCs that are appropriate to assign CPT code 0334T.

Response: We appreciate the commenters' suggestions. However, in regard to the commenter's cost analysis performed using the 38 CY 2012 claims for CPT code 27280, we do not believe that these 38 claims likely represent the cost of performing the procedure described by CPT code 0334T. As the commenter stated, CPT code 27280 was listed as an inpatient only service for CY 2012, currently remains on the inpatient only list for CY 2013, and is proposed to remain on the inpatient only list for CY 2014. CPT code 27280 is used primarily to report open sacroiliac joint fusion procedures, rather than minimally invasive SI joint fusion procedures. Therefore, while some of the 38 claims may involve the minimally invasive techniques, we are not convinced that these claims represent minimally invasive techniques, but consist mainly of open SI joint fusion procedures, which are the primarily reported procedures for this code. Regarding the commenters' suggested option to create a new device pass-through category, we do not discuss the merits of OPPS pass-through status applications in our proposed or final rules. Regarding the commenters' recommended option to assign CPT code 0334T to a New Technology APC or to create a new clinical APC for CPT code 0334T, we agree with the commenters that there may be a more appropriate APC to which we could assign CPT code 0334T based on resource use and clinical homogeneity. However, we believe that CPT code 0334T can be appropriately assigned to an existing clinical APC, which is preferable because other clinically similar procedures populate the APC. The final geometric mean cost of APC 0208 is approximately \$4,017. We agree that the resource use associated with the

procedure described by CPT code 0334T is likely to be greater than the resource use associated with the typical procedures assigned to APC 0208. Therefore, we believe that a more appropriate initial APC assignment based on clinical and resource homogeneity for this new procedure is APC 0052 (Level IV Musculoskeletal Procedures Except Hand and Foot). APC 0052 includes several orthopedic fusion procedures that are clinically similar to the procedure described by CPT code 0334T, and we believe that it is appropriate clinically to assign CPT code 0344T to APC 0052, which has a final geometric mean cost of approximately \$6,530. In accordance with our longstanding policy, we will review the assignment of CPT code 0334T in a future annual OPPS update, when we have available claims data for ratesetting.

After consideration of the public comments we received, we are not finalizing our CY 2014 proposal to maintain the assignment of CPT code 0334T to APC 0208. Rather, for CY 2014, we are assigning CPT code 0334T to APC 0052, which has a final geometric mean cost of approximately \$6,530.

5. Nervous System Services

a. Chemodenervation (APCs 0161 and 0204)

CPT codes 64615 (Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (e.g., for chronic migraine)) and 52287 (Cystourethroscopy, with injection(s) for chemodenervation of the bladder) both became effective January 1, 2013. For CY 2014, we proposed to continue to assign CPT code 52287 to APC 0161 (Level II Cystourethroscopy and Other Genitourinary Procedures), with a proposed payment rate of approximately \$1,201. In addition, we proposed to continue to assign CPT code 64615 to APC 0204 (Level I Nerve Injections), with a proposed payment rate of approximately \$214. (The proposed payment rates reflect the corrected proposed rates included in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

Comment: One commenter requested that CMS reassign CPT code 64615 from APC 0204 to APC 0206 (Level II Nerve Injections) because of the clinical similarity to the procedure described by CPT code 64613 (Chemodenervation of muscle(s); neck muscle(s) (eg, for spasmodic torticollis, spasmodic dysphonia)), which is assigned to APC

0206. This commenter stated that the payment rate for APC 0204 does not adequately pay for the cost of providing the procedure. The commenter submitted this same request in response to the CY 2013 OPPS/ASC final rule with comment period.

Response: We disagree with the commenter's assertion that the procedure described by CPT code 64615 is more similar to the procedure described by CPT code 64613. Based on the description of the procedure, the procedure described by CPT code 64615 is most similar to the procedure described by CPT code 64612 (Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)), which is assigned to APC 0204. The procedures described by CPT codes 64612 and 64615 both involve facial nerve muscles, whereas the procedure described by CPT code 64613 involves the neck muscles. Consequently, we believe that CPT code 64615 is appropriately assigned to APC 0204 based on its clinical homogeneity to CPT code 64612.

We note that, in addition to the payment for the procedure, hospitals would receive separate payment for the drug onabotulinumtoxin, which is described by HCPCS code J0585 (Injection, onabotulinumtoxin, 1 unit), when the drug is administered during the procedure.

Consistent with CMS' longstanding policy since the implementation of the OPPS in 2000, we evaluate, on an annual basis, all of the APC assignments for appropriateness. We note that because CPT code 64615 is a new code that became effective for CY 2013, we will have a full year of claims data available next year, and as with every HCPCS code or CPT code, we will reevaluate its APC assignment during the annual rulemaking cycle.

Comment: One commenter requested that CMS reassign CPT code 52287 from APC 0161 to APC 0162 (Level III Cystourethroscopy and Other Genitourinary Procedures). The commenter stated that the proposed APC assignment for CPT code 52287 is economically and clinically inappropriate. The commenter further stated that the procedure described by CPT code 52287 is more clinically similar to the procedure described by CPT code 52283 (Cystourethroscopy, with steroid injection into stricture), which is assigned to APC 0162. The commenter submitted this same request in response to the CY 2013 OPPS/ASC final rule with comment period.

Response: APC 0161 consists of a variety of procedures, some of which

describe cystourethroscopic procedures of the urethra and bladder. We believe that the procedure described by CPT code 52287 is more clinically similar to the other cystourethroscopic procedures assigned to APC 0161, such as the procedure described by CPT code 52281, than to procedures assigned to APC 0162, such as the procedure described by CPT code 52287 as mentioned by the commenter. We also note that in addition to a payment for the procedure at the payment rate for APC 0161, hospitals also receive separate payment for the chemodenervation drug. For the CY 2014 update, the payment rate for APC 0161 is approximately \$1,205. As has been our practice since the implementation of the OPPS, we annually review all of the items and services within an APC group to determine, with respect to comparability of the use of resources, any 2 times rule violations. In making this determination, we review all claims data and determine whether we need to make changes to the current APC assignments for the following year. We will reevaluate the status indicator and APC assignment for CPT code 52287 for the CY 2015 OPPS rulemaking cycle.

After consideration of the public comments received, we are finalizing our CY 2014 proposals, without modification, to continue to assign CPT code 64615 to APC 0204, and to continue to assign CPT code 52287 to APC 0161. The final CY 2014 geometric mean costs for APCs 0204 and 0161 are approximately \$203 and \$1,209, respectively.

b. Nerve Conduction Studies (APCs 0216 and 0218)

For CY 2013, the AMA's CPT Editorial Panel established seven new CPT codes to describe nerve conduction tests, which were effective January 1, 2013. For CY 2014, we proposed to continue to assign CPT codes 95907, 95908, 95909, and 95910 to APC 0215 (Level I Nerve and Muscle Services), with a proposed payment rate of approximately \$67. In addition, we proposed to reassign CPT codes 95911, 95912, and 95913 from APC 0218 (Level II Nerve and Muscle Services) to APC 0215. The descriptors for these seven CPT codes and our proposed APC assignments are listed in Table 26 below.

Comment: Some commenters expressed concern with the proposed APC assignments of CPT codes that describe the nerve conduction tests. The commenters stated that the proposed payment of \$67 for APC 0215 is inadequate because it does not cover the

expenses associated with providing these services. The commenters urged CMS to reconsider the proposed APC assignments for CPT codes 95907 through 95913, and suggested specific alternative APC assignments for these specific codes. Specifically, the commenters recommended the reassignment of CPT code 95907 from APC 0215 to APC 0218, the reassignment of CPT codes 95908, 95909, and 95910 from APC 0215 to APC 0216 (Level III Nerve and Muscle Services), and the reassignment of CPT codes 95911, 95912, and 95913 from APC 0218 to APC 0216.

We also received a comment in response to the CY 2013 OPPS/ASC final rule with comment period relating to these codes. The commenter stated that the CY 2013 OPPS payment rates for these new codes were significantly lower for these services when they were performed in the hospital outpatient setting compared to when they were performed in the physician office setting, and suggested that the lower payment rates would negatively impact beneficiary access to neurologic care.

Response: After further consultation with our medical advisors, we agree

with the commenters that a revision to the APC assignments for CPT codes 95907 through 95913 is necessary. Based on the nature of the procedures described by these codes and the additional information submitted to us by the commenters on the CY 2013 OPPS/ASC final rule with comment period and the CY 2014 OPPS/ASC proposed rule, we believe that the nerve conduction tests described by CPT codes 95908, 95909, 95910, 95911, 95912, and 95913 would be more appropriately assigned to APC 0216. In addition, we believe that the nerve conduction test described by CPT code 95907 would be more appropriately assigned to APC 0218.

Therefore, after consideration of the public comments we received, we are revising our CY 2014 proposed APC reassignment of CPT codes 95908, 95909, 95910, 95911, 95912, and 95913 from APC 0215 to APC 0216. In addition, we are revising our CY 2014 proposed APC reassignment of CPT code 95907 from APC 0215 to APC 0218. The final APC assignments for these codes, along with the final status indicators are listed in Table 26 below. The final CY 2014 payment rates for

CPT codes 95907 through 95913 are included in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

We remind hospitals that, consistent with our longstanding policy since the implementation of OPPS in 2000, we will reevaluate the APC assignments for these codes in next year's rulemaking cycle. As has been our practice, we annually review all the items and services within an APC group to determine, with respect to comparability of the use of resources, if the geometric mean cost of the highest cost item or service within an APC group is more than 2 times greater than the geometric mean cost of the lowest cost item or service within that same group. 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 note that, because CPT codes 95907 through 95913 became effective for CY 2013, we will not have applicable claims data available for these services for ratesetting until the CY 2015 rulemaking cycle.

TABLE 26.—FINAL CY 2014 APC ASSIGNMENTS FOR THE NERVE CONDUCTION CPT CODES

CPT Code	Long Descriptor	Proposed CY 2014 SI	Proposed CY 2014 APC	Final CY 2014 SI	Final CY 2014 APC
95907	Nerve conduction studies; 1-2 studies	S	0215	S	0218
95908	Nerve conduction studies; 3-4 studies	S	0215	S	0216
95909	Nerve conduction studies; 5-6 studies	S	0215	S	0216
95910	Nerve conduction studies; 7-8 studies	S	0215	S	0216
95911	Nerve conduction studies; 9-10 studies	S	0215	S	0216
95912	Nerve conduction studies; 11-12 studies	S	0215	S	0216
95913	Nerve conduction studies; 13 or more studies	S	0215	S	0216

c. Parasympathetic Function and Sympathetic Function (APC 0215)

In CY 2013, the AMA's Editorial Panel created two new codes to describe

testing of parasympathetic and sympathetic functions of the autonomic nervous system at the same time, with and without use of passive tilt: CPT

code 95943 (Simultaneous, independent, quantitative measures of both parasympathetic function and sympathetic function) and CPT code

95924 (Testing of autonomic nervous system function; combined parasympathetic and sympathetic adrenergic function testing with at least 5 minutes of passive tilt). For CY 2013, we assigned CPT code 95943 to APC 0215 (Level I Nerve and Muscle Tests), which has a CY 2013 payment rate of approximately \$43. We also assigned comment indicator "NI" to CPT code 95943 to indicate that the code was new for CY 2013 with an interim APC assignment that was subject to public comment following the publication of the CY 2013 final rule with comment period. We assigned CPT code 95924 (Testing of autonomic nervous system function; combined parasympathetic and sympathetic adrenergic function testing with at least 5 minutes of passive tilt) to APC 0218 (Level II Nerve and Muscle Tests), which has a CY 2013 payment rate of approximately \$80.

Comment: One commenter who addressed the interim APC assignment of CPT code 95943 believed that the test described by CPT code 95943 is more similar in terms of clinical homogeneity and resource use to the services assigned to APC 0218, and requested that CMS reassign CPT code 95943 to APC 0218 for CY 2014, which has a final rule geometric mean cost of approximately \$128. APC 0215 has a final rule geometric mean cost of approximately \$50. The commenter noted that the predecessor codes for CPT code 95943, CPT code 95921 (Testing of autonomic nervous system function; cardiovagal innervation (parasympathetic function)) and CPT code 95922 (Testing of autonomic nervous system function; vasomotor adrenergic innervation (sympathetic adrenergic function)), were assigned to APC 0218. In addition, the commenter stated that the test described by CPT code 95943 is almost identical to the test described by CPT code 95924, which is assigned to APC 0218. The commenter stated that, although the test described by CPT code 95924 is the only test that uses a tilt table, the monitor used to perform the test described by CPT code 95943 is more expensive than the monitor used to perform the test described by CPT code 95924.

Response: We agree with the commenter that the service described by CPT code 95943 is clinically similar to the other services assigned to APC 0218, including its predecessor codes, CPT codes 95921 and 95922. Therefore, for CY 2014, we are reassigning CPT code 95943 from APC 0215 to APC 0218.

We will reconsider the APC assignments for this code once claims data are available, as part of our usual ratesetting methodology for CY 2015.

d. Epidural Lysis (APCs 0203 and 0207)

For CY 2013, CPT code 62263 (Epidural lysis, multiple sessions) and CPT code 62264 (Epidural lysis on single day) are assigned to APC 0203 (Level IV Nerve Injections), with a payment rate of approximately \$857. For CY 2014, we proposed to reassign CPT code 62264, which had a proposed rule geometric mean cost of approximately \$874 from APC 0203 (which had a proposed rule geometric mean cost of approximately \$1,574) to APC 0207 (Level III Nerve Injections), which had a proposed rule geometric mean cost of approximately \$687.

Comment: One commenter objected to the reassignment of CPT code 62264 from APC 0203 to APC 0207 asserting that the resources used to perform the procedures described by CPT codes 62263 and 62264 are the same and that CPT code 62263 is rarely used.

Response: The geometric mean costs for performing the procedures described by CPT codes 62263 and 62264 were not the same for CY 2013: CPT code 62263 had a CY 2013 final rule geometric mean cost of approximately \$1,406, and CPT code 62264 had a CY 2013 final rule geometric mean cost of approximately \$876. The geometric mean costs of the procedures described by CPT codes 62263 and 62264 continued to differ by a similar magnitude for CY 2014: the CY 2014 proposed rule geometric mean cost of the procedure described by CPT code 62263 was approximately \$1,492, while the CY 2014 proposed rule geometric mean cost of CPT code 62264 was approximately \$874. However, for CY 2014, we determined that continuing to assign CPT code 62264 to APC 0203 would create a 2 times rule violation because the geometric mean cost of the APC increased from approximately \$881 in CY 2013 to approximately \$1,550 for CY 2014. To correct the 2 times rule violation, we proposed to reassign CPT code 62264 from APC 0203 to APC 0207, which has a final rule geometric mean cost of approximately \$672.

Based on updated claims data, the resources required to furnish the procedure described by CPT code 62264 (which has a final rule geometric mean cost of approximately \$883) continue to be more similar to the resources required for services assigned to APC 0207 (which has a final rule geometric mean cost of approximately \$672) than for services assigned to APC 0203 (which has a final rule geometric mean cost of approximately \$1,550). Therefore, after consideration of the public comment we received, we are finalizing our proposal to reassign CPT

code 62264 from APC 0203 to APC 0207 for CY 2014.

e. Cerebrospinal Shunt Reprogramming (APC 0692)

For CY 2014, we proposed to reassign CPT code 62252 (Reprogramming of programmable cerebrospinal shunt), which had a proposed rule geometric mean cost of approximately \$155, from APC 0691 (Level III Electronic Analysis of Devices), which had a proposed payment rate of approximately \$274, to APC 0692 (Level II Electronic Analysis of Devices), which had a proposed payment rate of approximately \$139. (These proposed rates reflect the corrected proposed rates included in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

Comment: One commenter asked CMS to explain the rationale for the proposed reassignment of CPT code 62252 from APC 0691 to APC 0692.

Response: We proposed to reassign CPT code 62252 from APC 0691 to APC 0692 because it would violate the 2 times rule if we continued to assign it to APC 0691.

After consideration of the public comment we received, we are finalizing our proposal to reassign CPT code 62252 from APC 0691 to APC 0692, which has a final rule geometric mean cost of approximately \$116. In addition, based on our review of the configuration of APCs 0691 and 0692, we determined that we need to improve the clinical and resource homogeneity of these two APCs. In order to avoid several 2 times rule violations in these APCs, we are reassigning CPT code 95971 (Simple neurostimulator analysis), which has a final rule geometric mean cost of approximately \$113 and CPT code 95972 (Complex neurostimulator analysis), which has a final rule geometric mean cost of approximately \$145 from the higher Level III APC 0691 (which has a final rule geometric mean cost of approximately \$277) to the lower Level II APC 0692 (which has a final rule geometric mean cost of approximately \$116). In addition, to avoid 2 times rule violations we are reassigning CPT code 62367 (Analysis of spinal fusion pump), which has a final rule geometric mean cost of approximately \$202, CPT code 62368 (Analysis with reprogramming), which has a final rule geometric mean cost of approximately \$216, CPT code 62369 (Analysis with reprogramming and fill), which has a final rule geometric mean cost of approximately \$339, and CPT code 62370 (Analysis with reprogramming and fill requiring the skill of a physician or other qualified

health care professional), which has a final rule geometric mean cost of approximately \$286, from the lower Level II APC 0692 to the higher Level III APC 0691, which has a final rule geometric mean cost of approximately \$277.

6. Ocular Services

a. Retinal Prosthesis (APC 0672)

For CY 2014, we proposed to continue to assign the category III CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy), to APC 0672 (Level III Posterior Segment Eye Procedures), based on the similarity of the procedure to the other services currently assigned to APC 0672. The device implanted during this procedure (HCPCS code C1841 (Retinal prosthesis)) includes all internal and external components, and was granted pass-through status beginning October 1, 2013.

Comment: One commenter requested that CMS reassign CPT code 0100T to a new APC with a payment rate of approximately \$6,500, which the commenter estimated by combining the costs of procedures that the commenter believed to be components of CPT code 0100T. The commenter also asserted that the procedure described by CPT code 0100T is more complex than the other procedures assigned to APC 0672.

Response: There are no claims data available for the procedure described by CPT code 0100T at this time. We estimate that more than 95 percent of the overall cost of the procedure is associated with the device, which is paid separately as a pass-through payment device. Because the device used in the procedure described by CPT code 0100T is in pass-through payment status, we do not believe that it is appropriate to create and assign CPT code 0100T to a new APC at this time. We also believe that the procedure described by CPT code 0100T is similar to the other procedures assigned to APC 0672. While we acknowledge that the procedure described by CPT code 0100T is complex, the other services assigned to APC 0672, for example the procedure described by CPT code 67113 (Repair of complex retinal detachment), are also complex and involve many different techniques and require extensive resources.

b. Tear Film (APC 0230)

For CY 2014, we proposed to assign the new Category III CPT code 0330T (Tear film imaging, unilateral or bilateral, with interpretation and

report), effective July 1, 2013, to APC 0230 (Level I Eye Tests and Treatments) based on the similarity of the service to the other services currently assigned to APC 0230.

Comment: One commenter requested that CMS reassign CPT code 0330T to APC 0698 (Level II Eye Tests and Treatments). The commenter believed that the clinical and resource similarities of the service described by CPT code 0330T to the services currently assigned to APC 0698 warrant reassignment.

Response: We believe that the service described by CPT code 0330T is most similar to the other imaging services assigned to APC 0230, such as corneal topography or eye photography. We currently have no claims data for this service for ratesetting purposes because CPT code 0330T became effective July 1, 2013, and is considered new. Once we have claims data for CPT code 0330T, we will reevaluate the APC assignment of CPT code 0330T in future years through our standard review process.

After consideration of the public comment we received, we are finalizing our CY 2014 proposal to assign CPT code 0330T to APC 0230.

7. Imaging

a. Myocardial Sympathetic Innervation Imaging (APC 0398)

Effective July 1, 2013, the AMA's CPT Editorial Panel created CPT code 0331T (Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment) and CPT code 0332T (Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment; with tomographic SPECT). For CY 2014, we proposed to assign CPT codes 0331T and 0332T to APC 0398 (Level I Cardiac Imaging), which had a proposed payment rate of approximately \$397. (The proposed payment rate reflects the corrected proposed rate in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

Comment: Several commenters disagreed with the proposed assignment of CPT codes 0331T and 0332T to APC 0398. The commenters stated that the proposed payment rate for APC 0398 would not cover the cost of performing the new procedures. Some of these commenters emphasized that the proposed payment rate for APC 0398 is substantially lower than the cost of the radiopharmaceutical alone used in these procedures. The commenters believed that the assignment of CPT codes 0331T and 0332T to APC 0398 would impede Medicare beneficiaries' access to these

new services. Some commenters suggested that CPT codes 0331T and 0332T be assigned to a New Technology APC with a payment rate that would better reflect the estimated costs for these procedures. Other commenters indicated that these new procedures are more comparable to the procedures assigned to APC 0377 (Level II Cardiac Imaging) in terms of clinical and resource similarities.

Response: We do not agree with the commenters that CPT codes 0331T and 0332T should be assigned to a New Technology APC for CY 2014 because we believe that these procedures are clinically similar to the other services assigned to either APC 0398 (Level I Cardiac Imaging) or APC 0377 (Level II Cardiac Imaging). However, because the estimated cost of the diagnostic radiopharmaceutical that is used in performing the procedures described by CPT codes 0331T and 0332T (HCPCS code A9582) is approximately \$1,320 based on the drug cost statistics file for the proposed rule, we agree with the commenters that it is more appropriate in terms of resource similarity to assign CPT codes 0331T and 0332T to APC 0377 and, therefore, are modifying the codes' APC assignment for CY 2014.

After consideration of the public comments we received, for CY 2014, we are assigning CPT codes 0331T and 0332T to APC 0377, which has a final geometric mean cost of approximately \$1,158.

b. Neurologic Imaging (APCs 0402, 0403, 0406 and 0414)

The pass-through payment status of HCPCS code A9584 (Iodine I-123 ioflupane, diagnostic, per study dose up to 5 millicuries) expires on December 31, 2013. For CY 2014, payment for this radiopharmaceutical, typically referred to as DaTscan, will be packaged with payment for CPT code 78607 (Brain imaging; tomographic (SPECT)), which had a CY 2014 proposed rule geometric cost of approximately \$1,179). The procedure described by CPT code 78607 is used to assist in the evaluation of adult patients with suspected Parkinson's disease. For CY 2014, we proposed to continue to assign CPT code 78607 to APC 0402 (Level II Nervous System Imaging), which had a proposed payment rate of approximately \$1,009. (The proposed payment rate reflects the corrected proposed rate in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.) We proposed to maintain the assignment of CPT code 78607 to APC 0402 for CY 2014, providing an exception to a 2 times rule violation involving the cost of CPT code 78645 as

compared to the cost of CPT code 78607 (78 FR 43592).

For CY 2014, we proposed to reassign CPT code 78647 (Cerebrospinal fluid flow, imaging (not including introduction of material); tomographic (SPECT)), which had a proposed rule geometric mean cost of approximately \$467 from APC 0402 (Level II Nervous System Imaging), which had a proposed rule geometric mean cost of approximately \$1,009 to APC 0403 (Level I Nervous System Imaging), which had a proposed rule geometric mean cost of approximately \$179.

For CY 2014, we proposed to reassign CPT code 78605 (Brain imaging, 4 or more static views), which had a CY 2014 proposed rule geometric mean cost of approximately \$835 from APC 0403 (Level I Nervous System Imaging), which has a CY 2013 payment rate of approximately \$264, to APC 0402 (Level II Nervous System Imaging) which had a CY 2014 proposed payment rate of approximately \$1,009.

For CY 2014, we also proposed to reassign CPT code 78801 (Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); multiple areas) from APC 0414 (Level II Tumor/Infection Imaging), which has a CY 2013 payment rate of approximately \$503, to APC 0406 (Level I Tumor/Infection Imaging), which had a proposed rule payment rate of approximately \$383. (The proposed payment rates cited above reflect the corrected proposed rates in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

Comment: Several commenters objected to the proposed reduction in the CY 2014 payment rate for the DaTscan imaging procedure (including the packaged radiopharmaceutical) as a result of packaging of the radiopharmaceutical into CPT code 78607 and retention of the procedure in APC 0402, following expiration of the pass-through status of the procedure. The commenters objected to the reduction from the pass-through payment amount of approximately \$1,975 for HCPCS code A9584 in addition to the payment of approximately \$458 for CPT code 78607 for CY 2013. The commenters believed that the payment rate reduction for CPT code 78607 (into which the radiopharmaceutical will be packaged for CY 2014) would hinder beneficiary access to care for this service. Several commenters believed that CPT code 78607 would be more appropriately assigned to APC 0308 (Positron Emission Tomography (PET) Imaging) rather than APC 0402 because CPT code

78607 is a new imaging service that uses more resources and is not clinically similar to the cisternography and shunt evaluation scans assigned to APC 0402. (We note that the CY 2014 final rule geometric mean cost of APC 0308 is approximately \$1,315.)

Response: We agree with the commenters that it would be appropriate to reassign CPT code 78607 to an APC that contains services more similar in terms of costs to CPT code 78607 and to correct the 2 times rule violation in APC 0402. However, we do not agree with the commenters that the procedure described by CPT code 78607 is clinically similar to PET scans. Therefore, we are not assigning CPT code 78607 to APC 0308. Based on clinical homogeneity and similar resource use, we are reassigning CPT code 78607 from APC 0402 to APC 0408 (Level III Tumor/Infection Imaging) for CY 2014, which has a final rule geometric mean cost of approximately \$1,161.

Comment: One commenter asked CMS to explain its rationale for proposing to reassign CPT code 78647 from APC 0402 to APC 0403. The commenter believed that this reassignment would decrease the payment rate for the procedure described by CPT code 78647.

Response: The final rule geometric mean cost of APC 0402 is approximately \$535, and the final rule geometric mean cost of APC 0403 is approximately \$163. The final rule geometric mean cost of CPT code 78647 is approximately \$434, which is much closer to the final rule geometric mean cost of APC 0402 than the final rule geometric mean cost of APC 0403. While there is no violation of the 2 times rule in APC 0403 due to the claims volume of the services in this APC, the geometric mean cost of CPT code 78647 is more than two times the geometric mean cost of the other services in APC 0403. Because the final rule geometric mean cost of CPT code 78647 is more similar to the geometric mean costs of the services assigned to APC 0402, we are not finalizing our proposal to reassign CPT code 78647 from APC 0402 to APC 0403. We will continue to maintain the code's current assignment to APC 0402 for CY 2014.

Comment: One commenter asked CMS to explain its rationale for proposing to reassign CPT code 78605 from APC 0403 to APC 0402 for CY 2014.

Response: Based on updated CY 2012 claims data, the final rule geometric mean cost of CPT code 78605 (approximately \$781) is much closer to the final rule geometric mean cost of APC 0402 (approximately \$535) than to

the final rule geometric mean cost of APC 0403 (approximately \$163). Therefore, based on the similarity of the costs of the services assigned to APCs 0402 and 0403, we are finalizing our proposal to reassign CPT code 78605 from APC 0403 to APC 0402.

Comment: One commenter asked CMS to explain its rationale for proposing to reassign CPT code 78801 from APC 0414 to APC 0406 for CY 2014.

Response: We proposed the reassignment of CPT code 78801 from APC 0414 to APC 0406 for CY 2014 because we had updated claims data for CY 2014 ratesetting, which indicated that the continued assignment of CPT code 78801 to APC 0414 would violate the 2 times rule. The final rule geometric mean cost of CPT code 78801 (approximately \$362) is much closer to the final rule geometric mean cost of APC 0406 (approximately \$384) than the final rule geometric mean cost of APC 0414 (approximately \$659), and is clinically similar to the other tumor imaging services assigned to APC 0406. Therefore, we are finalizing our proposal to reassign CPT code 78801 from APC 0414 to APC 0406 for CY 2014.

8. Radiology Oncology

a. Intraoperative Radiation Therapy (IORT) Related Services (APCs 0028 and 0065)

HCPCS code C9726 (Placement and removal (if performed) of applicator into breast for radiation therapy) was created, effective January 1, 2006, to describe the procedure of placing and removing (if performed) an applicator into the breast for radiation therapy. We became aware of the procedure via a New Technology APC application, and upon approval of the application, we created HCPCS code C9726 because there were no HCPCS codes that described this procedure. For CY 2013, HCPCS code C9726 is assigned to APC 0028, which has a payment rate of \$1,862.77. Based on our CY 2014 proposed rule claims data, HCPCS code C9726 had a proposed geometric mean cost of approximately \$2,165 based upon 8 single claims, and APC 0028 had a proposed geometric mean cost of approximately \$2,047.

The AMA's CPT Editorial Panel created two new Category I CPT codes for intraoperative radiation therapy (IORT) treatment delivery, effective January 1, 2012: CPT codes 77424 (Intraoperative radiation treatment delivery, x-ray, single treatment session) and 77425 (Intraoperative radiation treatment delivery, electrons, single

treatment session). For CY 2013, we finalized a policy to assign these CPT codes to APC 0065 (Level I Stereotactic Radiosurgery, MRgFUS, and MEG), with a CY 2013 payment rate of \$978.25 because we believed these IORT service codes were similar to other services assigned to APC 0065 in terms of clinical characteristics, and the range of estimated costs for IORT services (77 FR 68345). For CY 2014, we proposed to maintain the APC assignment for CPT codes 77424 and 77425 to APC 0065, which we proposed to rename “APC 0065 (IORT, MRgFUS, and MEG)”, with a proposed payment rate of approximately \$1,715. (The proposed payment rate reflects the corrected proposed rate in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

In the CY 2014 OPPS/ASC proposed rule, we noted that both CPT codes 77424 and 77425 describe the placement and removal (if performed) of an applicator into the breast for radiation therapy, as well as the delivery of radiation therapy when performed intraoperatively, and that it would no longer be required to report the placement and removal of the applicator via HCPCS code C9726 on a claim. Therefore, we proposed to delete HCPCS code C9726, effective January 1, 2014 (78 FR 43593). Under this proposal, hospitals would report the costs of the service to place and remove (if performed) an applicator into the breast for radiation therapy, as well as the delivery of radiation therapy when performed intraoperatively, with CPT codes 77424 and 77425, which we proposed to continue to assign to APC 0065.

Comment: Many commenters disagreed with CMS’ assertion that IORT services include the placement and removal (if performed) of an applicator into the breast for radiation therapy, as well as the delivery of radiation therapy when performed intraoperatively, and with the proposal to delete HCPCS code C9726 because it would no longer be required to report that service on the claim. Several commenters indicated that the service described by HCPCS code C9726 is performed by the surgeon before and after IORT delivery, and represents the cost of the applicator and hospital costs related to the surgeon’s placement of the applicator, while CPT codes 77424 and 77425 represent radiation therapy treatment delivery performed by the radiation oncologist and medical physicist and are limited to the technical costs of IORT delivery. Many commenters stated that the AMA’s CPT Editorial Panel did not include

placement and removal of the applicator in the descriptions of CPT codes 77424 and 77425. Some commenters also indicated that placement and removal of applicators for radiation therapy for various other parts of the body are separately reported on claims and paid under the OPPS. Some commenters expressed concern with the quality of the data used for ratesetting, such as the small number of single frequency claims available reporting CPT codes 77424 and 77425. One commenter suggested that CMS propose a comprehensive APC payment methodology for IORT for CY 2015 to include CPT codes 77424 and 77424 because the services are performed in a single operative session.

Response: Our proposal to delete HCPCS code C9726 was based on the premise that placement of an applicator is a necessary part of the delivery of IORT, and that the placement of an applicator was included in the procedures described by CPT codes 77424 and 77425. There are currently no service codes other than HCPCS code C9726 that separately describe placement of a rigid applicator for IORT breast radiation delivery, as there are for some other radiation delivery services. The commenters argued that the service that has been reported along with HCPCS code C9726 by providers on claims is surgical, not a radiation oncology service, and that the service is not included in the descriptions of CPT codes 77424 and 77425. Therefore, after considering all of the public comments on IORT, we are not finalizing our proposal to delete HCPCS code C9726 for CY 2014. However, to make the coding consistent with other intraoperative procedures involving catheters or applicators used for radiation therapy treatment of the breast, for CY 2014, we are designating HCPCS code C9726 as an add-on code to the primary procedure that involved the intraoperative placement of the applicator into the breast. We are revising the code descriptor for HCPCS code C9726 to read: “Placement and removal (if performed) of applicator into breast for intraoperative radiation therapy, add-on to primary breast procedure.” Payment for HCPCS code C9726 is being packaged into the payment for the primary procedure, consistent with our policy to package add-on codes for CY 2014.

We agree with the commenters that there are a small number of single frequency claims for CPT codes 77424 and 77425, and we believe that is the case for HCPCS code C9726 as well. We appreciate the commenters’ suggestions for alternative payment methodologies

for IORT and may consider such alternatives in the future.

After consideration of the public comments we received, we are not finalizing our proposal to delete HCPCS code C9726 for CY 2014. We are designating HCPCS code C9726 as an add-on code for which payment is being packaged into the payment for CPT codes 77424 and 77425, the primary procedures that involve the intraoperative placement of the applicator into the breast, consistent with our policy to package add-on codes for CY 2014. We are revising the code descriptor for HCPCS code C9726 to read: “Placement and removal (if performed) of applicator into breast for intraoperative radiation therapy, add-on to primary breast procedure.” We are continuing to assign CPT codes 77424 and 77425 to APC 0065 for CY 2014, which has a final geometric mean cost of \$1,253. We are also changing the descriptor of APC 0065 to “IORT, MRgFUS, and MEG”.

b. Proton Beam Therapy (APCs 0664 and 0667)

APC 0664 (Level I Proton Beam Radiation Therapy) includes two procedures: CPT code 77520 (Proton treatment delivery; simple, without compensation) and CPT code 77522 (Proton treatment delivery; simple, with compensation). APC 0667 (Level II Proton Beam Radiation Therapy) also includes two procedures: CPT code 77523 (Proton treatment delivery, intermediate) and CPT code 77525 (Proton treatment delivery, complex). The payment rates for proton beam radiation therapy services are set annually based on claims data according to the standard OPPS ratesetting methodology.

Based on the claims data used in developing the CY 2014 proposed rule, we determined a violation of the 2 times rule in APC 0664. As we discuss in section III.B. of this final rule with comment period, a 2 times rule violation occurs when the cost of the highest cost significant item or service within an APC group is more than 2 times greater than the cost of the lowest cost significant item or service within that same group. In making this determination, we consider only 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 cost to be significant. If neither of these claims thresholds is met, there is not a 2 times rule violation even if the highest cost item or service is more than 2 times greater than the cost of the lowest cost

item or service in the APC. In prior years, even though the cost of CPT code 77522 was more than 2 times the cost of CPT code 77520, there was no 2 times rule violation within APC 0664 because the claims volume for CPT code 77520 was not significant (72 FR 66719; 75 FR 71901; and 77 FR 68341). However, for CY 2014, the volume of claims in the proposed rule claims data for CPT code 77520 increased—the number of single claims was greater than 99 and contributed at least 2 percent of the single claims used to establish the cost of APC 0664—resulting in a 2 times rule violation within APC 0664.

To resolve the 2 times rule violation, in the CY 2014 OPPS/ASC proposed rule (78 FR 43593), we proposed to reassign CPT codes 77520 and 77522 from APC 0664 to APC 0667, and to revise the title of APC 0667 to “Proton Beam Radiation Therapy,” which would now include all proton beam radiation therapy services. We also proposed to delete APC 0664. We invited public comments on this proposal.

Comment: Several commenters stated that they duplicated CMS’ ratesetting calculations for proton beam therapy services and determined that the threshold for claims volume that would constitute a 2 times rule violation in APC 0664 was not met. The commenters asserted that because there was no 2 times rule violation within APC 0664 according to their calculations, CMS should not finalize its proposal to delete APC 0664 and reassign CPT codes 77520 and 77522 to APC 0667 in order to avoid a 2 times rule violation. The commenters also believed that the simple proton beam treatment delivery services assigned to APC 0664 are not clinically similar enough to warrant their combination with the intermediate and complex proton beam treatment delivery services currently assigned to APC 0667.

Response: Using the additional final rule claims data in accordance with our standard OPPS ratesetting methodology, we determined that the number of claims for CPT code 77520 is not significant and, therefore, a 2 times rule violation within APC 0664 does not exist for CY 2014.

After consideration of the public comments we received, because there is now no 2 times rule violation within APC 0664, we are not finalizing our proposal to delete APC 0664 and reassign CPT codes 77520 and 77522 to APC 0667. We are continuing the current APC configuration for CY 2014. As we do annually for all APCs, we will review the appropriateness of the APC assignments for proton beam therapy

services for the CY 2015 rulemaking cycle.

c. Stereotactic Radiosurgery (SRS) Services (APCs 0066 and 0067)

Since 2001, we have distinguished the various methods of delivery of stereotactic radiosurgery (SRS) with HCPCS G-codes. SRS includes two different radiation source types, specifically, Cobalt-60 and linear accelerator (linac). Among the linac-based SRS procedures, the current HCPCS G-codes distinguish between procedures that use robotic and non-robotic linac devices (66 FR 59865). In CY 2007, new CPT codes for SRS were established, and at that time, we recognized one of the three SRS CPT codes for separate payment under the OPPS. We did not replace all of the HCPCS G-codes for SRS with all of the new CPT codes in CY 2007 because we believed at that time that the distinctions reflected in the HCPCS G-codes should be maintained for APC assignment purposes. Specifically, in CY 2007 we replaced HCPCS code G0243 (Multi-source photon stereotactic radiosurgery, delivery including collimator changes and custom plugging, complete course of treatment, all lesions) with CPT code 77371 because this CPT code corresponded directly to procedures described by HCPCS code G0243. We refer readers to the CY 2007 OPPS final rule (71 FR 68023 through 68026) for a detailed discussion of the history of the SRS codes.

Since CY 2007, HCPCS codes G0173, G0251, G0339, G0340, and CPT code 77371 have been the codes used under the OPPS to describe SRS treatment delivery procedures. However, SRS techniques and equipment have evolved and expanded over time. In light of these developments and our understanding of current SRS technology and clinical practice, we have reexamined the HCPCS G-codes and CPT codes for SRS with the intent of identifying the codes that would best capture the significant differences between the various procedures while eliminating unnecessary complexity, redundancy, and outdated distinctions that no longer represent meaningful distinctions for purposes of OPPS payment. Based on our review of the current SRS technology, we understand that most current linac-based SRS technology incorporates some type of robotic feature. Therefore, we believe that it is no longer necessary to continue to distinguish robotic versus non-robotic linac-based SRS through the HCPCS G-codes.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43593 through 43594), we proposed to replace the existing four HCPCS codes: G0173, G0251, G0339, and G0340 with the SRS CPT codes 77372 and 77373. We stated that we believe that utilizing all of the CPT codes for SRS (CPT codes 77371, 77372, and 77373) would more accurately capture the distinctions between the various SRS procedures that are currently used; namely, (1) Cobalt-60 versus linac and (2) single session cranial treatment versus fractionated treatments. Table 16 of the proposed rule showed the complete list of HCPCS G-codes and CPT codes for SRS, along with their long descriptors. The table also showed the proposed CPT codes and their associated status indicators and APC assignments for the current HCPCS G-codes for SRS that we proposed to replace. We proposed to assign only CPT code 77373 to APC 0066, which we proposed to rename “Level I Stereotactic Radiosurgery.” We proposed to reassign CPT code 77371 and assign CPT code 77372, the two single session cranial treatment codes, to APC 0067, which we proposed to rename “Level II Stereotactic Radiosurgery.” We believe that the high degree of clinical similarity of CPT codes 77371 and 77372 supports the proposed grouping of these procedures together in the proposed renamed APC 0067. The CY 2014 proposed APC payment rates for the CPT codes for SRS were listed in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site). Further, we proposed to finalize their status indicators and their APC assignments and payment rates in this CY 2014 OPPS/ASC final rule with comment period.

We note that we published a corrected OPPS Addendum B payment file that was posted on the CMS Web site on September 6, 2013, after it was brought to our attention that the initial proposed payment rates that were published on July 19, 2013, for the SRS codes did not include the claims data for the SRS HCPCS G-codes. Specifically, our initial proposed payment rate of approximately \$2,481 for APC 0066 only included claims data for CPT code 77373 and did not include claims data for HCPCS codes G0251, G0339, and G0340. In addition, our initial proposed payment rate of approximately \$8,576 for APC 0067 only included claims data for CPT codes 77372 and 77371 and did not include claims data for HCPCS code G0173. Consequently, we corrected this error and posted the corrected payment rates for APCs 0066 and 0067 on

September 6, 2013. Because of this correction, we extended the public comment period for the CY 2014 SRS proposals to September 16, 2013 (78 FR 54842). Table 27 below shows the list of HCPCS G-codes and CPT codes for SRS, along with their long descriptors, and the corrected CY 2014 proposed APC payment rates.

In addition, although the SRS HCPCS G-codes will no longer be separately payable under the OPPS, the HCPCS codes will remain active under the MPFS for CY 2014. Consequently, we proposed to change the OPPS status indicator for HCPCS G-codes for SRS from status indicator “S” to “B” (Alternative code may be available under the OPPS) for CY 2014.

Comment: Most commenters agreed with CMS’ proposal and urged CMS to finalize the coding, APC assignment, and payment levels for the SRS CPT codes. The commenters agreed that utilizing the CPT codes would standardize the reporting of SRS services across all payers, which the hospital industry has favored since the SRS treatment delivery CPT codes were established in CY 2007. One commenter noted that the use of the CPT codes would eliminate confusion among providers regarding how to report the SRS treatment delivery services.

Response: We appreciate the commenters’ support for our proposal. We believe that adopting the SRS treatment delivery CPT codes and restructuring the SRS APCs appropriately distinguishes payment for single session cranial SRS treatment from fractionated SRS treatment.

Comment: Several commenters that utilize both the linear accelerator-based SRS technology and Cobalt-60 SRS technology supported CMS’ proposal and stated that the change would equalize payments for both technologies for single session cranial SRS. One commenter stated that the proposal is appropriate because there is no clinical data that supports the need for differential payment for these technologies. This commenter further stated that current medical literature cites no difference in clinical effectiveness for one system over

another, and stated that in terms of outcomes, the linac-based system is clinically comparable to a Cobalt-60 system for single session cranial SRS. In addition, some commenters stated that the proposal is consistent with the provisions of section 634 of the American Taxpayer Relief Act (ATRA) of 2012.

Response: We appreciate the commenters’ support for our proposal. As specified in the April 2013 OPPS Update CR (Transmittal 2664, CR 8228) dated March 1, 2013, section 634 of the ATRA requires that, effective April 1, 2013, if the payment amount for Cobalt-60 based SRS, as described by CPT code 77371, exceeds the payment amount for linear accelerator-based SRS, as described by HCPCS code G0173 (or a successor code), the payment for CPT code 77371 must be reduced to the payment amount for HCPCS code G0173. The requirement does not apply to rural hospitals, sole community hospitals, or rural referral centers. In this final rule with comment period, for CY 2014, we are reassigning CPT code 77371 and assigning CPT code 77372 (the successor codes for HCPCS code G0173) to APC 0067. Therefore, CPT codes 77371 and 77372 will have the same payment amount. We agree with the commenters that this APC assignment satisfies the requirements of section 634 of the ATRA.

Comment: Some commenters expressed concern regarding the proposal for SRS and suggested that CMS delay implementation of the proposal. The commenters suggested that, to pay appropriately for SRS services, CMS consider for CY 2015 the development of a comprehensive APC for the procedures assigned to APC 0067 (which includes CPT codes 77371 and 77372), similar to the comprehensive APC proposal for high-cost, device-dependent services. The commenters stated that single session cranial SRS procedures performed with either Cobalt 60-based SRS or linac-based SRS are device-dependent procedures and cannot be performed without use of the costly technology. The commenter further stated that having one comprehensive APC for single session

cranial SRS is appropriate and consistent with the requirements of section 634 of the ATRA. The commenters encouraged CMS to consider the comprehensive APC payment methodology to appropriately pay for services, regardless of the specific equipment used to deliver SRS treatment.

Response: We do not agree with the commenters’ suggestion to delay implementation of the proposal because we believe that adopting the CPT codes and restructuring the SRS APCs improve the clinical and resource homogeneity for SRS while satisfying the requirements of section 634 of the ATRA.

We appreciate the commenters’ suggestion to create a comprehensive APC payment methodology for SRS services. However, because such a change would require public notice and opportunity to comment, we will consider and evaluate the appropriateness of such a payment methodology in the future.

Comment: Some commenters who were not supportive of the proposals relating to SRS stated that the corrected proposed APC payment rates for the SRS codes were too low, and requested that CMS utilize the initial proposed APC payment rates for APCs 0066 and 0067.

Response: As explained above, we revised the initial proposed payment rates for APCs 0066 and 0067 after it was brought to our attention that our ratesetting for these APCs did not include claims data for the appropriate HCPCS codes, including the various HCPCS G-codes that were proposed for deletion. We should have included the CY 2012 SRS HCPCS G-code claims data in our proposed CY 2014 ratesetting; otherwise, some of the services would be significantly underrepresented in the APC payment calculations. We believe that the corrected proposed APC payment rates that include claims data for the SRS HCPCS G-codes accurately reflect all of the SRS services that are used to configure APCs 0066 and 0067.

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**TABLE 27.—PROPOSED (ORIGINAL AND CORRECTED) CY 2014 APC
ASSIGNMENTS FOR THE STEREOTACTIC RADIOSURGERY (SRS)
CPT CODES**

CY 2013 CPT Code	Long descriptor	CY 2013 APC	CY 2013 Payment	CY 2014 CPT Code	Long descriptor	Original Proposed OPPS CY 2014 APC	Corrected Proposed OPPS CY 2014 Payment[#]
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based	0127	\$3,300.64* ----- \$7,910.51*	77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based	0067	\$5,615.41
G0173	Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session	0067	\$3,300.64	77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based	0067	\$5,615.41
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	0065	\$978.25	77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions	0066	\$2,047.86
G0339**	Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment.	0067	\$3,300.64				
G0340	Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second	0066	\$2,354.79				

	through fifth sessions, maximum five sessions per course of treatment.						
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*Under section 634 of the ATRA of 2012, effective April 1, 2013, payment to rural hospitals, rural referral centers, and sole community hospitals for CPT code 77371 is \$7,910.51. Payment to most hospital outpatient facilities is \$3,300.64.

**Although not reflected in the above table (in order to avoid confusion), single session cranial cases currently billed with HCPCS code G0339 would be billed with CPT code 77372 beginning in CY 2014. Any other reporting of HCPCS code G0339 (other than single session cranial cases) would be reported beginning in CY 2014 with CPT code 77373.

#These payment rates reflect the corrected payment rates that were published on the CMS Web site on September 6, 2013.

Comment: Some commenters expressed concern with the proposed packaging of payments for certain CPT codes describing the Cobalt-60 SRS procedure. In particular, the commenters indicated that the proposal to package ancillary services, including certain SRS radiation planning codes, penalizes hospitals for providing the more efficient form of SRS, namely, the Cobalt-60 technology, which is provided as a single-day service. Some of the commenters stated that under CMS' packaging proposal, hospitals would experience a decrease in payment for

performing the Cobalt-60 procedure because the procedures that they perform on the same day would no longer be paid separately. In particular, the commenters were concerned that the proposed policy for packaging of payment for CPT codes 77290, 77295, 77300, 77334, and 77370, if finalized, would result in higher payments for patients treated with linac-based SRS technologies because the payment for planning services would not be packaged—that is, planning services occur on a different day than the day of delivery of linac-based SRS services.

Response: As discussed in section II.A.3. of this final rule with comment period, we are not finalizing our proposal to package payment of ancillary tests. The SRS planning services, specifically those described by CPT codes 77290, 77295, 77300, 77334, and 77370, for which payments were initially proposed to be packaged under our packaging proposal for ancillary services, will continue to be paid separately for CY 2014. The final CY 2014 long descriptors, status indicators, and APC assignments for these CPT codes are listed in Table 28 below.

**TABLE 28.—FINAL CY 2014 STATUS INDICATORS (SIs) AND APC ASSIGNMENTS FOR
CPT CODES 77290, 77295, 77300, 77334, and 77370**

CY 2014 CPT Code	Long Descriptor	Proposed OPPS CY 2014 SI	Proposed OPPS CY 2014 APC	Final OPPS CY 2014 SI	Final OPPS CY 2014 APC
77290	Therapeutic radiology simulation-aided field setting; complex	Q1	0310	X	0305
77295	Therapeutic radiology simulation-aided field setting; 3-dimensional	Q1	0316	X	0310
77300	Basic radiation dosimetry calculation, central axis depth dose calculation, tdf, nsd, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician	Q1	0305	X	0304
77334	Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)	Q1	0303	X	0303
77370	Special medical radiation physics consultation	Q1	0304	X	0304

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Comment: Some commenters questioned the use of claims data for certain HCPCS G-codes for determining the corrected payment rates for APCs 0066 and 0067. The commenters stated that the initial proposed payment rates were correct. In addition, some commenters did not believe that claims data for HCPCS code G0173 should have been used to determine the payment rate for APC 0067 because this code was more than likely reported for “other than brain” tumors. In addition, the commenters stated that the corrected payment rates result in a 2 times rule violation in both APC 0066 and APC 0067, and, therefore, CMS should not finalize its proposal.

Response: HCPCS code G0173 describes a single session linac-based

SRS procedure. We believe that this code is appropriately crosswalked to CPT code 77372, and adequately represents single session cranial SRS cases. Although a 2 times rule violation did occur in APC 0067, as we describe in section II.A.B.3. of this final rule with comment period, we may make exceptions to the 2 times rule in certain cases. In the case of the SRS treatment delivery services, we believe that adopting the CPT codes and restructuring the SRS APCs improves clinical and resource homogeneity for both types of cranial single session SRS procedures. Furthermore, assigning CPT codes 77371 and 77372 to the same APC also satisfies the requirements of section 634 of the ATRA. If CPT codes 77371 and 77372 were assigned to different

APCs, the payment rate for CPT code 77371 would have to be reduced to equal the payment rate for CPT code 77372. As a majority of the commenters preferred, we believe that the assignment of CPT codes 77371 and 77372 to the same APC, with the blended payment rate as opposed to current CY 2013 payment reduction for CPT code 77371, is most appropriate.

Comment: One commenter recommended that CMS exclude the claims data associated with HCPCS code G0251 when determining the payment rate for APC 0066. The commenter 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. The commenter

recommended that CMS reassign HCPCS code G0251 to its own APC, which is similar to the CY 2013 APC assignment.

Response: Both HCPCS code G0251 and CPT code 77373 describe fractionated cranial SRS services that involve between 1 to 5 fractions of treatment. Based on the code descriptor, we believe that the service described by HCPCS code G0251 is appropriately crosswalked to CPT code 77373.

Comment: Some commenters stated that CMS only used approximately 20 percent of the claims data for CPT code 77371 to set the payment rate for APC 0067, and suggested that CMS use more of the claims data for Cobalt-60 SRS in the ratesetting process.

Response: For the CY 2014 update, we proposed to set the payment rate for APC 0067 based on claims data for HCPCS code G0173 and CPT codes 77371 and 77372. To determine the corrected proposed APC payment rates, we used approximately 41 percent (953 single claims out of 4,672 total claims) of the claims for CPT code 77371 to set the proposed payment rate for APC 0067. For this final rule with comment period, we used approximately 27 percent (425 single claims out of 4,672 total claims) of the claims for CPT code 77371 and approximately 72 percent of the claims for HCPCS code G0173 (1,136 single claims out of 1,771 total claims) to set the payment rate for APC 0067. Based on these codes, our analysis of the latest hospital outpatient claims data shows a final CY 2014 geometric mean cost of approximately \$3,604 for APC 0067.

Comment: Several commenters disagreed with the proposal to replace the HCPCS G-codes and use the CPT codes to describe the SRS treatment delivery services. The commenters stated that the SRS HCPCS G-codes are preferable to the CPT codes because they accurately describe the current standard SRS techniques. The commenters further stated that the CPT code descriptors reflect old technologies. In addition, some commenters requested that CMS retain the existing APC structure and use of HCPCS G-codes for SRS treatment delivery services because they believed the HCPCS G-codes more accurately reflect the costs and practice of full body, cranial, multi- and single-session robotic SRS. One commenter also suggested that CMS delete CPT codes 77371 and 77372 and replace them with one code that describes a single session intracranial SRS treatment procedure with no mention of the radiation source in the code descriptor.

Response: As stated above, we believe that it is no longer necessary to continue to distinguish robotic versus non-robotic linac-based SRS through HCPCS G-codes. We believe that the CPT codes for SRS treatment delivery, although more general than the HCPCS G-codes, accurately describe the most significant distinctions between the various SRS procedures: (1) Cobalt-60 versus linac radiation sources; and (2) single session cranial versus fractionated treatments. If the three-code SRS delivery CPT coding scheme that was created by the CPT Editorial Panel for CY 2007 is considered to be inadequate by SRS stakeholders, we believe that coding reform in this area would be best addressed through a dedicated CPT workgroup that would include all of the various physician specialties, such as neurosurgery and radiation oncology, and the other stakeholders involved in the delivery of this critical treatment modality. We also believe that it is best that we generally refrain from creating supplemental HCPCS G-codes or C-codes that describe the attributes of a particular device under the assumption of more precise coding but without the benefit of a broad perspective of stakeholder and physician specialist input. Otherwise, we risk unintentionally creating a competitive advantage for a particular technology through the establishment and use of codes that may not be based on the most complete understanding of the clinical science of SRS treatment delivery.

Comment: Several commenters requested that CMS clarify the report instructions for CPT codes 77372 and 77373 because there is confusion regarding how these services should be reported. The commenters stated that the lack of clarity promotes inefficiency and ensures misuse of CPT codes.

Response: We agree with the commenters that the transition from the HCPCS G-codes to the CPT codes could be confusing in certain cases. Therefore, we are providing the following coding guidance for CPT codes 77371, 77372, and 77373. CPT code 77371 is to be used only for single session cranial SRS cases performed with a Cobalt-60 device, and CPT code 77372 is to be used only for single session cranial SRS cases performed with a linac-based device. The term “cranial” means that the pathological lesion(s) that are the target of the radiation is located in the patient’s cranium or head. The term “single session” means that the entire intracranial lesion or lesions that comprise the patient’s diagnosis are treated in their entirety during a single treatment session on a single day. CPT code 77372 is never to be used for the

first fraction or any other fraction of a fractionated treatment. CPT code 77372 is to be used only for single session cranial linac-based SRS treatment. Fractionated SRS treatment is any SRS delivery service requiring more than a single session of SRS treatment for a cranial lesion, up to a total of no more than five fractions, and one to five sessions (but no more than five) for non-cranial lesions. CPT code 77373 is to be used for any fraction (including the first fraction) in any series of fractionated treatments, regardless of the anatomical location of the lesion or lesions being radiated. Fractionated cranial SRS treatment is any cranial SRS delivery service that exceeds one treatment session and fractionated non-cranial SRS treatment is any non-cranial SRS delivery service, regardless of the number of fractions but never more than five. Therefore, CPT code 77373 is the exclusive code (and the use of no other SRS treatment delivery code is permitted) for any and all fractionated SRS treatment services delivered anywhere in the body, including, but not limited to, the cranium or head. CPT code 77372 is not to be used for the first fraction of a fractionated cranial SRS treatment series and must only be used in cranial SRS delivery service when there is a single treatment session to treat the patient’s entire condition.

Although we believe that this coding guidance is clear to ensure reporting compliance, we will activate coding edits to prevent the use of more than one type of SRS treatment delivery CPT code per diagnosis per patient along with no more than five fractions for CPT code 77373.

After consideration of the public comments we received, we are finalizing our CY 2014 proposal without modification. Specifically, we are finalizing our proposal to reassign CPT code 77371 to APC 0067; replace HCPCS code G0173 with CPT code 77372 and assign the code to APC 0067; and replace HCPCS codes G0251, G0339, and G0340 with CPT code 77373 and assign this code to APC 0066. In addition, although the SRS HCPCS G-codes will no longer be separately payable under the OPPS, the codes will remain active under the MPFS for CY 2014. Consequently, we are finalizing our proposal to change the status indicator for the HCPCS G-codes for SRS services to OPPS status indicator “B” (Alternative code may be available under the OPPS) for CY 2014. Table 29 below shows the final CPT codes for the SRS treatment delivery services, their status indicators, APC assignments, and payment rates for CY 2014.

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TABLE 29.—FINAL CY 2014 APC ASSIGNMENTS FOR THE STEREOTACTIC RADIOSURGERY (SRS) CPT CODES

CY 2013 CPT Code	Long descriptor	CY 2013 APC	CY 2013 Payment	CY 2014 CPT Code	Long descriptor	Final OPPS CY 2014 APC	Final OPPS CY 2014 Payment
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based	0127	\$3,300.64* ----- \$7,910.51*	77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based	0067	\$3,591.65
G0173	Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session	0067	\$3,300.64	77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based		
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	0065	\$978.25	77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions	0066	\$1,921.30
G0339	Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment.	0067	\$3,300.64				
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.	0066	\$2,354.79				

*Under section 634 of the ATRA of 2012, effective April 1, 2013, payment to rural hospitals, rural referral centers, and sole community hospitals is \$7,910.51. Payment to most hospital outpatient facilities is \$3,300.64.

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9. Respiratory Services

a. Bronchial Thermoplasty (APC 0415)

Effective January 1, 2013, the CPT Editorial Panel created two new Category I CPT codes: CPT code 31660 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe) and CPT code 31661 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes). These new CPT codes replaced two Category III CPT codes: CPT code 0276T (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe) and CPT code 0277T (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes), which were deleted as of January 1, 2013. In the CY OPPS/ASC 2013 final rule with comment period (77 FR 68352), we finalized a policy that, beginning January 1, 2014, device category C1886 (Catheter, extravascular tissue ablation, any modality (insertable)) will no longer be eligible for pass-through payments, and its device costs will be packaged with the costs of the procedures with which the HCPCS code C1886 device is reported in the claims data. We reiterated that final policy in the CY 2014 OPPS/ASC proposed rule (78 FR 43595). The HCPCS code C1886 device is used in the procedures described by CPT codes 31660 and 31661. Therefore, the HCPCS code C1886 device costs will be packaged with the costs of the procedures described by CPT codes 31660 and 31661. Bronchial thermoplasty CPT codes 0276T and 0277T are assigned to APC 0415 (Level II Endoscopy Lower Airway) for CY 2013, and we proposed to assign bronchial thermoplasty CPT codes 31660 and 31661 to APC 0415 for CY 2014 with a proposed payment rate of approximately \$2,177.

Comment: One commenter stated that bronchial thermoplasty CPT codes 31660 and 31661 (as well as the CPT codes 0276T and 0277T) are inappropriately assigned to APC 0415. The commenter expressed concern that under the CMS proposal to expire device HCPCS code C1886 from pass-through payment status, the payment rate for APC 0415 will not reflect the costs associated with CPT codes 31660 and 31661, the procedure with which the HCPCS code C1886 device is used. The commenter stated that the two bronchial thermoplasty CPT codes

available in CY 2012, CPT code 0276T and CPT code 0277T, were subject to noncoverage policies for all Category III CPT codes by most Medicare Administrative Contractors (MACs), which resulted in few Medicare claims for CY 2012, the claims data year used for CY 2014 ratesetting. The commenter further stated that claims data show that some providers submitted claims reporting bronchial thermoplasty services with the HCPCS code C1886 device, while others did not, and that, as a result, the HCPCS code C1886 device charge data understate the cost of the C1886 device, which is reportedly \$2,500.

The commenter also expressed its concerns regarding the composition of APC 0415. The commenter believed that the payment rate for APC 0415 is driven by claims reporting one high-volume code, 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)) because the proposed payment rate of APC 0415 of approximately \$2,177 is close to the CPT code 31629 proposed rule geometric mean cost of approximately \$2,122. The commenter recommended two options to increase the payment rate for bronchial thermoplasty services as a means to adequately pay for the cost of the service. One option was to split APC 0415 into two levels, with many of the higher volume, lower cost procedure codes assigned to the Level II Endoscopy Lower Airway APC and the lower volume, higher cost procedure codes assigned to a new proposed Level III Endoscopy Lower Airway APC. The second option recommended by the commenter was to assign CPT codes 31660 and 31661 to APC 0423 (Level II Percutaneous Abdominal and Biliary Procedures), which the commenter believed has a number of clinical similarities, including one pulmonary procedure described by CPT code 32998 (Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, radiofrequency, unilateral).

Response: Regarding the commenter's concerns about the claims data for bronchial thermoplasty services, we believe that the cost of the HCPCS code C1886 device is reflected in the proposed payment rate for APC 0415, the APC to which we proposed to assign CPT codes 31660 and 31661. In a data analysis of the claims reporting CPT codes 0276T and 0277T, we found that, of the 37 single frequency claims

available for the data analysis for CPT code 0276T, 16 single claims reported the HCPCS code C1886 device with a geometric mean cost of approximately \$3,726, while 21 single claims did not report the HCPCS code C1886 device, yet the geometric mean cost was approximately \$3,825. Therefore, it appears that hospitals did not separately report the HCPCS code C1886 device for pass-through payment on claims reporting CPT code 0276T but instead reported the cost of the HCPCS code C1886 device as part of the cost of the procedure described by CPT code 0276T. Of the 18 claims reporting the procedure described by CPT code 0277T in our CY 2012 claims data, 10 claims were submitted with the HCPCS code C1886 device reported separately, with a geometric mean cost of approximately \$4,175, while 8 claims were submitted without the HCPCS code C1886 device reported separately, with a somewhat lower geometric mean cost of \$2,780. However, our final geometric mean costs (based on the final rule claims data) for CPT codes 0276T and 0277T, \$4,019 and \$3,700, respectively, are similar to the geometric mean cost of bronchial thermoplasty services with the HCPCS code C1886 device reported separately that we found in our analysis of CPT codes 0276T and 0277T described above. Therefore, we believe that the payment rate for APC 0415 appropriately reflects the costs of the HCPCS code C1886 device.

We do not agree that APC 0423 would be a more appropriate APC assignment for CPT codes 31660 and 31661. Although there is one pulmonary procedure in APC 0423, CPT code 32998, it is a procedure with a percutaneous approach, which is very different than a bronchoscopy approach. In addition, we do not agree with the commenter's suggestion that APC 0415 be split into two lower airway endoscopy APCs. The creation of a Level III lower airway endoscopy APC suggested by the commenter would result in relatively few single frequency claims available for ratesetting—495 claims for the suggested Level III APC compared to 5,174 single claims for the suggested Level II APC, based on CY 2014 final rule claims data. This lower frequency would promote volatility of costs for such a Level III lower airway endoscopy APC. Based on the reasons set forth above, we are finalizing our proposal to assign bronchial thermoplasty services CPT codes 31660 and 31661 to APC 0415 for CY 2014, which has a geometric mean cost of approximately \$2,007.

b. Direct Laryngoscopy (APC 0074)

For CY 2013, we assigned CPT code 31571 (Laryngoscopy, direct, with injection into vocal cord(s), therapeutic; with operating microscope or telescope) to APC 0075 (Level V Endoscopy Upper Airway), with a payment rate of \$2,026.82. For CY 2014, we proposed to assign CPT code 31571 to APC 0074 (Level IV Endoscopy Upper Airway), with a proposed payment rate of approximately \$1,532. (The proposed payment rate reflects the corrected proposed rate in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

Comment: One commenter stated that the proposed rule cost of CPT code 31571 does not support the reassignment of this procedure code from APC 0075 to APC 0074. The commenter believed that the proposed payment rate for APC 0074 does not adequately cover the cost of the procedure described by CPT code 31571, in light of the fact that the geometric mean cost of CPT code 31571 increased from approximately \$1,849 for CY 2013 to \$1,956 in the CY 2014 proposed rule.

Response: The structure of APCs 0074 and 0075 required the proposed realignment of the procedures within those APCs to avoid 2 times rule violations. If CPT code 31571 remained assigned to APC 0075, a 2 times rule violation would have resulted because the cost of the procedure is more than two times less than the significant procedure with the highest geometric mean cost, CPT code 31276 (Nasal/sinus endoscopy, surgical with frontal sinus exploration, with or without removal of tissue from frontal sinus), which had a proposed rule geometric mean cost of approximately \$4,623. This situation appears to remain the case based on final rule claims data. The final rule geometric mean cost of CPT code 31571 is approximately \$1,951 and the final rule geometric mean cost of CPT code 31276 is approximately \$4,504, which would result in a 2 times rule violation if the two procedures were assigned to the same APC. We note that the geometric mean cost of APC 0074 has increased from \$1,390.85 for CY 2013, to approximately \$1,547 for the CY 2014 proposed rule, and approximately \$1,887 for this CY 2014 final rule with comment period. Furthermore, we believe that the procedure described by CPT code 31571 is similar in terms of clinical composition and resource costs to the other procedures assigned to APC 0074. The final rule geometric mean cost of CPT code 31571 is approximately \$1,951, while the final

rule geometric mean cost for APC 0074 is approximately \$1,887, and the final rule geometric mean cost for APC 0075 is approximately \$3,062. Therefore, we are finalizing our proposal to reassign CPT code 31571 from APC 0075 to APC 0074 for CY 2014.

c. Pulmonary Rehabilitation Services (APC 0077)

For CY 2014, we proposed to reassign HCPCS code G0424 (Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day) from APC 0102 (Level II Pulmonary Treatment) to APC 0077 (Level I Pulmonary Treatment), with a proposed payment rate of approximately \$39. (The proposed payment rate reflects the corrected proposed rate in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.) We note that, for CY 2013, HCPCS code G0424 was assigned to APC 0102 with a similar payment rate of approximately \$39.

CMS established HCPCS code G0424 effective January 1, 2010, to describe a one-hour session of pulmonary rehabilitation. This HCPCS code was established consistent with the requirements set forth in section 144(a)(1) of Public Law 110-275 (MIPPA), which added section 1861(fff) to the Act, to provide Medicare Part B coverage and payment for a comprehensive program of pulmonary rehabilitation services furnished to beneficiaries with chronic obstructive pulmonary disease, effective January 1, 2010.

Comment: Several commenters expressed concern about the reassignment of HCPCS code G0424 to APC 0077, which is the same APC to which HCPCS codes G0237 (Therapeutic procedures to increase strength or endurance of respiratory muscles, face to face, one on one, each 15 minutes (includes monitoring)), G0238 (Therapeutic procedures to improve respiratory function, other than described by G0237, one on one, face to face, per 15 minutes (includes monitoring)), and G0239 (Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring)), are assigned. Several commenters stated that the length of time in performing the service described by HCPCS code G0424 is not consistent with the length of time to perform the other services assigned to APC 0077. In particular, the commenters stated that HCPCS code G0424 represents a 60-minute to 90-minute procedure, which

is not similar to the time requirement of the two procedures assigned to APC 0077, HCPCS codes G0237 and G0238, which represent 15-minute procedures. Because of the time required to perform the service, the commenters believed that HCPCS code G0424 should not be assigned to the same APC as HCPCS codes G0237 and G0238. In addition, several commenters stated that the assignment of HCPCS code G0424 to APC 0077 would create a 2 times rule violation. Some commenters further believed that hospitals are underreporting the costs of the procedure described by HCPCS code G0424, and stated that hospitals may be confused about the differences in costs for the procedures described by HCPCS codes G0237 and G0238 (15-minute procedures) and G0424 (60–90 minute procedures). Some commenters recommended that CMS establish a payment for HCPCS code G0424 using claims data from HCPCS codes G0237, G0238, and G0239, similar to the simulated methodology that CMS used in CY 2010 before actual claims data for HCPCS code G0424 became available.

Response: Prior to CY 2012, we did not have available actual claims data for HCPCS code G0424, and consequently, for CY 2010 and CY 2011, we utilized a simulated methodology to arrive at an appropriate payment for the procedure described by HCPCS code G0424. We discussed this simulated methodology extensively in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74263 through 74267). Because HCPCS code G0424 became effective January 1, 2010, the first year of actual claims data for this service was used in the CY 2012 OPPS update. Specifically, in CY 2012, we had data available for HCPCS code G0424 for payments for OPPS services based on claims submitted from January 1, 2010 through December 31, 2010. Payment for HCPCS code G0424 for CY 2012 was approximately \$37.42. For the CY 2014 OPPS update, payment for the procedure described by HCPCS code G0424 is based on claims submitted from January 1, 2012 through December 31, 2012. Similar to our findings for the CY 2012 and CY 2013 OPPS updates, we have a very robust set of claims for the procedure described by HCPCS code G0424 for the CY 2014 update. Based on our latest hospital outpatient claims data, the resource cost associated with HCPCS code G0424 is comparable to the other services assigned to APC 0077. Specifically, our latest hospital outpatient claims data show that the geometric mean cost for HCPCS code G0424 is approximately \$43, based on 457,226 single claims (out of 459,199

total claims), which is similar to the proposed payment rate of approximately \$39 for APC 0077. We note that APC 0077 included various pulmonary treatments whose geometric mean costs range between \$23 and \$43. Based on the latest hospital outpatient claims data, we believe that HCPCS code G0424 can be appropriately reassigned to APC 0077.

Regarding the commenters' statement about hospitals underreporting the costs of the procedure described by HCPCS code G0424, we have no evidence of such underreporting. Furthermore, as we have previously stated, "[b]eyond 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 expect hospitals to report their services appropriately.

We disagree with the commenters' assertion that assigning HCPCS code G0424 to APC 0077 would create a 2 times rule violation. We reviewed the costs of the procedures that would be assigned to APC 0077, including the cost of the procedure described by HCPCS code G0424 and did not find a violation of the 2 times rule in the APC. 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 2 times rule violations. 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. For HCPCS code G0424, we evaluated its APC assignment for the CY 2014 update, and determined that APC 0077 is the appropriate assignment for this service based on its clinical homogeneity and resource similarity to the other services assigned to APC 0077.

After consideration of the public comments we received, we are finalizing our CY 2014 proposal, without modification, to reassign HCPCS code G0424 from APC 0102 to APC 0077. APC 0077 has a final CY 2014 geometric mean cost of approximately \$39. The final CY 2014 payment rate for HCPCS code G0424 can be found in Addendum B to this CY 2014 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

10. Other Services

a. Balloon Sinus Dilation (APCs 0074 and 0075)

For CY 2013, we assigned CPT codes 31295 (Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa), 31296 (Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)), and 31297 (Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)) to APC 0075 (Level V Endoscopy Upper Airway), with a payment rate of \$2,026.82. For CY 2014, we proposed to continue to assign CPT codes 31295, 31296, and 31297 to APC 0075.

Comment: One commenter stated that the proposed geometric mean cost of APC 0075 of approximately \$2,378 is driven by the cost and frequency of a single code, CPT code 31541 (Laryngoscopy, direct, operative, with excision of tumor and/or stripping of vocal cords or epiglottis; with operating microscope or telescope), which had a proposed geometric mean cost of approximately \$2,085, and comprised 61 percent of the APC's single frequency claims for ratesetting. The commenter requested that CMS analyze the appropriateness of continuing to assign CPT codes 31295, 31296, and 31297 to APC 0075 and/or the appropriateness of continuing to assign CPT code 31541 to APC 0075.

Response: Based on updated claims data, we reviewed the procedures in APC 0074 (Level IV Endoscopy Upper Airway) and APC 0075. During our review, we found 2 times rule violations in both APCs. To resolve one of the 2 times rule violations, we reassigned CPT code 31541 from APC 0075 to APC 0074 for CY 2014. As a result, the final rule geometric mean cost of APC 0075 increased to approximately \$3,062.

The final rule geometric mean costs of CPT codes 31295, 31296, and 31297 are \$2,456, \$2,894, and \$1,905, respectively. Therefore, while we are continuing to assign CPT codes 31295 and 31296 to APC 0075 for CY 2014, to avoid another 2 times rule violation, we are reassigning CPT code 31297, which has an appreciably lower geometric mean cost than the geometric mean cost of CPT codes 31295 and 31296, to APC 0074 for CY 2014. APC 0074 has a CY 2014 final geometric mean cost of approximately \$1,887.

After consideration of the public comments we received, we are continuing to assign CPT codes 31295 and 31296 to APC 0075 for CY 2014, as we proposed. However, we are

reassigning CPT code 31297 to APC 0074 for CY 2014. In addition, we are reassigning CPT code 31541 from APC 0075 to APC 0074 for CY 2014.

b. Radiofrequency Ablation of Uterine Fibroids (APC 0174)

We created HCPCS code C9736 (Laparoscopy, surgical, radiofrequency ablation of uterine fibroid(s), including intraoperative guidance and monitoring, when performed) effective July 1, 2013. The procedure became known to us by means of an application to assign the procedure to a New Technology APC. We assigned HCPCS code C9736 to APC 0131 (Level II Laparoscopy) because we believed that it has the greatest degree of clinical similarity to the laparoscopic procedures assigned to that APC. APC 0131 has a CY 2013 payment rate of \$3,487.15. We proposed to continue to assign HCPCS code C9736 to APC 0131 for CY 2014, with a proposed payment rate of approximately \$3,765. (The proposed payment rate reflects the corrected proposed rate in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

The AMA's CPT Editorial Panel recently created new Category III CPT code 0336T (Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency), to be effective January 1, 2014, which describes the procedure described by HCPCS code C9736. Because HCPCS code C9736 became effective July 1, 2013, there are no claims data available for this code for ratesetting purposes.

At its August 26, 2013 meeting, the HOP Panel recommended that CMS move HCPCS code C9736 from APC 0131 to APC 0174 (Level IV Laparoscopy).

Comment: A few commenters recommended that CMS reassign HCPCS code C9736 (or its successor code, CPT code 0336T) to APC 0174 for CY 2014 because the resources involved in performing the procedure are more similar to the resources used in performing procedures assigned to APC 0174. The commenters stated that two CPT codes assigned to APC 0174, CPT code 47370 (Laparoscopy, surgical, ablation of 1 or more liver tumor(s); radiofrequency) and CPT code 50542 (Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed), have clinical and resource characteristics similar to the characteristics of the procedures described by HCPCS code C9736. The commenters stated that both procedures are performed in an operating room

(OR) under general anesthesia and involve diagnostic laparoscopy, and both procedures use approximately 160 to 180 minutes of OR time. One commenter estimated that OR time for other procedures assigned to APC 0131 averages 122 minutes. Other commenters stated that the single-use RF probe used in the procedure described by HCPCS code C9736 costs \$2,584, which is part of more than \$3,400 in total device and supply costs. They added that other procedures assigned to APC 0131 are not as device intensive, whereas procedures assigned to APC 0174 are device intensive. The commenters also requested that CMS delete HCPCS code C9736 and use the new CPT code 0336T, upon its effective date, January 1, 2014.

Response: We do not have claims data on HCPCS code C9736 for ratesetting purposes because the code is new, effective July 1, 2013. We routinely assign procedure or service codes to clinical APCs before we have claims data that are indicative of the resource costs of a procedure or service. We make these assignments initially, using the best currently available information, while reviewing claims data once such data become available and making reassignments accordingly, based on those data. We agree with the HOP Panel and the commenters that resources used to perform the procedure described by HCPCS code C9736 appear to be more similar to the resources used to perform some of the services already assigned to APC 0174. Because new CPT code 0336T describes the procedure described by HCPCS code C9736 and is considered its successor code, we are deleting HCPCS code C9736, effective January 1, 2014, and assigning CPT code 0336T to APC 0174 for CY 2014. As with all new services under the OPPS, the APC assignment of CPT code 0336T is subject to review once our claims data begin to reflect the cost of this procedure.

After consideration of the public comments we received, we are deleting HCPCS code C9736, effective January 1, 2014, and assigning CPT code 0336T to APC 0174 for CY 2014, which has a final geometric mean cost of approximately \$8,623.

c. Magnetic Resonance Image Guided Focused Ultrasound (APC 0065)

The AMA's CPT Editorial Panel created two Category III CPT codes that describe Magnetic Resonance Image Guided Focused Ultrasound (MRgFUS) used in ablation of uterine fibroids, effective January 1, 2005: CPT codes 0071T (Focused ultrasound ablation of uterine leiomyomata, including MR

guidance; total leiomyomata volume less than 200 cc of tissue) and 0072T (Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue). The CMS HCPCS Workgroup created a third code related to MRgFUS, HCPCS code C9734 (Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance), effective April 1, 2013. HCPCS code C9734 originally described the service "with or without MR guidance". However, effective July 1, 2013, we changed the descriptor to only specify "with magnetic resonance guidance". For CY 2013, all three of the MRgFUS codes are assigned to APC 0067 (Level II Stereotactic Radiosurgery), with HCPCS code C9734 added to APC 0067 effective April 1, 2013. The CY 2013 payment rate for APC 0067 is \$3,300.64. For CY 2014, as part of a proposed restructuring of the Stereotactic Radiosurgery (SRS) APCs and procedures, we proposed to reassign SRS procedures to other APCs and to maintain intraoperative radiation therapy (IORT) and magnetoencephalography (MEG) procedures in APC 0065. We proposed to reassign the service codes for MRgFUS procedures to APC 0065 based on clinical coherence to the other procedures assigned to APC 0065. In addition, we proposed to rename APC 0065 "IORT, MRgFUS, and MEG," which has a CY 2014 proposed payment rate of approximately \$1,714 (78 FR 43593 through 43594). (The CY 2014 proposed payment rate reflects the corrected proposed rate in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.) The proposal to restructure the APCs that pay for SRS, IORT, MRgFUS, and MEG procedures would reduce the number of APCs under which payment is made for SRS, IORT, MRgFUS, and MEG procedures from four to three APCs. We note that there are no claims data for CPT codes 0071T and 0072T, or HCPCS code C9734, available for CY 2014 ratesetting purposes.

Comment: Commenters expressed concern about the CY 2014 proposed reassignment of MRgFUS services to APC 0065, and stated that MRgFUS services are not appropriate for assignment to APC 0065 based on clinical and resource characteristics of other services assigned to APC 0065. One commenter opined that MRgFUS services are more similar clinically to the SRS services assigned to APC 0067, in terms of treatment set-up, delivery of radiation, and post-procedure recovery,

except that MRgFUS services use nonionizing radiation. This commenter also believed that MRgFUS services are similar in resources to the SRS services assigned to APC 0067, estimating hospital costs for services described by CPT codes 0071T and 0072T at \$5,439 each, and the cost of the service described by HCPCS code C9734 at \$6,073, which are similar to the proposed payment rate of APC 0067 of approximately \$5,615.

A few commenters urged CMS not to reduce the payment rates for MRgFUS services, as part of restructuring the SRS APCs, or to package payment for other services related to MRgFUS. The commenters noted that the CY 2014 proposal would reduce the payment rate for MRgFUS services by nearly half of the amount of the payment rate for APC 0067 for CY 2013, in addition to reductions in payment as a result of the packaging of related radiation oncology services.

One commenter identified a number of services performed with MRgFUS for which CMS has proposed to package payment and estimated the foregone separate payments for these services, if CMS packages them, to total approximately \$2,800. The commenter recommended that, if CMS finalizes packaging of these services, CMS compensate providers for performance of the MRgFUS services by assigning MRgFUS procedure codes to either APC 0229 (Level II Endovascular Revascularization of the Lower Extremity), which has a proposed payment rate of approximately \$10,314, or a New Technology APC reflecting a similar level of resources use. The commenter acknowledged that there are few Medicare claims data reporting the MRgFUS procedure codes, and stated that the procedures described by CPT codes 0071T and 0072T are generally performed on younger women and that, although HCPCS code C9734 is a new code effective in CY 2013, the commenter expects there will be a significant number of patients over age 65 with metastatic bone cancer who will receive treatment with the procedure described by HCPCS code C9734.

Response: We do not agree with the commenter that MRgFUS procedures are similar to SRS procedures assigned to APC 0067 because of the clinical differences between MRgFUS and SRS, which is a specialized type of radiation therapy. We believe that MRgFUS procedures are more similar to the services in restructured APC 0065, which are distinct from SRS clinical characteristics. We note there are no claims data available for CPT codes 0071T and 0072T or HCPCS code C9734

for CY 2014 ratesetting. Regarding the cost estimates for MRgFUS procedures presented by the commenter, it is our longstanding policy to reassign procedures to APCs based on Medicare claims data that support reassignment, rather than relying on external cost estimates.

After consideration of the public comments we received, we are finalizing our proposal to reassign CPT codes 0071T, 0072T, and HCPCS code C9734 to APC 0065 for CY 2014. The final rule geometric mean cost of APC 0065 is approximately \$1,253.

Our proposed and final packaging policies for CY 2014 are discussed in section II.A.3. of this final rule with comment period.

d. Flow Cytometry (APC 0433)

For CY 2014, we proposed to reassign CPT code 88184 (Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker) from APC 0433 (Level II Pathology) to APC 0344 (Level IV Pathology), with a proposed payment rate of approximately \$273. (The proposed payment rate reflects the corrected proposed rate in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.) In addition, for CY 2014, we proposed to package payment for CPT code 88185 (Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker (list separately in addition to code for first marker)), which is currently assigned to APC 0342 (Level I Pathology) as an add-on code. We refer readers to section II.A.3. of this final rule with comment period for further discussion of our proposed and final payment methodology for add-on codes for CY 2014.

Comment: One commenter expressed disappointment with CMS' decision to decrease the payment rate for flow cytometry CPT codes 88184 and 88185.

Response: We note that the CY 2013 payment rate for CPT code 88184 was approximately \$23 and the CY 2013 payment rate for CPT code 88185 was approximately \$13. For CY 2014, we proposed to reassign CPT code 88184 from APC 0433 to APC 0344 with a payment rate of approximately \$273 based on our claims data for the proposed rule.

We also proposed to package payment for CPT code 88185 because it is an add-on code. We refer readers to section II.A.3. of this final rule with comment period for further discussion of our final payment methodology for add-on codes for CY 2014.

Based on our latest hospital outpatient claims data, we decided not

to revise the APC assignment for CPT code 88184 and instead decided to retain the code's assignment to APC 0433 (Level II Pathology), which is the same APC to which CPT code 88184 was assigned for CY 2013. Analysis of the claims data shows a final rule geometric mean cost of approximately \$35 for CPT code 88184, which is similar to the final rule geometric mean cost of approximately \$37 for APC 0433.

After consideration of the public comment that we received and review of our latest hospital outpatient claims data for this final rule with comment period, we are revising our proposal and will continue to assign CPT code 88184 to APC 0433 for CY 2014. CPT code 88184 has a final payment rate of approximately \$37 for CY 2014, which is slightly higher than the payment rate of approximately \$23 for CY 2013. This final payment rate also can be found in Addendum B to this CY 2014 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site). The final policy for packaging CPT code 88185 as an add-on code for CY 2014 is discussed in section II.A.3. of this final rule with comment period.

e. Hormone Pellet Implant (APC 0420)

For CY 2014, we proposed to reassign CPT code 11980 (Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)) from APC 0340 (Level I Minor Procedures) to APC 0420 (Level II Minor Procedures), with a proposed payment rate of approximately \$103. (The proposed payment rate reflects the corrected proposed rate in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

In the proposed rule, we note that we proposed to make some changes related to APC 0340 for CY 2014. We proposed to revise the title of APC 0340 from "Minor Ancillary Procedures" to "Level I Minor Procedures" and to establish a second level APC to describe minor ancillary procedures, specifically, APC 0420, with the title of "Level II Minor Procedures," as listed in Addendum A to the CY 2014 OPPS/ASC proposed rule, which was posted on the CMS Web site. Based on our review of the latest CY 2012 hospital outpatient claims data, we believed that these changes were necessary to pay appropriately for the services assigned to APC 0340.

Comment: One commenter expressed concern about the APC assignment of CPT code 11980 and suggested two options to address the code's APC assignment. Under the first option, the

commenter suggested that CMS consider establishing a new APC that describes minor ancillary procedures, specifically a Level III Minor Procedures APC, and assign CPT code 11980 to this newly created APC. Because there are several procedures with varying costs assigned to APC 0340 and APC 0420, the commenter suggested restructuring the minor procedures APCs by establishing payment ranges for each level of service. In particular, the commenter suggested that the Level I Minor Procedures APC would have a geometric means cost in the range of \$0 to \$120, the Level II Minor Procedures APC would have a geometric mean cost in the range of \$121 to \$300, and the Level III Minor Procedures would have a geometric mean cost of greater than \$300. As an alternative option, the commenter recommended that CMS reassign CPT code 11980 to APC 0189 (Level III Female Reproductive Procedure).

Response: As the commenter stated, the procedure described by CPT code 11980 involves both testosterone pellets for men and estradiol pellets for women. Because all the procedures in APC 0189 relate to female procedures, we do not believe that APC 0189 would be an appropriate APC assignment for CPT code 11980. In addition, based on our review of the updated hospital outpatient claims data, we believe the two-level APC appropriately pays for the minor procedures that are currently assigned to APCs 0340 and 0420.

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, for any 2 times rule violations. 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 of CPT code 11980 for the CY 2015 OPPS rulemaking cycle.

After consideration of the public comment that we received, we are finalizing our proposal to reassign CPT code 11980 to APC 0420, which has a final geometric mean cost of approximately \$99 for CY 2014. The final CY 2014 payment rate for CPT code 11980 can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

f. Peyronie Disease Injection Procedure (APC 0164)

For CY 2014, we proposed to reassign CPT code 54200 (Injection procedure for peyronie disease) from APC 0164 (Level

II Urinary and Anal Procedures) to APC 0126 (Level I Urinary and Anal Procedures), with a proposed payment rate of approximately \$137, based on its clinical and resource similarity to other procedures assigned to APC 0126. (The proposed payment rate reflects the corrected proposed rate in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

Comment: One commenter expressed concern with the proposal to reassign CPT code 54200 to APC 0126 and requested that CMS continue to assign this code to APC 0164, which is the APC assignment for CY 2013. The commenter stated the CPT code 54200 is clinically similar to the procedures described by CPT codes 54220 (Irrigation of corpora cavernosa for priapism) and 54235 (Injection of corpora cavernosa with pharmacologic agent(s) (eg, papaverine, phentolamine)), which are assigned to APC 0164. The commenter indicated that all three procedures (CPT codes 54200, 54220, and 54235) involve needle placements and should be assigned to the same APC. In addition, the commenter requested that CMS establish a low geometric mean cost of \$163 for APC 0164.

Response: We examined the latest CY 2012 hospital outpatient claims data, which are based on claims submitted from January 1, 2012 through December 31, 2012, and we agree with the commenter's suggestion to continue to assign CPT code 54200 to APC 0164. Our analysis reveals that the resource cost associated with the procedure described by CPT code 54200 is similar to the resource cost of the procedure described by CPT code 54220, which is assigned to APC 0164. Specifically, the geometric mean cost for CPT code 54200 is approximately \$167 based on 330 single claims (out of 351 total claims), which is similar to the geometric mean cost of approximately \$166 for CPT code 54220 based on 25 single claims (out of 427 total claims). Based on the claims data, we believe that CPT code 54200 should continue to be assigned to APC 0164.

With regard to the commenter's suggestion to set the geometric mean cost at \$163 for APC 0164, we do not cap the geometric mean cost based on suggested amounts. The geometric mean cost is determined based on consideration of the costs of all of the procedures and the number of claims within a given APC. We refer readers to section II.A. of this final rule with comment period for a discussion of our methodology in determining the APC geometric mean costs.

After consideration of the public comment we received, we are not finalizing our proposal to reassign CPT code 54200 from APC 0164 to APC 0126 for CY 2014. Rather, we are maintaining the APC assignment for CPT code 54200 to APC 0164, which has a final CY 2014 geometric mean cost of approximately \$212. The final CY 2014 payment rate for CPT code 54200 can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

g. Negative Pressure Wound Therapy (NPWT) (APC 0016)

We established HCPCS code 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 wound(s) surface area less than or equal to 50 square centimeters) and HCPCS code 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 wound(s) surface area greater than 50 square centimeters), effective January 1, 2013, to provide a payment mechanism for negative pressure wound therapy services furnished through a disposable device. We assigned these services to APC 0016 (Level IV Debridement & Destruction), which has a CY 2013 payment rate of approximately \$210. For CY 2014, we proposed to continue to assign HCPCS codes G0456 and G0457 to APC 0016, with a proposed payment rate of approximately \$272. (The proposed payment rate reflects the corrected proposed rate in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

Comment: Some commenters requested that CMS reassign HCPCS codes G0456 and G0457 from APC 0016 to proposed APC 0186 (Level III Skin Repair). The commenters believed that, based on clinical homogeneity and resource costs of the other procedures assigned to proposed APC 0186, proposed APC 0186 is the most appropriate assignment for HCPCS codes G0456 and G0457. Another commenter stated that the cost of providing NPWT is in the range of \$450 to \$500, which more closely aligns with the CY 2013 payment rate of approximately \$393 for proposed APC

0135 (Level IV Skin Repair). One commenter believed that HCPCS codes G0456 and G0457 are clinically similar to the wound care procedures described by CPT codes 12020, 13100, 13101, 15002, and 15003, which were assigned to APC 0135 for CY 2013.

Response: We disagree with the commenters' assertion that HCPCS codes G0456 and G0457 are similar, in terms of clinical homogeneity or resource costs, to CPT codes 12020, 13100, 13101, and 15002. Our analysis of the latest hospital outpatient claims data indicates that the resource costs for the services described by CPT codes 12020, 13100, 13101, and 15002 are in the range of \$474 to \$570. Specifically, the geometric mean cost for CPT code 12020 is approximately \$522 based on 1,082 single claims (out of 2,254 total claims), for CPT code 13100, approximately \$474 based on 81 single claims (out of 341 total claims), for CPT code 13101, approximately \$570 based on 1,198 single claims (out of 3,725 total claims), and for CPT code 15002, approximately \$547 based on 657 single claims (out of 4,119 total claims). (We have not included the geometric mean cost for CPT code 15003 in this discussion because it is an add-on code that will be packaged in the CY 2014 OPPS update.) We believe that the resource costs for the services described by the negative pressure wound therapy HCPCS codes G0456 and G0457 may be slightly higher than the resource costs for the services described by the negative pressure wound therapy CPT codes 97605 and 97606, but not as significant as those services described by CPT codes 12020, 13100, 13101, and 15002. Our claims data show that the geometric mean cost for HCPCS code 97605 is approximately \$100 based on 66,355 single claims (out of 85,285 total claims), and approximately \$140 for CPT code 97606 based on 7,681 single claims (out of 10,771 total claims). Based on the nature of the procedure, the advice from our medical advisors, and our claims data for CPT codes 12020, 13100, 13101, 15002, 97605, and 97606, we believe that APC 0016, which has a geometric mean cost of approximately \$276, is the more appropriate APC assignment for HCPCS codes G0456 and G0457 because these procedures describe debridement-type services rather than skin repair procedures.

Because HCPCS codes G0456 and G0457 are new for CY 2013, we expect to have claims data next year, at which time, we will reevaluate the APC assignments for both codes in preparation for the CY 2015 rulemaking cycle. We remind hospitals that we

review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

Comment: One commenter who responded to the CY 2013 OPPS/ASC final rule with comment period believed that the CY 2013 payment rate of approximately \$210 for both HCPCS codes G0456 and G0457 is inappropriate considering that the current national average selling price for the device used with the procedure is approximately \$270. In addition, the commenter requested that CMS revise the status indicator of HCPCS codes G0456 and G0457 from “T” (Significant Procedure, Multiple Reduction Applies) to “S” (Significant Procedure, Not Discounted When Multiple) in order to not undercompensate hospitals for performing the procedure when it is performed with other services on the same day.

Response: For the CY 2014 update, the payment rate for HCPCS codes G0456 and G0457 will increase from \$210 for CY 2013 to approximately \$275 for CY 2014. As stated above, because HCPCS codes G0456 and G0457 are new for CY 2013, we expect to have claims data next year, at which time we will reevaluate the APC assignments for both codes in preparation for the CY 2015 rulemaking cycle.

With regards to the status indicator assignment of HCPCS codes G0456 and G0457, we note that all codes assigned to APC 0016 are crosswalked to status indicator “T” and have no corresponding “S” status indicator. In addition, we do not believe that every service or procedure should be paid at 100 percent. The multiple procedure reduction for status indicator “T” services recognizes that efficiencies are gained when multiple procedures are performed in a single session. We believe that this policy is appropriately applied to the wound treatment procedures in question.

After consideration of the public comments that we received, we are finalizing our CY 2014 proposal, without modification, to continue to assign HCPCS codes G0456 and G0457 to APC 0016, which has a final CY 2014 geometric mean cost of approximately \$276. The final CY 2014 payment rate for HCPCS codes G0456 and G0457 can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

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

For CY 2014, 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 0013 (Level II Debridement & Destruction) with a proposed payment rate of approximately \$83. (The proposed payment rate reflects the corrected proposed rate in the September 6, 2013 OPPS Addendum B, which was posted on the CMS Web site.)

Comment: Many of the commenters disagreed with the proposed APC assignment for HCPCS code G0460. Several commenters stated that the proposed payment rate of approximately \$83 for APC 0013 does not adequately pay for the cost of providing the service described by HCPCS code G0460. Some of the commenters reported that the actual cost to provide PRP services is between \$400 and \$450. Other commenters reported a specific cost of \$458 to perform the procedure. Most of the commenters stated that HCPCS code G0460 is inappropriately assigned to APC 0013 and urged CMS to reassign the code to APC 0135 (Level IV Skin Repair), which had a proposed payment rate of approximately \$862. One commenter stated that PRP services are more analogous to the tissue-based wound procedures that are assigned to APC 0135 (Level III Skin Repair) for CY 2013, which has a payment rate of \$393.38 for the first 100cm².

Response: We reviewed all the codes assigned to the Debridement & Destruction APCs as well as the Skin Repair APCs. After further consultation with our medical advisors, we agree with the commenters that HCPCS code G0460 would be more appropriately assigned to one of the Skin Repair APCs. For CY 2014, there are four Skin Repair APCs. We have renumbered these APCs with sequential numbers as follows: (1) APC 0326 (Level I Skin Repair); (2) APC 0327 (Level II Skin Repair); (3) APC 0328 (Level III Skin Repair); and (4) APC 0329 (Level IV Skin Repair). After consideration of the public comments we received, and based on the clinical comparability of the procedure and the approximate resource costs associated with the procedure as compared to other procedures assigned to the Skin Repair APCs, we believe that APC 0327 is the most appropriate APC assignment for HCPCS code G0460. APC 0327 has a final geometric mean cost of approximately \$411 for CY 2014. The final CY 2014 payment rate for HCPCS code G0460 can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

It has been our practice since the implementation of the OPPS in 2000 to 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 and determine whether an APC reassignment is necessary for the CY 2015 ratesetting.

i. Payment for Radioisotopes Derived From Non-Highly Enriched Uranium (HEU) Sources (APC 1442)

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the elderly (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 Administration has established an agenda 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 5-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 from non-HEU sources over the costs for radioisotopes produced by HEU sources (77 FR 68316). 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.

Comment: Several commenters requested changes in the additional payment for Technetium-99m produced from non-highly enriched uranium (non-HEU) sources, as described by HCPCS code Q9969. One commenter was concerned that CMS did not utilize stakeholder feedback to craft a more effective payment methodology, such as ensuring that the payment leads to Full Cost Recovery higher in the supply chain, or paying radiopharmacies for the additional costs of maintaining segregated channels for HEU and LEU.

One commenter was concerned about the beneficiary's responsibility for a 20-percent copayment. That commenter also believed that the \$10 payment was too low. Specific changes requested by commenters included elimination of the copayment, increase in the payment rate, expanding it to other radioisotopes, and modifying the payment in response to industry suggestions during stakeholder meetings and/or paying separately for diagnostic radiopharmaceuticals.

Response: We implemented this payment for a specific purpose based on industry and government concerns and considering stakeholder requests and stakeholder feedback. We determined that non-HEU sourced Mo-99, the Tc-99m precursor, is expected to cost more than current sources from legacy reactors, and this increased cost will adversely impact hospitals. In evaluating that concern, we determined that there is a probability that those costs will not be passed on uniformly as the industry converts. Therefore, we used our authority under section 1833(t)(2)(E) of the Act to ensure payment equity among hospitals to propose and finalize a policy through rulemaking that created this additional payment to address the incremental cost of obtaining Tc-99m from the new sources of supply. 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 2014 and have not identified any new information that would cause us to modify the payment at this time. We do not agree with the commenters' 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.

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 requires that, under the OPPS, a category of devices be eligible for

transitional pass-through payments for at least 2, but not more than 3 years. This pass-through payment eligibility period begins with the first date on which transitional pass-through payments may be made for any medical device that is described by the category. We may establish a new device category for pass-through payment in any quarter. Under our established policy, we base the pass-through status expiration date for a device category on the date on which pass-through payment is effective for the category, which is the first date on which pass-through payment may be made for any medical device that is described by such category. 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.

There currently are three device categories eligible for pass-through payment. These device categories are described by HCPCS codes C1830 (Powered bone marrow biopsy needle) and C1840 (Lens, intraocular (telescopic)), which we made effective for pass-through payment as of October 1, 2011; and HCPCS code C1886 (Catheter, extravascular tissue ablation, any modality (insertable)), which we made effective for pass-through payment as of January 1, 2012. Recognizing that these three device categories were eligible for at least 2, but not more than 3, years of pass-through status, in the CY 2013 OPPS/ASC final rule with comment period, we finalized the expiration of pass-through payment for all three of these HCPCS codes, which will expire after December 31, 2013 (77 FR 68352). Therefore, in accordance with our established policy, after December 31, 2013, we will package the respective costs of the HCPCS codes C1830, C1840, and C1886 devices into the costs of the procedures with which the devices are reported in the hospital claims data used in OPPS ratesetting.

b. CY 2014 Policy

As previously stated, we 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). In the CY 2013 OPPS/ASC proposed rule (78 FR 43595), in the case of device category C1840, we proposed that the device costs be packaged only when billed with CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens), which became effective on July 1, 2012. We announced the policy that device category C1840 must be billed with CPT code 0308T, effective July 1, 2012, in Transmittal 2483, dated June 8, 2012. CPT code 0308T is currently assigned to APC 0234 (Level IV Anterior Segment Eye Procedures), which had a proposed geometric mean cost of approximately \$1,794. When the HCPCS code C1840 device costs are packaged into the cost of CPT code 0308T (and the equivalent procedure described by HCPCS code C9732 for the first half of 2012), the proposed geometric mean cost of the procedure is approximately \$15,249. Based on this geometric mean cost for CPT code 0308T, we proposed to create new APC 0351 (Level VII Anterior Segment Eye Procedures), and to assign CPT code 0308T to this APC, which had a proposed geometric mean cost of approximately \$15,249. We stated in the proposed rule that the geometric mean cost for CY 2014 that will be reported in the final rule for this new APC will depend on the geometric mean cost of CPT code 0308T (including the cost of HCPCS code C1840) as calculated using claims data available for the final rule.

Comment: One commenter requested that CMS extend the pass-through payment period of HCPCS code C1830 because one local Medicare contractor had denied ASC payment at least twice because the Medicare claim form was reportedly incorrectly completed. The commenter stated that there is a lack of consistent guidance on how ASC claims for pass-through items are to be submitted.

Response: We are not extending the period of pass-through payment of HCPCS code C1830. Under the ASC payment system, § 416.164(b)(2) of the regulations requires that we pay separately for certain implantable items and services that have pass-through status under the OPPS.

HCPCS code C1830 was made effective for pass-through payment as of October 1, 2011, and we finalized a December 31, 2013 expiration date from pass-through payment for HCPCS code C1830 under the OPPS in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68353). We cannot extend the pass-through payment status of HCPCS code C1830 through CY 2014, because such an extension would make

the pass-through payment status effective longer than the maximum 3-year period permitted under section 1833(t)(6)(B)(iii) of the Act. As we stated in the proposed rule, after December 31, 2013, the costs for devices described by HCPCS code C1830 will be packaged into the costs of the procedure with which the device is reported in the hospital claims data used in the development of the OPPTS relative payment weights that will be used to establish the ASC payment rates for CY 2014 (78 FR 43638). Therefore, we are not altering the decision to expire category C1830 from pass-through payment as of January 1, 2014, or our ASC policy. We are not aware of systematic problems with billing of HCPCS code C1830 either in the OPPTS payment system or the ASC payment system. The commenter cited that there were several instances in which one local contractor rejected HCPCS code C1830 claims from an ASC. Our OPPTS claims data reflect that nearly 1,900 claims from for HCPCS code C1830 were processed with a geometric mean cost of approximately \$126. Therefore, it appears that most HCPCS code C1830 pass-through payment claims were adjudicated successfully in the OPPTS, and we believe this is true in the ASC setting as well. Because pass-through devices are contractor priced in the ASC, there may be more interactions between ASCs and MACs on pass-through claims than is typical for hospitals. We are not aware of widespread problems with ASC processing of claims for HCPCS code C1830.

Comment: One commenter concurred with the proposed assignment of CPT code 0308T to new APC 0351, as well as the designation of this procedure as device-intensive in the ASC setting. The commenter also urged CMS to only use claims from hospitals that are customers of the manufacturer of the HCPCS code C1840 device as claims used with CPT code 0308T because that company is reportedly the sole manufacturer of the device. The commenter noted that four claims were from a hospital that was not a customer, and which apparently reported costs with CPT code 0308T that were much too low to represent the HCPCS code C1840 device cost.

Response: We appreciate the commenter's support for the APC assignment of CPT code 0308T. Regarding the recommendation to use claims only from customers of the device manufacturer, we do not generally screen claims in the manner suggested by the commenter.

After consideration of the public comments we received, we are

maintaining our previous decision to expire device categories C1830, C1840, and C1886 from pass-through payment status, which we finalized in the CY 2013 OPPTS/ASC final rule with comment period, and we are finalizing our proposal to package the costs of these devices with the procedures with which they are billed. We also are finalizing for CY 2014 the proposed assignment of CPT code 0308T to APC 0351. The final CY 2014 geometric mean cost of APC 0351 is approximately \$15,606.

As we indicated in the CY 2014 OPPTS/ASC proposed rule, with the expiration of device categories C1830, C1840, and C1886 from pass-through payment status at the end of CY 2013, there are no currently active categories for which we would expire pass-through status in CY 2014. If we create new device categories for pass-through payment status during the remainder of CY 2013 or during CY 2014, we will propose future expiration dates in accordance with the statutory requirement that they be eligible for pass-through payments for at least 2, but not more than 3, years from the date on which pass-through payment for any medical device described by the category may first be made. (There is one new device category eligible for pass-through payment that we created effective October 1, 2013, C1841 (Retinal prosthesis, includes all internal and external components). However, this category will not expire in CY 2014.)

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 eligible device's pass-through payment amount. 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 OPPTS updates.

Currently, we have published a list of all procedural APCs with the CY 2013 portions (both percentages and dollar amounts) 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>. 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 2014 Policy

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43595), we proposed to continue, for CY 2014, 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 2014, 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 beginning on or after January 1, 2010, 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 2014 OPPS/ASC proposed rule (78 FR 43595), for CY 2014, 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 2014 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 (78 FR 43596).

In addition, in the CY 2014 OPPS/ASC proposed rule (78 FR 43596), we proposed to update the list of all procedural APCs with the final CY 2014 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 2014 device pass-through payment

applications and by CMS in reviewing those applications.

We did not receive any public comments on these proposals. Therefore, we are finalizing them for CY 2014 without modification. In addition, we will update, 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 2014 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 2014 device pass-through payment applications and by CMS in reviewing those applications.

3. Changes to Device Pass-Through Criteria: Integral and Subordinate Criterion

We established a number of specific criteria that new medical devices must meet to be considered eligible for pass-through payments under section 1833(t)(6) of the Act (42 CFR 419.66; 65 FR 18480 and 65 FR 47672 through 47674). In the CY 2014 OPPS/ASC proposed rule (78 FR 43596), we proposed to change one of these criteria for device pass-through payment, described at § 419.66(b)(3), which requires that a device “is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted whether or not it remains with the patient when the patient is released from the hospital” (65 FR 47674).

Regarding the existing regulation at § 419.66(b)(3), applicants for device pass-through status have continued to ask what is meant by the phrase “integral and subordinate part of the service furnished,” and more specifically, what the terms “integral” and “subordinate” mean. These terms have not been specifically defined or described in prior regulatory language, preamble, or guidance. In an effort to reduce further confusion and ensure all applicants understand the intent of the existing regulation, we proposed to provide guidance on the meaning of the term “integral” and delete the term “subordinate” from the existing regulation in the proposed rule. In the proposed rule, we stated that we have interpreted the term “integral” to mean that the device is necessary to furnish or deliver the primary procedure with which it is used. For example, a pacemaker is integral to the procedure of implantation of a pacemaker. We have interpreted the accompanying term “subordinate” in conjunction with the

term “integral,” in that a “subordinate” device is dependent upon the overall procedure of implanting the device, and we have not interpreted the term separately, or applied the term “subordinate” as a separate criterion. Because of confusion among pass-through status applicants regarding the use of both terms “integral” and “subordinate,” and because we do not believe it is necessary that the regulation specifically state that a device must be subordinate to the procedure, in addition to the requirement that a device be integral to the procedure, and have not treated “subordinate” as a separate criterion, as previously explained, we proposed to delete the term “subordinate” from this criterion’s regulatory text under existing § 419.66(b)(3). The proposed revised § 419.66(b)(3) regulatory language read as follows: “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, whether or not it remains with the patient when the patient is released from the hospital.”

We did not receive any public comments on this proposal. Therefore, we are finalizing, without modification, our proposal to delete the term “subordinate” from this criterion’s regulatory text under existing § 419.66(b)(3). The final revised § 419.66(b)(3) regulatory language reads as follows: “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, whether or not it remains with the patient when the patient is released from the hospital.”

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

1. Background

To ensure equitable payment when the 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 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).

2. Policy for CY 2014

In the CY 2014 OPPS/ASC proposed rule (78 FR 43596 through 43597), beginning in CY 2014, we proposed to modify 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. For CY 2013 and prior years, our policy has 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 proposed to reduce OPPS payment, for the applicable APCs listed in Table 17 of the proposed rule, by the full or partial credit a hospital receives for a replaced device. Specifically, under this proposed policy for CY 2014, hospitals would be required to report 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 listed in Table 18 of the proposed rule that is 50 percent or greater than the cost of the device. Under this proposal, hospitals would no longer be required to append the “FB” or “FC” modifier when receiving a device at no cost or with a full or partial credit.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43596 through 43597), for CY 2014, we 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 modified CY 2014 policy applies (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: A majority of commenters supported CMS’ proposed adjustment to the OPPS payment for no cost/full credit and partial credit devices, while some commenters requested that CMS rescind its proposal because they believed it would cause additional administrative burden. One commenter argued that using the “FD” value code methodology in the OPPS would lead to inaccuracy of claims. One commenter stated that, in some cases, if a full credit were received, the entire APC payment would be consumed by the credit and the hospital would receive no payment for the procedural portion of the service. That commenter suggested that CMS develop a floor for the offset and urged CMS to work with hospital stakeholders to better understand the overall impact to hospitals and to ensure that hospitals would be appropriately paid for the procedural aspect of the device/lead replacement. Another commenter requested that CMS remove APCs 0082, 0083 0104, 0229, 0319, and 0656 from the final listing of APCs covered by the no cost/full credit policy.

Response: We appreciate the support of our proposal by the majority of commenters. We disagree with commenters’ assertion that the proposed change from the “FB”/“FC” modifiers to the “FD” value code for the adjustment to OPPS payment for no cost/full credit and partial credit devices would cause added administrative burden. We believe that the use of the “FD” value code will not cause added administrative burden for hospitals. We also disagree with the assertion that using the “FD” value code methodology in the OPPS would lead to an inaccuracy in claims. We believe that the use of the “FD” value code methodology could lead to greater accuracy in our claims data. However, we are sensitive to the commenter’s concerns that, in some cases, if a full credit were received, the entire APC payment would be consumed by the credit and the hospital would receive no payment for the nondevice portion of the costs related to the service. Therefore, we are limiting the OPPS payment deduction for the applicable APCs listed below in Table 30 of this final rule with comment period to the total amount of the device offset when the “FD” value code appears on a claim. Hospitals would still be required to report the amount of the credit in the amount portion for value code “FD” when the hospital receives a credit for a replaced device listed in Table 18 of the proposed rule that is 50 percent or greater than the cost of the device. We continue to believe that APCs 0082, 0083, 0104, 0229, 0319, and 0656 are appropriately identified as APCs to which the no cost/full credit and partial credit device adjustment policy will apply for CY 2014.

After consideration of the public comments we received, we are finalizing our CY 2014 proposal to modify 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, we are finalizing our proposal to require hospitals to report 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 listed in Table 31 of this final rule with comment period that is 50 percent or greater than the cost of the device. We also are finalizing our proposal to limit the OPPS payment deduction for the applicable APCs listed below in Table 30 of this final rule with comment period to the total amount of

the device offset when the “FD” value code appears on a claim.

We proposed to update the lists of APCs and devices to which the proposed modified no cost/full credit and partial credit device adjustment policy would apply for CY 2014, consistent with the three criteria discussed earlier in this section, based on the final CY 2012 claims data available for the CY 2014 OPPS/ASC final rule with comment period.

We examined the offset amounts calculated from the CY 2014 final rule data and the clinical characteristics of the final CY 2014 APCs to determine which APCs meet the criteria for CY 2014. Based on the CY 2012 claims data available for this final rule with comment period, we are not making any changes to the proposed lists of APCs and devices to which this modified policy applies.

Table 30 below lists the APCs to which the finalized modified payment adjustment policy for no cost/full credit and partial credit devices applies in CY 2014.

Table 31 below lists the devices to which the finalized modified payment adjustment policy for no cost/full credit and partial credit devices applies in CY 2014.

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**TABLE 30.—APCs TO WHICH THE MODIFIED NO COST/FULL CREDIT
AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY
APPLIES IN CY 2014**

CY 2014 APC	CY 2014 APC Title
0039	Level I Implantation of Neurostimulator Generator
0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes
0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes
0082	Coronary or Non-Coronary Atherectomy
0083	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization
0085	Level II Electrophysiologic Procedures
0086	Level III Electrophysiologic Procedures
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes
0090	Level I Insertion/Replacement of Permanent Pacemaker
0104	Transcatheter Placement of Intracoronary Stents
0106	Insertion/Replacement of Pacemaker Leads and/or Electrodes
0107	Level I Implantation of Cardioverter-Defibrillators (ICDs)
0108	Level II Implantation of Cardioverter-Defibrillators (ICDs)
0227	Implantation of Drug Infusion Device
0229	Level II Endovascular Revascularization of the Lower Extremity
0259	Level VII ENT Procedures
0293	Level VI Anterior Segment Eye Procedures
0315	Level II Implantation of Neurostimulator Generator
0318	Implantation of Neurostimulator Pulse Generator and Electrode
0319	Level III Endovascular Revascularization of the Lower Extremity
0385	Level I Prosthetic Urological Procedures
0386	Level II Prosthetic Urological Procedures
0425	Level II Arthroplasty or Implantation with Prosthesis
0648	Level IV Breast Surgery
0654	Level II Insertion/Replacement of Permanent Pacemaker
0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing
0656	Transcatheter Placement of Intracoronary Drug-Eluting Stents
0674	Prostate Cryoablation
0680	Insertion of Patient Activated Event Recorders

**TABLE 31.—DEVICES TO WHICH THE MODIFIED NO COST/FULL CREDIT
AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY
APPLIES IN CY 2014**

CY 2014 Device HCPCS Code	CY 2014 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
C1820	Generator, neuro rechg bat sys
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

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V. OPPTS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals**A. OPPTS 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 (also referred to as biologics). 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 (Pub. L. 107–186); 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 Part B for which payment was made on the first date the hospital OPPTS 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 OPPTS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as “drugs.” As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Proposed CY 2014 pass-through drugs and biologicals and their designated APCs were assigned status indicator “G” in Addenda A and B to the proposed rule, which are available via the Internet on the CMS Web site.

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. If the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, the

pass-through payment amount is determined by the Secretary to be equal to the average price for the drug or biological for all competitive acquisition areas and the year established under such section as calculated and adjusted by the Secretary. However, we note that the Part B drug competitive acquisition program (CAP) has been postponed since CY 2009, and such a program has not been reinstated for CY 2014.

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 OPPTS, 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 Status in CY 2013

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43598), we proposed that the pass-through status of 15 drugs and biologicals would expire on December 31, 2013, as listed in Table 19 of the proposed rule (78 FR 43599). All of these drugs and biologicals will have received OPPTS pass-through payment for at least 2 years and no more than 3 years by December 31, 2013. These drugs and biologicals were approved for pass-through status on or before January 1, 2012. 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, and

our new groups of policy packaged products described in section II.A.3. of the proposed rule, namely 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 OPPTS drug packaging threshold for that calendar year (which is \$90 for CY 2014), 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 OPPTS 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 OPPTS drug packaging threshold, we would provide separate payment at the applicable relative ASP-based payment amount (which is ASP+6 percent for CY 2014, as discussed further in section V.B.3. of this final rule with comment period).

Comment: One commenter recommended that CMS provide pass-through status for new drugs, specifically diagnostic radiopharmaceuticals, for a full 3-year period. The commenter asserted that providing pass-through status for 3 years would help provide a more current and accurate data set on which to base payment for the associated nuclear medicine procedure into which the radiopharmaceutical is subsequently packaged. To provide for a full 3-year pass-through period, the commenter recommended that the pass-through status for drugs and biologicals expire on a quarterly basis rather than on an annual basis.

Response: As we stated in the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74287), the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68363), 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 but not more than 3 years, after the product’s first payment as a hospital outpatient service under Medicare Part B. 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 status proposed and finalized through the annual rulemaking process. Each year, when proposing to expire the pass-through 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 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 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. We further note that we are in full compliance with the requirements of the Act, which states that pass-through status is given for at least 2 but no more than 3 years.

Comment: One commenter stated that the pass-through status for HCPCS code Q4131 (Epifix, per square centimeter) should not expire on December 31, 2013, because this product has not received pass-through payments for a period of at least 2 years after the payment was first made for this product as a hospital outpatient service under Medicare Part B, as required by statute. The commenter indicated that pass-through payment for HCPCS code Q4131 was first made in February 2012.

Response: Upon review of our CY 2012 claims data, we agree with the commenter that HCPCS code Q4131 has

not received pass-through payments for the minimum period of “at least 2 years” as required by statute. Therefore, we are not finalizing our proposal to expire the pass-through status for HCPCS code Q4131 on December 31, 2013.

After consideration of the public comments we received, we are modifying our proposal to expire the pass-through status of the 15 drugs and biologicals that were listed in Table 19 of the CY 2014 OPPS/ASC proposed rule (78 FR 43599). The pass-through status for HCPCS code Q4131 will not expire on December 31, 2013, but will continue for CY 2014. Table 32 lists the drugs and biologicals for which pass-through status will expire on December 31, 2013, as well as the final status indicators and the final APC assignments for these drugs and biologicals for CY 2014.

TABLE 32.—DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS WILL EXPIRE DECEMBER 31, 2013

CY 2014 HCPCS Code	CY 2014 Long Descriptor	CY 2014 SI	CY 2014 APC
A9584	Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries	N	N/A
C9285	Lidocaine 70 mg/tetracaine 70 mg, per patch	N	9285
J0131	Injection, acetaminophen, 10 mg	N	9283
J0485	Injection, belatacept, 1 mg	K	9286
J0490	Injection, belimumab, 10 mg	K	1353
J0638	Injection, canakinumab, 1mg	K	1311
J0712	Injection, ceftaroline fosamil, 10 mg	N	9282
J1572	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg	K	0947
J2507	Injection, pegloticase, 1 mg	K	9281
J7180	Injection, factor xiii (antihemophilic factor, human), 1 i.u	K	1416
J9042	Injection, brentuximab vedotin, 1 mg	K	9287
J9179	Injection, eribulin mesylate, 0.1 mg	K	1426
J9228	Injection, ipilimumab, 10 mg	K	9284
Q4124	Oasis Ultra Tri-Layer matrix, per square centimeter	N	9365

3. Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Status in CY 2014

In the CY 2014 OPPS/ASC proposed rule (78 FR 43599), we proposed to continue pass-through status in CY 2014 for 18 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, 2013. These drugs and biologicals, which were approved for pass-through status between April 1, 2012 and July 1, 2013, were listed in Table 20 of the proposed rule (78 FR 43600). The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through April 1, 2013 were assigned status indicator “G” in Addenda A and B of the proposed rule. Addenda A and B for 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 2014, which is the amount that drugs and biologicals receive under section 1842(o) of the Act.

Therefore, for CY 2014, 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 2014. We proposed that a \$0.00 pass-through payment amount would be paid for most pass-through drugs and biologicals under the CY 2014 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 contrast agents, diagnostic radiopharmaceuticals, anesthesia drugs, and our new groups of

policy packaged products described in section II.A.3. of this final rule with comment period, namely 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 2014 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 2014 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 42722 and 42723).

In CY 2014, as is consistent with our CY 2013 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through 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 status during CY 2014, 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 is also not available, we proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

Comment: One commenter requested that CMS provide a higher payment amount for radiopharmaceuticals that are granted pass-through status.

Response: We note that, for CY 2014, consistent with our CY 2013 payment policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to provide payment for both diagnostic and therapeutic radiopharmaceuticals with pass-through 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, WAC if ASP is unavailable, and 95 percent of the radiopharmaceutical’s most recent AWP if 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 status during CY 2014, we proposed to follow the standard ASP methodology to determine its pass-through payment rate under the OPPS to account for the acquisition as well as pharmacy overhead and handling costs. We continue to believe that a single payment is appropriate for diagnostic radiopharmaceuticals with pass-through status in CY 2014, 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 handling and overhead costs.

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 status based on the ASP methodology. If a diagnostic or therapeutic radiopharmaceutical receives pass-through status during CY 2014, 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 is also 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, over the last 6 years, we implemented a policy whereby payment for all nonpass-through diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs is packaged into payment for the associated procedure. In the CY 2014 OPPS/ASC proposed rule, we proposed to continue the packaging of these items, and we also proposed new groups of policy-packaged products described in section II.A.3. of the proposed rule, namely 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, regardless of their per day cost, in CY 2014. 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 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 IV.A.2. 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 would, therefore, 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 2013, we proposed to continue to set the associated copayment amount to zero for CY 2014 for pass-through diagnostic

radiopharmaceuticals, contrast agents, and anesthesia drugs that would otherwise be packaged if the item did not have pass-through status. We also proposed to set the associated copayment amount to zero for the additional categories of policy-packaged products proposed for CY 2014 described in section II.A.3. of the proposed rule.

The separate OPPS payment to a hospital for the pass-through diagnostic radiopharmaceutical, contrast agent, anesthesia drug, and the additional categories of policy-packaged products proposed for CY 2014 is not subject to a copayment according to the statute. Therefore, we proposed to not publish a copayment amount for these items in Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site).

Comment: Commenters supported the CY 2014 proposal to continue to set the associated copayment amounts to zero for pass-through diagnostic radiopharmaceuticals, contrast agents, and other drugs and biologicals that would otherwise be packaged if the product did not have pass-through status. The commenters noted that this policy is consistent with statutory requirements and provides cost-saving benefits to beneficiaries. One commenter requested that CMS expand the \$0 copayment policy to pass-through therapeutic radiopharmaceuticals as well.

Response: We appreciate the commenters' support of our proposal. 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 would otherwise be packaged if the item did not have pass-through status. However, therapeutic radiopharmaceuticals without pass-through status are not packaged but are paid at ASP+6 percent. Therefore, the copayment for a therapeutic radiopharmaceutical with pass-through status cannot be zero but must be based on the payment amount for the therapeutic radiopharmaceutical when it does not have pass-through status.

After consideration of the public comments 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 status to zero for CY 2014. We also are finalizing our proposal to extend this policy to the additional categories of policy-packaged drugs and biologicals that have pass-through status, and to set a copayment amount of zero for these drugs and biologicals for CY 2014.

The 26 drugs and biologicals that will continue to have pass-through status for CY 2014 or have been granted pass-through status as of January 2014 are shown in Table 33 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 33 includes those coding changes.

BILLING CODE 4120-01-P

**TABLE 33.—DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS
IN CY 2014**

CY 2013 HCPCS Code	CY 2014 HCPCS Code	CY 2014 Long Descriptor	Final CY 2014 SI	Final CY 2014 APC
C1204	A9520	Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries	G	1463
C9130	J1556	Injection, immune globulin (Bivigam), 500 mg	G	9130
C9131	J9354	Injection, ado-trastuzumab emtansine, 1 mg	G	9131
C9132	C9132	Prothrombin complex concentrate (human), Kcentra, per i.u. of Factor IX activity	G	9132
C9290	C9290	Injection, bupivacaine liposome, 1 mg	G	9290
C9292	J9306	Injection, pertuzumab, 1 mg	G	9292
C9293	C9293	Injection, glucarpidase, 10 units	G	9293
C9294	J3060	Injection, taliglucerase alfa, 10 units	G	9294
C9295	J9047	Injection, carfilzomib, 1 mg	G	9295
C9296	J9400	Injection, ziv-aflibercept, 1 mg	G	9296
C9297	J9262	Injection, omacetaxine mepesuccinate, 0.01 mg	G	9297
C9298	J7316	Injection, ocriplasmin, 0.125 mg	G	9298
N/A	C9133	Factor ix (antihemophilic factor, recombinant), Rixubus, per i.u.	G	1467
N/A	C9441	Injection, ferric carboxymaltose, 1 mg	G	9441
N/A	C9497	Loxapine, inhalation powder, 10 mg	G	9497
N/A	J7508	Tacrolimus, Extended Release, Oral, 0.1 mg	G	1465
N/A	J9371	Injection, Vincristine Sulfate Liposome, 1 mg	G	1466
J0178	J0178	Injection, aflibercept, 1 mg vial	G	1420
J0716	J0716	Injection, centruroides (scorpion) immune f(ab)2, up to 120 milligrams	G	1431
J7315	J7315	Mitomycin, ophthalmic, 0.2 mg	G	1448
J9019	J9019	Injection, asparaginase (erwinaze), 1,000 iu	G	9289
Q4122	Q4122	Dermacell, per square centimeter	G	1419
Q4127	Q4127	Talymed, per square centimeter	G	1449
Q4131	Q4131	Epifix, per square centimeter	G	9366
Q4132	Q4132	Grafix core, per square centimeter	G	9368
Q4133	Q4133	Grafix prime, per square centimeter	G	9369

*HCPCS codes C9133, C9441, C9497, J7508, and J9371 are effective January 1, 2014.

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4. Provisions for Reducing Transitional Pass-Through Payments for 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 to Offset Costs Packaged into APC Groups

a. Background

Prior to CY 2008, diagnostic radiopharmaceuticals and contrast agents were paid separately under the OPPTS 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 OPPTS 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 OPPTS/ASC proposed rule (78 FR 43601), we proposed to continue to package payment for all nonpass-through diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs and to begin 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, as discussed in section II.A.3. of this final rule with comment period.

b. Payment Offset Policy for Diagnostic Radiopharmaceuticals

As previously noted, radiopharmaceuticals are considered to be drugs for OPPTS 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. There are currently two diagnostic radiopharmaceuticals with pass-through status under the OPPTS. HCPCS code A9584 (Iodine I-123 ioflupane, diagnostic, per study dose,

up to 5 millicuries) was granted pass-through status using HCPCS code C9406 beginning July 1, 2011, and we proposed that its pass-through status would expire on December 31, 2013. HCPCS code C1204 (Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries) was granted pass-through status beginning October 1, 2013. We currently apply the established radiopharmaceutical payment offset policy to pass-through payment for these products. As described earlier in section V.A.3. of this final rule with comment period, we proposed that new pass-through diagnostic radiopharmaceuticals would be paid at ASP+6 percent, while those new pass-through diagnostic radiopharmaceuticals without ASP information would be paid at WAC+6 percent or, if WAC is not available, payment would be based on 95 percent of the product's most recently published AWP.

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.

In the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60480 through 60484), we finalized a policy to redefine policy-packaged drugs as only nonpass-through diagnostic radiopharmaceuticals and contrast agents, as a result of the policy discussed in sections V.A.4. and V.B.2.d. of the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60471 through 60477 and 60495 through 60499, respectively) that treats nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural

orifice) with newly approved pass-through status beginning in CY 2010 or later as devices, for purposes of the OPPTS, rather than drugs.

To determine the actual APC offset amount for pass-through diagnostic radiopharmaceuticals that takes into consideration the otherwise applicable OPPTS 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 OPPTS payment for the pass-through diagnostic radiopharmaceutical by this amount. For CY 2014, as we did in CY 2013, we proposed to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals.

Beginning in CY 2011 and as discussed in the CY 2011 OPPTS/ASC final rule with comment period (75 FR 71934 through 71936), we finalized a policy to require hospitals to append modifier "FB" to specified nuclear medicine procedures and to report a token charge of less than \$1.01 in cases in which the diagnostic radiopharmaceutical is received without cost or with full credit. Beginning in CY 2014, we proposed to no longer require hospitals to append modifier "FB" to specified nuclear medicine procedures or to report a token charge of less than \$1.01 in cases in which the diagnostic radiopharmaceutical is received at no cost/full credit (78 FR 43601). Under this proposed policy, the OPPTS payment amount for nuclear medicine procedures are not reduced when a diagnostic radiopharmaceutical is received at no cost or full credit. Based on claims data, it appears that hospitals rarely receive diagnostic radiopharmaceuticals at no cost or full credit. Therefore, we do not believe that the burden on hospitals of adhering to the nuclear medicine "FB" modifier policy continues to be warranted.

Comment: Commenters recommended that CMS publish preliminary offset amounts for diagnostic radiopharmaceuticals and contrast agents with the proposed rule to allow for meaningful assessment of and public comment on the data.

Response: The exact data used to calculate all of the proposed and final payment rates, including the associated offset amounts, for the CY 2014 OPPTS are available for purchase under a CMS data use agreement through the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. This Web site 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 CMS diagnosis codes and revenue code payment amounts. We do not post the offset amounts by APC until publication of the final rule with comment period because we assign services to APCs based on our estimate of their full resource cost, including, but not limited to, packaged diagnostic radiopharmaceuticals and contrast agents. The offset amount is the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor diagnostic radiopharmaceuticals and contrast agents when considering a new diagnostic radiopharmaceutical and contrast agent for pass-through payment and has no bearing on APC assignment.

Comment: One commenter believed that CMS should not discontinue the

requirement for hospitals to append modifier “FB” to specified nuclear medicine procedures in cases in which the diagnostic radiopharmaceutical is received at no cost or full credit. The commenter suggested that this is a relatively new policy and, therefore, should be maintained for at least another year.

Response: Based on claims data, it appears that hospitals rarely receive diagnostic radiopharmaceuticals at no cost or full credit. Therefore, we do not believe that the “FB” modifier policy, as it relates to diagnostic radiopharmaceuticals, is warranted.

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 2014 OPPS/ASC proposed rule (78 FR 43601). We will

continue to reduce the payment amount for procedures in the APCs listed in Table 34 in this final rule with comment period by the full policy-packaged offset amount appropriate for diagnostic radiopharmaceuticals. We also are finalizing our proposal to no longer require hospitals to append modifier “FB” to specified nuclear medicine procedures or to report a token charge of less than \$1.01 in cases in which the diagnostic radiopharmaceutical is received at no cost or full credit. Under this finalized policy, the OPPS payment amount for nuclear medicine procedures is not reduced when a diagnostic radiopharmaceutical is received at no cost or full credit.

Table 34 below displays the APCs to which nuclear medicine procedures will be assigned in CY 2014 and for which we expect that an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

TABLE 34.—APCs TO WHICH A DIAGNOSTIC RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2014

CY 2014 APC	CY 2014 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. Currently, there are no contrast agents with pass-through status under the OPPS. As described in section V.A.4.c. of the proposed rule (78 FR 43602), we proposed that new pass-through contrast agents would be paid at ASP+6 percent, while those new pass-through contrast agents without ASP information would be paid at WAC+6 percent or, if WAC is not available, at 95 percent of the product's most recently published AWP.

Although there are currently no contrast agents with pass-through status, we believe that a payment offset is necessary in the event that a new contrast agent is approved for pass-through status during CY 2014 in order to provide an appropriate transitional pass-through payment for new contrast agents because all of these items are packaged when they do not have pass-through status. In accordance with our standard offset methodology, in the CY 2014 OPSP/ASC proposed rule (78 FR 43602), we proposed, for new contrast agents that are approved for pass-through status as a drug or biological during CY 2014, to deduct from the payment an amount that reflects the portion of the APC payment associated with predecessor contrast agents. This was proposed in order to ensure that 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). For CY 2014, as we did in CY 2013, we proposed to continue to apply this same policy to contrast agents. Specifically, we proposed to utilize 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 OPSP payment amount, 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 OPSP payment for the pass-through contrast agent by this amount. We proposed to continue to apply this methodology for CY 2014 to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 22 of the proposed rule (78 FR 43602 through 43603), a specific offset based on the procedural APC would be applied to the payment for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

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 34 above, and these APCs are displayed in Table 35 below. The methodology used to determine a

threshold cost for application of a contrast agent offset policy is described in detail in the CY 2010 OPSP/ASC final rule with comment period (70 FR 60483 through 60484). For CY 2014, we proposed to continue to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 22 of the proposed rule (78 FR 43602 through 43603), 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.

As we proposed, for this final rule with comment period, 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, including contrast agents, 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 OPSP clinical APC.

After consideration of the public comments we received, we are finalizing our proposal for CY 2014 without modification. We will continue to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 35 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 35.—APCs TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2014

CY 2014 APC	CY 2014 APC Title
0080	Diagnostic Cardiac Catheterization
0082	Coronary or Non-Coronary Atherectomy
0083	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization
0093	Vascular Reconstruction/Fistula Repair
0104	Transcatheter Placement of Intracoronary Stents
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
0653	Vascular Reconstruction/Fistula Repair with Device
0656	Transcatheter Placement of Intracoronary Drug-Eluting Stents
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 Products Packaged According to the 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

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. As discussed in section II.A.3. of the CY 2014 OPPS/ASC proposed rule, as a part of our proposed 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, we specifically proposed 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 43570 through 43572). We believe that a payment offset, similar to the offset

currently in place for pass-through devices, diagnostic radiopharmaceuticals, and contrast agents, is necessary in order to provide an appropriate transitional pass-through payment 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 because all of these are packaged, or proposed to be packaged, when they do not have pass-through status. In accordance with our standard offset methodology, we proposed for CY 2014 to deduct an amount that reflects the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made from the payment for pass-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 (78 FR 43603).

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). For CY 2014, we proposed to apply this same policy to 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 (78 FR 43603). Specifically, in the case of pass-through skin substitutes, we proposed to utilize

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 proposed to utilize 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 proposed to 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 43603).

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal, without modification, to recognize that when a skin substitute with pass-through status is billed with any procedural APC listed in Table 36 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 status is billed with any procedural APC listed in Table 37 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 36 below displays the APCs to which skin substitute procedures will be assigned in CY 2014 and for which we expect that an APC offset could be applicable in the case of skin substitutes with pass-through status.

Table 37 below displays the APCs to which MPI procedures will be assigned in CY 2014 and for which we expect that an APC offset could be applicable in the case of a stress agent with pass-through status.

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.

TABLE 36.—APCs TO WHICH A SKIN SUBSTITUTE OFFSET MAY BE APPLICABLE FOR CY 2014

CY 2014 APC	CY 2014 APC Title
0328	Level III Skin Repair
0329	Level IV Skin Repair

TABLE 37.—APCs TO WHICH A STRESS AGENT OFFSET MAY BE APPLICABLE FOR CY 2014

CY 2014 APC	CY 2014 APC Title
0100	Cardiac Stress Tests
0377	Level II Cardiac Imaging

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

1. Background

Under the CY 2013 OPSS, we currently pay for drugs, biologicals, and radiopharmaceuticals that do not have pass-through 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 OPSS 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 OPSS payment rate for the associated procedure or service. (Transmittal A–01–133, issued on November 20, 2001, explains in greater detail the rules regarding separate payment for packaged services.)

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 OPSS/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 \$60 for CYs 2008 and 2009. For CY 2010, we set the packaging threshold at \$65; for CY 2011, we set the packaging threshold at \$70;

for CY 2012, we set the packaging threshold at \$75; and for CY 2013, we set the packaging threshold at \$80.

Following the CY 2007 methodology, for the CY 2014 OPSS/ASC proposed rule (78 FR 43604), 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 2014 and rounded the resulting dollar amount (\$87.70) 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.

We chose the PPI for Prescription Drugs as it reflects price changes associated with the average mix of all pharmaceuticals in the overall economy. In addition, we chose this price series because it is publicly available and regularly published, improving public access and transparency. Forecasts of the PPI for Prescription Drugs are developed by IHS Global Insight, Inc., a nationally recognized economic and financial forecasting firm. As actual inflation for past quarters replaced forecasted amounts, the PPI estimates for prior quarters have been revised (compared with those used in the CY 2007 OPSS/ASC final rule with

comment period) and have been incorporated into our calculation. Based on the calculations described above, we proposed a packaging threshold for CY 2014 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).)

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 2014 OPPS/ASC proposed rule (78 FR 43604), to determine the proposed CY 2014 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 2012 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2012 claims processed before January 1, 2013 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 diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, and implantable biologicals that we proposed to continue to package in CY 2014, or for the new categories of policy-packaged products proposed for CY 2014, as discussed in section II.A.3. of the proposed rule.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2014, 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 70 FR 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 2014, as discussed in more detail in section V.B.3.b. of the proposed rule) to calculate the CY 2014 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2012 (data that were used for payment purposes in the physician's office setting, effective April 1, 2013) to

determine the proposed rule per day cost.

As is our standard methodology, for CY 2014, we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2012 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, 2013. 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 2012 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 2012 HCPCS codes that were reported to the CY 2013 HCPCS codes that we displayed in Addendum B of the proposed rule (which is available via the Internet on the CMS Web site) for payment in CY 2014.

Comment: The majority of commenters objected to the proposed increase in the OPPS packaging threshold to \$90 for CY 2014. The commenters recommended that CMS consider either eliminating the drug packaging threshold and providing separate payment for all drugs with HCPCS codes or freezing the packaging threshold at \$80 for CY 2014. A few commenters suggested that CMS limit increases in the packaging threshold amount to the hospital market basket update factor for the year that is reflective of all statutory adjustments.

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 the

commenters' recommendations to pay separately for all drugs, biologicals, and radiopharmaceuticals for CY 2014 or to eliminate or to freeze the packaging threshold at \$80.

We disagree with the commenters who suggested that CMS limit increases in the outpatient drug packaging threshold amount to the hospital update factor for the year, reflective of all statutory adjustments or the market basket update. As stated above, we continue to believe that updating the \$50 threshold of 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. As we stated in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085), we believe that the PPI for Prescription Drugs reflects price changes at the wholesale or manufacturer stage. Because OPPS payment rates for drugs and biologicals are generally based on the ASP data that are reported by their manufacturers, we believe that the PPI for Prescription Drugs is an appropriate price index to use to update the packaging threshold for CY 2007 and beyond. In contrast, the market basket update contains numerous price proxies, including, but not limited to, proxies for wages and salaries, utilities, and nonlabor-related expenses, that are not related to price increases for prescription drugs. Therefore, we believe that the market basket as a whole is not an appropriate mechanism for determining the outpatient drug packaging threshold amount. Within the calculation of the market basket update, we use the PPI for Prescription Drugs specifically to measure the price growth for prescription drugs, but price changes for prescription drugs are only one component of price changes for the numerous items and services hospitals purchase.

Since publication of the CY 2014 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 2014 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 2014. We then rounded the resulting updated dollar amount (\$91.27) to the nearest \$5 increment, which yielded a figure of \$90. Therefore, after consideration for 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 2014 packaging threshold of \$90.

Our policy during previous cycles of the OPPTS 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 OPPTS/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 OPPTS/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 final rule with comment period, we used ASP data from the first quarter of CY 2013, 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, 2013, along with updated hospital claims data from CY 2012. We note that we also used these data for budget neutrality estimates and impact analyses for this 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 2013. 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, 2013. These payment rates will then be updated in the January 2014 OPPTS update, based on the most recent ASP data to be used for physician's office and OPPTS payment as of January 1, 2014. For items that do not currently have an ASP-based payment rate, we recalculated their mean unit cost from all of the CY 2012 claims data and updated cost report information available for this CY 2014 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in this CY 2014 OPPTS/ASC final rule with comment period may be different from the same drug HCPCS code's packaging status determined based on the data used for the proposed rule. Under such circumstances, we proposed to continue to follow the established policies initially adopted for the CY 2005 OPPTS

(69 FR 65780) in order to more equitably pay for those drugs whose cost fluctuates relative to the proposed CY 2014 OPPTS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2013. Specifically, for CY 2014, 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 2013 and that were proposed for separate payment in CY 2014, and that then have per day costs equal to or less than the CY 2014 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2014 final rule, would continue to receive separate payment in CY 2014.

- HCPCS codes for drugs and biologicals that were packaged in CY 2013 and that are proposed for separate payment in CY 2014, and that then have per day costs equal to or less than the CY 2014 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2014 final rule, would remain packaged in CY 2014.

- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2014 but then have per day costs greater than the CY 2014 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2014 final rule, would receive separate payment in CY 2014.

We did not receive any public comments on our proposal to apply the established policies initially adopted for the CY 2005 OPPTS (69 FR 65780) in order to more equitably pay for those drugs whose cost fluctuates relative to the CY 2014 OPPTS 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 2014.

We note that we proposed to package HCPCS codes 90734 (Meningococcal conjugate vaccine, serogroups a, c, y and w-135 (tetraivalent), for intramuscular use), J0630 (Injection, calcitonin salmon, up to 400 units), and J1570 (Injection, ganciclovir sodium, 500 mg) for CY 2014. Using updated ASPs and the CY 2012 hospital claims data available for this final rule with comment period, HCPCS codes 90734,

J0630, and J1570 now have per day costs greater than \$90. In accordance with our established policy for such cases, for CY 2014 we will pay for HCPCS codes 90734, J0630, and J1570 separately.

In addition, because we did not have claims data for HCPCS code J7191 (Factor viii (antihemophilic factor (porcine)), per IU) in the CY 2014 OPPTS/ASC proposed rule, we had proposed a status indicator of "E" for this product in CY 2014. However, since publication of the proposed rule, we have received claims data and the per day cost for this product is more than the \$90 CY 2014 packaged threshold. HCPCS code J7191 will be paid separately and will be assigned a status indicator of "K" for CY 2014.

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

In the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66776), we began recognizing, for OPPTS 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 OPPTS recognized for payment only the HCPCS code that described the lowest dosage of a drug or biological. We extended this recognition to multiple HCPCS codes for several other drugs under the CY 2009 OPPTS (73 FR 68665). 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 2008 OPPTS/ASC final rule with comment period (72 FR 66775), we explained that once claims data were available for these previously unrecognized HCPCS codes, we would determine the packaging status and resulting status indicator for each HCPCS code according to the general, established HCPCS code-specific methodology for determining a code's packaging status for a given update year. However, we also stated that we planned to closely follow our claims data to ensure that our annual packaging determinations for the different HCPCS codes describing the same drug or biological did not create inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others.

In the CY 2010 OPPTS/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. We analyzed CY 2008 claims data for the HCPCS codes describing different dosages of the same drug or biological that were newly recognized in CY 2008 and found that our claims data would result in several different packaging determinations for different codes describing the same drug or biological. Furthermore, we found that our claims data included few units and days for a number of newly recognized HCPCS codes, resulting in our concern that these data reflected claims from only a small number of hospitals, even though the drug or biological itself may be reported by many other hospitals under the most common HCPCS code. Based on these findings from our first available claims data for the newly recognized HCPCS codes, we believed that adopting our standard HCPCS code-specific packaging determinations for these codes could lead to payment incentives for hospitals to report certain HCPCS codes instead of others, particularly because we do not currently require hospitals to report all drug and biological HCPCS codes under the OPPS in consideration of our previous policy that generally recognized only the lowest dosage HCPCS code for a drug or biological for OPPS payment.

For CY 2014, we continue to believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to payment incentives for hospitals to report certain HCPCS codes for drugs instead of others. Making packaging determinations on a drug-specific basis eliminates these incentives 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 2014 OPPS/ASC proposed rule (78 FR 43606), 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 2014.

For CY 2014, 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 2012 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 2014 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 2012 claims data to make the packaging determinations for these drugs: HCPCS codes J3471 (Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)); J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units); Q0171 (Chlorpromazine hydrochloride, 10 mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen); Q0172 (Chlorpromazine hydrochloride, 25 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); Q0176 (Perphenazine, 8 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); Q0177 (Hydroxyzine pamoate, 25 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); and Q0178 (Hydroxyzine pamoate, 50 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).

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 \$90 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than \$90 (so that all HCPCS codes for the same drug or biological would be separately payable).

We did not receive any public comments on this proposal. Therefore, we are finalizing our CY 2014 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. The packaging status of each drug and biological HCPCS code to which this methodology will apply is displayed in Table 38 below.

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TABLE 38.—HCPCS CODES TO WHICH THE CY 2014 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2014 HCPCS Code	CY 2014 Long Descriptor	CY 2014 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1070	Injection, testosterone cypionate, up to 100 mg	N
J1080	Injection, testosterone cypionate, 1 cc, 200 mg	N
J1440	Injection, filgrastim (g-csf), 300 mcg	K
J1441	Injection, filgrastim (g-csf), 480 mcg	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
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

CY 2014 HCPCS Code	CY 2014 Long Descriptor	CY 2014 SI
Q0164	Prochlorperazine maleate, 5 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	N
Q0165	Prochlorperazine 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	N
Q0167	Dronabinol, 2.5 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	N
Q0168	Dronabinol, 5 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	N
Q0169	Promethazine hydrochloride, 12.5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0170	Promethazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0171	Chlorpromazine hydrochloride, 10 mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0172	Chlorpromazine hydrochloride, 25 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	N
Q0175	Perphenazine, 4 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	N
Q0176	Perphenazine, 8 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	N

CY 2014 HCPCS Code	CY 2014 Long Descriptor	CY 2014 SI
Q0177	Hydroxyzine pamoate, 25 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	N
Q0178	Hydroxyzine pamoate, 50 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	N

BILLING CODE 4120-01-C**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 2014 OPPS/ASC proposed rule (78 FR 43608), 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). We referred to this methodology as our standard drug payment methodology.

In CY 2010, 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” (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 overhead adjustment methodology through CY 2012, and further refined our overhead adjustment methodology 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 OPPI drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPI/ASC final rule with comment period (77 FR 68383 through 68385).

We noted in the CY 2013 OPPI/ASC final rule with comment period (77 FR 68386) that application of the standard drug payment methodology, with the overhead adjustment, has always yielded a finalized payment rate in the range of ASP+4 percent to ASP+6 percent for nonpass-through separately payable drugs. We stated that the historic ASP+4 to ASP+6 percentage range is an appropriate payment rate for separately payable drugs and biologicals administered within the HOPD, including acquisition and pharmacy overhead and related expenses. However, 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, 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.

In that final rule with comment period, we discussed that 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), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary. In the CY 2013 OPPI/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 OPPI. We also noted that ASP+6 percent is an appropriate payment amount because it is consistent with the range of payment amounts yielded by our drug payment methodologies over the past 7 years. Therefore, considering stakeholder and provider feedback, continued limitations of the hospital claims and cost data on drugs and biologicals, and Panel recommendations, in the CY 2013 OPPI/ASC final rule with comment period (77 FR 68389), 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, referred to as 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 biological for CY 2013 (77 FR 68389).

b. CY 2014 Payment Policy

In the CY 2014 OPPI/ASC proposed rule (78 FR 43608), we proposed to continue our CY 2013 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, referred to as 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. The commenters stated that ASP+6 percent is administratively simple, improves stability of drug and biological payments, and better covers the costs of drug acquisition and pharmacy overhead. 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. One commenter recommended that CMS design a payment strategy that would maintain the current ASP+6 percent for branded drug products but provide for a much higher payment rate for multi-source generic drugs.

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 2014 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 2014. With regard to the development of a multi-tiered payment strategy that would encourage the use of generic drugs over their branded counterparts, we made no such proposal and, therefore, consider this comment outside the scope of the proposed rule.

Comment: Some commenters recommended that CMS require hospitals to bill all drugs with HCPCS codes under revenue code 0636 in order to improve its data on packaged drugs.

Response: We do not accept the commenter's recommendation that CMS require drugs and biologicals to be reported under revenue code 0636. We believe that drugs and biologicals also may be appropriately reported in revenue code categories other than revenue code 0636, including, but not limited to, revenue codes 025x and 062x. As we stated in the CY 2011 OPPI/ASC final rule with comment period (75 FR 71966), we recognize that hospitals may carry the costs of drugs and biologicals in multiple cost centers and that it may not be appropriate to report the cost of all drugs and biologicals in one specified revenue code. In addition, we generally require hospitals to follow National Uniform Billing Committee (NUBC) guidance for the choice of an appropriate revenue code that is also appropriate for the hospital's internal accounting processes.

Comment: One commenter asked that, for CY 2014, CMS consider paying for influenza and PPV vaccines at 106 percent of ASP instead of paying for the items at reasonable cost.

Response: We consider this comment outside the scope of the proposed rule.

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 2014. 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, which illustrate the final CY 2014 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, 2013, or WAC, AWP, or mean unit cost from CY 2012 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 2014 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2014 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of 2013 (July 1, 2013 through September 30, 2013) are used to set the payment rates that are released for the quarter beginning in January 2014 near the end of December 2013. 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 2013 are based on mean unit cost in the available CY 2012 claims data. If ASP information becomes available for payment for the quarter beginning in January 2014, 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 2013 ASP data) that do not have ASP information available for the quarter beginning in January 2014. These drugs and biologicals will then be paid based on mean unit cost data derived from CY 2012 hospital claims. Therefore, the payment rates listed in Addenda A and B to this final rule with comment period are not for January 2014 payment purposes and are only illustrative of the CY 2014 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 2013, 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 2014. Therefore, in the CY 2014 OPPS/ASC proposed rule (78 FR 43609), we proposed for CY 2014 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 2012 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).

Comment: 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 ASP 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 radiopharmaceutical 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 which we believe would be inappropriate.

Comment: One commenter indicated that the proposed payment rate for the therapeutic radiopharmaceutical identified by HCPCS code A9517 (Iodine i-131 sodium iodide capsule(s), therapeutic, per millicurie) decreased by 54 percent compared to the CY 2013 payment rate and questioned the reason for this proposed reduction.

Response: The CY 2013 payment rate for HCPCS code A9517 is \$17.74 per millicurie. The proposed CY 2014 payment rate for HCPCS code A9517 was \$18.70, which is a 5.4 percent increase compared to the CY 2013 payment rate. The final CY 2014 payment rate for HCPCS code A9517 is \$18.52, which is a 4.4 percent increase compared to the CY 2013 payment rate.

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 are also finalizing our proposal to continue to rely on CY 2012 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable. The CY 2014 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 for Blood Clotting Factors

For CY 2013, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPSS and continued paying an updated furnishing fee. That is, for CY 2013, we provided payment for blood clotting factors under the OPSS 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 2013 updated furnishing fee was \$0.188 per unit.

In the CY 2014 OPSS/ASC proposed rule (78 FR 43609), for CY 2014, 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 OPSS is consistent with the methodology applied in the physician office and

inpatient hospital setting, and first articulated in the CY 2006 OPSS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPSS/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 with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPSS/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 OPSS/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 pay for blood clotting factors at ASP+6 percent and to continue to apply the furnishing fee for blood clotting factors provided in the OPD.

Response: We appreciate the commenters' support of our policy.

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 OPSS 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.

6. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes but Without OPSS Hospital Claims Data

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) did not address the OPSS 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 OPSS 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. For CYs 2008 and 2009, we finalized a policy to provide payment for new drugs (excluding contrast agents and diagnostic radiopharmaceuticals) and biologicals (excluding implantable biologicals for CY 2009) with HCPCS codes, but which did not have pass-through status and were without OPSS hospital claims data, at ASP+5 percent and ASP+4 percent, respectively, consistent with the final OPSS payment methodology for other separately payable drugs and biologicals. New therapeutic radiopharmaceuticals were paid at charges adjusted to cost based on the statutory requirement for CY 2008 and CY 2009 and payment for new diagnostic radiopharmaceuticals was packaged in both years.

For CY 2010, we continued to provide payment for new drugs (excluding contrast agents) and biologicals with HCPCS codes that do not have pass-through status and are without OPSS hospital claims data at ASP+4 percent, consistent with the CY 2010 payment methodology for other separately payable nonpass-through drugs and biologicals. We also finalized a policy to extend the CY 2009 payment methodology to new therapeutic radiopharmaceutical HCPCS codes, consistent with our final policy in the CY 2010 OPSS/ASC final rule with comment period (74 FR 60581 through 60526), providing separate payment for therapeutic radiopharmaceuticals that do not crosswalk to CY 2009 HCPCS codes, do not have pass-through status, and are without OPSS hospital claims data at ASP+4 percent. This policy was continued in CYs 2011, 2012, and 2013, paying for new drugs, biologicals, and

radiopharmaceuticals that do not have pass-through status, and are without OPPS hospital claims data at ASP+5 percent, ASP+4 percent, and ASP+6 percent, respectively, consistent with the final OPPS payment methodology for other separately payable drugs and biological during those payment years.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43610), we proposed to 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 2014 payment methodology for other separately payable nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals to pay at ASP+6 percent based on the statutory default. 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 2014, we also proposed 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 2014 HCPCS codes that do not crosswalk to predecessor HCPCS codes). This is consistent with the proposed policy packaging 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 the proposed rule and this final rule with comment period.

In accordance with the OPPS ASP methodology, in the absence of ASP data, for CY 2014, 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 noted 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 finalized ASP-based amount (proposed for CY 2014 at ASP+6 percent) for items that have not been granted pass-through status. This proposed policy, which utilizes the ASP methodology that requires us to use WAC data when ASP data are unavailable and 95 percent of AWP when WAC and ASP data are unavailable, 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 are also 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, we proposed to announce any changes to the payment amounts for new drugs and biologicals in this CY 2014 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2014 if later quarter ASP submissions (or more recent WACs or AWP) 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 2014 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 2014 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 2014 OPPS/ASC final rule with comment period.

There are several nonpass-through drugs and biologicals that were payable in CY 2012 and/or CY 2013 for which we did not have CY 2012 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 2014, 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 (78 FR 43610). This rationale was first adopted in the CY 2006 OPPS/ASC final rule with comment period (70 FR 68666 and 68667). We proposed to package items for which we estimated the per day administration cost to be less than or equal to \$90 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 package regardless of cost) in CY 2014. We also proposed that the CY 2014 payment for separately payable items without CY 2012 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 26 of the proposed rule (78 FR 43611).

Finally, there were 11 drugs and biologicals, shown in Table 27 of the proposed rule (78 FR 43612), that were payable in CY 2012 but for which we lacked CY 2012 claims data and any other pricing information for the ASP methodology for the CY 2014 OPPI/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. We continued this policy for CY 2011, CY 2012, and CY 2013 (75 FR 71973, 76 FR 74334, and 77 FR

68396, respectively). For CY 2014, we proposed to continue to assign status indicator “E” to drugs and biologicals that lack CY 2012 claims data and pricing information for the ASP methodology. All drugs and biologicals without CY 2012 hospital claims data and data based on the ASP methodology that were assigned status indicator “E” on this basis at the time of the proposed rule for CY 2014 were displayed in Table 27 of the proposed rule (78 FR 43612). We also proposed to continue our policy to assign the products status indicator “K” and pay for them separately for the remainder of CY 2014 if pricing information were to become available.

We did not receive any public comments on our CY 2014 proposals to provide payment for new drugs, biologicals, and therapeutic radiopharmaceuticals using the ASP methodology and to use an estimated per day cost in order to determine the packaging status of drugs and

biologicals for which we have pricing information available but do not have hospital claims data available.

Therefore, we are finalizing these proposals without modification. The final estimated units per day and status indicators for drugs and biologicals for which we have pricing information available but do not have hospital claims data available for CY 2014 are displayed in Table 39 below.

We also did not receive any public comments on our proposal to continue to assign status indicator “E” to drugs and biologicals that lack CY 2012 claims data and pricing information for the ASP methodology and, therefore, we are finalizing this proposal without modification. All drugs and biologicals without CY 2012 hospital claims data and data based on the ASP methodology that are assigned status indicator “E” on this basis at the time of this final rule with comment period for CY 2014 are displayed in Table 40 below.

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TABLE 39.—DRUGS AND BIOLOGICALS WITHOUT CY 2012 CLAIMS DATA

CY 2014 HCPCS Code	CY 2014 Long Descriptor	Estimated Average Number of Units Per Day	CY 2014 SI	CY 2014 APC
90581	Anthrax vaccine, for subcutaneous or intramuscular use	1	K	1422
J0205	Injection, alglucerase, per 10 units	420	K	0900
J0215	Injection, alefacept, 0. 5 mg	29	K	1633
J0364	Injection, apomorphine hydrochloride, 1 mg	1	N	N/A
J0725	Injection, chorionic gonadotropin, per 1,000 usp units	1	N	N/A
J1324	Injection, enfuvirtide, 1 mg	216	K	1361
J2724	Injection, protein c concentrate, intravenous, human, 10 iu	1540	K	1139
J2725	Injection, protirelin, per 250 mcg	4	K	1357
J2941	Injection, somatropin, 1 mg	1	N	N/A
J3355	Injection, urofollitropin, 75 iu	2	K	1741
J7196	Injection, antithrombin recombinant, 50 i. U.	268	K	1332
J7513	Daclizumab, parenteral, 25 mg	2	K	1612
J8562	Fludarabine phosphate, oral, 10 mg	1	N	N/A
J8650	Nabilone, oral, 1 mg	4	K	1424
J9216	Injection, interferon, gamma 1-b, 3 million units	1	K	0838
J9226	Histrelin implant (supprelin la), 50 mg	1	K	1142
J9300	Injection, gemtuzumab ozogamicin, 5 mg	1	K	9004
Q0515	Injection, sermorelin acetate, 1 microgram	70	K	3050

TABLE 40.—DRUGS AND BIOLOGICALS WITHOUT CY 2012 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

CY 2014 HCPCS Code	CY 2014 Long Descriptor	CY 2014 SI
90393	Vaccina immune globulin, human, for intramuscular 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
J0395	Injection, arbutamine hcl, 1 mg	E
J1180	Injection, dyphylline, up to 500 mg	E
J1435	Injection estrone per 1 MG	E
J1446	Injection, TBO-Filgrastim, 5 micrograms	E
J1562	Injection, immune globulin (vivaglobin), 100 mg	E
J1620	Injection, gonadorelin hydrochloride, per 100 mcg	E
J1730	Injection, diazoxide, up to 300 mg	E
J1835	Injection, itraconazole, 50 mg	E
J2460	Injection, oxytetracycline hcl, up to 50 mg	E
J2725	Injection, protirelin, per 250 mcg	E
J2940	Injection, somatrem, 1 mg	E
J3365	Injection, iv, urokinase, 250,000 i.u. vial	E
J9165	Injection, diethylstilbestrol diphosphate, 250 mg	E
J9219	Leuprolide acetate implant, 65 mg	E
Q0515	Injection, sermorelin acetate, 1 microgram	E

BILLING CODE 4120-01-C**C. Nuclear Medicine Procedure-to-Radiolabeled Product Edits**

Beginning January 1, 2008, CMS implemented OPPS edits that require hospitals to include a HCPCS code for a radiolabeled product when a separately payable nuclear medicine procedure is present on a claim. In the CY 2014 OPPS/ASC proposed rule (78 FR 43612), we proposed to no longer require the nuclear medicine procedure-to-radiolabeled product edits. Under this proposal, hospitals would still be expected to adhere to the guidelines of correct coding and append the correct radiolabeled product code to the claim

when applicable. However, claims would no longer be returned to providers when HCPCS codes for radiolabeled products do not appear on claims with nuclear medicine procedures.

Comment: Several commenters indicated that CMS should continue to apply the nuclear medicine procedure-to-radiolabeled product edits to ensure that all packaged costs are included on nuclear medicine claims in order to establish appropriate payment rates in the future.

Response: We do not agree with commenters that we should continue the nuclear medicine procedure-to-radiolabeled product edits. We believe

that hospitals have now had several years of experience reporting procedures involving radiolabeled products and have grown accustomed to ensuring that they code and report charges so that their claims fully and appropriately reflect the costs of those radiolabeled products. 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.

After consideration of the public comments we received, we are finalizing our proposal to no longer require the nuclear medicine procedure-to-radiolabeled product edits. Hospitals

will still be expected to adhere to the guidelines of correct coding and append the correct radiolabeled product code to the claim when applicable.

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 2014 entails estimating spending for two groups of items. The first group of items consists of device categories that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2014. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2013 or beginning in CY 2014. The sum of the CY 2014 pass-through estimates for these two groups of device categories equals the total CY 2014 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 2013 OPPS/ASC final rule with comment period (77 FR 68397). 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), we include an estimate of any implantable biologicals 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 proposed to be reinstated for CY 2014. Because we will pay for most nonpass-through separately payable drugs and biologicals under the CY 2014 OPPS at ASP+6 percent, as we discussed in section V.B.3. of this final rule with comment period, which represents the otherwise applicable fee schedule amount associated with most pass-through drugs and biologicals, and because we will pay for CY 2014 pass-through drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of this final rule with comment period, our estimate of drug and biological pass-through payment for CY 2014 for this group of items was \$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, as we proposed, we are policy-

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 for CY 2014, as discussed in section II.A.3. of this final rule with comment period. All of these policy-packaged drugs and biologicals with pass-through status will be paid at ASP+6 percent like other pass-through drugs and biologicals for CY 2014. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through status approved prior to CY 2014 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 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 2014. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2013 or beginning in CY 2014. The sum of the CY 2014 pass-through estimates for these two groups of drugs and biologicals equals the total CY 2014 pass-through spending estimate for drugs and biologicals with pass-through status.

B. Estimate of Pass-Through Spending

As we proposed in the CY 2014 OPPS/ASC proposed rule (78 FR 43613), we are setting the applicable pass-through payment percentage limit at 2.0

percent of the total projected OPPS payments for CY 2014, consistent with section 1833(t)(6)(E)(ii)(II) of the Act, and our OPPS policy from CY 2004 through CY 2013 (77 FR 68398).

For the first group of devices for pass-through payment estimation purposes, there is one device category, C1841 (Retinal prosthesis, includes all internal and external components), receiving pass-through payment for CY 2013, made effective subsequent to the proposed rule on October 1, 2013, that will continue to be eligible for pass-through payment for CY 2014. As discussed in section IV.A. of this final rule with comment period, we finalized in the CY 2013 OPPS/ASC final rule with comment period the expiration of pass-through payment for three device categories after the end of CY 2013. Therefore, we estimate that CY 2014 pass-through expenditures for the first group of pass-through device categories to be \$0.5 million. In estimating our CY 2014 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 2014 (of which there are none); 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, 2014; and contingent projections for new device categories established in the second through fourth quarters of CY 2014. We are using 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.

We did not receive any public comments regarding our proposed estimate for device pass-through spending. For this final rule with comment period, the estimate of CY 2014 pass-through spending for this second group of device categories is \$9.5 million, which is a slight decrease from the \$10 million estimate in the proposed rule (78 FR 43613). Using our established methodology, we are establishing that the total estimated pass-through spending for device categories for CY 2014 (spending for the first group of device categories (\$0.5 million) plus spending for the second group of device categories (\$9.5 million)) will be \$10 million.

To estimate CY 2014 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 status for CY 2014, we utilized the most recent Medicare physician's office 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 2014 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 status in CY 2014, 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 include in the CY 2014 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 determined that the 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. For the proposed rule, using the methodology described above, we calculated a CY 2014 proposed spending estimate for this first group of drugs and biologicals of approximately \$0.962 million.

We did not receive any public comments on our proposed methodology for calculating the spending estimate for the first group of drugs and nonimplantable biologicals. Therefore, for this final rule with comment period, we are finalizing our proposed methodology. Using our established methodology and updated data and information, we calculated a final CY 2014 spending estimate for the first group of drugs and nonimplantable biologicals of approximately \$1.4 million.

To estimate CY 2014 pass-through spending for drugs and biologicals in the second group (that is, drugs and

biologicals that we knew at the time of development of the final rule are newly eligible for pass-through payment in CY 2014, additional drugs and biologicals that we estimate could be approved for pass-through status subsequent to the development of the final rule and before January 1, 2014, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2014), we 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 2014 pass-through payment estimate. We also consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2014 pass-through payments for this second group of drugs, we calculated a spending estimate for this second group of drugs and biologicals of approximately \$0.165 million.

We did not receive any public comments on our proposed methodology for estimating CY 2014 pass-through payments for this second group of drugs and nonimplantable biologicals. Therefore, for this final rule with comment period, we are finalizing our proposed methodology. Using that methodology and updated data and information, we calculated a final CY 2014 spending estimate for this second group of drugs and implantable biologicals of approximately \$0.9 million.

As discussed in section V.A. of this final rule with comment period, radiopharmaceuticals are considered drugs for pass-through purposes. Therefore, we include radiopharmaceuticals in our CY 2014 pass-through spending estimate for drugs and biologicals. Our CY 2014 estimate for total pass-through spending for drugs and biologicals (spending for the first group of drugs and biologicals (\$1.4 million) plus spending for the second group of drugs and biologicals (\$0.9 million)) equals \$2.3 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 2014 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2014 will be approximately \$12.3 million

(approximately \$10 million for device categories and approximately \$2.3 million for drugs and biologicals), which represents 0.02 percent of total projected OPPS payments for CY 2014. We estimate that pass-through spending in CY 2014 will not amount to 2.0 percent of total projected OPPS CY 2014 program spending.

VII. OPPS Payment for Hospital Outpatient Visits

A. Background

Currently, hospitals report HCPCS visit codes to describe three types of OPPS services: clinic visits, emergency department (ED) visits, and critical care services, including trauma team activation. Historically, we have recognized the CPT and HCPCS codes

describing clinic visits, Type A and Type B (ED) visits, and critical care services, which are listed below in Table 41. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74338 through 74346) for a full discussion of our policy on OPPS payment for hospital outpatient visits for CY 2013 and prior years.

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TABLE 41.—CY 2013 HCPCS CODES USED TO REPORT CLINIC AND EMERGENCY DEPARTMENT VISITS AND CRITICAL CARE SERVICES

CY 2013 HCPCS Code	CY 2013 Descriptor
Clinic Visit HCPCS Codes	
99201	Office or other outpatient visit for the evaluation and management of a new patient (Level 1)
99202	Office or other outpatient visit for the evaluation and management of a new patient (Level 2)
99203	Office or other outpatient visit for the evaluation and management of a new patient (Level 3)
99204	Office or other outpatient visit for the evaluation and management of a new patient (Level 4)
99205	Office or other outpatient visit for the evaluation and management of a new patient (Level 5)
99211	Office or other outpatient visit for the evaluation and management of an established patient (Level 1)
99212	Office or other outpatient visit for the evaluation and management of an established patient (Level 2)
99213	Office or other outpatient visit for the evaluation and management of an established patient (Level 3)
99214	Office or other outpatient visit for the evaluation and management of an established patient (Level 4)
99215	Office or other outpatient visit for the evaluation and management of an established patient (Level 5)
Emergency Department Visit HCPCS Codes	
99281	Emergency department visit for the evaluation and management of a patient (Level 1)
99282	Emergency department visit for the evaluation and management of a patient (Level 2)
99283	Emergency department visit for the evaluation and management of a patient (Level 3)
99284	Emergency department visit for the evaluation and management of a patient (Level 4)
99285	Emergency department visit for the evaluation and management of a patient (Level 5)
G0380	Type B emergency department visit (Level 1)
G0381	Type B emergency department visit (Level 2)

G0382	Type B emergency department visit (Level 3)
G0383	Type B emergency department visit (Level 4)
G0384	Type B emergency department visit (Level 5)
Critical Care Services HCPCS Codes	
99291	Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes
99292	Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes
G0390	Trauma response associated with hospital critical care service

B. 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 through 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 appears to be broadly endorsed by the stakeholder community.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43614 through 43616), for CY 2014, we proposed to modify our longstanding policies related to hospital outpatient clinic and ED visits. Rather than recognizing five levels of clinic and

ED visits respectively, we proposed to create three new alphanumeric Level II HCPCS codes to describe all levels of each type of clinic and ED visit, as discussed in greater detail below. We stated that we believe a policy that recognizes a single visit level for clinic visits, Type A ED visits, and Type B ED visits for payment under the OPPS is appropriate for several reasons. First, we indicated that the proposal is in line with our strategic goal of using larger payment bundles to maximize hospitals' incentives to provide care in the most efficient manner as stated in section II.A.3. of the proposed rule. We stated that we believed this proposal will remove any incentives hospitals may have to provide medically unnecessary services or expend additional, unnecessary resources to achieve a higher level of visit payment under the OPPS. Second, we stated that we believe that it is important to consider ways in which we can reduce the administrative burden that Medicare payment policies place on hospitals, while maintaining our ability to calculate accurate payment rates under the OPPS. We believed that replacing the 20 HCPCS codes currently recognized for clinic visits and ED visits with three new alphanumeric Level II HCPCS codes would reduce administrative burden and would be easily adopted by hospitals, because the three new codes would require hospitals to distinguish only among clinic visits, Type A ED visits, and Type B ED visits. We stated that discontinuing the use of the five levels of HCPCS visit codes for clinic and Type A and Type B ED visits would reduce hospitals' administrative burden by eliminating the need for them to develop and apply their own internal guidelines to differentiate among five levels of resource use for every clinic visit and ED visit they provide, and by eliminating the need to distinguish between new and established patients. Third, we stated that our proposal would allow a large universe of claims

to be utilized for ratesetting for each of the three newly proposed alphanumeric Level II HCPCS visit codes. We stated that we believe this large volume of claims available for ratesetting for each of the newly proposed alphanumeric Level II HCPCS visit codes will allow us to capture a very broad spectrum of cases ranging from extremely low complexity cases to extremely high complexity cases. We believed this large and diverse spectrum of clinical complexity and resource variation within the claims as well as the very high volume of claims that we proposed to use for ratesetting for the newly proposed alphanumeric Level II HCPCS visit new codes will allow us to have very accurate data upon which to develop accurate and appropriate payments. Lastly, we also stated that we believe that removing the differentiation among five levels of intensity for each visit will eliminate any incentive for hospitals to "upcode" patients whose visits do not fall clearly into one category or another.

For these reasons, for CY 2014, we proposed to discontinue our longstanding policy of recognizing five distinct visit levels for clinic visits and ED visits based on the existing HCPCS E/M codes, and instead recognize three new alphanumeric HCPCS codes for each visit type. Specifically, we proposed to create a new alphanumeric HCPCS G-code for hospital use only representing any clinic visit under the OPPS and to assign the newly created alphanumeric clinic visit HCPCS G-code to its own newly created APC 0634. Using CY 2012 claims data, we proposed to develop CY 2014 OPPS payment rates for the new HCPCS G-code based on the total geometric mean cost of the levels 1 through 5 CPT E/M codes for clinic visits currently recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). We stated that while we would use data for CPT codes 99201 through 99205 and 99211 through 99215 from

claims billed in CY 2012 to calculate the geometric mean cost for new APC 0634, we would no longer recognize those CPT codes when they appear on hospital claims effective January 1, 2014. We also proposed to no longer recognize a distinction between new and established patient clinic visits. Under this proposal, all clinic visits would be reported using the new HCPCS G-code, regardless of whether or not the patient has been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit.

In addition, in the CY 2014 OPSS/ASC proposed rule (78 FR 43614 through 43617), we proposed to discontinue our longstanding policy of recognizing five distinct visit levels for Type A ED visits and instead proposed to create a new alphanumeric HCPCS G-code for hospital use only representing any Type A ED visit under the OPSS. We proposed to assign the newly created alphanumeric Type A ED visit HCPCS G-code to its own newly created APC 0635. Using CY 2012 claims data, we proposed to develop CY 2014 OPSS payment rates for new HCPCS G-code based on the total geometric mean cost of the levels 1 through 5 CPT E/M codes for Type A ED visits currently recognized under the OPSS (CPT codes 99281 through 99285). We stated that while we would use data for CPT codes 99281 through 99285 from claims billed in CY 2012 to calculate the geometric mean cost for new APC 0635, we would no longer recognize those CPT codes when they appear on hospital claims effective January 1, 2014. Similarly, we also proposed to discontinue our longstanding policy of recognizing five distinct visit levels for Type B ED visits and instead proposed to create a new alphanumeric HCPCS G-code representing all Type B ED visits under the OPSS. We proposed to assign the newly created alphanumeric Type B ED visit HCPCS G-code to its own newly created APC 0636. Using CY 2012 claims data, we proposed to develop CY 2014 OPSS payment rates for new HCPCS G-code based on the total geometric mean cost of the levels 1 through 5 HCPCS codes for Type B ED visits currently recognized under the OPSS (HCPCS codes G0380 through G0384). We stated that while we would use data for HCPCS codes G0380 through G0384 from claims billed in CY 2012 to calculate the geometric mean cost for new APC 0636, we would no longer recognize those HCPCS codes for Type B ED visits when they appear on hospital claims effective January 1, 2014.

We noted that we would use the hospital claims data for the three new

HCPCS G-codes when available for future ratesetting. We summarized the proposed changes to the visit coding and payment structure in Table 29 of the proposed rule (78 FR 43616). We welcomed public comments on our CY 2014 proposal to recognize a single visit level for clinic, Type A ED, and Type B ED visits for payment under the OPSS. We stated that we believe this proposal will allow us to make accurate payments for visits broad-scale because we will be using data from the universe of hospital outpatient visits, for which we have an extremely high volume of claims representing the entire spectrum of costs incurred by hospitals. Nonetheless, we indicated that we were interested in hearing from stakeholders regarding whether a different approach may be preferable to capture the resource utilization for extremely low complexity cases as well as extremely high complexity cases or to otherwise recognize a difference among visit levels. We stated that while we do not believe, based on our current assessment, that it is necessary to provide additional payment levels or carve out these cases to make accurate and appropriate payments for visits, we were interested in hearing from hospitals whether there are certain cases that would not be best accommodated by a single level of payment. If such cases exist, we welcomed stakeholder input into whether and how this proposal could be changed in the final rule to either make exceptions for or accommodate these special cases. We stated that if commenters provided compelling comments describing such special cases or the need for additional payment levels, should they exist, and if there are alternative policies that would more accurately and appropriately pay for visits, we would consider implementing a different policy in the final rule. We noted that, to the extent that commenters recommended that additional levels of payment or special high complexity or low complexity cases be recognized, we also would be interested in how we should define and differentiate those levels or cases.

Comment: Commenters specifically opposed CMS' proposal to collapse the current five levels of ED visits into a single visit level for both Type A and Type B ED visits. Commenters stated that the proposed single payment for Type A ED and Type B ED visits captures too broad a range of ED visits, which could result in payment rates that are inadequate for treatment of beneficiaries who require higher levels of care. Commenters also stated that a

single ED visit level would result in higher copayment amounts for beneficiaries receiving services consistent with a lower level ED visit. Commenters expressed concern that hospitals would pressure physicians and hospital staff to reduce the time in the ED to lessen the potential loss of revenues associated with a single level ED visit payment, potentially leading to a deterioration of patient care.

Commenters argued that the proposed ED visit policy is inequitable to hospitals that consistently have a more complex case-mix and a greater than average utilization of the higher level ED visit codes, such as trauma centers, teaching hospitals, and hospitals that have taken steps to shift lower-acuity ED patients into Type B EDs or onsite or nearby urgent care clinics.

Commenters urged CMS to exclude trauma care from any consolidation of ED payment levels to ensure that designated trauma centers are fairly paid for the care they provide. Commenters expressed reservations about a single payment for ED visits in light of a potential increase in ED usage and ED patient acuity due to newly insured individuals having access to care under the Affordable Care Act.

Commenters also argued that there is a bias toward lower level visit code costs in calculating the geometric mean cost for the new collapsed visit codes as higher level visit codes are more often billed with separately paid procedures on the same day of service. Commenters expressed additional reservations with the proposed policy in light of their inability to conduct impact analysis on the proposed policy due to initial errors in the CY 2014 OPSS/ASC proposed rule data. Commenters also stated the proposed policy removes CMS' ability to track and document differences in patient acuity and is inconsistent with CMS' previously stated purpose in creating Medicare Severity Diagnosis-Related Groups (MS-DRGs) under the IPPS to account for differences in costs due to differences in patient severity.

Moreover, commenters stated that the proposed policy should not be implemented in CY 2014 due to its interaction with CMS' proposal to expand packaging of services and hospitals' administrative training sessions currently underway to implement International Classification of Diseases, 10th Edition (ICD-10). Commenters asserted that the proposed policy would create added administrative burden as other payers will continue to require the reporting of the five E/M code levels. Commenters suggested that CMS work with the AMA to develop facility-specific CPT codes

for Type A ED and Type B ED visits and seek input from industry stakeholders, specifically hospital representatives, to develop descriptions for these new codes that allow for their consistent application by hospital outpatient departments. Commenters also recommended that CMS develop hospital-specific national guidelines for hospitals to report ED visits.

Commenters stated that they did not understand why this proposal is necessary in light of CMS' previous statements that hospitals are generally billing appropriately and in a consistent manner that distinguishes among the different levels of visits based on the required hospital resources and CMS' current utilization of Comprehensive Error Rate Testing (CERT), Recovery Audit Contractors (RACs), Zone Program Integrity Contractors (ZPICs), and other methods of review to identify medically unnecessary services. Commenters stated that CMS should conduct selected focused audits in lieu of the proposed policy if CMS believes that hospitals are upcoding.

Response: We appreciate all of the public comments we received on our proposal to collapse the current five levels of ED visits into a single visit level for both Type A and Type B ED visits. We specifically sought comment on whether there are certain high or low complexity cases that would not be best accommodated by a single level of payment. We stated in the proposed rule that, if such cases exist, we would welcome stakeholder input into whether and how this proposal could be changed in the final rule to either make exceptions for or accommodate these special cases. We also stated in the proposed rule that if commenters provided compelling comments describing such special cases or the need for additional payment levels, should they exist, and if there are alternative policies that would more accurately and appropriately pay for visits, we would consider implementing a different policy in the final rule. As discussed above, we received several comments that a single payment for an ED visit might underrepresent resources required to treat the most complex patients, such as trauma patients. We find this to be a compelling issue, for which an alternative payment structure, possibly including more than one payment level, may be warranted. However, at this time, additional study is 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. For CY 2014, we believe it is 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. We will maintain the current coding structure consisting of five visit levels for CY 2014 while we consider alternative payment structures.

Comment: Commenters suggested the following alternatives to our proposed policy: One commenter requested that CMS alter its proposal and create one APC for Type A ED and Type B ED visits as proposed, but continue to allow the reporting of the current CPT E/M codes instead of creating new HCPCS codes. Multiple commenters suggested that CMS employ a three acuity level model to pay for Type A ED and Type B ED visits under the OPPIs. Another commenter suggested CMS continue to use the current CPT codes for clinic E/M services but assign the CPT codes to one of three ED Visit APCs. One commenter suggested CMS create three composite ED services based on the ancillary services packaged with ED claim. A few commenters 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 thoughtful and detailed alternatives presented by commenters. We need additional time to study and fully consider these alternatives and other comments received with respect to how our proposed ED visits policy would affect payments for the most complex patients. We believe it is best to delay any change in ED visit coding while we consider further the most appropriate payment structure for Type A and Type B ED visits.

Comment: Commenters generally opposed our proposal to create a single new alphanumeric HCPCS G-code for hospital use only representing all clinic visits under the OPPIs and to assign the newly created alphanumeric clinic visit HCPCS G-code to its own newly created APC 0634. Some commenters raised similar concerns about a single payment for clinic visits as they did for ED visits, although there were fewer objections to a single payment for clinic visits and those objections lacked the forcefulness and specificity of the objections to a single level of payment for Type A and Type B ED visits. A few commenters stated that, while they did not favor a single payment for clinic visits, given the nature of the services provided at clinic visits, a single payment level would be acceptable. A majority of commenters supported CMS' proposal

to eliminate the distinction between "new" and "established" patient visits. As with ED visits, commenters stated that the proposed single clinic visit code and associated single payment are overly broad, which could result in payment rates that are inadequate for treatment of beneficiaries who require higher levels of care and higher copayment amounts for beneficiaries receiving lower level visits. Commenters expressed concern that hospitals would pressure physicians and hospital staff to reduce the time in clinic visits to lessen the potential loss of revenues associated with a single level clinic visit payment, potentially leading to a deterioration of patient care. Commenters asserted that the proposed policy would create added administrative burden as other payers will continue to require the reporting of the five E/M CPT codes to describe clinic visits. Commenters argued that the proposed policy is inequitable to many tertiary care and teaching hospitals, including those hospitals that consistently have a more complex case-mix and a greater than average utilization of the higher level E/M codes. Commenters also argued there is a likely bias toward lower level visit code costs in calculating the geometric mean cost for the new collapsed visit codes as higher level visit codes are more often billed with separately paid procedures on the same day of service. Commenters expressed additional reservations with the proposal in light of their inability to conduct impact analysis on the proposed policy due to initial errors in the CY 2014 OPPIs/ASC proposed rule data. Commenters stated that the proposed policy removes CMS' ability to track and document differences in patient acuity and is inconsistent with CMS' previously stated purpose in creating MS-DRGs under the IPPS to account for differences in costs due to differences in patient severity. Moreover, commenters stated the proposed policy should not be implemented in CY 2014 due to its interaction with CMS' proposal to expand packaging and hospitals' administrative training sessions currently underway to implement ICD-10. Commenters suggested CMS work with the 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, specifically hospital representatives, to develop descriptions for these new codes that allow for their consistent application by hospital outpatient clinics. Commenters also recommended that CMS develop

hospital-specific national guidelines for hospitals to report clinic visits.

Commenters expressed a lack of understanding of why this proposal is necessary in light of CMS' previous statements that hospitals are generally billing appropriately and in a consistent manner that distinguishes among the different levels of visits based on the required hospital resources and CMS' current utilization of CERT, RACs, ZPICs, and other methods of review to identify medically unnecessary services. Commenters stated that CMS should conduct selected focused audits in lieu of the proposed policy if CMS believes that hospitals are upcoding.

Response: We appreciate all of the public comments we received on our proposed policy to create a single new alphanumeric HCPCS G-code for hospital use only representing any clinic visit under the OPPI and the assignment of the newly created alphanumeric clinic visit HCPCS G-code to its own newly created APC 0634. We disagree with the commenters that the proposed clinic visit code is overly broad. While we agree that the proposed clinic APC encompasses a range of visits for beneficiaries with different medical issues, 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 a 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 do not observe wide disparity among the estimated geometric mean costs for new or established clinic visits in our data, and there is significantly less disparity in estimated geometric mean costs among the current five clinic visit levels than there is among the five ED visit levels.

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 the newly created alphanumeric Level II HCPCS clinic visit code 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 overall case-mix. We also note that the range among the geometric mean cost of the current five clinic visit levels is much smaller than the range for the current five levels of ED visits. In addition, the commenters' support for eliminating distinctions for new and established patients suggests that hospitals prefer the administrative ease of not tracking new or established patients even though we make differential payment for these visits, and we observe differential costs for these CPT codes in our claims data.

We disagree with the commenters' statement that there is a likely bias toward including more lower level visit code costs in calculating the geometric mean cost for the new collapsed visit codes. Commenters have argued that higher level visit codes are more often billed with separately paid procedures on the same day of service and that we are less likely to be able to isolate claims with a single higher level CPT code. For clinic visits, we observed comparable distributions of claims between higher and lower levels across new and established clinic visit CPT codes in both the single bill claims used for ratesetting and all claims. We concluded that the distribution of claims data among higher and lower level CPT codes used to establish the proposed payment rate for APC 0634 is comparable to the total distribution of claims among CPT code levels in the CY 2012 claims data in our CPT cost files. We do not believe that our single bill methodology biases the resulting geometric mean in any way.

We disagree with commenters that our proposal for a single payment is contrary to CMS' stated purpose in creating MS-DRGs under the IPPS to account for differences in costs due to differences in patient severity. MS-DRGs are designed to reflect significant differences in resource costs for an inpatient stay. The MS-DRG classification of a particular discharge is based, as appropriate, on the patient's age, sex, principal diagnosis (that is, the diagnosis established after study to be chiefly responsible for causing the patient's admission to the hospital), secondary diagnoses, procedures performed, and discharge status. A single payment for a clinic visit does not pose the same level of financial risk. The observed cost differences among levels of CPT codes in the claims data are not dramatic. Further, hospitals will receive separate payment for many other

services furnished in the same encounter and will not incur the same level of financial risk as for an inpatient stay.

Regarding the commenters' inability to conduct impact analysis on our visit proposal because of some initial limited errors in the proposed rule payment files, we note that we released corrected data files on August 28, 2013, and extended the comment period to September 16, 2013, on the technical corrections noted in the correcting document published in the **Federal Register** on September 6, 2013 (78 FR 54842). For a more detailed discussion of the OPPI data process, we refer readers to section II.A. of this final rule with comment period.

We disagree with the commenters that hospitals would pressure physicians and hospital staff to furnish a diminished level of care to beneficiaries in an attempt to mitigate any potential loss of revenue associated with a single level clinic visit payment that is based on an average of relative costs of all clinic visit codes and is proportional to their appearance in the claims data. As with all prospective payment systems that depend upon a prospectively established payment derived from relative cost, less costly cases generate greater net revenue for the hospital than more costly cases. Payments may be greater than or less than the cost of any particular case. It is our belief and continued expectation that hospitals and physicians and other practitioners will furnish appropriate care to Medicare beneficiaries.

We continue to believe discontinuing the use of the five levels of HCPCS visit codes for clinic visits will reduce hospitals' administrative burden by eliminating the need for them to develop and apply their own internal guidelines to differentiate among five levels of resource use for every clinic visit they provide. We believe the advantages of this reduced administrative burden outweigh any potential loss in CMS' ability to track and document differences in patient acuity for clinic visits. We note that the level of CPT code is not the only method for assessing patient acuity. Diagnosis coding and the type and frequency of other services billed on a visit claim also communicate patient acuity. We disagree with the commenters that finalization of our proposed clinic visit policy should be delayed because of our CY 2014 proposal to expand packaging or the presence of hospital training sessions to implement ICD-10 coding. We note that our CY 2014 OPPI packaging policies create no additional administrative

burden for hospital coding for visits. We continue to expect hospitals to correctly code for the services they furnish. We also believe that the combination of a single HCPCS G-code to describe all clinic visits, the discontinuance of the requirement that hospitals track criteria for billing either new or established clinic visits, and the discontinuance of the requirement for hospitals to distinguish different clinic visit levels through internal guidelines will result in significant administrative simplification for hospitals.

With regard to national guidelines, we have stated that it would be desirable to many hospitals to have national guidelines (76 FR 74345 through 74346). However, we also understand that it would be disruptive and administratively burdensome to other hospitals that have successfully adopted internal guidelines to implement any new set of national guidelines. 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, we would consider such codes for OPPI use.

With regard to the comment that the proposal is unexpected, each annual rulemaking cycle includes some proposed policy changes to the OPPI, and some of those proposals may be more or less predictable. We believe that, despite hospitals' use of internal guidelines, differentiating between five different clinic visit levels is challenging because the difference between consecutive levels is incremental and nuanced. A single code and a single level of payment for all clinic visits eliminate the difficulty of distinguishing, for example, a level 1 clinic visit versus a level 2, or a level 2 versus a level 3, etc. A single code also negates the ability or incentive for hospitals to "upcode" patients whose visits do not fall clearly into one

category or another, and removes any financial advantage to any hospitals that would engage in upcoding in the future.

Comment: Commenters suggested the following alternatives to our proposed policy: One commenter suggested that CMS alter its proposal and create one APC for each type of E/M visit per encounter as proposed, but continue to allow the reporting of the current CPT E/M codes instead of creating new HCPCS codes. Multiple commenters suggested that CMS employ a three acuity level model to pay for clinic visits under the OPPI. Another commenter suggested that CMS continue to use the current CPT codes for clinic E/M services but assign the CPT codes to one of two Clinic Visit APCs.

Response: We appreciate the thoughtful and detailed suggestions presented by the commenters. We continue to believe that creating a new HCPCS code is more appropriate than maintaining the current CPT coding and then creating a separate payment. Separate CPT codes would continue to require guidelines. It also would be more difficult to eliminate the distinction between new and established clinic visits while continuing to recognize CPT codes that make that distinction. With regard to creating three APCs rather than one, we do not believe this achieves the incentive for efficiency associated with a single clinic visit code, and that three APCs would maintain some of the same incentives in the current five levels of APCs. At this time we believe that collapsing the existing five levels of clinic visit codes into one new alphanumeric HCPCS G-code and assigning this code to new APC 0634 is the optimal OPPI payment policy for clinic visits.

After consideration of the public comments we received, we are finalizing our proposal to create a new alphanumeric HCPCS code, G0463 (Hospital outpatient clinic visit for

assessment and management of a patient), for hospital use only representing any clinic visit under the OPPI and to assign new HCPCS code G0463 to new APC 0634. We also are finalizing our proposal to use CY 2012 claims data to develop CY 2014 OPPI payment rates for the new 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 OPPI (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we are finalizing our proposal to no longer recognize a distinction between new and established patient clinic visits.

We are not finalizing our proposal for CY 2014 to discontinue our longstanding policy of recognizing five distinct visit levels for Type A ED visits and to create a new alphanumeric HCPCS G-code for hospital use only representing any Type A ED visit under the OPPI. Similarly, we are not finalizing our proposal for CY 2014 to discontinue our longstanding policy of recognizing five distinct visit levels for Type B ED visits and to create a new alphanumeric HCPCS G-code for hospital use only representing any Type B ED visit under the OPPI. In addition, we are not finalizing our proposal to assign the newly created alphanumeric Type A ED visit HCPCS G-code to its own newly created APC 0635, nor are we finalizing our proposal to assign the newly created alphanumeric Type B ED visit HCPCS G-code to its own newly created APC 0636. Instead, we will 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 establish the CY 2014 OPPI payment under our established standard process (77 FR 68399 through 68404). These codes and their APC assignments for CY 2013 compared to their APC assignments for CY 2014 are depicted below in Table 42.

TABLE 42.—CY 2013 CLINIC AND EMERGENCY DEPARTMENT VISIT HCPCS CODES AND APC ASSIGNMENTS COMPARED TO CY 2014 CLINIC AND EMERGENCY DEPARTMENT VISIT HCPCS CODES AND APC ASSIGNMENTS

Visit Type	CY 2013		CY 2014	
	HCPCS Code	APC	HCPCS Code	APC
CLINIC VISIT	99201	0604	G0463	0634
	99202	0605		
	99203	0606		
	99204	0607		
	99205	0608		
	99211	0604		
	99212	0605		
	99213	0605		
	99214	0606		
	99215	0607		
TYPE A ED VISIT	99281	0609	99281	0609
	99282	0613	99282	0613
	99283	0614	99283	0614
	99284	0615	99284	0615
	99285	0616	99285	0616
TYPE B ED VISIT	G0380	0626	G0380	0626
	G0381	0627	G0381	0627
	G0382	0628	G0382	0628
	G0383	0629	G0383	0629
	G0384	0630	G0384	0630

We intend to further explore the issues described above related to ED visits, for example, concerns about excessively costly patients, such as trauma patients, and potential alternatives that commenters provided to address this issue. We may propose changes to the coding and APC assignments for ED visits in future rulemaking.

C. Payment for Critical Care Services

In the CY 2014 OPPI/ASC proposed rule (78 FR 43616 through 43617), we proposed to continue the methodology established in the CY 2011 OPPI/ASC final rule with comment period for calculating a payment rate for critical care services that includes packaged payment of ancillary services. For CY 2010 and in prior years, the AMA CPT Editorial Panel defined critical care 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)) to include a wide range of ancillary services such as electrocardiograms, chest X-rays, and pulse oximetry. As we have stated in manual instruction, we expect hospitals to report in accordance with CPT guidance unless we instruct otherwise. For critical care in particular, we instructed hospitals that any services that the CPT Editorial Panel indicates are included in the reporting of CPT code 99291 (including those services that would otherwise be reported by and paid to hospitals using any of the CPT codes specified by the CPT Editorial Panel) should not be billed separately. Instead, hospitals were instructed to report charges for any services provided as part of the critical care services. In establishing payment rates for critical

care services and other services, CMS packages the costs of certain items and services separately reported by HCPCS codes into payment for critical care services and other services, according to the standard OPPI methodology for packaging costs (Medicare Claims Processing Manual, Pub. 100–04, Chapter 4, Section 160.1).

For CY 2011, the AMA CPT Editorial Panel revised its guidance for the critical care codes to specifically state that, for hospital reporting purposes, critical care codes do not include the specified ancillary services. Beginning in CY 2011, hospitals that report in accordance with the CPT guidelines should report all of the ancillary services and their associated charges separately when they are provided in conjunction with critical care. Because the CY 2011 payment rate for critical care services was based on hospital claims data from CY 2009, during which time hospitals would have reported

charges for any ancillary services provided as part of the critical care services, we stated in the CY 2011 OPPTS/ASC final rule with comment period that we believed it was inappropriate to pay separately in CY 2011 for the ancillary services that hospitals may now report in addition to critical care services (75 FR 71988). Therefore, for CY 2011, we continued to recognize the existing CPT codes for critical care services and established a payment rate based on historical data, into which the cost of the ancillary services was intrinsically packaged. We also implemented 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 noted in the CY 2011 OPPTS/ASC final rule with comment period that the payment status of the ancillary services would not change when they are not provided in conjunction with critical care services. We assigned status indicator "Q3" (Codes That May Be Paid Through a Composite APC) to the ancillary services to indicate that payment for these services is packaged into a single payment for specific combinations of services and made through a separate APC payment or packaged in all other circumstances, in accordance with the OPPTS payment status indicated for status indicator "Q3" in Addendum D1 to the CY 2011 OPPTS/ASC final rule with comment period. The ancillary services that were included in the definition of critical care prior to CY 2011 and that are conditionally packaged into the payment for critical care services when provided on the same date of service as critical care services for CY 2011 were listed in Addendum M to that final rule with comment period.

Because the CY 2012 costs for critical care services were based upon CY 2010 claims data, which reflected the CPT billing guidance that was in effect prior to CY 2011, in the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74343 through 74344), we continued the methodology established in the CY 2011 OPPTS/ASC final rule with comment period of calculating a payment rate for critical care services based on our historical claims data, into which the cost of the ancillary services is intrinsically packaged for CY 2012. We also continued 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.

As we discussed in the CY 2013 OPPTS/ASC final rule with comment period, the CY 2011 hospital claims data on which the CY 2013 payment rates are based reflect the first year of claims billed under the revised CPT guidance to allow the reporting of all the ancillary services and their associated charges separately when they are provided in conjunction with critical care (77 FR 68402). Because our policy to establish relative payment weights based on geometric mean cost data for CY 2013 represented a change from our historical practice to base payment rates on median costs, and because we had hospital claims data for the first time reflecting the revised coding guidance for critical care, we reviewed the CY 2011 hospital claims data available for the CY 2013 OPPTS/ASC final rule with comment period and determined that the data showed increases in both the geometric mean and median line item costs as well as the geometric mean and median line item charges for CPT code 99291, when compared to CY 2010 hospital claims data. Specifically, we noted that the geometric mean and median line item costs increased 13 percent and 16 percent, respectively, and the geometric mean and median line item charges increased 11 percent and 14 percent, respectively. Additionally, when compared to CY 2010 hospital claims data, CY 2011 hospital claims data showed no substantial change in the ancillary services that were presented on the same claims as critical care services, and also showed continued low volumes of many ancillary services. We stated in the CY 2013 OPPTS/ASC final rule with comment period that, had the majority of hospitals changed their billing practices to separately report and charge for the ancillary services formerly included in the definition of critical care CPT codes 99291 and 99292, we would have expected to see a decrease in the costs and charges for these CPT codes, and a significant increase in ancillary services reported on the same claims. We indicated that the lack of a substantial change in the services reported on critical care claims, along with the increases in the line item costs and charges for critical care services, strongly suggested that many hospitals did not change their billing practices for CPT code 99291 following the revision to the CPT coding guidance effective January 1, 2011.

In light of not having claims data to support a significant change in hospital billing practices, we stated in the CY 2013 OPPTS/ASC final rule with comment period that we continued to

believe that it is inappropriate to pay separately in CY 2013 for the ancillary services that hospitals may now report in addition to critical care services. Therefore, for CY 2013, we continued our CY 2011 and CY 2012 policy to recognize the existing CPT codes for critical care services and establish a payment rate based on historical claims data. We also continued to implement claims processing edits that conditionally package payment for the ancillary services that were reported on the same date of service as critical care services in order to avoid overpayment. We stated that we would 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.

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43617), we stated that when compared to CY 2011 hospital claims data used for the CY 2013 OPPTS ratesetting, CY 2012 hospital claims data used for the CY 2014 OPPTS ratesetting showed 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 did not change their billing practices for CPT code 99291 following the revision to the CPT coding guidance effective January 1, 2011. In light of not having claims data to support a significant change in hospital billing practices, we stated that we continue to believe that it is inappropriate to pay separately in CY 2014 for the ancillary services that hospitals may now report in addition to critical care services. Therefore, for CY 2014, we proposed to continue our CY 2011, CY 2012, and CY 2013 policy 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.

Comment: Commenters recommended that CMS, in setting the payment rate for packaging ancillary services into the critical care services, establish a methodology that ensures that multiple cost report revenue centers are included in the review.

Response: The methodology that the commenters recommended is consistent with the methodology we already have in place. As discussed in section II.A.1.c. of this final rule with comment period, we calculate hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each

hospital for which we have claims data. We apply 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. Therefore, we base our cost estimation of each packaged ancillary service on the most specific cost center to which the revenue code reported with that service maps. We then package the cost that we estimate as a result of that process into the geometric mean cost calculation for critical care.

After consideration of the public comments received, we are finalizing our proposal to continue our CY 2011, CY 2012, and CY 2013 policy to recognize the existing CPT codes for critical care services and establish a payment rate based on historical claims data. We also are finalizing our proposal 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 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.

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 OPDS. The Medicare regulations that implement this provision specify, under 42 CFR 419.21, that payments under the OPDS 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 OPDS/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 OPDS/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 OPDS/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 OPDS/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. In contrast, CMHC-based PHPs are largely concentrated in certain geographical areas with particular

prevalence in Florida, Texas, and Louisiana. 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 and then adding that number to the CY 2011 final CMHC median. 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*, No. 10–949, 2011 WL 3102049 (W.D.Tex. 2011), *aff’d*, No. 11–50682, 2012 WL 2161137 (5th Cir. June 15, 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* at *6).

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 2013 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 means rather than on the medians. For CY 2013, we established the four PHP APC per diem payment rates based on geometric mean cost levels calculated using the most recent claims data for each provider type. We refer readers to the CY 2013 OPPS/ASC final rule with comment period for a more detailed discussion (77 FR 68406 through 68412).

B. PHP APC Update for CY 2014

In the CY 2014 OPPS/ASC proposed rule (78 FR 43618 through 43622), for CY 2014, we proposed 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 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 2012 CMHC claims data, and proposed hospital-based PHP APC geometric mean per diem costs for Level I and Level II PHP services using only CY 2012 hospital-based PHP claims data. These proposed geometric mean per diem costs that were shown in Table 30 of the CY 2014 OPPS/ASC proposed rule (78 FR 43620) are reflected in Table 42a below.

TABLE 42a.—PROPOSED CY 2014 GEOMETRIC MEAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHP SERVICES, BASED ON CY 2012 CLAIMS DATA

APC	Group Title	Proposed Geometric Mean Per Diem Costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	\$94.51
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	\$106.20
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	\$212.85
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	\$215.13

For CY 2014, the proposed geometric mean per diem costs for days with 3 services (Level I) was approximately \$95 for CMHCs and approximately \$213 for hospital-based PHPs. The proposed geometric mean per diem costs for days

with 4 or more services (Level II) was approximately \$106 for CMHCs and approximately \$215 for hospital-based PHPs.

The CY 2014 proposed geometric mean per diem costs for CMHCs

calculated under the proposed CY 2014 methodology using CY 2012 claims data have remained relatively constant when compared to the CY 2013 final geometric mean per diem costs for CMHCs established in the CY 2013

OPPS/ASC final rule with comment period (77 FR 68412), with proposed geometric mean per diem costs for Level I PHP services increasing from approximately \$87 to approximately \$95 for CY 2014, and proposed geometric mean per diem costs for Level II PHP services decreasing from approximately \$113 to approximately \$106 for CY 2014.

The CY 2014 proposed geometric mean per diem costs for hospital-based PHPs calculated under the proposed CY 2014 methodology using CY 2012 claims data show more variation when compared to the CY 2013 final geometric mean per diem costs for hospital-based PHPs, with proposed geometric mean per diem costs for Level I PHP services increasing from approximately \$186 to approximately \$213 for CY 2014, and proposed geometric mean per diem costs for Level II PHP services decreasing from approximately \$235 to approximately \$215 for CY 2014.

The proposed CY 2014 geometric mean per diem costs for the PHP APCs were shown in Tables 31 and 32 of the CY 2014 OPPS/ASC proposed rule (78 FR 43620 through 43621). We invited public comments on these proposals.

Comment: Many commenters supported the continued distinction between APC payments for PHP services provided by CMHCs and APC payments for PHP services provided by hospital-based PHPs. These commenters believed that the cost structures of the two provider types are significantly different and, therefore, the payments should be different. Conversely, a few commenters stated that they do not like the distinction between provider types. Instead, these commenters believed that CMHCs and hospital-based PHPs should receive the same payment rates. The commenters believed that the ratesetting methodology used to establish payment rates for PHP services also has fueled a fundamental shift in payments away from less expensive CMHCs to more expensive hospital-based PHPs, resulting in overall higher CMS expenditures for the same services, which is discriminating against CMHCs that provide identical PHP services.

One commenter did not agree with CMS' statement that "CMHCs have a lower cost structure than hospital-based PHP providers, in part because the data showed that CMHCs provide fewer PHP services in a day and use less costly staff than hospital-based PHPs." The commenter stated that CMS implies that "CMHCs provide less valuable services than hospital-based PHPs, hire less qualified staff, and overall perform very

poorly compared to hospital-based PHPs."

Some commenters also continued to support CMS' creation of two-tiered payments for partial hospitalization services. They believed that these changes to the PHP payment structure have been a positive step in addressing the twin goals of ensuring long-term stability and improving the accuracy of payments.

Response: We understand the concerns raised by the commenters regarding the differences between CMHC PHP APC per diem payment rates and hospital-based PHP APC per diem payment rates. We are not discriminating against CMHCs or any other health care provider, nor are we encouraging the use of a specific provider type which would lead to a shift in payments; we are calculating the payment rates for PHP services based on the claims and cost report data submitted by our providers. We continue to believe that it is important to calculate PHP APC per diem payment rates based on the data for each type of provider in order to appropriately pay for PHP services. We also believe that the CMHC and the hospital-based PHP APC per diem payment rates accurately reflect the claims and cost report data of CMHCs and hospital-based providers, respectively. The PHP APC per diem payment rates are directly related to the accuracy of the claims and cost report data submitted by providers. Therefore, it is imperative that providers submit accurate claims and cost reports in order for the payment rates to most accurately reflect the costs to providers. The resulting PHP APC per diem payment rates reflect the cost of what providers expend to maintain such programs.

CMHCs and hospital-based PHPs continue to show significant differences in their costs. As we explained in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74347), we attributed the decrease in costs to CMHCs having a lower cost structure than hospital-based PHP providers, in part, because the data showed (and continue to show) that CMHCs provide fewer PHP services in a day and use less costly staff than hospital-based PHPs. In other words, hospital-based providers have traditionally provided more services than CMHCs during a PHP day. Providing fewer services during a PHP day results in less overhead expense for the provider; that is, less time the provider needs to pay staff, less time the provider needs to heat the building, and less time the provider needs to light the building. Therefore, providing fewer PHP services during a day directly contributes to a lower overall cost

structure. We did not intend to imply that, in comparison to hospital-based PHPs, CMHCs provide inferior, less valuable or poor quality services or are poor performers; we were merely stating the differences in these providers' cost structures based on cost analysis. In light of these differences in cost structures between provider types, it is inappropriate to treat CMHCs and hospital-based PHP providers in the same manner. We have been concerned that paying hospital-based PHPs at a lower payment rate than their cost structure reflects could lead to closures and possible access problems for hospital-based programs providing services to Medicare beneficiaries, given that hospital-based PHPs offer the widest access to PHP services because they are located across the country. At the same time, we believe it is inappropriate to overpay CMHCs in comparison to their cost structures.

We appreciate the commenters who continue to support the two-tiered payments for PHP services. We believe that paying providers based on the four PHP APC per diem payment rates supports continued access to the PHP benefit, while also providing appropriate payment based on the unique cost structures of CMHCs and hospital-based PHPs.

Finally, we consistently monitor the OPPS to identify potential refinements that would improve the accuracy and stability of the payment system. We will continue to monitor the impact of our payment policies on the PHP benefit and its providers.

Comment: A few commenters expressed concern regarding the adverse impact the proposed payment rates for CY 2014 would have on CMHC providers across the country. One commenter stated that since the adoption of the provider-specific structure in CY 2011, payment for partial hospitalization services provided by CMHCs has decreased by approximately 50 percent. This commenter indicated that, in CY 2013, the per diem payment rates for PHP services provided by CMHCs decreased by another 4.4 percent as a result of changing the methodology from median-based relative payment weights to geometric mean-based relative payment weights. The commenter also stated that, for CY 2014, CMS is proposing to further decrease payments for PHP services provided by CMHCs by approximately 3.8 percent. A few commenters stated that many Medicare CMHCs have closed over the years and they believed that payment rate reductions are a primary reason for the closures. These commenters pointed out

that another reduction in the per diem payment rates may result in more CMHC closures, therefore decreasing the number of providers and available resources for the most disadvantaged portion of the beneficiary population.

Commenters also expressed concern regarding the decrease in payment rates for Level II hospital-based PHP services. One commenter stated that the proposed 9.2 percent decrease in the Level II per diem payment rate for hospital-based PHPs would result in inadequate payment for hospitals' direct and indirect costs and that any further reductions to Medicare payment rates will put their program in jeopardy. A few commenters requested that CMS suspend the proposed PHP per diem payment rates for CY 2014 and, instead, maintain the CY 2013 PHP per diem payment rates for CY 2014.

Response: We understand the concerns raised by the commenters that a reduction in payment rates for CY 2014 will not adequately pay for their costs to provide PHP services and may result in closures for both CMHCs and hospital-based PHPs. However, based on the final geometric mean per diem costs for CY 2014, CMHCs will receive an increase in geometric mean per diem costs from CY 2013 to CY 2014 for APC 0172 Level I (3 service days) from \$87.39 to \$99.39 and the geometric mean per diem costs for APC 0173 Level II (4 or more service days) will basically remain the same (\$112.12 for CY 2014 compared to \$112.82 for CY 2013). Hospital-based PHPs also will receive an increase in geometric mean per diem costs from CY 2013 to CY 2014 for APC 0175 Level I (3 service days) from \$185.90 to \$190.82. Only the geometric mean per diem costs for APC 0176 Level II (4 or more service days) will decrease from CY 2013 to CY 2014 from \$234.81 to \$214.39. As discussed in the prior response, we believe that the CMHC and the hospital-based PHP APC per diem payment rates accurately reflect the claims and cost report data of the CMHCs and hospital-based providers, respectively. The resulting PHP APC per diem payment rates and the APC payment structures reflect the cost of what providers expend to maintain such programs. Therefore, it is unclear to us why this would lead to program or business closures. 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 a 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. However, we take seriously the

commenters' concerns that a reduction in PHP APC per diem payment rates could erode the viability of PHPs and make it more difficult for beneficiaries to receive needed mental health services. Therefore, we monitor facility closings and openings to make sure that access issues do not exist, and we will continue to do so in the future.

In response to the comment that the payment rates for PHP services have decreased as a result of changing the methodology from median-based relative payment weights to geometric mean-based relative payment weights, we have made changes throughout the history of the OPPS with a goal of deriving more accurate information from available claims and cost report data, as well as increasing the benefits of using a metric that more accurately describes the range of costs associated with providing services and, thus, resulting in the most appropriate payments. We continue to believe that basing the relative payment weights on geometric mean costs promotes better stability in the payment system by making OPPS payments more reflective of the range of costs associated with providing services. Therefore, we believe that using geometric mean costs to calculate the relative payment weights for the OPPS represents an improvement to our cost estimation process and leads to the establishment of relative payment weights that are more reflective of service cost patterns.

Finally, in response to commenters requesting that we suspend the proposed CY 2014 PHP payment rates and maintain the CY 2013 PHP APC payment rates, as we discussed above, we cannot establish payment rates that do not accurately reflect current claims and cost report data. Therefore, we are not suspending implementation of the CY 2014 PHP APC per diem payment rates.

Comment: Several commenters indicated that the proposed PHP per diem payment rates for CY 2014 show again that payment rates continue to materially fluctuate from one year to another. The commenters expressed concern regarding the variation in payment from year to year for this critically important service and noted that significant fluctuations from year to year make budgeting difficult for hospital-based PHPs. Another commenter asked if the decrease in the APC 0176 payment rate is due solely to the costs associated with the services, or if the decrease is compounded by the other significant changes in the proposed rule—namely, a significant change in the packaging of services,

which will shift significant dollars around in the OPPS system.

Response: We recognize the commenters' concern regarding variance in payment rates from year to year. We believe that payment rates for PHP services fluctuate from year to year based on a variety of factors, including direct changes to the PHP APC per diem payment rate, changes to the OPPS, and provider-driven changes.

Over the past several years, we have made changes to PHP APC per diem payment rates to more accurately align the payments with costs. The changes have included establishing separate APCs and associated per diem payment rates for CMHCs and hospital-based providers based on each provider's costs, under which we pay one amount for days with 3 services and another amount for days with 4 or more services.

Additionally, 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. Further, changes in payment policy also may have effects on the payment rates each year. For example, basing the relative payment weights on geometric mean costs rather than median costs affected the payment rates.

Finally, provider-driven changes affect the payment rates. The case-mix and number of services provided, as well as changes to the charging structure and the variety of hospitals and CMHCs providing the services, contribute to changes in the payment rates. Providers may choose to update or maintain their charges each year based on a variety of business reasons, but these changes to charges often vary depending on the different services each provider furnishes as well as the business decisions of the provider. Therefore, a provider's decision to change its mix of services or to change its charges and clinical practice for some services also contributes to the fluctuation in payment rates. Therefore, both policy and data changes influence the changes in the PHP APC payment rates, as they do for all services each year.

In response to the commenter who asked if the decrease in the payment rate for APC 0176 is due solely to the costs associated with PHP services, or if the decrease is compounded by other significant changes in the proposed rule, the decrease is due to both. There is a decrease in the Level II PHP hospital-based geometric mean per diem costs of approximately \$21 from the CY 2013 Level II hospital-based PHP per diem amount of \$235 to the CY 2014 Level II

hospital-based PHP per diem amount of approximately \$214 before any changes that may result from relative payment weights associated with other services in the OPPTS. That said, we believe that the payment rate for APC 0176 continues to accurately reflect the costs associated with providing PHP services in the hospital setting.

We will continue to explore ways to minimize fluctuations in the PHP

payment rates because we agree that a high level of volatility is not desirable. However, we also believe that changes in estimated costs 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.

In summary, after consideration of the public comments we received, we are

finalizing our CY 2014 proposal, without modification, to update the four PHP APC per diem payment rates based on geometric mean cost levels calculated using the most recent claims data for each provider type. The updated PHP APCs geometric mean per diem costs for PHP services that we are finalizing for CY 2014 are shown in Tables 43 and 44 below.

TABLE 43.--CY 2014 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	\$99.39
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	\$112.12

TABLE 44.--CY 2014 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	\$190.82
0176	Level II Partial Hospitalization (4 or more services) for Hospital-based PHPs	\$214.39

C. Discussion of Possible Future Initiatives, Request for Public Comments, and Summary of Public Comments Received

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43621 through 43622), we noted that we are considering a number of possible future initiatives that may help to ensure the long-term stability of PHPs and further improve the accuracy of payment for PHP services. Along with our broad, ongoing objectives of ensuring stability of the PHP benefit and promoting payment accuracy for PHPs, we want to ensure that PHPs are used by individuals who are specifically in need of such services. The PHP benefit was designed to assist individuals with an acute exacerbation of a psychiatric illness to manage debilitating symptoms and prevent the need for admission and readmission into hospitals. Accordingly, we stated that we are considering a

number of possible future modifications to certain aspects of the PHP benefit. We did not propose new Medicare policy in this discussion of possible future modifications in the CY 2014 OPPTS/ASC proposed rule. Instead, we requested public comments on possible future initiatives.

For example, under the current methodology, we use the most recent claims data to compute geometric mean per diem costs for Level I (3 services per day) and Level II (4 or more services per day) PHP services for CMHCs and for hospital-based PHPs. We are interested in examining the payment structure for PHP services to determine whether alternative methodologies to pay for PHP services would reduce unnecessary care while maintaining or increasing the quality of care provided. We invited public comments on alternative payment methodologies.

Another area in which we solicited public comments is whether payment based on an episode of care, or a per diem similar to those used in the inpatient psychiatric facility (IPF) PPS, would result in more appropriate payment for PHP services than the current payment structure. The IPF PPS is a per diem prospective payment system for inpatient psychiatric hospital services furnished in psychiatric hospitals, and psychiatric units in acute care hospitals and critical access hospitals. The IPF PPS base rate is adjusted to account for patient and facility characteristics that contribute to higher costs per day, including age, diagnosis-related group assignment, comorbidities, days of the stay, geographic wage area, rural location, teaching status, cost of living for IPFs located in Alaska and Hawaii, and the presence of a qualifying emergency

department. The IPF PPS methodology includes a payment provision for interrupted stays, additional payment for outlier cases, and a per treatment payment for electroconvulsive therapy (ECT) treatments. For detailed information regarding the implementation of the IPF PPS, we refer readers to the FY 2005 IPF PPS final rule published in the **Federal Register** on November 15, 2004 (69 FR 66922). To find additional information about the IPF PPS, we refer readers to the CMS Web site at: <http://www.cms.hhs.gov/inpatientpsychfacilpps>.

Comment: Commenters primarily opposed changing the PHP payment methodology from a per diem based calculation to an episode of care based calculation. We received several public comments requesting a single payment for PHP services, as well as several public comments stating that there is a need for more research to determine the best method of payment. Mainly, commenters suggested that CMS take three steps: (1) Establish a ratesetting task force to develop a new payment rate methodology that captures all relevant data and reflects the real costs to providers to deliver these services; (2) examine the Medicare mental health benefits; and (3) encourage legislative changes to expand mental health services. These commenters stressed that any proposed change to the payment methodology for PHP services must involve relevant stakeholders in Federal agencies (such as SAMHSA) as well as representatives from CMHCs and hospital providers and associations.

Response: We appreciate the commenters' input and suggestions and will take them under advisement for future refinements.

Comment: Commenters indicated that the Medicare PHP benefit is critical in keeping beneficiaries out of emergency rooms and in the community, and urged CMS to proceed cautiously in proposing reforms that may erode what is already a fragile safety net of providers. The commenters believed that any changes to the PHP payment methodology should not be considered in isolation. The commenters suggested that CMS look at Medicare benefits for psychiatric services overall and take the necessary steps to develop coverage of a comprehensive set of services across all settings of care that meet the needs of the population.

Several commenters cited a recent report sponsored by the National Association of Psychiatric Health Systems which they said found that the benefits derived from patients participating in PHPs extend the time between readmissions. According to

their analysis, the time-to-readmission ratio for these Medicare beneficiaries was 131 days versus 59 days between admissions for those beneficiaries who did not participate in PHPs.

Many commenters representing hospitals and hospital associations indicated that it would be premature to assume that a change in the payment methodology would achieve the goals that CMS has described in the proposed rule without statutory changes to the existing PHP benefit. A few commenters indicated that in the absence of any relevant payment research or substantive proposals, they could not comment on whether an episode of care or a per diem based payment for the PHP benefit would result in more suitable payment rates, indicating that additional research is an important next step before determining whether or not either approach would have the intended effects and is sustainable.

One commenter believed that improvements in PHP models can be made and suggested that CMS consider other treatment approaches that are less rigid than the current PHP guidelines, especially the required number of service hours and days of treatment required per week. The commenter believed that more flexibility in this area is necessary to accommodate patients' work and family schedules. For example, a model of intensive outpatient services estimated at 3 hours per day, 3 days per week would allow more flexibility to meet patient needs clinically and personally. The commenter did not believe that the application of an episode of care payment methodology for PHP services would be appropriate due to the vagueness of the period and the intensity and uniqueness of each patient's illness. However, the commenter supported CMS' efforts to communicate with stakeholders on possible future initiatives for PHP services.

Commenters also stated that an enhanced per diem payment rate that reflects the costs of treating patients with more complicated clinical needs similar to the IPF PPS would also be worth considering.

Many commenters representing hospital associations indicated that it would be useful to evaluate the way in which overall Medicare mental health benefits are structured. The commenters believed that, compared to the scope of services many private health insurers cover, Medicare benefits are much narrower. The commenters stated, for instance, that Medicare beneficiaries are currently limited to only 190 days of inpatient psychiatric hospital care in

their lifetime. According to the commenters, no other Medicare inpatient hospital service has this type of arbitrary cap on benefits. In addition, the commenters stated that, rather than covering the full continuum of behavioral health care services, Medicare currently covers only inpatient psychiatric care, hospital-based and CMHC-based PHP services, and office-based services. The commenters further stated that the PHP benefit is drawn very narrowly so as to only cover care for the most acutely ill patients who would otherwise require hospitalization. As a result, according to the commenters, the parts of the continuum missing from current Medicare benefits include formal coverage of intensive outpatient care, residential treatment, psychosocial rehabilitation, and care management. The commenters believed that this makes it difficult for providers to provide Medicare beneficiaries with the appropriate services at the right level and time.

These commenters stated that broadening the Medicare mental health benefit structure to encompass the other components of the continuum would require statutory changes. The commenters believed that making minimal changes, such as revising the PHP payment structure, will not address the larger limitations of the Medicare benefit design.

One commenter recommended that a single provider-based payment structure be established for PHP services that reflects the intensity of services that people with serious mental illnesses generally require because this benefit is meant to substitute for inpatient care or as a step-down level of care. To achieve long-term stability and payment accuracy, the commenter suggested that CMS maintain the per diem payment methodology. The commenter believed that an episode-of-care payment methodology is more appropriate for the typical and predictable treatment of physical ailments and issues, but not for mental health treatment.

One commenter recommended that CMS establish the same payment rates and two-tiered payment structure for all providers with no differentiation between payment rates for hospital-based PHP services and payments rates for PHP services provided by CMHCs. The commenter also urged CMS to establish quality and outcomes criteria to evaluate performance, influence future ratesetting, and provide rewards to individual providers for outstanding quality and outcomes while at the same time keeping their cost under control.

Response: We appreciate the commenters' suggestions and recommendations for strengthening the PHP benefit and payment structure. We will take them under advisement for any future refinements.

Another area on which we solicited public comments was physician certification/recertification that an individual would require inpatient psychiatric care in the absence of PHP services. In order for a hospital or CMHC to be paid for partial hospitalization services furnished to a Medicare beneficiary, a physician must certify (and recertify when such services are furnished over a period of time), among other things, that the individual would require inpatient psychiatric care in the absence of such services. In addition, an individualized written plan of treatment for furnishing such services must be established and reviewed periodically by a physician, and such services must be furnished while the individual is under the care of a physician. For more details, we refer readers to 42 CFR 424.24(e).

Current regulations specify that a physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment. A recertification is required as of the 18th day of partial hospitalization services. Subsequent recertifications are required at intervals established by the provider, but no less frequently than every 30 days. We invited public comments on whether the current requirement under § 424.24(e)(3)(ii) of the regulations, which requires the first recertification by the physician to be as of the 18th day of partial hospitalization services, reflects current PHP treatment practices. Specifically, we stated that we were interested in whether the first recertification date should be changed to some other standard that accords with best practices and why.

Comment: Several commenters indicated that they had no recommended changes to physician certification and recertification requirements and did not believe that an alternative recommendation is warranted at this time. The commenters indicated that they did not believe that there was any reason to change the 18-day recertification requirement and the "no longer than 30 days" length of time requirement for a subsequent recertification. In addition, the commenters indicated that their organization member hospitals have not identified these requirements as a problem, nor are they aware of any best practices that would suggest the need for such a change in the requirements.

Response: We thank the commenters for their input and suggestions and will take them under advisement for future refinements.

With respect to the individualized written plan of treatment for furnishing partial hospitalization services, as discussed above, a physician must establish and periodically review the written plan of treatment. The written plan of treatment sets forth the physician's diagnosis, the type, amount, duration, and frequency of the services, and the treatment goals under the written plan. The physician determines the frequency and duration of the PHP services taking into account accepted norms of medical practice and a reasonable expectation of improvement in the patient's condition. (We refer readers to § 424.24(e)(2) of the regulations.) We indicated that we are interested in what requirements should be included in the written plan of treatment to better direct PHP resources toward appropriate discharge and follow-up with appropriate support services. Specifically, we invited public comments on two issues: (1) the best way that discharge from a PHP could be expedited for those individuals no longer at risk of inpatient psychiatric hospitalization; and (2) whether the written plan of treatment requirements under § 424.24(e)(2)(i)(C), which require that the written plan of treatment set forth the treatment goals, should be revised to require that specific actions be taken by the physician and/or staff to assist a beneficiary in transitioning from a PHP to a lower level of care. For example, we are interested in whether the written plan of treatment should require that, upon discharge, patients have written instructions that include:

- A full list of their medications, dosages and any necessary prescriptions;
- Their next scheduled appointment with a psychiatrist or qualified practitioner who may bill for his or her professional services under Medicare Part B, including the phone number, address, and appointment date and time;
- A confirmed place to live in a stable environment with support services; and
- Other care coordination information.

Comment: With regard to additions to the written plan of treatment, several commenters supported including in the written plan of treatment a full list of patients' medications, dosages, and any necessary prescriptions as well as written notice of the next scheduled appointment with a psychiatrist or qualified practitioner who may bill for his or her professional services under

Medicare Part B, including the phone number, address and appointment date and time. However, the commenters did not believe that it would be feasible for a PHP to provide a "confirmed place to live in a stable environment with support services" for its patients. The commenters noted that among the admission criteria for a PHP is the requirement that the patient "have an adequate support system to sustain/maintain themselves outside the partial hospitalization program." The commenters believed that, while a PHP may be able to provide some limited assistance for a patient to maintain and enhance his or her stable environment, the program cannot ensure the sustainability of the environment or keep a patient enrolled in a PHP until that environment can be established.

The commenters pointed out that ensuring this type of environment would require intensive case management. The commenters believed that, if intensive case management was included in the PHP benefit available to Medicare beneficiaries, it would be a helpful enhancement to the program. Therefore, the commenters urged CMS to continue stakeholder engagement to discuss the goals of additional documentation requirements within the written plan of treatment.

Several commenters suggested additional requirements for the written plan of treatment to better direct PHP resources to ensure appropriate discharges and follow-up services, such as expedited discharge for patients who are no longer at risk for inpatient psychiatric hospitalizations, and specific actions to assist patients at discharge, including providing written instructions for medications, documentation of the next appointment with the appropriate Medicare Part B participating practitioner, confirmation of a place of residence, and other care coordination information. One commenter stated that the PHP medical necessity criterion should include care for the acute exacerbation of a psychiatric condition and care for prevention of admission or readmission to the hospital. One commenter suggested that any written treatment plan for a patient receiving PHP services include goals that will curtail the patient's need for a higher level of care through adherence to the PHP's attendance requirements and his or her prescribed medication regimen, identify the patient's symptoms and prognosis for improvement, and take into consideration the patient's coping skills. The commenter stated that the treatment plan must be concise. Another commenter agreed that the diagnosis of

a patient enrolled in a PHP should be consistent with those attributable to persons with chronic and persistent mental illnesses and included in the written treatment plan for PHP services.

Response: We thank the commenters for their input and suggestions and will take them under advisement for future refinements.

We also stated that we were interested in receiving public feedback about quality measures for a PHP. Quality health care is a high priority for CMS. We implement quality initiatives to ensure quality health care for Medicare beneficiaries through accountability and public disclosure. We use quality measures under various quality initiatives, which utilize pay-for-reporting and public reporting mechanisms. We requested public comments on quality measures for PHP services for future consideration. Specifically, if we were to establish quality measures for PHP services and require quality data reporting, what should be included in those measures? In addition, should the quality measures be similar or identical to those measures established for IPFs under the IPF Quality Reporting (IPFQR) Program?

In the CY 2014 OPPS/ASC proposed rule (78 FR 43622), we stated that we would appreciate feedback on all of these areas for future consideration and invited public comments on these issues.

Comment: Many commenters indicated that they have long supported the quality measures that are now included as part of the IPFQR program, and noted that the measures are well tested, reliable, and valid and have broad stakeholder support. The commenters asked that CMS initiate a conversation with the measure developers to determine if any of these measures would be suitable for the outpatient setting. In particular, the commenters indicated that the care transition measure (HBIPS 7) and the antipsychotic medication measures (HBIPS 4 and 5) are likely candidates and worthy of further discussion. Other commenters also suggested that CMS consider the HBIPS 6 measure regarding continuity of care and the HBIPS 1 measure regarding admission screening for violence risk, substance use, psychological trauma history, and patient strengths. These commenters stated that preserving the continuity of care between the inpatient and outpatient setting is an important goal, and indicated that starting with these inpatient measures may prove informative as CMS moves forward in considering alternative measures for the hospital outpatient department setting.

Many commenters urged CMS to work collaboratively with the Technical Expert Panel that it has established to develop, test, and fully vet any measure concepts before proceeding with measure development. Many commenters supported measuring the quality and safety of behavioral health care across the continuum of care and indicated that it may be appropriate to implement measures for PHPs. However, the commenters stated that any measures selected to assess the quality of PHP services should be specified, tested and National Quality Forum (NQF)-endorsed for that care setting, and reviewed by the Measure Applications Partnership (MAP) before the measures are proposed for inclusion under a quality reporting program for PHP services provided on an outpatient basis. One commenter supported the development of quality measures for PHP services and recommended that CMS work with SAMHSA on their proposed *National Behavioral Health Quality Framework* that was recently released for public comment, to determine how this framework might apply or be modified to apply to quality measures for PHP services.

Another commenter stated that the quality indicators CMS are seeking must be very specific and relate to the patient's current outpatient visit. The commenter suggested the following quality indicators and discharge requirements for PHP services in order to evaluate performance: (1) Access—The number of program days of scheduled operation from the time of a request for services to the first scheduled day of service; (2) Treatment Intensity—The percentage of scheduled attendance consistent with a minimum attendance average of 4 days per calendar week over an episode of care; (3) Discharge Planning—The percentage of patients with a scheduled follow-up appointment within 14 days after the date of discharge (as needed); and (4) Continuity of Care—The percentage of post-discharge continuity of care plans provided to the next level of care providers upon discharge.

Another commenter suggested that, instead of calculating the PHP APC per diem payment rates using claims data, CMS should use the quality of the provided services to base payments, including record reviews, denials due to lack of medical necessity or inadequate documentation, site visits, interviews with patients, and most importantly patient outcomes. The commenter stated that rewarding providers for higher quality care as measured by selected standards instead of rewarding providers for increasing the cost of the

services provided is a better way to improve the quality of any service. The commenter further stated that establishing quality measures will support constructive changes throughout the payment system and will encourage performance improvements by all providers (regardless of setting—CMHC or hospital outpatient department). The commenter believed that value-based purchasing incentives (rather than antiquated payment methodologies involving cost-based purchasing) is more appropriate to improve the quality of care provided.

Response: We thank the commenters for their input and suggestions and will take them under advisement for future refinements.

We appreciate the wide range of comments we received from health and behavioral health care associations, hospitals, providers and professionals interested in future initiatives related to partial hospitalization services. We will take them into consideration for further rulemaking to strengthen the PHP benefit and payment structure.

D. 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 2014 OPPS/ASC proposed rule (78 FR 43622), 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 2014, excluding outlier payments. CMHCs are projected to receive 0.07 percent of total OPPS payments in CY 2014, excluding outlier payments. Therefore, we proposed to designate 0.0016 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 2014, we proposed to continue to set the threshold for CY 2014 at 3.40 times the highest CMHC PHP APC payment rate (that is, APC 0173 (Level II Partial Hospitalization)). 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 2014, we proposed to continue to pay 50 percent of CMHC per diem costs over the threshold. In section II.G. of the CY 2014 OPPS/ASC proposed rule (78 FR 43622), 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, 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.

Comment: A few commenters stated that no changes should be made to outlier payments for CMHCs.

Response: We appreciate the commenters' input.

After consideration of the public comments we received, we are finalizing our CY 2014 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 0.16 percent of outlier payments or 0.0016 percent of total estimated OPPS payments to CMHCs for PHP outlier payments. For CY 2014, as proposed, we are setting the CMHC outlier threshold at 3.40 multiplied by the APC 0173 payment amount and the CY 2014 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 2014 OPPS/ASC proposed rule (78 FR 43622), for the CY 2014 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 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 2014. Therefore, we proposed to not remove any procedures from the inpatient list for CY 2014.

Comment: Several commenters requested that CMS remove CPT codes 37182 (Insertion of transvenous intrahepatic portosystemic shunt(s) (TIPS) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract formation/dilatation, stent placement and all associated imaging guidance and documentation); 37183 (Revision of transvenous intrahepatic portosystemic shunt(s) (TIPS) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract recanalization/dilatation, stent placement and all associated imaging guidance and documentation); 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 2014 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 37182, 37183, 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 2014.

Comment: Some commenters requested that CMS add CPT codes 44202 (Laparoscopy, surgical; enterectomy, resection of small intestine, single resection and anastomosis), 44203 (Laparoscopy, surgical; each additional small intestine

resection and anastomosis), 44204 (Laparoscopy, surgical; colectomy, partial, with anastomosis); 44205 (Laparoscopy, surgical; colectomy, partial, with removal of terminal ileum with ileocolostomy), 44206 (Laparoscopy, surgical; colectomy, partial, with end colostomy and closure of distal segment (Hartmann type procedure)), 44207 (Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis)), 44208 (Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis) with colostomy), and 44213 (Laparoscopy, surgical, mobilization (take-down) of splenic flexure performed in conjunction with partial colectomy (List separately in addition to primary procedure)) to the inpatient list.

Response: We reevaluated data on CPT codes 44206, 44207, 44208, and 44213 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 these procedures can be safely performed only in the inpatient setting. Therefore, we are adding CPT codes 44206, 44207, 44208, and 44213 to the inpatient list. We note that CPT codes 44202, 44203, 44204, and 44205 are currently assigned to the inpatient list.

Comment: Other commenters requested that CMS add CPT codes 33233 (Removal of permanent pacemaker pulse generator only), 33234 (Removal of transvenous pacemaker electrode(s): single lead system, atrial or Ventricular), 33235 (Removal of transvenous pacemaker electrode(s):

dual lead system), 33241 (Removal of pacing cardioverter defibrillator pulse generator only), and 33244 (Removal of single or dual chamber pacing cardioverter-defibrillator electrodes; by transvenous extraction) to the inpatient list.

Response: We reevaluated data on CPT codes 33233, 33234, 33235, 33241, and 33244 using recent utilization data and further clinical review performed by CMS medical advisors. As a result of the reevaluation, we determined that these five procedures can be safely performed in the outpatient setting. Therefore, we are not adding CPT codes 33233, 33234, 33235, 33241, and 33244 to the inpatient list for CY 2014.

Comment: A few commenters requested that the inpatient list be eliminated in its entirety.

Response: We continue to believe that the inpatient only list is a valuable tool for ensuring that the OPPS only pays for services that can safely be performed in the hospital outpatient setting, and we are not eliminating the inpatient only list at this time. We believe that there are many surgical procedures that cannot be safely performed on a typical Medicare beneficiary in the hospital outpatient setting. Therefore, it would be inappropriate for us to assign them separately payable status indicators and establish payment rates in the OPPS.

Comment: One commenter recommended that CMS remove the fourth criterion, "A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis," to determine whether codes potentially could be removed from the inpatient list because it will be difficult, if not impossible, to meet this criterion.

Response: We disagree with the commenter that this criterion is impossible to meet and note that the criterion has been a part of our longstanding and established methodology for identifying any procedures that potentially could be removed from the inpatient list for a number of years without significant concern raised by public commenters. We also remind the commenter that removal from the inpatient list does not necessarily require that all five criteria be satisfied. It is possible that a procedure could be removed from the inpatient list even if only a subset of the five criteria is satisfied for a particular service. Therefore, we do not find reason to remove the fourth criterion from our established methodology for identifying any procedures that potentially could be removed from the inpatient list. If this were the case for a service (even though it may appear unlikely), the service may be a good candidate for removal from the inpatient list.

After consideration of the public comments we received, we are finalizing our proposal to continue to use the methodology described in the November 15, 2004 final rule with comment period to identify any procedure that may be removed from the inpatient list, and are modifying our proposal for procedures on the inpatient list for CY 2014 by adding CPT codes 44206, 44207, 44208, and 44213 to the CY 2014 inpatient only list.

The procedures that we are adding to the inpatient only list for CY 2014 and their CPT codes, long descriptors, and status indicators are displayed in Table 45 below.

TABLE 45.—PROCEDURES ADDED THE INPATIENT ONLY LIST FOR CY 2014

HCPCS Code	Long Descriptor	CY 2014 Status Indicator
44206	Laparoscopy, surgical; colectomy, partial, with end colostomy and closure of distal segment (Hartmann type procedure)	C
44207	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis)	C
44208	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis) with colostomy	C
44213	Laparoscopy, surgical, mobilization (take-down) of splenic flexure performed in conjunction with partial colectomy	C

The complete list of codes that we will be paid by Medicare in CY 2014 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

A. Supervision of Hospital Outpatient Therapeutic Services

1. Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in CAHs and Certain Small Rural Hospitals

In the CY 2009 OPPTS/ASC proposed rule and final rule with comment period (73 FR 41518 through 41519 and 73 FR 68702 through 68704, respectively), we clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare in hospitals, as well as in provider-based departments of hospitals, as set forth in the CY 2000 OPPTS final rule with comment period (65 FR 18525). In the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60575 through 60591), we finalized a technical correction to the title and text of the applicable regulations at 42 CFR 410.27 to clarify that this standard applies in CAHs as well as hospitals. In response to concerns expressed by the hospital community, in particular CAHs and small rural hospitals, that they would have difficulty meeting this standard, on March 15, 2010, we instructed all Medicare contractors not to evaluate or enforce the supervision requirements for therapeutic services provided to outpatients in CAHs from January 1, 2010 through December 31, 2010, while the agency revisited the supervision policy during the CY 2011 OPPTS/ASC rulemaking cycle.

Due to continued concerns expressed by CAHs and small rural hospitals, we extended this notice of nonenforcement ("enforcement instruction") as an interim measure for CY 2011, and expanded it to apply to small rural hospitals having 100 or fewer beds (75 FR 72007). We continued to consider the issue further in our annual OPPTS notice and comment rulemaking, and implemented an independent review process in 2012 to obtain advice from the Hospital Outpatient Payment Panel (the Panel) on this matter (76 FR 74360 through 74371). Under this process used since CY 2012, the Panel considers and advises CMS regarding stakeholder requests for changes in the required level of supervision of individual hospital outpatient therapeutic services. In addition, we extended the enforcement instruction the past 2 years (through CY 2012 and CY 2013) to

provide hospitals with adequate opportunity to become familiar with the new independent review process and submit evaluation requests, and to meet the required supervision levels for all hospital outpatient therapeutic services (we refer readers to 76 FR 74371 and 77 FR 68425). In the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68426), we stated that we expect CY 2013 to be the final year that the enforcement instruction would be in effect, as during this year there would be additional opportunities for stakeholders to bring their issues to the Panel, and for the Panel to evaluate and provide us with recommendations on those issues. The current enforcement instruction is available on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html?redirect=/HospitalOutpatientPPS/01_overview.asp.

In CY 2012 and CY 2013, the Panel met and considered several requests from CAHs and other stakeholders for changes in the required level of supervision for observation and other services. Based on the Panel's recommendations, we modified our supervision requirements to provide that most of the services considered may be furnished under general supervision, in accordance with applicable Medicare regulations and policies. These decisions are posted on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CY2013-OPPTS-General-Supervision.pdf>.

We believe the independent Panel review advisory process has proved an effective means for the hospital community to identify hospital outpatient therapeutic services that can safely be furnished under general supervision, where the supervising practitioner does not have to be immediately available in person to provide assistance and direction. Therefore, as we discussed in the CY 2014 OPPTS/ASC proposed rule (78 FR 43623), we believe it is appropriate to allow the enforcement instruction to expire at the end of CY 2013, to ensure the quality and safety of hospital and CAH outpatient therapeutic services paid by Medicare. We stated in the proposed rule that, for CY 2014, we anticipated allowing the enforcement instruction to expire, such that all outpatient therapeutic services furnished in hospitals and CAHs would require a minimum of direct supervision unless the service is on the list of services that may be furnished under general supervision or is designated as

a nonsurgical extended duration therapeutic service (the list of services is available on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CY2013-OPPTS-General-Supervision.pdf>). In the proposed rule, we stated that we were interested in receiving public comments on any potential impacts on access to care and quality of care for specific services that may result from allowing the enforcement instruction to expire at the end of CY 2013. We requested public comments on specific services for which CAHs and small rural hospitals anticipate difficulty furnishing the required direct supervision, including specific factors that may contribute to the lack of available staff.

Comment: Most commenters urged CMS to extend the direct supervision enforcement instruction for at least one more year in order to study the possible unintended consequences on Medicare beneficiary access to care and, at the same time, to develop policies that exempt CAHs and small, rural PPS hospitals from the requirement for direct supervision. The commenters stated that some small rural hospitals and CAHs have insufficient staff available to furnish direct supervision in CY 2014. The primary contributing factors cited were difficulty recruiting physician and nonphysician practitioners to practice in rural areas, and a desire by patients to see the providers they are familiar and comfortable with locally, outside of working hours. The commenters stated that it is particularly difficult to furnish direct supervision for critical specialty services, such as radiation oncology services, that cannot be supervised by a hospital emergency department physician or nonphysician practitioner, because of the volume of emergency patients or lack of specialty expertise.

These commenters believed that if the direct supervision requirement is enforced in CY 2014 for CAHs and small rural hospitals, some of these facilities will be forced to close altogether, and others will have to limit their hours of operation for chemotherapy, intravenous infusion of antibiotics and other drugs, cardiac and pulmonary rehabilitation, observation, blood transfusion, radiation oncology and wound care services. The commenters expressed concern that hospital revenues would be reduced from these business lines, and that some patients would elect to discontinue their care because of increased cost or inability to travel farther distances to obtain access to these services. The commenters

believed that reduced access will result in additional hospital readmissions and increased Medicare spending. Several commenters believed that access will be especially difficult given the anticipated increase in utilization likely to begin in 2014 as a result of the implementation of the online health insurance marketplaces and the expansion of Medicaid under the Affordable Care Act.

MedPAC stated in its public comment that, in light of the decision to enforce the supervision instructions, CMS should continue working with the Panel to define services that are appropriate for general supervision.

Response: We continue to believe that direct supervision is the most appropriate level of supervision for most hospital outpatient therapeutic services under the “incident to” provisions of section 1861(s)(2)(B) of the Act, as we discussed in the CY 2011 OPPTS/ASC final rule with comment period (75 FR 72006). Most hospital outpatient therapeutic services must be furnished directly (are not delegable); therefore, general supervision would not be appropriate for the majority of services. The independent Panel review advisory process was established through notice and comment rulemaking as the means of identifying hospital outpatient therapeutic services that can safely be furnished under general supervision, where the supervising practitioner does not have to be immediately available in person to provide assistance and direction (76 FR 74360 through 74371). We encourage hospitals to continue using the Panel process to bring to CMS’ attention services that may not require the immediate availability of a supervising practitioner, especially where it is possible to reduce the burden on the workforce available to small rural hospitals and CAHs while ensuring the quality and safety of patient care. We encourage hospitals and CAHs to continue using the established Panel process to request changes they believe would be appropriate in supervision levels for individual hospital outpatient therapeutic services, especially those the commenters mentioned that have not yet been evaluated by the Panel, such as blood transfusion, chemotherapy and radiation therapy, and wound care services. Instructions for submitting evaluation requests are available on the Panel Web site at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

Regarding pulmonary rehabilitation (PR) and cardiac rehabilitation (CR)

services also mentioned by the commenters, in the CY 2009 OPPTS/ASC final rule with comment period (74 FR 60573), we stated that while we have some flexibility to determine the type of practitioner who may supervise other hospital outpatient therapeutic services, in the case of PR, CR, and intensive cardiac rehabilitation (ICR) services, the statutory language does not provide such flexibility. Section 1861(eee)(2)(B) of the Act imposes strict requirements, describing the direct physician supervision standard for PR, CR, and ICR services, and does not give flexibility to modify the requirement to allow for other supervisory practitioners.

After consideration of the public comments we received, we are not extending the enforcement instruction another year for CY 2014. The enforcement instruction will expire December 31, 2013.

2. Supervision Requirements for Observation Services

In the CY 2011 OPPTS/ASC final rule with comment period (75 FR 71999 through 72013), we revised the supervision requirements for observation services furnished in the hospital by designating observation services (HCPCS codes G0378 (Hospital observation services, per hour) and G0379 (Direct admission of patient for observation care)) as nonsurgical extended duration therapeutic services (“extended duration services”). As we provided in the CY 2011 OPPTS/ASC final rule with comment period and 42 CFR 410.27(a)(1)(iv)(E), extended duration services require direct supervision at the initiation of the service, which may be followed by general supervision for the remainder of the service at the discretion of the supervising physician or appropriate nonphysician practitioner, once that practitioner has determined that the patient is stable. The determination by the supervising physician or appropriate nonphysician practitioner that the beneficiary is stable and may be transitioned to general supervision must be documented in progress notes or in the medical record (75 FR 72011).

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43624), we stated that since we designated observation services as extended duration services, we have received several inquiries from stakeholders regarding whether Medicare requires multiple evaluations of the beneficiary during the provision of observation services. Specifically, stakeholders asked whether, once the supervising physician or appropriate nonphysician practitioner transitions

the beneficiary to general supervision and documents the transition in the medical record, Medicare requires further assessment of the beneficiary either per hour (because observation services are billed per hour) or at some other point during provision of the service. In the CY 2014 OPPTS/ASC proposed rule, we stated that we are clarifying that, for observation services, if the supervising physician or appropriate nonphysician practitioner determines and documents in the medical record that the beneficiary is stable and may be transitioned to general supervision, general supervision may be furnished for the duration of the service. Medicare does not require an additional initiation period(s) of direct supervision during the service.

Comment: Commenters supported this clarification, stating that it answers many questions regarding whether Medicare requires hourly evaluations of the patient during the provision of observation services.

Response: We appreciate the commenters’ support and are finalizing our clarification without modification. We believe that this clarification will assist hospitals in furnishing the required supervision of observation services without undue burden on their staff.

B. Application of Therapy Caps in CAHs

For outpatient physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP) (collectively, “outpatient therapy”) services covered under Medicare Part B, section 1833(g) of the Act applies annual, per beneficiary limitations on incurred expenses, commonly referred to as “therapy caps,” for these services. There is one therapy cap for OT services and another separate therapy cap for PT and SLP services combined. As we discussed in the CY 2014 OPPTS/ASC proposed rule (78 FR 43624), in the CY 2014 Medicare Physician Fee Schedule (MPFS) proposed rule (78 FR 43332), we proposed to subject outpatient therapy services furnished by a CAH to the therapy caps and, if extended by statute, the exceptions process and the manual medical review process beginning on January 1, 2014. The American Taxpayer Relief Act of 2012 (Pub. L. 112–240) required that therapy services furnished by a CAH during 2013 are counted toward the therapy caps using the MPFS rate, and we proposed to continue this methodology for 2014 and subsequent years. CAHs will still be paid for therapy services under the reasonable cost methodology for CAH outpatient services described under section 1834(g) of the Act. We refer

readers to the CY 2014 MPFS final rule with comment period for detailed information about our proposal, a summation of the public comments we received on the proposal and our responses, and detailed information about our final policy. After consideration of all of the public comments we received, in the CY 2014 MPFS final rule, we are finalizing our proposal to apply the therapy caps and related provisions to services furnished by a CAH beginning on January 1, 2014. We are including in this CY 2014 OPPTS/ASC final rule with comment period a reference to the final policy as an additional means to direct CAHs' attention to our policies in the CY 2014 MPFS final rule.

C. Requirements for Payment of Outpatient Therapeutic ("Incident To") Hospital or CAH Services

1. Overview

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43624 through 43626), we proposed to amend the Medicare conditions of payment for therapeutic outpatient hospital or CAH services and supplies furnished "incident to" a physician's or nonphysician practitioner's service (which we refer to as hospital or CAH outpatient therapeutic services) to require that individuals furnishing these services do so in compliance with applicable State law. Under current policy, we generally defer to hospitals to ensure that State scope of practice and other State rules relating to health care delivery are followed, such that these services are performed only by qualified personnel in accordance with all applicable laws and regulations. We proposed to revise the existing regulations to explicitly require that individuals who perform hospital or CAH outpatient therapeutic services must do so in compliance with applicable State laws and regulations as a condition of payment under Medicare Part B. In this section, we are using the term "hospital" to include a CAH unless otherwise specified. Although the term "hospital" does not generally include a CAH, section 1861(e) of the Act provides that the term "hospital" includes a CAH if the context otherwise requires. We believe it would be appropriate to apply our policy regarding compliance with applicable State law, as we do for other conditions of payment for hospital outpatient therapeutic services, to CAHs as well as other hospitals.

2. Background

Section 1861(s)(2)(B) of the Act establishes the benefit category for

hospital "incident to" medical and other health services, which are paid under Medicare Part B. The statute specifies that "incident to" services are "hospital services (including drugs and biological which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services." In the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74369 through 74370), we clarified that hospital outpatient therapeutic services furnished incident to a physician's service even when described by benefit categories other than the specific "incident to" provision in section 1861(s)(2)(B) of the Act (for example, radiation therapy services described under section 1861(s)(4) of the Act). Because hospital outpatient therapeutic services are furnished incident to a physician's professional service, the conditions of payment that derive from the "incident to" nature of the services paid apply to all hospital outpatient therapeutic services.

In addition to the requirements of the statute, the regulation at 42 CFR 410.27 sets forth specific requirements that must be met in order for a hospital to be paid under Medicare Part B for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service (hospital or CAH outpatient therapeutic services). Section 410.27 describes hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's services as therapeutic services and provides the conditions of payment. Specifically, § 410.27(a) provides that Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service. These are defined, in part, as all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals that cannot be self-administered, if they are furnished—

- By or under arrangements made by the participating hospital or CAH, except in the case of a SNF resident as provided in 42 CFR 411.15(p);

- As an integral although incidental part of a physician's or nonphysician practitioner's services;

- In the hospital or CAH or in a department of the hospital or CAH, as defined in 42 CFR 413.65 [a provider-based department]; and

- Under the direct supervision (or other level of supervision as specified by CMS for the particular service) of a physician or a nonphysician practitioner. For purposes of this section, "nonphysician practitioner," as defined in § 410.27(g), means a clinical psychologist, licensed clinical social worker, physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse-midwife.

Sections 410.27(b) through (f) provide additional conditions of payment for partial hospitalization services, drugs and biologicals, emergency services, and services furnished by an entity other than the hospital (or CAH). We commonly refer to the services described in § 410.27 as "incident to" services.

In recent years, we have discussed and refined the supervision regulations under § 410.27, which are conditions of Medicare Part B payment for hospital outpatient "incident to" ("therapeutic") services. For example, we have discussed our belief that direct supervision is the most appropriate level of supervision for most of these services, unless personal supervision or personal performance of the services by the physician or nonphysician practitioner is more appropriate, given the "incident to" nature of the services as an integral although incidental part of a physician's or nonphysician practitioner's services (74 FR 60584, 75 FR 72006, and 76 FR 42281). We have stated our historical interpretation of section 1861(s)(2)(B) of the Act, specifically, that "incident to" services are furnished under the order of a physician (or nonphysician practitioner), the physician is involved in the management of the patient, and the physician supervises the provision of those services when he or she does not provide them directly (75 FR 72006). This is reflected in our requirement for a minimum of direct supervision, except for a limited set of services that may be furnished under general supervision or are designated as nonsurgical extended duration therapeutic services which require direct supervision initially with potential transition to general supervision (we refer readers to the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CY2013-OPPS-General-Supervision.pdf>).

In § 410.27(a)(1)(iv)(C) and (D), we regulate the qualifications of physicians and nonphysician practitioners supervising other personnel that are personally performing a service, or part of a service. In the CY 2011 OPPTS/ASC

final rule with comment period, we stated our belief that that in order to furnish assistance and direction, the supervising practitioner would have to be State-licensed and possess hospital privileges to perform the supervised procedure (75 FR 72007). Similarly, in the CY 2010 OPPTS/ASC final rule with comment period, we stated that the supervisory practitioner “must have, within his or her State scope of practice and hospital-granted privileges, the ability to perform the service or procedure” that he or she is supervising (74 FR 60580).

Similarly, we provide in the Medicare Benefit Policy Manual (MBPM, Pub. 100–02) that hospital outpatient therapeutic services and supplies must be furnished under the order of a physician or other practitioner practicing within the extent of the Act, the Code of Federal Regulations, and State law (Chapter 6, Section 20.5.2 of the MBPM). Section 20.5.2 of the MBPM specifies that the services must be furnished by hospital personnel under the appropriate supervision of a physician or nonphysician practitioner in accordance with 42 CFR 410.27 and 482.12. This does not mean that each occasion of service by a nonphysician need also be the occasion of the actual rendition of a personal professional service by the physician responsible for care of the patient. However, during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient’s progress and, when necessary, to change the treatment regimen. A hospital service or supply would not be considered incident to a physician’s service if the attending physician merely wrote an order for the services or supplies and referred the patient to the hospital without being involved in the management of that course of treatment.

Central to the issue of services that hospitals may bill to Medicare that are not performed personally by the physician is the assessment of the qualifications of the individuals to whom the services are delegated. As medical practice has evolved over time, the services performed in the hospital outpatient setting have expanded to include more complicated services such as advanced surgery and a complex variety of radiation therapy. In addition, the types of services that can be furnished incident to a physician’s or nonphysician practitioner’s services have expanded. Under current Medicare Part B payment policy, we generally defer to hospitals to ensure that State

scope of practice laws are followed and that the personnel who furnish hospital outpatient therapeutic (“incident to”) services are licensed and are otherwise qualified to do so. Specifically, we have stated that, considering that hospitals furnish a wide array of complex outpatient services and procedures, including surgical procedures, we would expect that hospitals have the credentialing procedures, bylaws, and other policies in place to ensure that hospital outpatient services furnished to Medicare beneficiaries are being provided only by qualified practitioners in accordance with all applicable laws and regulations (74 FR 60584; Chapter 6, Section 20.5.4 of the MBPM). However, our payment regulations do not contain restrictions on the types of auxiliary personnel that can perform hospital outpatient therapeutic (“incident to”) services, other than rules relating to supervision by a physician or qualified nonphysician practitioner, and do not specifically require that performance of these services be in compliance with applicable State law. Over the past years, several situations have come to our attention where Medicare was billed for “incident to” services that were performed by an individual who did not meet the State standards for those services in the State in which services were performed. The physician or nonphysician practitioner billing for the services would have been permitted under State law to personally furnish the services, but the services were actually provided by other individuals who were not in compliance with State law in providing the particular services (or aspect of the services).

Although we would expect that all hospital services for which Medicare payment is made would be furnished in accordance with State law, the Medicare requirements for hospital outpatient therapeutic services and supplies incident to a physician’s services (§ 410.27, discussed above) do not specifically make compliance with State law a condition of payment for services (or aspects of services) and supplies furnished and billed as “incident to” services. Nor do any of the payment regulations regarding hospital outpatient therapeutic services and supplies incident to the services of nonphysician practitioners contain this requirement. Therefore, Medicare has had limited recourse when hospital outpatient therapeutic (“incident to”) services are not furnished in compliance with State law.

In 2009, the Office of Inspector General (OIG) issued a report entitled “Prevalence and Qualifications of

Nonphysicians Who Performed Medicare Physician Services” (OEI–09–06–00430) that considered, in part, the qualifications of auxiliary personnel providing “incident to” physician services. After finding that services were being provided and billed to Medicare by auxiliary personnel “. . . who did not possess the required licenses or certifications according to State laws, regulations, and/or Medicare rules,” the OIG recommended that we revise the “incident to” rules to, among other things, “require that physicians who do not personally perform the services they bill to Medicare ensure that no persons except . . . nonphysicians who have the necessary training, certification, and/or licensure pursuant to State laws, State regulations, and Medicare regulations personally perform the services under the direct supervision of a licensed physician.” In the CY 2014 OPPTS/ASC proposed rule (78 FR 43624 through 43626), we proposed amendments to our regulations in order to address this recommendation.

3. Proposed and Final Policy

To ensure that the practitioners and other personnel providing hospital outpatient therapeutic services to Medicare beneficiaries incident to a physician’s or nonphysician practitioner’s service do so in accordance with the requirements of the State in which the services are furnished, and to ensure that Medicare payments can be recovered when such services are not furnished in compliance with the State law, in the CY 2014 OPPTS/ASC proposed rule (78 FR 43624 through 43626), we proposed to add a new condition of payment to the “incident to” regulations at § 410.27, Therapeutic outpatient hospital or CAH services and supplies incident to a physician’s or nonphysician practitioner’s service: Conditions. Specifically, we proposed to add a provision under a new paragraph (a)(1)(vi) under § 410.27 to specify that “Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician’s or nonphysician practitioner’s service . . . if they are furnished “In accordance with applicable State law.” We stated that the proposed policy would recognize the role of States in establishing the licensure and other qualifications of physicians and other health care professionals for the delivery of hospital (or CAH) outpatient therapeutic services.

We indicated that the proposal is consistent with other areas of the Medicare program where CMS defers to State rules regarding the delivery of

hospital services. For example, in determining who can admit patients as inpatients of a hospital, the hospital conditions of participation (CoPs) defer to State law and the authority of the hospital's governing body and medical staff to grant admitting privileges in accordance with the laws of the State in which the hospital is located. Section 482.12(c)(2) provides: "Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital." The CoP also provides that, "If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section [which lists practitioners that must care for Medicare patients], that patient is under the care of a doctor of medicine or osteopathy." Therefore, in determining who may admit inpatients to a hospital, Medicare defers to State law rules. As we stated in a recent rule addressing credentialing and privileging and telemedicine services under the CoPs (77 FR 29047): "CMS recognizes that practitioner licensure laws and regulations have traditionally been, and continue to be, the provenance of individual States, and we are not seeking to preempt State authority in this matter." Similarly, under the CoP at 42 CFR 482.22(a), we provide that a hospital's medical staff which grants admitting privileges "must include doctors of medicine or osteopathy. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of nonphysician practitioners determined as eligible for appointment by the governing body." Under the CoP at 42 CFR 482.11(c), the hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

We believe it is appropriate to similarly require as a condition of payment for individual services that all hospital outpatient services furnished incident to a physician's or nonphysician practitioner's services be furnished in accordance with State law requirements. As evidenced by these examples, throughout the Medicare program, the qualifications required for the delivery of health care services are generally determined with reference to State law. In addition to the health and safety benefits we believe would accrue to the Medicare patient population, this approach would assure that Federal dollars are not expended for services that do not meet the standards of the States in which they are being furnished, and provides the ability for the Federal Government to recover

funds paid where services and supplies are not furnished in accordance with State law.

We solicited public comments on our proposal.

Comment: Several commenters supported the general premise that individuals who provide services and supplies incident to a physician's services must do so in compliance with State law. However, the commenters opposed the "broad nature" of the proposed regulatory text because they believed that it might expose hospitals to liability under the False Claims Act in situations where a hospital improperly billed Medicare for services because the physician or practitioner had some minor defect with his or her license or certification, but there was no concern about a practitioner acting outside the scope of practice or the quality of care furnished. Several commenters asserted that the proposal is not necessary or appropriate because sanctions for these issues are already available under the CoPs and section 1156 of the Act. These commenters noted that section 1156 of the Act requires hospitals to ensure that the services it furnishes are of a quality that meet professionally recognized standards of care, and, upon a finding that in a substantial number of cases the hospital failed to comply substantially with this obligation, or that it grossly and flagrantly violated this obligation in one or more instances, the hospital is subject to a corrective action plan. The commenters noted that, while the sanction for violating the CoPs and the penalties under section 1156 of the Act do not include payment recoupment for the particular services furnished, the sanctions, including termination of the Medicare provider agreement and corrective action plans, are significant.

Several commenters supported the proposal because they recommended that CMS allow hospital personnel to continue working, possibly indefinitely, without the direct supervision of physicians or other qualified nonphysician practitioners in certain smaller hospitals. These commenters believed the proposal would be an important means of ensuring that ancillary personnel are properly trained, experienced, and potentially—in some States—even licensed, given that they would furnish services relatively independently in CAHs and small rural hospitals without direct supervision. The commenters stated that the proposal would ensure that technicians and other individuals furnishing "incident to" services are properly educated, trained, and experienced, and would ensure high quality care, not just

for Medicare beneficiaries, but for all patients.

Response: We agree with commenters that the CoPs and other statutory provisions provide for corrective action plans as a condition to continued eligibility to provide Medicare and Medicaid services on a reimbursable basis. However, we believe it is appropriate to also recoup payment for individual services if they are not furnished in accordance with applicable State law, and that the possibility of sanctions in the form of payment recoupment can help ensure compliance with the law.

We are concerned with the comments that indicated that our proposed revision to § 410.27 is necessary, in the absence of a direct supervision standard for payment, to ensure the safety and quality of care or compliance with State law. The instruction regarding enforcement of supervision requirements (discussed in section XI.A. of this final rule with comment period) does not relieve CAHs or small rural hospitals of their obligations under State law, the hospital CoPs, or section 1156 of the Act, to ensure that the individuals who furnish hospital outpatient therapeutic services are licensed and otherwise qualified to do so. The enforcement instruction (available on the CMS Web site at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Physician_Supervision_NonenfNotice.pdf) specifically states, "CMS continues to expect the hospitals covered under this notice to fulfill all other Medicare program requirements when providing services to Medicare beneficiaries and when billing Medicare for those services. While CMS is instructing contractors not to enforce the supervision requirements for outpatient therapeutic services in these hospitals for CY 2010–2013, we continue to emphasize quality and safety for services provided to all patients in these facilities." We note that as discussed in section X.A.1. of this final rule with comment period, the enforcement instruction will not be extended for CY 2014. These public comments reinforce our belief that conditions of payment for individual services, in the form of both the outpatient supervision rules and the proposed requirement for compliance with State laws, are necessary to ensure the safety and quality of care for Medicare beneficiaries. The hospital outpatient supervision rules are directed at ensuring that supervisory practitioners are licensed or authorized by the State and possess hospital

privileges to direct and, if necessary, intervene in the services they supervise (75 FR 72007), while our proposed requirement for compliance with applicable State law ensures that supervised individuals are licensed and qualified to provide the services or aspects of services that are delegated to them.

After consideration of the public comments we received, we are finalizing proposed new paragraph (a)(1)(vi) under § 410.27, without modification, to provide that Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service if they are furnished ". . . In accordance with applicable State law." This final policy does not impose any new requirements on hospitals that bill the Medicare program because practitioners and other personnel furnishing services already are required to comply with the laws of the State in which the services are furnished. This regulatory change simply adopts the existing requirements as a condition of payment under Medicare. Codifying this requirement provides the Federal government with a clear basis to deny Medicare payment when services are not furnished in accordance with applicable State law, as well as to ensure that Medicare pays for services furnished to beneficiaries only when the services meet the requirements imposed by the States to regulate health care delivery for the health and safety of their citizens.

4. Technical Correction

In the CY 2014 OPPS/ASC proposed rule (78 FR 43626), we stated that, in our review of § 410.27, we noted that paragraph (a) defines therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service as "all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals that cannot be self-administered." Section 1861(s)(2)(B) of the Act describes these services as "hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services." The statute includes in this benefit category "drugs and biologicals which are not usually self-administered by the patient." In the CY 2014 OPPS/ASC proposed rule, we proposed to make a technical correction that would

amend the description of these drugs and biologicals at § 410.27(a) to more appropriately reflect the statutory language. Specifically, we proposed to delete the phrase "drugs and biologicals that cannot be self-administered" and replace it with the phrase "drugs and biologicals which are not usually self-administered." Under this proposed technical correction, the language of § 410.27(a) would read, "Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service, which are defined as all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals which are not usually self-administered. . . ."

We did not receive any public comments on this proposed technical correction. Therefore, we are finalizing the correction without modification.

D. Collecting Data on Services Furnished in Off-Campus Provider-Based Departments

As we discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 43626) and in the CY 2014 Medicare Physician Fee Schedule (MPFS) proposed rule (78 FR 43301), 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 (for example, we refer readers to Carol M. Ostrom, "Why You Might Pay Twice for One Visit to a Doctor," *Seattle Times*, November 3, 2012, and Ann O'Malley, Amelia M. Bond, and Robert Berenson, *Rising Hospital Employment of Physicians: Better Quality, Higher Costs?*, Issue Brief No. 136, Center for Studying Health System Change, August 2011). 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 physician's office. As more physician practices become hospital-based, news articles have highlighted beneficiary liability that is incurred when services are provided in a hospital-based physician practice. MedPAC has questioned the appropriateness of increased Medicare payment and beneficiary cost-sharing when physicians' offices become hospital

outpatient departments and has recommended that Medicare pay selected hospital outpatient services at the MPFS rates (MedPAC March 2012 Report to Congress, "Addressing Medicare Payment Differences across Settings," presentation to the Commission on March 7, 2013).

The total payment (including both Medicare program payment and beneficiary cost-sharing) generally is higher when outpatient services are furnished in the hospital outpatient setting rather than in a freestanding clinic or in a physician office. When a service is furnished in a freestanding clinic or a physician office, only one payment is made to the physician (under the MPFS). However, when a service is provided in a hospital or a "physician office" that is a provider-based department of a hospital, Medicare pays the hospital a "facility fee" and pays the physician separately for the physician portion of the service. When a service is furnished in a hospital (or a provider-based department of a hospital), the payment to the physician is lower than the payment to the physician for the same service furnished outside the hospital (or the provider-based department of a hospital). However, the total payment (facility fee plus physician fee) is generally more for a service furnished in a hospital (or a provider-based department of a hospital) than for the same service furnished in a freestanding clinic or a physician office. The beneficiary pays coinsurance for both the physician payment and the hospital outpatient payment.

Upon acquisition of a physician practice, hospitals frequently treat the practice locations as off-campus provider-based departments of the hospital and bill Medicare for services furnished at those locations under the OPPS. (For further information on the provider-based regulations at 42 CFR 413.65, we refer readers to <http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol2/pdf/CFR-2010-title42-vol2-sec413-65.pdf>). Since October 1, 2002, we have not required hospitals to seek from CMS a determination of provider-based status for a facility that is located off campus. We also do not have a formal process for gathering information on the frequency, type, and payment of services furnished in off-campus provider-based departments of the hospital.

We stated in the CY 2014 OPPS/ASC and MPFS proposed rules that in order to better understand the growing trend toward hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-

based outpatient departments, we were considering collecting information that would allow us to analyze the frequency, type, and payment of services furnished in off-campus provider-based hospital departments. We stated that we have considered several potential methods for physician and hospital claims. Claims-based approaches could include: (1) For physician services, creating a new place of service (POS) code for off campus departments of a provider as part of item 24B of the CMS-1500 claim form, comparable to current POS codes such as “22 Outpatient” and “23 Emergency Room-Hospital” when physician services are furnished in an off-campus provider-based department; or (2) creating a HCPCS modifier that could be reported with every code for services furnished in an off-campus provider-based department of a hospital on the CMS-1500 claim form for physician services and the UB-04 (CMS Form 1450) for hospital outpatient claims. In addition, we have considered asking hospitals to break out the costs and charges for their provider-based departments as outpatient service cost centers on the Medicare hospital cost report, CMS Form 2552-10. We noted that some hospitals already break out these costs voluntarily or because of cost reporting requirements for the 340B Drug Discount Program, but this practice is not consistent or standardized. In the proposed rules, we invited public comments on the best means for collecting information on the frequency, type, and payment of services furnished in off-campus provider-based departments of hospitals.

Comment: While most commenters agreed on the need to collect information on the frequency, type, and payment of services furnished in off-campus provider-based departments of hospitals, they expressed different opinions on how to best collect these additional data. Some commenters preferred identifying services furnished in provider-based departments on the Medicare cost report, while other commenters preferred one of the claims-based approaches. Some commenters supported either approach and noted the trade-offs in terms of the type of data that could be collected accurately and the administrative burden involved. Some commenters suggested that CMS convene a group of stakeholders to develop consensus on the best approach. 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. For example, commenters indicated that limiting the data collection to cost report approaches results in little administrative burden for physicians because they do not file cost reports, but could result in varying degrees of administrative effort for hospitals, depending on the specific cost reporting requirements.

Several commenters noted that some hospitals already voluntarily identify costs specific to provider-based departments on their cost reports. These commenters asserted that because cost and charge information is already reported separately, there would be no additional burden, although additional variables or changes to the structure of the cost report may be required. In addition, the commenters noted that cost report information would be transparent and audited for accuracy. One commenter recommended aggregate reporting of all off-campus provider-based departments as one or several cost centers. Another commenter suggested that CMS consider assigning separate subprovider numbers for off-campus departments similar to those used for rehabilitation and psychiatric units.

Other commenters believed that a HCPCS modifier would more clearly identify specific services provided, 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. However, other commenters, using this same fact about the number of existing claims-based modifiers, argued that additional modifiers would increase administrative burden because this approach would increase the modifiers that would need to be considered when billing. Commenters recommended that CMS consider the establishment of a new POS code 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 provider-based department. Some commenters stated that establishing a new POS code would generate a better outcome under the MPFS than the OPFS because, under the OPFS, a single claim is more likely to contain lines for services furnished in both on-campus and off-campus departments of the hospital on the same day for the same beneficiary.

MedPAC believed there may be some limited value in collecting data on

services furnished in off-campus provider-based departments to validate the accuracy of site-of-service reporting when the physician's office is off-campus but bills as an outpatient department, but did not recommend a particular data collection approach. MedPAC indicated that any data collection effort should not prevent the development of policies to align payment rates across settings.

Response: We appreciate the public feedback in response to our solicitation of public comments in the CY 2014 OPFS/ASC and MPFS proposed rules. We will take the public comments received into consideration as we continue to consider approaches to collecting data on services furnished in off-campus provider-based departments.

XI. CY 2014 OPFS Payment Status and Comment Indicators

A. CY 2014 OPFS 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 OPFS. They indicate whether a service represented by a HCPCS code is payable under the OPFS or another payment system and also whether particular OPFS policies apply to the code. The complete list of the CY 2014 status indicators and their definitions is displayed in Addendum D1 on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. The CY 2014 status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. The changes to CY 2014 status indicators and their definitions are discussed in detail below.

In the CY 2014 OPFS/ASC proposed rule (78 FR 43627), for CY 2014, we proposed to create a new status indicator “J1” to identify HCPCS codes that are paid under a comprehensive APC. We proposed that a claim with the new proposed status indicator “J1” would trigger a comprehensive APC payment for the claim.

The public comments that we received on the status indicator “J1” are discussed in detail in section II.A.2.e. of this final rule with comment period. After consideration of the public comments we received, we have decided to finalize status indicator “J1”

but with a delayed effective date of CY 2015.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43627), for CY 2014, we proposed to delete status indicator “X” and assign ancillary services that are currently assigned status indicator “X” to either status indicator “Q1” or “S.” Services assigned status indicator “Q1” include many minor diagnostic tests that are generally ancillary to and performed with another service. However, services assigned to status indicator “Q1” also may be performed alone. Given the nature of these services and their role in hospital outpatient care, we stated that we believe that when these services are performed with another service, they should be packaged, but that they should be separately paid when performed alone. Therefore, we stated that we believe it is appropriate to conditionally package all ancillary services that are currently assigned to status indicator “X,” and we proposed to assign them to status indicator “Q1.” We also proposed that preventive services currently assigned status indicator “X” would continue to receive separate payment in all cases and be assigned status indicator “S” for CY 2014. These proposed changes are discussed in greater detail in section II.A.3. of this final rule with comment period. In addition, we proposed to revise the definition of status indicator “Q1” by removing status indicator “X” from the packaging criteria, so that codes assigned status indicator “Q1” are STV-packaged, rather than STVX-packaged, because status indicator “X” was proposed for deletion.

The public comments that we received regarding ancillary services assigned to status indicator “X” are discussed in detail in section II.A.3. of this final rule with comment period. As discussed in that section, we are not finalizing our CY 2014 proposal to package ancillary services. Therefore, we are not deleting status indicator “X” for CY 2014.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43628), for CY 2014, we proposed to revise the definitions of status indicators “S” and “T” to remove the word “significant” from these definitions. We stated that it is no longer necessary to distinguish significant procedures from ancillary services because we proposed to delete the status indicator that describes ancillary services. We also proposed to add the word “service” to the definitions of status indicators “S” and “T” to indicate “procedure or service; not discounted when multiple,” as applicable to status indicator “S” and “procedure or service; multiple

reduction applies,” as applicable to status indicator “T.”

Comment: One commenter recommended that CMS consider allowing different status indicator assignments for HCPCS codes within an APC (for example, some of the codes within an APC could be assigned status indicator “S” and others could be assigned status indicator “T”) and evaluate the need to permit HCPCS codes within the same APC to have a different assigned status indicator than that assigned to the APC under which it is being paid. The commenter believed this was needed to ensure appropriate payments and access to affected services.

Response: We appreciate the commenter’s interest in refining the methodology used for assigning status indicators “S” and “T” under the OPPS. However, we did propose a change to our policy of assigning status indicators to APCs and, therefore, are not making such a change for CY 2014. However, we may consider this comment during future rulemaking.

After consideration of the public comments we received, we are finalizing our CY 2014 proposal, without modification. We are finalizing our proposal to revise the definitions of status indicators “S” and “T” to remove the word “significant” from these definitions; and to add the word “service” to the definition of status indicator “S” to indicate “procedure or service; not discounted when multiple” and to status indicator “T” to indicate “procedure or service; multiple reduction applies.” We believe that these revisions better describe the entire range of procedures and services that will be assigned these status indicators for CY 2014.

In addition, we proposed to update the definition of status indicator “A” for CY 2014. We proposed to remove “Routine Dialysis Services for ESRD Patients Provided in a Certified Dialysis Unit of a Hospital” from the list of items and services applicable for the definition of status indicator “A” because these services are not recognized by OPPS when submitted on an outpatient hospital Part B bill type and are instead assigned to status indicator “B.”

We did not receive any public comments regarding our proposed update of the definition of status indicator “A.” Therefore, we are adopting, as final, our proposal for CY 2014.

B. CY 2014 Comment Indicator Definitions

In the CY 2014 OPPS/ASC proposed rule (78 FR 43628), for the CY 2014 OPPS, we proposed to use the same two comment indicators that are in effect for the CY 2013 OPPS.

- “CH”—Active HCPCS codes 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 2014 OPPS/ASC proposed rule to indicate HCPCS codes for which the status indicator or APC assignment, or both, were proposed for change in CY 2014 compared to their assignment as of June 30, 2013. We stated that we believe that using the “CH” indicator in the proposed rule would facilitate the public’s review of the changes that we proposed for CY 2014.

We proposed to use the “CH” comment indicator in this CY 2014 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 2014 compared to their assignment as of December 31, 2013. We stated that the 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 2014 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 2014 compared to the CY 2013 descriptors would be labeled with comment indicator “NI” in Addendum B to the CY 2014 OPPS/ASC final rule with comment period. However, we stated that in order to receive the comment indicator “NI,” the CY 2014 revision to the code descriptor (compared to the CY 2013 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 this CY 2014 OPPS/ASC final rule with comment period. Like all codes labeled with comment indicator

“NI,” we stated that we would respond to public comments and finalize their OPPTS treatment in the CY 2015 OPPTS/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 2014 also would be labeled with comment indicator “NI” in Addendum B to the CY 2014 OPPTS/ASC final rule with comment period.

Only HCPCS codes with comment indicator “NI” in this CY 2014 OPPTS/ASC final rule with comment period are subject to comment. HCPCS codes that do not appear with comment indicator “NI” in this CY 2014 OPPTS/ASC final rule with comment period are not open to public comment, unless we specifically request additional comments elsewhere in this final rule with comment period.

Comment: One commenter requested that CMS create a new comment indicator for changes to an APC assignment and to keep comment indicator “CH” to designate changes to status indicators. The commenter also suggested that CMS create a new comment indicator to indicate that a code’s descriptor has changed significantly while retaining comment indicator “NI” to indicate that a code is brand new.

Response: We have no operational need to create additional comment indicators that are specific to various types of changes. Therefore, we believe that the CY 2013 definitions of the OPPTS comment indicators continue to be appropriate for CY 2014 and we are continuing to use those definitions without modification for CY 2014. The final definitions of the OPPTS status indicators are listed in Addendum D2 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 ASCs, we refer readers to the CY 2012 OPPTS/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 OPPTS/ASC final rule with comment period (76 FR 74378 through 74379) and

the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68434 through 68467).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under § 416.2 and § 416.166 of the regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPTS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and that would not 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 status under the OPPTS; (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 OPPTS; and (5) certain radiology services for which separate payment is allowed under the OPPTS. 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 OPPTS 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 OPPTS payment policies, we also provide quarterly update change requests (CRs) for ASC 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) outside of the formal rulemaking process 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, therefore, are implemented through the January and July quarterly updates. We refer readers to Table 41 in the CY 2012 OPPTS/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 OPPTS 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 OPPTS rulemaking cycle is particularly important because the OPPTS 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 OPPI/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 2014 OPPI/ASC proposed rule (and respond to those comments in this CY 2014 OPPI/ASC final rule with comment period) or whether we are soliciting public comments in this CY 2014 OPPI/ASC final rule with comment period (and responding to those comments in the CY 2015 OPPI/ASC final rule with comment period).

We note that we sought public comment in the CY 2013 OPPI/ASC final rule with comment period on the new Category I and III CPT and Level II HCPCS codes that were effective January 1, 2013. We also sought public comment in the CY 2013 OPPI/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2012. These new codes, with an effective date of October 1, 2012, or January 1, 2013, were flagged with comment indicator "NI" in Addenda AA and BB to the CY 2013 OPPI/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 2013 OPPI/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 2014 OPPI/ASC final rule with comment period.

2. Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April 2013 and July 2013 for Which We Solicited Public Comments in the CY 2014 OPPI/ASC Proposed Rule

In the April 2013 and July 2013 CRs, we made effective for April 1, 2013 and July 1, 2013, respectively, a total of nine new Level II HCPCS codes and two new Category III CPT codes that describe covered ASC services that were not addressed in the CY 2013 OPPI/ASC final rule with comment period.

In the April 2013 ASC quarterly update (Transmittal 2662, CR 8237, dated March 1, 2013), we added one new surgical Level II HCPCS code and three new drug and biological Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services, respectively. Table 33 of the CY 2014 OPPI/ASC proposed rule (78 FR 43630) listed the new Level II HCPCS codes that were implemented April 1, 2013, along with their proposed payment indicators for CY 2014.

In the July 2013 quarterly update (Transmittal 2717, Change Request 8328, dated May 31, 2013), we added one new surgical Level II HCPCS code to the list of covered surgical procedures and one new vaccine Level II HCPCS code, and three new drug and biological Level II HCPCS codes to the list of covered ancillary services. Table 34 of the CY 2014 OPPI/ASC proposed rule, as corrected (78 FR 43630; Table 34 was corrected in the September 6, 2013 correcting document (78 FR 54845)) listed the new Level II HCPCS codes that were implemented July 1, 2013, along with their proposed payment indicators and proposed ASC payment rates for CY 2014.

We assigned payment indicator "K2" (Drugs and biologicals paid separately when provided integral to a surgical procedure on the ASC list; payment based on OPPI rate) to the six new drug and biological Level II HCPCS codes that are separately paid when provided in ASCs. We assigned payment indicator "L1" (Influenza vaccine; pneumococcal vaccine; packaged item/service, no separate payment made) to the new vaccine Level II HCPCS code and payment indicator "G2" (Non-office-based surgical procedure added in CY 2008 or later; payment based on

OPPI relative payment weight) to the two new surgical Level II HCPCS codes.

We solicited public comment on the proposed CY 2014 ASC payment indicators and payment rates for the covered surgical procedures and covered ancillary services listed in Tables 33 and 34 of the proposed rule, as corrected (78 FR 43630; Table 34 was corrected in the September 6, 2013 correcting document (78 FR 54845)). Those HCPCS codes became payable in ASCs beginning April 1, or July 1, 2013, and are paid at the ASC rates posted for the appropriate calendar quarter on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html.

The HCPCS codes listed in Table 33 of the CY 2014 OPPI/ASC proposed rule (78 FR 43630) were included in Addenda AA or BB to the proposed rule, as corrected (which are available via the Internet on the CMS Web site). We note that all ASC addenda are only available via the Internet on the CMS Web site. Because the payment rates associated with the new Level II HCPCS codes that became effective July 1, 2013 (listed in Table 34 of the proposed rule, as corrected) were not available to us in time for incorporation into the Addenda to the OPPI/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 2014 OPPI/ASC final rule with comment period. Thus, the codes implemented by the July 2013 ASC quarterly update CR and their proposed CY 2014 payment rates (based on July 2013 ASP data) that are displayed in Table 34 of the CY 2014 OPPI/ASC proposed rule as corrected (78 FR 43630; 78 FR 54845) were not included in Addenda AA or BB to the proposed rule, as corrected (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 2014 OPPI/ASC final rule with comment period, consistent with our annual update policy.

We solicited public comment on these proposed payment indicators and the proposed payment rates for the new Level II HCPCS codes that were newly recognized as ASC covered surgical procedures or covered ancillary services in April 2013 and July 2013 through the quarterly update CRs, as listed in Tables

33 and 34 of the CY 2014 OPPS/ASC proposed rule, as corrected (78 FR 43630; 78 FR 54845). We proposed to finalize their payment indicators and their payment rates in this CY 2014 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding our proposals. We are adopting as final for CY 2014 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 and July 2013 through the quarterly update CRs as shown below, in Tables 46 and 47, respectively. These new HCPCS codes are also displayed in Addenda AA and BB to this final rule with comment

period. We note that after publication of the CY 2014 OPPS/ASC proposed rule, the CMS HCPCS Workgroup created permanent HCPCS J-codes for CY 2014 to replace certain temporary HCPCS C-codes made effective for CY 2013. These permanent CY 2014 HCPCS J-codes are listed alongside the temporary CY 2013 HCPCS C-codes in Tables 46 and 47 below.

TABLE 46.—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2013

CY 2013 HCPCS Code	CY 2014 HCPCS Code	CY 2014 Long Descriptor	Final CY 2014 Payment Indicator
C9130	J1556	Injection, immune globulin (Bivigam), 500 mg	K2
C9297	J9262	Injection, omacetaxine mepesuccinate, 0.01 mg	K2
C9298	J7316	Injection, ocriplasmin, 0.125 mg	K2
C9735	C9735	Anoscopy; with directed submucosal injection(s), any substance	G2

TABLE 47.—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2013

CY 2013 HCPCS Code	CY 2014 HCPCS Code	CY 2014 Long Descriptor	Final CY 2014 Payment Indicator
C9131	J9354	Injection, ado-trastuzumab emtansine, 1 mg	K2
C9736	0336T	Laparoscopy, surgical, radiofrequency ablation of uterine fibroid(s), including intraoperative guidance and monitoring, when performed	G2
Q2033	90673	Influenza virus vaccine Influenza virus vaccine, trivalent, derived from recombinant DNA (RIV3), hemagglutinin (HA) protein only, preservative and antibiotic free, for intramuscular use	L1
Q2050*	Q2050	Injection, Doxorubicin Hydrochloride, Liposomal, Not Otherwise Specified, 10 mg	K2
Q2051*	J3489	Injection, Zoledronic Acid, 1 mg	K2

Through the July 2013 quarterly update CR, we also implemented ASC payment for two new Category III CPT

codes as ASC covered ancillary services, effective July 1, 2013. These codes were listed in Table 35 of the CY 2014 OPPS/

ASC proposed rule, as corrected (78 FR 43631; Table 35 was corrected in the September 6, 2013 correcting document

(78 FR 54845)), along with their proposed payment indicators and proposed payment rates for CY 2014. Because the payment rates associated with the new Category III CPT codes that became effective for July were not available to us in time for incorporation into the Addenda to the OPPS/ASC proposed rule, our policy is to include the codes, their proposed payment indicators, and proposed payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. The codes listed in Table 35 of the CY 2014 OPPS/ASC proposed rule, as corrected (78 FR 43631; 78 FR 54845) and their final payment indicators and rates are included in Addendum BB to

this CY 2014 OPPS/ASC final rule with comment period.

We proposed to assign payment indicator “Z2” (Radiology service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight) to the two new Category III CPT codes implemented in July 2013. ASC covered ancillary services are certain items and services that are integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS. We solicited public comment on the proposed payment indicators and the payment rates for the new Category III CPT codes that were newly recognized as ASC covered ancillary services in July 2013 through

the quarterly update CR, as listed in Table 35 of the proposed rule, as corrected. We proposed to finalize their payment indicators and their payment rates in this CY 2014 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding this proposal. We are adopting as final for CY 2014 the ASC payment indicators for the covered ancillary services described by the new Category III CPT codes implemented in the July 2013 CR as shown in Table 48 below. The new CPT codes implemented in July 2013 are also displayed in Addendum BB to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 48.—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2013 AS ASC COVERED ANCILLARY SERVICES

CY 2014 CPT Code	CY 2014 Long Descriptor	Final CY 2014 Payment Indicator
0331T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment	Z2
0332T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment; with tomographic SPECT	Z2

3. Process for New Level II HCPCS Codes and Category I and III CPT Codes for Which We Are Soliciting Public Comments in This CY 2014 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 2014 OPPS/ASC proposed rule (78 FR 43631), we proposed to continue this process for CY 2014. Specifically, for CY 2014, we proposed to include in Addenda AA and BB to the CY 2014 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2014, that would be incorporated in the January 2014 ASC quarterly update CR and the new Level II HCPCS codes, effective October 1, 2013 or January 1, 2014, that would be released by CMS in its October 2013 and January 2014 ASC quarterly update CRs. We stated that these codes would be flagged with comment indicator “NI” in Addenda AA and BB to this CY 2014 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 the CY 2014 OPPS/ASC final rule with comment period and would be finalized in the CY 2015 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding this proposed process. For CY 2014, 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, 2013, or January 1, 2014, 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

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. Upon review, we did not identify any procedures that are currently excluded from the ASC list of procedures that met the definition of a covered surgical procedure based on our expectation that they would not pose a significant safety risk to Medicare beneficiaries or would require an overnight stay if performed in ASCs. Therefore, in the CY 2014 OPPS/ASC proposed rule (78 FR 43631), we did not propose additions to the list of ASC covered surgical procedures for CY 2014.

Comment: One commenter reiterated a previous request that, with knowledge of the anatomic location, CMS should apply the safety criteria to the entire spectrum of services reportable by an unlisted code. The commenter believed that, under such an analysis, CMS

would determine that the following unlisted codes associated with eye procedures would not compromise patient safety and, therefore, should be added to the list of ASC covered surgical procedures: CPT code 66999 (Unlisted procedure, anterior segment of eye); CPT code 67299 (Unlisted procedure, posterior segment); CPT code 67399 (Unlisted procedure, ocular muscle); CPT code 67999 (Unlisted procedure, eyelids); CPT code 68399 (Unlisted procedure, conjunctiva); and CPT code 68899 (Unlisted procedure, lacrimal system).

Response: As we have stated in the past (72 FR 42484 through 42486; 75 FR 72032 through 72033; 76 FR 74380; and 77 FR 68439), procedures that are reported by the CPT unlisted codes are not eligible for addition to the ASC list because we do not know what specific procedure would be represented by an unlisted code. Our charge requires us to evaluate each surgical procedure for potential safety risk and expected need

for overnight monitoring and to exclude from ASC payment procedures that would be expected to pose a threat to beneficiary safety or require active medical monitoring at midnight following the procedure. It is not possible to evaluate procedures that would be reported by unlisted CPT codes according to these criteria. This final policy is discussed in detail in the August 2, 2007 final rule (72 FR 42484 through 42486).

Comment: Commenters requested that CMS add the procedures described by the 54 CPT codes displayed in Table 49 below to the list of ASC covered surgical procedures. The commenters argued that these procedures are as safe as procedures that are currently on the list of ASC covered procedures and, based on a survey, ASCs report positive outcomes when these procedures are performed on non-Medicare patients.

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**TABLE 49.--PROCEDURES REQUESTED FOR ADDITION TO THE CY 2014
LIST OF ASC COVERED SURGICAL PROCEDURES**

CY 2014 CPT Code	CY 2014 Short Descriptor
19307	Mast mod rad
22551	Neck spine fuse&remov bel c2
22552*	Addl neck spine fusion
22554	Neck spine fusion
22612	Lumbar spine fusion
22851	Apply spine prosth device
23470	Reconstruct shoulder joint
23472*	Reconstruct shoulder joint
27093***	Injection for hip x-ray
27095***	Injection for hip x-ray
27415	Osteochondral knee allograft
27447*	Total knee arthroplasty
27524	Treat kneecap fracture
35907*	Excision graft abdomen
41899**	Dental surgery procedure
44970	Laparoscopy appendectomy
44979**	Laparoscope proc app
54332	Revise penis/urethra
54336	Revise penis/urethra
54411*	Remov/replc penis pros comp
54417*	Remv/replc penis pros compl
54535	Extensive testis surgery
54650	Orchiopexy (Fowler-Stephens)
57282	Colpopexy extraperitoneal
57310	Repair urethrovaginal lesion
57425	Laparoscopy surg colpopexy
58260	Vaginal hysterectomy
58262	Vag hyst including t/o
58541***	Lsh uterus 250 g or less
58542***	Lsh w/t/o ut 250 g or less
58543	Lsh uterus above 250 g
58570***	Tlh uterus 250 g or less
58571***	Tlh w/t/o 250 g or less
60240	Removal of thyroid

CY 2014 CPT Code	CY 2014 Short Descriptor
60500	Explore parathyroid glands
62290***	Inject for spine disk x-ray
63011	Remove spine lamina 1/2 scrcl
63012	Remove lamina/facets lumbar
63015	Remove spine lamina >2 crvcl
63016	Remove spine lamina >2 thr
63017	Remove spine lamina >2 lmbr
63020	Neck spine disk surgery
63030	Low back disk surgery
63035	Spinal disk surgery add-on
63040	Laminotomy single cervical
63042	Laminotomy single lumbar
63045	Remove spine lamina 1 crvl
63046	Remove spine lamina 1 thr
63047	Remove spine lamina 1 lmbr
63048	Remove spinal lamina add-on
63055	Decompress spinal cord thr
63056	Decompress spinal cord lmbr
63075	Neck spine disk surgery
63076	Neck spine disk surgery

* Procedure paid only as inpatient procedure

** Unlisted CPT code

*** Procedure currently on ASC list of covered procedures

Response: We reviewed all of the eligible surgical procedures that commenters requested for addition to the ASC list of covered surgical procedures. Of the 54 requested procedures requested for addition to the ASC list, we did not review the 6 procedures that are reported by CPT codes that are on the OPPS inpatient only list (identified with one asterisk in Table 49) or the 2 procedures that may be reported by CPT unlisted codes because these codes are not eligible for addition to the ASC list (identified with two asterisks in Table 49), consistent with our final policy which is discussed in detail in the August 2, 2007 final rule (72 FR 42484 through 42486; 42 CFR 416.171(c)). In addition, we did not review the 7 procedures reported by CPT codes that are already on the ASC list of covered surgical procedures

(identified with three asterisks in Table 49).

With regard to the remaining 39 procedures in Table 49 that commenters requested be added to the list of ASC covered surgical procedures, we do not agree that all of the procedures are appropriate for provision to Medicare beneficiaries in ASCs. Although the commenters asserted that the procedures they were requesting for addition to the list are as safe as procedures already on the list, our review did not support those assertions. We exclude from ASC payment any procedure for which standard medical practice dictates that the beneficiary who undergoes the procedure would typically be expected to require active medical monitoring and care at midnight following the procedure (overnight stay) as well as all surgical procedures that our medical advisors

determine may be expected to pose a significant safety risk to Medicare beneficiaries when performed in an ASC. 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).

In our review of the procedures listed in Table 49, we found that many of the

procedures either would be expected to pose a threat to beneficiary safety or require active medical monitoring 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. However, we agree with commenters that the procedures described by CPT codes 27415, 27524, 60240, and 60500 meet the criteria under § 416.166 and would be safely performed in the ASC setting and would not require overnight stays. We are adding these CPT codes to the ASC list of covered surgical procedures for CY 2014.

After consideration of the public comments we received, we are finalizing the addition of the four procedures requested by the commenters to the CY 2014 list of ASC covered surgical procedures. The procedures, their descriptors, and payment indicators are displayed in Table 50 below.

TABLE 50.—NEW ASC COVERED SURGICAL PROCEDURES FOR CY 2014

CY 2014 HCPCS Code	CY 2014 Long Descriptor	Final CY 2014 ASC Payment Indicator
27415	Osteochondral allograft, knee, open	G2
27524	Open treatment of patellar fracture, with internal fixation and/or partial or complete patellectomy and soft tissue repair	G2
60240	Thyroidectomy, total or complete	G2
60500	Parathyroidectomy or exploration of parathyroid(s);	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 OPFS 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 OPFS relative payment weight), depending on whether we estimated it would be paid according to the standard ASC payment methodology based on its OPFS 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, permanently office-based, or non-office-based, after taking into account updated volume and utilization data.

(2) Changes for CY 2014 to Covered Surgical Procedures Designated as Office-Based

In developing the CY 2014 OPFS/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 2012 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 OPFS relative payment weight) in CY 2013, as well as for those procedures assigned one of the temporary office-based payment

indicators, specifically “P2*,” “P3*,” or “R2*” in the CY 2013 OPFS/ASC final rule with comment period (77 FR 68444 through 68448).

In the CY 2014 OPFS/ASC proposed rule (78 FR 43632), we stated that our review of the CY 2012 volume and utilization data resulted in our identification of three covered surgical procedures that we believe meet the criteria for designation as office-based. We stated that the data indicated that these procedures are performed more than 50 percent of the time in physicians’ offices and that our medical advisors believe the services are of a level of complexity consistent with other procedures performed routinely in physicians’ offices. The three CPT codes we proposed to permanently designate as office-based were listed in Table 36 of the CY 2014 OPFS/ASC proposed rule (78 FR 43632). We invited public comment on this proposal.

Comment: One commenter disagreed with the policy to make payment at the lower of the ASC rate or the MPFS nonfacility PE RVU payment amount for procedures that CMS identifies as office-based. This commenter expressed concern that this policy does not provide adequate payment for some services performed in an ASC.

Response: We have responded to this comment in the past and we continue to believe that our policy of identifying low complexity procedures that are usually provided in physicians’ offices

and limiting their payment in ASCs to the physician's office payment amount is necessary and valid. We believe this is the most appropriate approach to prevent payment incentives for services to move from physicians' offices to ASCs for the many newly covered low complexity procedures on the ASC list. We refer readers to our response to this comment in the CY 2010, CY 2011, CY 2012, and CY 2013 OPPS/ASC final rules with comment period (74 FR 60605 through 60607; 75 FR 72034 through 72036; 76 FR 74401; and 77 FR 68444 through 68445, respectively).

Comment: One commenter believed that the procedure described by CPT

code 37761 (Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg) should not be designated as office-based. This commenter suggested that inaccurate coding for place of service results in the volume and utilization data indicating that the procedure is performed more than 50 percent of the time in physicians' offices and that the level of complexity associated with CPT code 37761 is not consistent with other procedures performed routinely in physicians' offices.

Response: Our review of the CY 2012 volume and utilization data indicates that CPT code 37761 is performed 53

percent of the time in physicians' offices. Our policy is to designate as office-based those procedures that are performed more than 50 percent of the time in physicians' offices; therefore, we are designating CPT code 37761 as office-based for CY 2014 as we proposed.

After consideration of the public comments we received, we are finalizing our CY 2014 proposal to designate the procedures described by CPT codes 26341, 36595, and 37761 as permanently office-based as displayed in Table 51 below.

TABLE 51.—ASC COVERED SURGICAL PROCEDURES NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2014

CY 2014 CPT Code	CY 2014 Long Descriptor	CY 2013 ASC Payment Indicator	Proposed CY 2014 ASC Payment Indicator*	Final CY 2014 ASC Payment Indicator*
26341	Manipulation, palmar fascial cord (ie, dupuytren's cord), post enzyme injection (eg, collagenase), single cord	G2	P3	P3
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg	G2	R2	R2
36595	Mechanical removal of pericatheter obstructive material (eg, fibrin sheath) from central venous device via separate venous access	G2	P3	P3

* Final payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates. According to the statutory formula, current law requires a negative update to the MPFS payment rates for CY 2014. For a discussion of those rates, we refer readers to the CY 2014 MPFS final rule with comment period.

We also reviewed CY 2012 volume and utilization data and other information for the eight procedures finalized for temporary office-based status in Table 51 and Table 53 in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68442 through 68444 and 68448). Among these eight procedures, there were very few claims data for four procedures: CPT code 0099T (Implantation of intrastromal corneal ring segments); CPT code 0124T (Conjunctival incision with posterior extracapsular placement of

pharmacological agent (does not include supply of medication)); 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); and CPT code 67229 (Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy). Consequently, we

proposed to maintain their temporary office-based designations for CY 2014.

The volume and utilization data for one procedure that has a temporary office-based designation for CY 2013, CPT code 0227T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)), is sufficient to indicate that this procedure is not performed predominantly in physicians' offices and, therefore, should not be assigned an office-based payment indicator in CY 2014. Consequently, we proposed to

assign payment indicator “G2” to this covered surgical procedure code in CY 2014 (78 FR 43632).

The three remaining procedures that have temporary office-based designations for CY 2013 were proposed to be packaged under the OPPS for CY 2014 as discussed in section II.A.3. of the proposed rule. Consequently, we proposed to assign payment indicator “N1” to the following three covered surgical procedure codes in 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);
- CPT code 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound); and
- CPT code 0300T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; each

additional wound (list separately in addition to code for primary procedure)).

The proposed CY 2014 payment indicator designations for the eight procedures that were temporarily designated as office-based in CY 2013 were displayed in Table 37 of the CY 2014 OPPS/ASC proposed rule (78 FR 43632 through 43633). The procedures for which the proposed office-based designations for CY 2014 are temporary also were indicated by asterisks in Addendum AA to the proposed rule, as corrected (which is available via the Internet on the CMS Web site). We invited public comment on these proposals.

We did not receive any public comments on these proposals. For CY 2014, we are finalizing our proposal, without modification, to continue to designate four of the eight procedures (listed in Table 37 of the CY 2014 OPPS/ASC proposed rule (78 FR 43632 through 43633) and restated in Table 52 below), which were designated as

temporarily office-based for CY 2013, as temporarily office-based for CY 2014. In addition, we are finalizing our proposal to not designate CPT code 0227T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)) as office-based in CY 2014 and are assigning payment indicator “G2” to this code. Finally, we are finalizing our proposal to assign payment indicator “N1” to HCPCS code 0300T because this procedure will be packaged under the OPPS for CY 2014. However, we are not finalizing our proposal to package the procedures identified by HCPCS codes 0226T and 0299T under the OPPS. We reviewed CY 2012 volume and utilization data and other information for HCPCS codes 0226T and 0299T which had temporary office-based designations in CY 2013. Because there are very few claims reporting HCPCS codes 0226T and 0299T, we will maintain their temporary office-based designations for CY 2014.

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TABLE 52.—CY 2014 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2013 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2014 CPT Code	CY 2014 Long Descriptor	CY 2013 ASC Payment Indicator	CY 2014 ASC Payment Indicator**
0099T	Implantation of intrastromal corneal ring segments	R2*	R2*
0124T	Conjunctival incision with posterior extrасcleral placement of pharmacological agent (does not include supply of medication)	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*	R2*
0227T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)	R2*	G2
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2*	R2*
0300T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; each additional wound (list separately in addition to code for primary procedure)	R2*	N1
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*
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. According to the statutory formula, current law requires a negative update to the MPFS payment rates for CY 2014. For a discussion of those rates, we refer readers to the CY 2014 MPFS final rule with comment period.

As we discuss in section XII.B.3. of the CY 2014 OPPS/ASC proposed rule (78 FR 43631) and this final rule with comment period, we incorporate new Category I and Category III CPT codes and new Level II HCPCS codes that are effective October 1, 2013 and January 1,

2014 in this final rule with comment period. Because these codes were not available to us until after the CY 2014 OPPS/ASC proposed rule was published, these codes were not included in that rule. After reviewing the clinical characteristics, utilization,

and volume of related codes, we determined that two of the procedures described by new CPT codes would be predominantly performed in physicians' offices. However, because we had no utilization data for the procedures specifically described by these new CPT

codes, we made the office-based designations temporary rather than permanent and we will reevaluate the procedures when data become available.

The temporary payment indicators for the two office-based procedures

displayed in Table 53 below are flagged with comment indicator "NI" in Addendum AA 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. We will respond to any public comments received in the CY 2015 OPPS/ASC final rule with comment period.

TABLE 53.—FINAL CY 2014 PAYMENT INDICATORS FOR NEW CY 2014 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2014 CPT Code	CY 2014 Long Descriptor	CY 2014 ASC Payment Indicator**
10030	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst), soft tissue (eg, extremity abdominal wall, neck), percutaneous	P2*
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed	P3*

* 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. According to the statutory formula, current law requires a negative update to the MPFS payment rates for CY 2014. For a discussion of those rates, we refer readers to the CY 2014 MPFS final rule with comment period.

c. ASC Covered Surgical Procedures 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 2014

As discussed in section II.A.2.e of the CY 2014 OPPS/ASC proposed rule (78 FR 43558 through 43561), for CY 2014, we proposed to create 29 comprehensive APCs to replace 29 of the most costly device-dependent APCs under the OPPS. 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. We proposed to apply our standard APC ratesetting methodology to the remaining 10 device-dependent APCs to calculate their CY 2014 OPPS payment rates.

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 OPPS ancillary services that are provided integral to surgical procedures that 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. In addition, to avoid duplicate payment

for separately paid ancillary services provided integral to the surgical procedure because the OPPS relative weights for comprehensive APCs include costs for ancillary services, we proposed that the ASC payment rates and device offset amounts for comprehensive APCs would be based on the CY 2014 OPPS relative payments weights that have been calculated using the standard APC ratesetting methodology instead of the relative payment weights that are based on the comprehensive service.

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 create comprehensive APCs to replace 29 of the 39 device-dependent APCs under the OPPS, we proposed to define ASC device-intensive procedures as those procedures that are assigned to any APC with a device offset percentage

greater than 50 percent based on the standard OPPS APC ratesetting methodology. 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 this modified definition of device-intensive procedures, reflecting the proposed APC assignments of procedures and APC device offset percentages based on the CY 2012 OPPS claims and cost report data available for the proposed rule.

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 2014 were listed in Table 38 of the CY 2014 OPPS/ASC proposed rule (78 FR 43634 through 43635). The CPT code, the CPT code short descriptor, the proposed CY 2014 ASC payment indicator (PI), the proposed CY 2014 OPPS APC assignment, the proposed CY 2014 OPPS APC device offset percentage, and an indication if the full credit/partial credit (FB/FC) device adjustment policy would apply were also listed in Table 38. All of these procedures were included in Addendum AA to the proposed rule, as corrected (which is available via the Internet on the CMS Web site). We invited public comment on this proposal.

Comment: Some commenters expressed the same general concerns made in previous rulemakings regarding the sufficiency of ASC payment for device-related services and recommended modifications to the ASC device-intensive payment methodology. The commenters argued that CMS should apply the device-intensive payment methodology to all procedures for which CMS can establish a median device cost and not just to the procedures where the device offset percentage is greater than 50 percent of the APC cost under the OPPS. In a related suggestion, some commenters urged CMS to establish the threshold used to determine device-intensive procedures at 50 percent of the “unadjusted” ASC payment rate (OPPS relative weight multiplied by the ASC conversion factor) instead of the OPPS payment rate. The commenters also made the same argument as made 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 42504), 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 (that is, the device offset percentage is greater than 50). In the CY 2014 OPPS/ASC proposed rule (78 FR 43558 through 43561), we proposed to create comprehensive APCs to replace 29 of the 39 device-dependent APCs under the OPPS. Because of this proposed change for the OPPS, we proposed to define ASC device-intensive procedures as those procedures that are assigned to any APC with a device offset percentage greater than 50 percent. Because we are not implementing the comprehensive APC policy under the OPPS until CY 2015, as discussed in section II.A.2.e. of this final rule with comment period, we are not finalizing this proposal for the ASC payment system and will continue to use our current definition of device-intensive procedures.

We do not agree with the commenters that the device-intensive methodology should be applied to all procedures where a device offset can be established. Nor do we agree with the commenters who suggested using a threshold to determine device-intensive procedures that is based on 50 percent of the ASC payment rate instead of the OPPS payment rate. We continue to believe that when device costs comprise 50 percent or less of total procedure costs, those costs are less likely to be as predictable across sites-of-service. Accordingly, we believe that it is possible for ASCs to achieve efficiencies relative to HOPDs when providing those procedures, and that the application of the ASC conversion factor to the entire ASC payment weight is appropriate. We refer readers to our response to this comment in the CY 2010, CY 2011, CY 2012, and CY 2013 OPPS/ASC final rules with comment period (74 FR 60608 and 60609; 75 FR 72039; 76 FR 74409; and 77 FR 68449, respectively).

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, because 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 refer readers to our response to this comment in the CY

2009, CY 2010, CY 2011, CY 2012 and CY 2013 OPPS/ASC final rules with comment period (73 FR 68735; 74 FR 60608 through 60609; 75 FR 72039; 76 FR 74409; and 77 FR 68449, respectively).

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 create 29 comprehensive APCs to replace 29 of the most costly device dependent APCs under the OPPS, but we will not implement the comprehensive APC policy until CY 2015. Therefore, under the ASC payment system, we are not finalizing our proposal to revise § 416.171(b)(2) to define ASC device-intensive procedures as those procedures that are assigned to any APC with a device offset percentage greater than 50 percent. For CY 2014, we will continue to define ASC device-intensive procedures as those procedures that are assigned to device-dependent APCs under the OPPS with device costs greater than 50 percent of the APC cost. We are updating the ASC list of covered surgical procedures that are eligible for payment according to our current device-intensive procedure payment methodology and reflecting the APC assignments of procedures and APC device offset percentages based on the CY 2012 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 54 below as device-intensive and subject to the device-intensive procedure payment methodology for CY 2014. The CPT code, the CPT code short descriptor, the final CY 2014 ASC payment indicator (PI), the final CY 2014 OPPS APC assignment, the final CY 2014 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 54 of this final rule with comment period. 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 current OPPS policy. The established ASC policy adopts the OPPS policy and 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 OPPI to which this policy applies. We refer readers to the CY 2009 OPPI/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 OPPI/ASC proposed rule (78 FR 43596 through 43598), we proposed to modify our existing policy of reducing OPPI payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Currently under the OPPI, our policy is to reduce OPPI 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 proposed to reduce OPPI payment for applicable APCs by the full or partial credit a provider receives for a replaced device.

Although we proposed to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPI, we proposed to maintain our current 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 OPPI, 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 proposed to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device

without cost or with full or partial credit, respectively. We also proposed to update the list of ASC covered device-intensive procedures that would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2014. Table 38 of the CY 2014 OPPI/ASC proposed rule (78 FR 43634 through 43635) 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 2014. Specifically, when a procedure that was listed in Table 38 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 38 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 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 38 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 of the cost of a device. In order to report that they received a partial credit of 50 percent or more 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 of the cost of the replacement device. Beneficiary coinsurance would continue to be based on the reduced payment amount. We invited public comment on these proposals.

We did not receive any comments on our CY 2014 proposal to continue the no cost/full credit and partial credit device adjustment policy for ASCs. For CY 2014, as proposed, we will reduce the payment for the device implantation procedures listed in Table 54 below that are subject to the adjustment 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 54 below when the device is furnished without cost or with full credit. In addition, for CY 2014, we will reduce the payment for the device implantation procedures listed in Table 54 below that are subject to the adjustment 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 of the device cost. The ASC must append the HCPCS "FC" modifier to the HCPCS code for a surgical procedure listed in Table 54 below that is subject to the partial credit device adjustment policy when the facility receives a partial credit of 50 percent or more of the cost of a device.

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**TABLE 54.—ASC COVERED SURGICAL PROCEDURES DESIGNATED AS
DEVICE-INTENSIVE FOR CY 2014, INCLUDING ASC COVERED SURGICAL
PROCEDURES FOR WHICH THE NO COST/FULL CREDIT OR PARTIAL
CREDIT DEVICE ADJUSTMENT POLICY WILL APPLY**

CPT Code	Short Descriptor	Final CY 2014 ASC PI	Final CY 2014 OPPS APC	Final CY 2014 Device- Dependent APC Offset Percent	FB/FC Policy Will Apply
24361	Reconstruct elbow joint	J8	0425	60%	Yes
24363	Replace elbow joint	J8	0425	60%	Yes
24366	Reconstruct head of radius	J8	0425	60%	Yes
24370	Revise reconst elbow joint	J8	0425	60%	Yes
24371	Revise reconst elbow joint	J8	0425	60%	Yes
25441	Reconstruct wrist joint	J8	0425	60%	Yes
25442	Reconstruct wrist joint	J8	0425	60%	Yes
25446	Wrist replacement	J8	0425	60%	Yes
27446	Revision of knee joint	J8	0425	60%	Yes
33206	Insert heart pm atrial	J8	0089	69%	Yes
33207	Insert heart pm ventricular	J8	0089	69%	Yes
33208	Insrt heart pm atrial & vent	J8	0655	73%	Yes
33212	Insert pulse gen snl lead	J8	0090	67%	Yes
33213	Insert pulse gen dual leads	J8	0654	70%	Yes
33214	Upgrade of pacemaker system	J8	0655	72%	Yes
33221	Insert pulse gen mult leads	J8	0654	70%	Yes
33224	Insert pacing lead & connect	J8	0655	73%	Yes
33225	L ventric pacing lead add-on	J8	0655	73%	Yes
33227	Remove&replace pm gen singl	J8	0090	67%	Yes
33228	Remv&replc pm gen dual lead	J8	0654	70%	Yes
33229	Remv&replc pm gen mult leads	J8	0654	70%	Yes
33230	Insrt pulse gen w/dual leads	J8	0107	81%	Yes
33231	Insrt pulse gen w/mult leads	J8	0107	81%	Yes
33240	Insrt pulse gen w/singl lead	J8	0107	81%	Yes
33249	Nsert pace-defib w/lead	J8	0108	82%	Yes
33262	Remv&replc cvd gen sing lead	J8	0107	81%	Yes
33263	Remv&replc cvd gen dual lead	J8	0107	81%	Yes
33264	Remv&replc cvd gen mult lead	J8	0107	81%	Yes

CPT Code	Short Descriptor	Final CY 2014 ASC PI	Final CY 2014 OPPS APC	Final CY 2014 Device-Dependent APC Offset Percent	FB/FC Policy Will Apply
33282	Implant pat-active ht record	J8	0680	74%	Yes
37227	Fem/popl revasc stnt & ather	J8	0319	52%	No
37231	Tib/per revasc stent & ather	J8	0319	52%	No
53440	Male sling procedure	J8	0385	63%	Yes
53444	Insert tandem cuff	J8	0385	63%	Yes
53445	Insert uro/ves nck sphincter	J8	0386	70%	Yes
53447	Remove/replace ur sphincter	J8	0386	70%	Yes
54400	Insert semi-rigid prosthesis	J8	0385	63%	Yes
54401	Insert self-contd prosthesis	J8	0386	70%	Yes
54405	Insert multi-comp penis pros	J8	0386	70%	Yes
54410	Remove/replace penis prosth	J8	0386	70%	Yes
54416	Remv/repl penis contain pros	J8	0386	70%	Yes
55873	Cryoablate prostate	J8	0674	57%	No
61885	Insrt/redo neurostim 1 array	J8	0039	86%	Yes
61886	Implant neurostim arrays	J8	0315	88%	Yes
62361	Implant spine infusion pump	J8	0227	81%	Yes
62362	Implant spine infusion pump	J8	0227	81%	Yes
63650	Implant neuroelectrodes	J8	0040	55%	Yes
63655	Implant neuroelectrodes	J8	0061	66%	Yes
63663	Revise spine eltrd perq aray	J8	0040	55%	Yes
63664	Revise spine eltrd plate	J8	0040	55%	Yes
63685	Insrt/redo spine n generator	J8	0039	86%	Yes
64553	Implant neuroelectrodes	J8	0040	55%	Yes
64555	Implant neuroelectrodes	J8	0040	55%	Yes
64561	Implant neuroelectrodes	J8	0040	55%	Yes
64565	Implant neuroelectrodes	J8	0040	55%	Yes
64568	Inc for vagus n elect impl	J8	0318	87%	Yes
64569	Revise/repl vagus n eltrd	J8	0040	55%	Yes
64575	Implant neuroelectrodes	J8	0061	66%	Yes
64580	Implant neuroelectrodes	J8	0061	66%	Yes
64581	Implant neuroelectrodes	J8	0061	66%	Yes
64590	Insrt/redo pn/gastr stimul	J8	0039	86%	Yes
65770	Revise cornea with implant	J8	0293	65%	No

CPT Code	Short Descriptor	Final CY 2014 ASC PI	Final CY 2014 OPPS APC	Final CY 2014 Device-Dependent APC Offset Percent	FB/FC Policy Will Apply
69714	Implant temple bone w/stimul	J8	0425	60%	Yes
69715	Temple bone implnt w/stimulat	J8	0425	60%	Yes
69717	Temple bone implant revision	J8	0425	60%	Yes
69718	Revise temple bone implant	J8	0425	60%	Yes
69930	Implant cochlear device	J8	0259	84%	Yes
0282T	Periph field stimul trial	J8	0040	55%	Yes
0283T	Periph field stimul perm	J8	0318	87%	Yes
0302T	Icar ischm mntrng sys compl	J8	0089	69%	Yes
0304T	Icar ischm mntrng sys device	J8	0090	67%	Yes
0316T	Replc vagus nerve pls gen	J8	0039	86%	Yes
0319T	Insert subq defib w/eltrd	J8	0107	81%	Yes
0321T	Insert subq defib pls gen	J8	0107	81%	Yes
0323T	Rmvl & replc subq pls gen	J8	0107	81%	Yes
G0448	Place perm pacing cardiovert	J8	0108	82%	Yes

e. ASC Treatment of Surgical Procedures Removed From the OPPS Inpatient List for CY 2014

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. There are no procedures proposed for removal from the OPPS inpatient list for CY 2014, so in the CY 2014 OPPS/ASC proposed rule (78 FR 43636) we did not propose any procedures for possible inclusion on the ASC list of covered surgical procedures under this section.

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 2014 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary items and services because of changes that are being proposed under the OPPS for CY

2014. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2013 may be proposed for packaged status under the CY 2014 OPPS and, therefore, also under the ASC payment system for CY 2014. More specifically, as discussed in section II.A.3. of the CY 2014 OPPS/ASC proposed rule (78 FR 43568 through 43576), we proposed to package the following categories of ancillary or adjunctive services under the OPPS for CY 2014: Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; drugs and biologicals that function as supplies when used in a surgical procedure; clinical diagnostic laboratory tests; procedures described by add-on codes; ancillary services (status indicator "X"); diagnostic tests on the bypass list; and device removal procedures.

To maintain consistency with the OPPS, we proposed that these services also would be packaged under the ASC payment system for CY 2014. Comment indicator "CH," discussed in section XII.F. of the proposed rule (78 FR 43639), was used in Addendum BB to the proposed rule, as corrected (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 2014.

Except for the Level II HCPCS codes and Level III CPT codes listed in Table 34 and Table 35 of the CY 2014 OPPS/ASC proposed rule, as corrected (78 FR 43630 through 43631; 78 FR 54845), all ASC covered ancillary services and their proposed payment indicators for CY 2014 were included in Addendum BB to the proposed rule, as corrected. We invited public comment on this proposal.

We did not receive any public comments on our proposal. Therefore, 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 2014 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 were, therefore, 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 2013 OPPS/ASC final rule with comment period (77 FR 68434 through 68467), we updated the CY 2012 ASC payment rates for ASC covered surgical procedures with payment indicators of “A2,” “G2,” and “J8” using CY 2011 data, consistent with the CY 2013 OPPS update. Payment rates for device-intensive procedures also were updated to incorporate the CY 2013 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 2014 MPFS final rule with comment period) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2013 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 2013 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 2013 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 2014

In the CY 2014 OPPS/ASC proposed rule (78 FR 43636 through 43637), we proposed to update ASC payment rates for CY 2014 using the established rate calculation methodologies under § 416.171 and using our proposed modified definition for device-intensive procedures as discussed above. Because the proposed OPPS relative payment weights are based on geometric mean costs for CY 2014, the ASC system will use 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, incorporating the device-intensive procedure methodology as appropriate. Thus, we proposed to update the payment amounts for device-intensive procedures, using our proposed modified definition of device intensive procedures, based on the CY 2014 OPPS device offset percentages that have been calculated using the standard APC ratesetting methodology, and to make payment for office-based procedures at the lesser of the proposed CY 2014 MPFS nonfacility PE RVU-based amount or the proposed CY 2014 ASC payment amount calculated according to the standard ratesetting methodology. We invited public comment on these proposals.

Comment: With regard to device removal procedures, commenters recommended that CMS modify its policy to package procedures in the ASC when the procedures are conditionally packaged in the OPPS. The commenters stated that, under this policy, no Medicare payment would be made for device removal procedures performed in an ASC if the device was removed and not replaced because the device removal

procedures are proposed to be conditionally packaged under the OPPS.

Response: We agree with the commenters’ concerns regarding payment for device removal procedures performed in an ASC. Under the OPPS, a conditionally packaged code (status indicators “Q1” or “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 surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator “N1”) under the ASC payment system. Under the OPPS, we are finalizing a proposal to conditionally package device removal codes for CY 2014. Therefore, under our current ASC policy to package payment for services that are conditionally packaged in the OPPS, no Medicare payment would be made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim. We believe that our ASC policy to package procedures that are conditionally packaged in the OPPS should be modified with regard to device removal procedures so that these procedures will continue to be separately paid in the ASC.

After consideration of the public comments we received, we are finalizing our proposal to calculate CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For the 71 device removal procedures that are conditionally packaged in the OPPS (status indicator “Q2”), we will not follow our usual policy to package these procedures in the ASC but, instead, will assign the current ASC payment indicators associated with these procedures and continue to provide separate payment in CY 2014.

c. Waiver of Coinsurance and Deductible for Certain Preventive Services

As discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 43637), 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 2014 in the CY 2014 OPPS/ASC proposed rule (78 FR 43637). We identify the specific services with a double asterisk in Addenda AA and BB to this final rule with comment period.

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. 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). For CY 2014, CPT code 33249, the primary code for CRT-D services, is

proposed for continued assignment to APC 0108 but CPT code 33225 is proposed to be packaged under the OPPS.

Consequently, in the CY 2014 OPPS/ASC proposed rule (78 FR 43637), we proposed that CPT code 33225 would also be packaged under the ASC payment system for CY 2014. Because CPT code 33225 is proposed to be packaged under the ASC payment system and, therefore, 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. Therefore, we proposed that the ASC payment rate for CRT-D services (procedures described by CPT codes 33249 and 33225) would be based on the OPPS relative payment weight for APC 0108 for CY 2014 and that ASCs would no longer be required to assign HCPCS code G0448 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.

As indicated in section II.A.2.e. of this final rule with comment period, after consideration of public comments we received regarding the proposed OPPS comprehensive APC policy, we are finalizing our proposal to create 29 comprehensive APCs to replace 29 of the most costly device-dependent APCs under the OPPS but we will not implement the finalized comprehensive APC policy until CY 2015. Consequently, CPT code 33225 will not be packaged under the OPPS for CY 2014 but will be separately paid. Therefore, we are not finalizing our proposal to package CPT code 33225 under the ASC payment system. For CY 2014, we will continue our current policy regarding ASC payment for CRT-D services. The CY 2014 ASC payment rate for CRT-D services will be based on the OPPS payment rate applicable to APC 0108 when procedures described by CPT codes 33225 and 33249 are performed on the same date of service in an ASC. ASCs will 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 will be 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 will be based on APC 0655 using the device-intensive methodology.

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 continue to 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 continue to be assigned to APC 0163. 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 2014 OPPS/ASC proposed rule (78 FR 43637), we did not propose any changes to our current policy regarding ASC payment for LDR prostate brachytherapy services for CY 2014.

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 OPPTS. 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 OPPTS 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 OPPTS. In the CY 2013 OPPTS/ASC proposed rule (77 FR 45169), we further clarified our policy regarding the payment indicator assignment of codes that are conditionally packaged in the OPPTS (status indicators “Q1” and “Q2”). Under the OPPTS, 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 OPPTS are always packaged (payment indicator “N1”) under the ASC payment system. Thus, our final policy generally aligns ASC payment bundles with those under the OPPTS (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 OPPTS at the OPPTS 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 OPPTS/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 OPPTS/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 OPPTS 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 OPPTS/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 OPPTS relative payment weight and will, therefore, 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 OPPTS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPTS or, if OPPTS 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 OPPTS.

Other separately paid covered ancillary services in ASCs, specifically corneal tissue acquisition and device categories with OPPTS pass-through status, do not have prospectively established ASC payment rates according to the final policies of the revised ASC payment system (72 FR 42502 and 42508 through 42509; 42 CFR 416.164(b)). Under the revised ASC payment system, corneal tissue acquisition is paid based on the invoiced costs for acquiring the corneal tissue for transplantation. Devices that are eligible for pass-through payment under the OPPTS are separately paid

under the ASC payment system. Currently, the four devices that are eligible for pass-through payment in the OPPTS are described by HCPCS code C1830 (Powered bone marrow biopsy needle), HCPCS code C1840 (Lens, intraocular (telescopic)), HCPCS code C1841 (Retinal prosthesis, includes all internal and external components), and HCPCS code C1886 (Catheter, extravascular tissue ablation, any modality (insertable)). Payment amounts for HCPCS codes C1830, C1840, C1841, and C1886 under the ASC payment system are contractor priced. In the CY 2013 OPPTS/ASC final rule with comment period, we finalized the expiration of pass-through payment for HCPCS codes C1830, C1840, and C1886, which will expire after December 31, 2013 (77 FR 68353). Therefore, after December 31, 2013, the costs for devices described by HCPCS codes C1830, C1840, and C1886 will be packaged into the costs of the procedures with which the devices are reported in the hospital claims data used in the development of the OPPTS relative payment weights that are used to establish ASC payment rates for CY 2014. 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 2014.

b. Payment for Covered Ancillary Services for CY 2014

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43638 through 43639), for CY 2014, we proposed to update the ASC payment rates and make changes to ASC payment indicators as necessary to maintain consistency between the OPPTS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2014 OPPTS and ASC payment rates. We also proposed to set the CY 2014 ASC payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the proposed CY 2014 OPPTS rates.

Consistent with established ASC payment policy (72 FR 42497), the proposed CY 2014 payment for separately payable covered radiology services was based on a comparison of the proposed CY 2014 MPFS nonfacility PE RVU-based amounts (we refer readers to the CY 2014 MPFS proposed rule) and the proposed CY 2014 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). Alternatively, payment for a radiology service may 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, as corrected, 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 were assigned payment indicator “Z2” (Radiology 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 were assigned payment indicator “Z3” (Radiology 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 2014 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 2014 and, therefore, set the payment indicator to “Z2” for radiology services that use contrast agents.

Most covered ancillary services and their proposed payment indicators were listed in Addendum BB to the proposed rule, as corrected (which is available via the Internet on the CMS Web site). We

invited public comment on these proposals.

Comment: One commenter requested that the procedure described by CPT code 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system) (list separately in addition to code for primary procedure)) be excluded from the OPPS policy to package add-on codes due to impact on the proposed CY 2014 ASC payment rates for cardiac resynchronization therapy implant procedures (CRT-P, which is identified by CPT codes 33206 (Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial) and 33207 (Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular)) that include this add-on code. The commenter indicated that the proposed ASC payment rates for CRT-P services decrease by about 35 percent due to OPPS packaging of the add-on CPT code 33225.

Response: Our payment policies under the revised ASC payment system for covered ancillary services provide 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 provide packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators “N,” “Q1,” and “Q2”) under the OPPS. As detailed in section II.A.3.c. of this final rule with comment period, we are finalizing our proposal to package procedures described by add-on codes under the OPPS for CY 2014. Therefore, in order to align the ASC payment bundles with those under the OPPS, the ASC payment for CPT code 33225 will be packaged into the payment for the associated procedures and will not be separately paid in CY 2014.

Comment: Commenters stated that hospitals perform more ancillary services than ASCs and, therefore, greater packaging is appropriate under the OPPS, but not under the ASC payment system. Commenters also suggested that, because laboratory tests associated with ASC procedures are paid under the Clinical Laboratory Fee Schedule, duplicate payment will occur if the OPPS relative weights that are used to calculate ASC payment rates include costs for laboratory tests.

Response: As detailed in section II.A.3. of this final rule with comment

period, we are finalizing our proposal to package the following items and services under the OPPS for CY 2014: (1) Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; (2) drugs and biologicals that function as supplies when used in a surgical procedure; (3) clinical diagnostic laboratory tests; (4) procedures described by add-on codes; and (5) device removal procedures. However, we are not finalizing our proposal to package ancillary services or diagnostic tests on the bypass list under the OPPS for CY 2014. Therefore, with respect to the commenters’ concerns about the proposed packaging of ancillary services, ancillary services will continue to have separate payment in CY 2014 under the OPPS.

With respect to the concern raised by commenters regarding duplicate payment of laboratory tests, packaging laboratory services under the OPPS will increase the relative payment weights and, subsequently, the ASC payment rates for those surgical procedures that include laboratory tests when provided in the hospital outpatient department. However, because we uniformly scale the ASC relative payment weights each update year to make them budget neutral, the changes to the relative payment weights that are associated with laboratory packaging will not result in duplicate or additional Medicare payment in aggregate. In addition, because the packaged laboratory tests are spread over many APCs, we also believe that the impact on particular services is minor. Furthermore, fewer laboratory tests should be necessary in the ASC as diagnostic evaluations are not performed in the ASC.

After consideration of the public comments we received, we are providing CY 2014 payment for covered ancillary services in accordance with the policies finalized in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68458 through 68459). Covered ancillary services and their final CY 2014 payment indicators are listed in Addendum BB (which is available via the Internet on the CMS Web site) to this 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 Pub. L. 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 2014

As discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 43639), we did not receive any requests for review to establish a new NTIOL class for CY 2014 by March 1, 2013, the due date published in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68461).

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 2014.

4. Announcement of CY 2014 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 2015, 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 3, 2014. 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/ASCPayment/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” is also assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). In this CY 2014 OPPS/ASC final rule with comment period, we 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 2013 OPPS/ASC final rule with comment period.

The “CH” comment indicator is used in Addenda AA and BB to the proposed rule, as corrected (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 2014 OPPS/ASC proposed rule (78 FR 43640), we did not propose any changes to the definitions of the ASC payment and comment indicators for CY 2014. We referred readers to Addenda DD1 and DD2 to the CY 2014 OPPS/ASC proposed rule (which are available via the Internet on the CMS Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2014 update.

Addenda DD1 and DD2 to this final rule with comment period (which are available via the Internet on the CMS Web site) contain the complete list of payment and comment indicators for the CY 2014 update.

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 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 this final rule with comment period), 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 hospital wage indices 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, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003. The reclassification provision provided at section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available raw pre-floor and pre-reclassified hospital wage indices results in the most appropriate adjustment to the labor portion of ASC costs. In addition, use of the unadjusted hospital wage data avoids further reductions in certain rural statewide wage index values that result from reclassification. We continue to believe that the unadjusted hospital wage indices, which are updated yearly and are used by many other Medicare payment systems, appropriately account

for geographic variation in labor costs for ASCs.

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 indices 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). We have applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA).

When all of the areas contiguous to the 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 indices 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 indices for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.

Comment: Several commenters made the same recommendation that was made in the CY 2010 (74 FR 60625), CY 2011 (75 FR 72059), CY 2012 (76 FR 74446), and CY 2013 (77 FR 68463) rulemakings—that is, that CMS adopt for the ASC payment system the same wage index values used for hospital payment under the OPPS.

Response: We have responded to this comment in the past, and believe our prior rationale for using unadjusted wage indices is still a sound one. We continue to believe that the unadjusted hospital wage indices, which are updated yearly and are used by almost all Medicare payment systems, appropriately account for geographic variance in labor costs for ASCs. We refer readers to our response to this comment in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72059). We discuss our budget neutrality adjustment for changes to the wage indices below in section XIV.H.2.b. of this final rule with comment period.

After consideration of the public comments we received, we are continuing our established policy to account for geographic wage variation in labor cost when calculating individual ASC payment by applying the pre-floor and pre-reclassified hospital wage index

values that CMS calculated for payment, using updated CBSAs. Further, we are continuing our established policy to use the average of the wage indices for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index. For CY 2014, we also are continuing our policy established in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72058 through 72059) to set the ASC wage index by calculating the average of all wage indices for urban areas in the State when there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, and all contiguous areas to the CBSA are rural.

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2014 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). Consistent with our established policy, in the CY 2014 OPPS/ASC proposed rule (78 FR 43640 through 43641), we proposed to scale the CY 2014 relative payment weights for ASCs according to the following method. Holding ASC utilization and the mix of services constant from CY 2012, we proposed to compare the total payment using the CY 2013 ASC relative payment weights with the total payment using the CY 2014 relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2013 and CY 2014. We proposed to use the ratio of CY 2013 to CY 2014 total payment (the weight scaler) to scale the ASC relative payment weights for CY 2014. The proposed CY 2014 ASC scaler is 0.9102 as corrected (78 FR 43641; 78 FR 54843, 54845) 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. At the time of the CY 2014 proposed rule, we had available 98 percent of CY 2012 ASC claims data. For this final rule with comment period, we have approximately 99 percent of all ASC claims data for CY 2012.

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 2012 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2012 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>.

For this final rule with comment period, we used our methodology described above to calculate the scaler adjustment using updated ASC claims data. The final CY 2014 scaler adjustment is 0.9235. This scaler adjustment is necessary to make the difference in aggregate ASC payments calculated using the CY 2013 ASC relative payment weights and the CY 2014 relative payment weights budget neutral. We calculated the difference in aggregate payments due to the change in relative payment weights holding constant the ASC conversion factor, the most recent CY 2012 ASC utilization from our claims data, and the CY 2013 wage index values. For this final CY 2014 calculation, we used the CY 2013 ASC conversion factor updated by the CY 2014 CPI-U, which is projected to be 1.7 percent, less the multifactor productivity adjustment of 0.5 percent, as discussed below in section XIV.H.2.b. of this final rule with comment period.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, in the CY 2014 OPPS/ASC proposed rule (78 FR 43641 through 43642), for the CY 2014 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 2014, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2012 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2014 pre-floor and pre-reclassified hospital wage indices. Specifically, holding CY 2012 ASC utilization and service-mix and the proposed CY 2014 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2013 pre-floor and pre-reclassified hospital wage indices and the total adjusted payment using the proposed CY 2014 pre-floor and pre-reclassified hospital wage indices. 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 2013 pre-floor and pre-reclassified hospital wage indices to the total adjusted payment calculated with the proposed CY 2014 pre-floor and pre-reclassified hospital wage indices and applied the resulting ratio of 1.0004 (the proposed CY 2014 ASC wage index budget neutrality adjustment) to the CY 2013 ASC conversion factor to calculate the proposed CY 2014 ASC conversion factor. We note that, on February 28, 2013, OMB issued OMB Bulletin No. 13-01 announcing revisions to the delineation of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The proposed pre-floor and pre-reclassified hospital wage indices for FY 2014 do not reflect OMB's new area delineations. Because the ASC wage indices are the pre-floor and pre-reclassified hospital wage indices, the CY 2014 ASC wage indices do not reflect the OMB changes.

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. Illustrative examples of how the MFP adjustment would be applied to the ASC payment system update are found in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43642), based on IHS Global Insight’s (IGI’s) 2013 first quarter forecast with historical data through 2012 fourth quarter, for the 12-month period ending with the midpoint of CY 2014, the CPI-U update was projected to be 1.4 percent. Also, based on IGI’s 2013 first quarter forecast, the MFP adjustment for the period ending with the midpoint of CY 2014 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. The methodology for calculating the MFP adjustment was finalized 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). Because the ASCQR Program affects payment rates beginning in CY 2014, there would be 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 1.4 percent by the MFP adjustment of 0.5 percentage point, resulting in an MFP-adjusted CPI-U update factor of 0.9 percent for ASCs meeting the quality reporting requirements. Therefore, we proposed to apply a 0.9 percent MFP-adjusted CPI-U update factor to the CY 2013 ASC conversion factor for ASCs meeting the quality reporting requirements. We proposed to reduce the CPI-U update of 1.4 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 –1.1 percent quality reporting/MFP-adjusted CPI-U update factor to the CY 2013 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 2014 CPI-U update and MFP adjustment), we would use such data, if appropriate, to determine the CY 2014 ASC update for the final rule with comment period.

For CY 2014, we also proposed to adjust the CY 2013 ASC conversion factor (\$42.917) by the wage adjustment for budget neutrality of 1.0004 in addition to the MFP-adjusted update factor of 0.9 percent discussed above, which results in a proposed CY 2014 ASC conversion factor of \$43.321 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we proposed to adjust the CY 2013 ASC conversion factor (\$42.917) by the wage adjustment for budget neutrality of 1.0004 in addition to the quality reporting/MFP-adjusted update factor of –1.1 percent discussed above, which results in a proposed CY 2014 ASC conversion factor of \$42.462. We invited public comment on these proposals.

Comment: As in previous years, commenters requested that CMS adopt the hospital market basket to update the ASC payment system instead of using the CPI-U. The commenters argued that the CPI-U does not fairly represent the costs borne by the ASC industry because the prices measured in the basket of

goods comprising the index reflect the types and weights of categories typical of an American household, rather than an outpatient surgical provider.

Commenters believed that the hospital market basket more closely reflects the cost structure of ASCs than does the basket of goods included in the CPI-U. Commenters stated that adopting the hospital market basket to update ASC payment rates would minimize the divergence in CY 2014 payments in ASCs compared to HOPDs and would ensure continued beneficiary access to ASCs.

Commenters also indicated that the hospital market basket is a more appropriate index to use for the ASC update now that CMS is required to apply the MFP adjustment to the ASC annual update. Commenters stated that, as an output price index, the CPI-U index already accounts for productivity thus ASCs, in essence, are receiving a productivity adjustment that is twice that applied to the HOPD update. Because CMS has discretion regarding the index used to update ASCs, but is required in statute to adjust the ASC update by the MFP, commenters urged CMS to use the hospital market basket, which is an input price index that does not already account for productivity, to update ASC payment rates and thereby allow the appropriate application of the required productivity adjustment. These commenters suggested that if the CPI-U continues to be used to update ASC payment rates, CMS should remove the productivity gains from the CPI-U. Commenters also requested that the 10-year MFP measurement period be uniform in ASCs and HOPDs so that there is no discrepancy in the estimates of the MFP that will provide additional divergence between the ASC and HOPD updates.

Response: 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 and that use of the hospital market basket would minimize the divergence in the payment rates between the OPPIs and ASC payment system, we believe that 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 appreciate the commenter's suggestion to adjust the CPI-U for productivity and will take this suggestion into consideration should we propose changes to the ASC update factor in the future. Regarding alignment of the MFP adjustment across payment systems, for the reasons stated in the CY 2011 MPFS final rule with comment period (75 FR 73396), we believe that it is more appropriate to align the MFP adjustment with the update timeframe for each payment system rather than aligning the MFP adjustment across payment systems.

After consideration of the public comments we received, we are applying our established methodology for determining the final CY 2014 ASC conversion factor. Using more complete CY 2012 data for this final rule with comment period than was available for the proposed rule, we calculated a wage index budget neutrality adjustment of 1.0009. Based on IGI's 2013 third quarter forecast, the CPI-U for the 12-month period ending with the midpoint of CY 2014 is now projected to be 1.7 percent, while the MFP adjustment (using the revised IGI series to proxy the labor index used in the MFP forecast calculation 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 1.2 percent for ASCs that meet the quality reporting requirements. The final ASC conversion factor of \$43.471, for ASCs that meet the quality reporting requirements, is the product of the CY 2013 conversion factor of \$42.917 multiplied by the wage index budget neutrality adjustment of 1.0009 and the MFP-adjusted CPI-U payment update of 1.2 percent. For ASCs that do not meet the quality reporting requirements, we are reducing the CPI-U update of 1.7 percent by 2.0 percentage points and then we are applying the 0.5 percent MFP reduction, resulting in a -0.8 percent quality reporting/MFP-adjusted CPI-U update factor. The final ASC conversion factor of \$42.612 for ASCs that do not meet the quality reporting requirements is the product of the CY 2013 conversion factor of \$42.917

multiplied by the wage index budget neutrality adjustment of 1.0009 and the quality reporting/MFP-adjusted CPI-U payment update of -0.8 percent.

3. Display of CY 2014 ASC Payment Rates

Addenda AA and BB to this CY 2014 OPPI/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 2014 for covered surgical procedures and covered ancillary services, respectively. 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 2014 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 OPPI/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 2014. 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 2014 Payment Weight" are the relative payment weights for each of the listed services for CY 2014. The payment weights for all covered surgical procedures and covered ancillary services whose ASC payment rates are based on OPPI relative payment weights were scaled for budget neutrality. Thus, 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 2014 payment rate displayed in the “CY 2014 Payment Rate” column, each ASC payment weight in the “CY 2014 Payment Weight” column was multiplied by the CY 2014 conversion factor of \$43.471. 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 2014 Payment Weight” column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The “CY 2014 Payment” column displays the CY 2014 national unadjusted ASC payment rates for all items and services. The CY 2014 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 2013.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are to be excluded from payment in ASCs for CY 2014.

We did not receive any public comments regarding the continuation of our policy to provide CY 2014 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 2014 for covered surgical procedures and covered ancillary services, respectively, and provide additional information related to the CY 2014 rates.

XIII. Hospital Outpatient Quality Reporting Program Updates

A. Background

1. Overview

CMS has implemented quality measure reporting programs for multiple settings of care. These programs promote higher quality, more efficient health care for Medicare beneficiaries. The quality data reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (Hospital OQR) Program, formerly known as the Hospital Outpatient

Quality Data Reporting Program (HOP QDRP), has been generally modeled after the quality data reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (Hospital IQR) Program (formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program). Both of these quality reporting programs for hospital services have financial incentives for the reporting of quality data to CMS.

CMS also has implemented quality measure reporting programs for other settings of care and for certain professionals, including:

- 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.

Finally, CMS has implemented a Hospital Value-Based Purchasing Program and an end-stage renal disease (ESRD) Quality Incentive Program 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, as well as conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. To the extent possible under various authorizing statutes, our ultimate goal is to align the clinical quality measure requirements of the Hospital OQR Program and various other programs, such as the Hospital IQR Program, the ASCQR Program, and the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, authorized

by the Health Information Technology for Economic and Clinical Health Act, so that the burden for reporting will be reduced. As appropriate, we will consider the adoption of measures with electronic specifications, to enable the collection of this information as part of care delivery. Establishing such an alignment will require interoperability between EHRs, and CMS data collection systems, with data being calculated and submitted via certified EHR technology; additional infrastructural development on the part of hospitals and CMS; and the adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. Once these activities are accomplished, the adoption of many measures that rely on data obtained directly from EHRs will enable us to expand the Hospital OQR Program measure set with less cost and burden to hospitals.

In implementing this and other quality reporting programs, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68467 through 68469) for the discussion of the principles for our considerations for future measures, and we intend to generally apply these same principles in future rulemaking.

Comment: One commenter requested that for burden reduction purposes, CMS should not implement more than two chart-abstracted measures per year.

Response: We consider potential reporting burden on hospitals. We do weigh the relevance and the utility of measures against potential burden on providers. We thank the commenters for the feedback and will take it into consideration for future proposals. We note that we are working toward the eventual adoption of electronically-specified measures, which will reduce the burden of chart-abstracted measures.

Comment: A few commenters recommended that CMS ensure that the proposed measures are specified to provide an opportunity for stakeholders’ input.

Response: We note that all the proposed measures are fully specified and we have provided links to the detailed measure specifications. Since all of the proposed measures are NQF-endorsed, the specifications were all submitted to NQF by the measure stewards. We believe that these measure specifications will provide the detailed information needed for the public to understand the measures being proposed and to provide meaningful comments on the proposed measures during the rulemaking process. Proposed measures are not included in the Hospital OQR Specifications Manual because we generally incorporate

specifications for measures to be used in the program into the Hospital OQR Specifications Manual, along with implementation guidance after publication of the final rule with comment period, but prior to implementation. For maintenance of technical specifications, our general policy is to provide six months lead time between Hospital OQR Specifications Manual publication and the start date of collection so that providers have adequate time to prepare for new reporting requirements.

2. Statutory History of the Hospital Outpatient Quality Reporting (Hospital OQR) Program

We refer readers to the CY 2011 OPPTS/ASC final rule with comment period (75 FR 72064) for a detailed discussion of the statutory history of the Hospital OQR Program.

3. Measure Updates and Data Publication

a. Process for Updating Quality Measures

Technical specifications for the Hospital OQR Program measures are listed in the Hospital OQR Specifications Manual, which is posted on the CMS QualityNet Web site at: <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPages%2FSpecsManualTemplate&cid=1228772438492>.

We maintain the technical specifications for the measures by updating this Hospital OQR Specifications Manual and including detailed instructions and calculation algorithms. In some cases where the specifications are available elsewhere, we may include links to Web sites hosting technical specifications. These resources are for hospitals to use when collecting and submitting data on required measures.

In the CY 2009 OPPTS/ASC final rule with comment period (73 FR 68766 through 68767), we established an additional subregulatory process for making updates to the measures we have adopted for the Hospital OQR Program. We believe that a measure can be updated through this subregulatory process provided it is a nonsubstantive change. We expect to make the determination of what constitutes a substantive versus a nonsubstantive change on a case-by-case basis.

Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as

the addition of a hospice exclusion to the 30-day mortality measures). We believe that non-substantive changes may include updates to measures based upon changes to guidelines upon which the measures are based. We will revise the Hospital OQR Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. As stated in CY 2009 OPPTS/ASC, we also will post the updates on the QualityNet Web site at <https://www.QualityNet.org>. We will provide sufficient lead time for facilities to implement the changes where changes to the data collection systems would be necessary. We generally release the Hospital OQR Specifications Manual every 6 months and release addenda as necessary. This release schedule provides at least 3 months of advance notice for nonsubstantive changes such as changes to ICD-10, CPT, NUBC, and HCPCS codes, and at least 6 months of advance notice for changes to data elements that would require significant systems changes.

We will continue to use rulemaking to adopt substantive updates to measures we have adopted for the Hospital OQR Program. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example, changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice.

We believe that the policy finalized in the CY 2009 OPPTS/ASC final rule adequately balances our need to incorporate nonsubstantive updates to Hospital OQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process. These policies regarding what is considered substantive versus non-substantive apply to all measures in the Hospital OQR Program.

Comment: One commenter noted that the conversion of a measure to use ICD-10-CM/PCS should be considered a substantive change that follows current

proposed rulemaking processes. The commenter requested clarification regarding the publication, preview, and comment period via rulemaking for ICD-9-CM to ICD-10-CM/PCS mappings for all value sets for diagnoses and procedures used by measures specified in this rule.

Response: In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504), we included examples in the Hospital OQR Program context of what we might generally regard as nonsubstantive changes to measures. Our examples included updated diagnosis or procedure codes, medication updates for categories of medications, or a broadening of age ranges.

We will be transitioning all of our billing and measurement systems from ICD-9 to ICD-10. In preparation for this transition, we: (1) translated the ICD-9 versions of the measure specifications to ICD-10; (2) recently published this crosswalk for the Hospital OQR Program on our Web site at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalOutpatientQualityReportingProgram.html>; and, (3) solicited comment on this crosswalk from July 1, 2013 through August 31, 2013.

We normally incorporate coding updates for the measures using our established subregulatory process because such updates do not change the basic, underlying concepts being measured. Moving from ICD-9 to the ICD-10 coding system falls within the parameters of our subregulatory process. However, we recognize that in moving to ICD-10 coding, there may be some nuances in the measures that, when translated, result in unanticipated differences in performance, and consequently, prior measure results do not correspond to results for the same measures under the new coding system. In this situation, we will determine whether to continue publicly reporting the quarters of data that were collected under the ICD-9 coding system, or report only the newer quarters of data collected under the ICD-10 coding system. We intend to study the effect of transitioning to the ICD-10 system on trendability of results once implementation has occurred and data are available to do so in order to inform this future policy.

We will continue to use rulemaking to adopt substantive updates to measures we have adopted for the Hospital OQR Program. However, any change to a measure would need to be evaluated on a case by-case basis to determine whether or not it is, in fact, substantive.

b. Publication of Hospital OQR Program Data

We refer readers to the CY 2014 OPPTS/ASC proposed rule (78 FR 43645) for the discussion of our policy for the publication of Hospital OQR Program data on *Hospital Compare* and non-interactive CMS Web sites.

Comment: One commenter encouraged CMS to ensure the *Hospital Compare* Web site remains user-friendly, even though it must present data that can be complicated and potentially confusing if not well structured. The commenter emphasized that the information published on *Hospital Compare* be accurate and fair, but also impartial and presented in plain English at a sixth-grade reading level. The commenter recommended that CMS display data on *Hospital Compare* in a simple format with easy navigation and minimal graphics in the interest of data that loads quickly on a variety of devices and at slower internet connection speeds. The commenter encouraged CMS to offer the data in languages commonly spoken in the United States, and cites the Medicare Prescription Drug Benefit Manual, Chapter 2, Section 30.7 to point out that CMS has standards governing Web site translation that should be applied for the purpose of making the data available on *Hospital Compare* more accessible.

Response: We thank this commenter for this thoughtful feedback regarding the public reporting of data on *Hospital Compare*. We will look at the feasibility of modifying the Web site to incorporate these suggestions.

B. Process for Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

In the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68471), for the purpose of streamlining the rulemaking process, we finalized a policy that, beginning with the CY 2013 rulemaking, when we adopt measures for the Hospital OQR Program as beginning with a payment determination and subsequent years, these measures are automatically adopted for all subsequent years' payment determinations, unless we propose to remove, suspend, or replace the measures.

C. Removal or Suspension 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 rulemaking, we finalized a process for

immediate retirement (a term we later changed to "removal") of Hospital IQR Program measures based on evidence that the continued use of the measure as specified raised patient safety concerns (74 FR 43864 through 43865). We adopted this same immediate measure retirement policy for the Hospital OQR Program in the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60634).

In the CY 2013 OPPTS/ASC final rule with comment period, we changed the term from "retirement" to "removal," in line with the same change in the Hospital IQR Program. We discuss our reasons for this change at 77 FR 68472 through 68473. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185), we finalized a set of criteria to use when determining whether to remove measures from the Hospital IQR Program (formerly known as the RHQDAPU Program) measures. 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 by commenters during Hospital IQR Program rulemaking, and we determined that these criteria are also applicable in evaluating Hospital OQR Program quality measures for removal. In the CY 2013 OPPTS/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 these criteria, we take into account the views of the MAP in the evaluation of measure removal. Furthermore, for efficiency and streamlining purposes, we strive to eliminate redundancy of similar measures.

Comment: A few commenters urged CMS to remove 7 previously adopted Hospital OQR Program measures (OP-9, OP-10, OP-14, OP-15, OP-20, OP-22,

and OP-25), which are either not NQF-endorsed or not recommended by the MAP.

Response: While this comment is outside the scope of what we proposed, we would like to provide some clarification. In the CY 2013 OPPTS/ASC final rule with comment period, we responded to the same comments on these measures. We refer readers to our responses in 77 FR 68472 through 68473.

2. Removal of Two Chart-Abstracted Measures from the Hospital OQR Program

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43646 through 43647), we proposed in section XIII.C.2, titled "Proposed Removal of Two Chart-Abstracted Measures From the Hospital OQR Program," to remove two measures from the Hospital OQR Program for the CY 2016 payment determination and subsequent years: (1) OP-19: Transition Record with Specified Elements Received by Discharged ED Patients, and (2) OP-24: Cardiac Rehabilitation Measure: Patient Referral from an Outpatient Setting. We reflected our proposal in a chart (78 FR 43647) depicting measures we proposed to remove, and also referred in the title of the chart to CY 2016 as the first payment year affected by our proposal. However, in section XIII.H.2.b of the proposed rule (78 FR 43653), titled "Effects of Proposed Changes on data submission for CY 2015 and CY 2016 Payment Determinations and Subsequent Years," we proposed to remove these measures for the CY 2015 payment determination and subsequent years. We received comments regarding this contradictory information and inquiries about when the proposed removal of both OP-19 and OP-24 would actually be effective. We would like to address those comments here before discussing individual measures.

Comment: Many commenters noted that the discussions in the preamble of the proposed rule regarding the removal of OP-19 and OP-24 were inconsistent in sections XIII.C.2 and XIII.H.2.b. of the proposed rule. Commenters requested clarification and many also encouraged CMS to remove these measures for the CY 2015 payment determination and subsequent years.

Response: We would like to apologize for this error and wish to clarify that we intended to propose removing these measures for the CY 2015 payment determination and subsequent years, and instead inadvertently referred to their removal as being proposed for the CY 2016 payment determination and subsequent years in XIII.C.2. We

appreciate commenters support for removing OP–19 and OP–24 for the CY 2015 payment determination and subsequent years.

The rationales for proposing to remove these measures are discussed below.

a. Removal of OP–19: Transition Record with Specified Elements Received by Discharged ED Patients

We previously adopted measure OP–19 for the Hospital OQR Program for the CY 2013 payment determination with data collection beginning with January 1, 2012 encounters in the CY 2011 OP/AS final rule with comment period. Shortly after data collection for this measure began in January 2012, hospitals raised concerns about the measure specifications, including potential privacy issues related to releasing certain elements of the transition record to either the patient being discharged from an emergency department or the patient's caregiver. Some examples provided by hospitals are the release of sensitive lab results or radiological findings to a parent, spouse, or guardian of a minor patient, or to the responsible party for a physically incapacitated patient.

In order to address the safety concerns related to confidentiality as raised by the industry in the above discussion, in April 2012, we took immediate action to suspend OP–19. On April 12, 2012, we released a Memorandum entitled SDPS 12–100–OD, “Revised: Temporary Suspension of Hospital Outpatient Quality Reporting Measure OP–19: Transition Record with Specified Elements Received by Discharged Patients” to make clear our intent not to use any data submitted on this measure for payment determinations, public reporting, or data validation. This memorandum can be located at <http://qualitynet.org> under the option “Email Notifications” within the “Hospitals—Outpatient” drop down menu found at the top of the page.

In the CY 2013 OP/AS final rule with comment period (77 FR 68474 through 68476) for the CY 2014 payment determination and subsequent years, we confirmed that we suspended the collection of data for the measure OP–19: Transition Record with Specified Elements Received by Discharged ED Patients, which specified that either patients *or their caregivers* (emphasis added) receive a transition record at the time of ED discharge.

We chose to suspend this measure rather than to immediately remove the measure from the program at the time, because the probability of harm occurring was relatively low; any

potential harm that occurred would not be the direct result of patient care rendered at facilities; and the measure steward, the American Medical Association Physician Consortium for Performance Improvement (AMA–PCPI), believed that the measure could be quickly re-specified in a manner that would mitigate the concerns raised by hospitals and stakeholders. In the CY 2013 OP/AS final rule with comment period, we noted that the measure steward was working to revise the measure specifications to address the concerns raised by affected parties. We also noted that the measure was scheduled for NQF maintenance review in 2013. We stated that after completion of the NQF maintenance process, we anticipated that normal program operations for this measure could resume once we updated the Hospital OQR Specifications Manual and made any necessary changes to our data collection infrastructure. In addition, we stated that we would notify hospitals of changes in the suspension status of the measure for the Hospital OQR Program via email blast. However, we indicated that if we determined that these concerns cannot be adequately addressed by measure specifications, we would propose to remove this measure in a future OP/AS rule.

We have determined that the measure cannot be implemented with the degree of specificity that would be needed to fully address the concerns of stakeholders without being overly burdensome to both hospitals and CMS. The measure steward resolved the safety issue by refining the measure, but the refinement has made data abstraction more subjective because individual hospitals can determine which information should be included in the transition record in order to comply with this measure. In the absence of standardized data elements, we were not able to resolve this issue of data abstraction for common data elements, and therefore, could not ensure consistency of data submission and accuracy of measure results.

We also learned that all aspects for this transition record measure are currently required to meet the Medicare EHR Incentive Program's meaningful use (MU) core objective for eligible hospitals and critical access hospitals (CAHs) to provide patients the ability to view online, download, and transmit information about a hospital admission. This measure is workable in the Medicare EHR Incentive Program because, unlike the Hospital OQR Program, it does not rely on chart-abstraction, which can result in variations in data elements. Instead, the

Medicare EHR Incentive Program incorporates a methodology that includes standardized data elements. In addition, there are no comparable patient privacy concerns, since in the Medicare EHR Incentive Program, patient e-data is password protected.

This MU core objective provides patients discharged from the inpatient department or Emergency Department (ED) online access to the ED visit data. These ED visit data are the specified data elements included in the OP–19 Transition Record measure. This means that if we were to keep this measure, hospitals would need to submit this data for both the Hospital OQR Program using chart-abstraction and via attestation for the MU core objective. Therefore, to reduce duplicative requirements among programs and measurement burden, we proposed to remove this measure from the Hospital OQR Program. We invited public comment on the proposed removal of this measure from the Hospital OQR Program.

Comment: Many commenters stated that data collection for measure OP–19 is burdensome and strongly supported CMS' justifications for removing the measure.

Response: We thank the commenters for supporting our decision to remove OP–19 for the CY 2015 payment determination and subsequent years.

Comment: One commenter noted that, in the case of OP–19, hospitals were instructed to continue to report some value for this measure because the CMS data systems are not able to accommodate a missing field without error. The commenter stated that while OP–19 was suspended, reporting hospitals needed to continue to collect and report data and ensure that the data field for OP–19 was completed to ensure the entire file would be accepted into the CMS clinical data warehouse.

Response: We appreciate the commenter's concern. We refer the reader to the CY 2012 OP/AS final rule with comment period (77 FR 68475 through 68476) for a discussion of this same topic. We reiterate that, while it is true that the burden of populating some value in the data field for OP–19 is indeed placed on the reporting hospital, it is not accurate that the hospital is now or ever was required to continue to collect OP–19 data by chart abstraction or to report a meaningful value for OP–19 to the clinical data warehouse once we suspended the measure. In our memorandum to suspend OP–19, in subsequent discussions in the **Federal Register**, and in our educational materials and educational support calls, we attempted to make clear that we

would not use or validate any data that came in for OP-19.

We agree it is burdensome that our current system will not accept a null value for OP-19. An upcoming release of our Hospital Reporting system will address this issue by removing OP-19 and OP-24 from our data collection fields. This system release is anticipated for summer 2014. We have also instructed the system contractor to build flexibility into the data collection system so that, in the future, we are able to execute our policy for suspension or removal of measures without causing undue burden to the reporting community.

After consideration of the public comments we received, we are finalizing the removal of OP-19 with the clarification that removal applies for the CY 2015 payment determination and subsequent years.

b. Removal of OP-24: Cardiac Rehabilitation Measure: Patient Referral from an Outpatient Setting

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68476), we

deferred data collection for this measure to January 1, 2014 encounters. This was due to the unavailability of detailed abstraction instructions for data collection in time for the July 2012 release of the Hospital OQR Specifications Manual. These instructions were needed for chart-abstraction beginning on January 1, 2013. We also indicated that this measure would be applied to the CY 2015 payment determination.

In the CY 2014 OPPS/ASC proposed rule, we proposed to remove this measure from the Hospital OQR Program due to continued difficulties with defining the measure care setting. The measure specifications provided by the measure steward, the American College of Cardiology (ACC), identify the applicable care setting as a 'Clinician Office/Clinic.' However, in developing the specifications for this measure for a hospital outpatient clinic setting, several issues arose, including difficulty in accurately identifying hospital outpatient visits for evaluation and management purposes using either

chart abstraction or HOPD claims data, and difficulty in determining the particular hospital outpatient clinic visit that resulted in a cardiac rehabilitation referral for any given patient. Therefore, given the difficulties in accurately applying the measure to the hospital outpatient setting, we proposed to remove OP-24 from the Hospital OQR Program. We invited public comment on this proposal.

Comment: Many commenters strongly supported CMS' justification for removing measure OP-24.

Response: We appreciate all the feedback supporting our proposal to remove OP-24 from the Hospital OQR Program measure set for the CY 2015 payment determination and subsequent years.

After consideration of the public comments we received, we are finalizing the removal of OP-19 and OP-24 for the CY 2015 payment determination and subsequent years.

Hospital OQR Program Measures Removed for the CY 2015 Payment Determination and Subsequent Years	
NQF#	Measure
0649	OP-19: Transition Record with Specified Elements Received by Discharged ED Patients
0643	OP-24: Cardiac Rehabilitation Measure: Patient Referral from an Outpatient Setting

D. Quality Measures Previously Adopted for the CY 2014 and CY 2015 Payment Determinations and Subsequent Years

The table below lists 25 measures that we previously adopted and retained for

the CY 2014 and CY 2015 payment determination and subsequent years under the Hospital OQR Program. This table also includes OP-19 and OP-24, with a notation that we are removing

these two measures for the CY 2015 payment determination and subsequent years.

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Hospital OQR Program Measures for the CY 2014 and CY 2015 Payment Determinations and Subsequent Years	
NQF#	Measure Name
0287	OP-1: Median Time to Fibrinolysis
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes
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
0270	OP-6: Timing of Antibiotic Prophylaxis
0268	OP-7: Prophylactic Antibiotic Selection for Surgical Patients
0514	OP-8: MRI Lumbar Spine for Low Back Pain
--	OP-9: Mammography Follow-up Rates
--	OP-10: Abdomen CT – Use of Contrast Material
0513	OP-11: Thorax CT – Use of Contrast Material
0489	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
--	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*
0491	OP-17: Tracking Clinical Results between Visits
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0649	OP-19: Transition Record with Specified Elements Received by Discharged ED Patients***
--	OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional
0662	OP-21: Median Time to Pain Management for Long Bone Fracture
--	OP-22: ED- Patient 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
0643	OP-24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting***
--	OP-25: Safe Surgery Checklist Use
--	OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures**

* Public reporting for OP-15 continues to be deferred at the time of this CY 2014 OPPS/ASC proposed rule.

** 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

***In this final rule with comment period, we are removing OP-19 and OP-24 for the CY 2015 payment determination and subsequent years.

Comment: Some commenters expressed views regarding some of the previously finalized measures that CMS intends to continue using under the Hospital OQR Program. Commenters also provided suggestions on these measures, regarding measure implementation, adding exceptions, and revising measure specifications.

Response: We thank the commenters for their comments. Because these comments address measures that we have finalized in the past through notice and comment rulemaking, we do not believe they are within the scope of this current rulemaking. However, we intend to consider all of these views for future rulemaking and Hospital OQR Program development.

E. Quality Measures for the CY 2016 Payment Determination and Subsequent Years

In the CY 2014 OPPS/ASC proposed rule (78 FR 43647 through 43651), we proposed to adopt five new measures for the Hospital OQR Program for the CY 2016 payment determination and subsequent years. These measures include one HAI measure—Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), currently collected by the Centers for Disease Control and Prevention (CDC) via the National Healthcare Safety Network (NHSN)—and four chart-abstracted measures. The chart-abstracted measures are: (1) Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures (NQF #0564), (2) Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients (NQF #0658), (3) Endoscopy/Polyp surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659), and (4) Cataracts: Improvement in Patient's Visional Function within 90 Days Following Cataract Surgery (NQF #1536).

All of the proposed measures were included on a publicly available document entitled "List of Measures

Under Consideration for December 1, 2012" on the NQF Web site at: http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx in compliance with section 1890A(a)(2) of the Act. Section 1890A(a)(2) is part of the pre-rulemaking process established under section 1890A of the Act, and requires the Secretary to make available to the public by December 1st of each year a list of certain categories of quality and efficiency measures that the Secretary is considering for the Medicare program. The measures we proposed were reviewed by the MAP in its "MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS," which has been made available on the NQF Web site at: http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx. 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.

All five of the proposed measures are NQF-endorsed, and therefore meet the requirements that measures selected for the program "reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities" under section 1833(t)(17)(C)(i) of the Act. Furthermore, the services targeted in the proposed measures are services commonly provided to patients who visit hospital outpatient departments and, for this reason, we believe that these proposed measures are appropriate for the measurement of quality of care furnished by hospitals in outpatient settings as required under section 1833(t)(17)(C)(i) of the Act.

We proposed to collect aggregate data (numerators, denominators, exclusions) for the four chart-abstracted measures via an online, Web-based tool that will be made available to HOPDs via the QualityNet Web site, just as we do for OP-22. This Web-based tool is currently

in use in the Hospital OQR Program to collect structural measure information.

More information regarding the proposed method of collection was provided in section XIII.H.2. of the proposed rule (78 FR 43653).

To enhance our efforts to collect high quality data for the Hospital OQR measures while minimizing burden for HOPDs, we also sought public comment on whether we should collect patient-level data via certified EHR technology on the four proposed chart-abstracted measures (this would not apply to the one HAI measure, Influenza Vaccination Coverage among Healthcare Personnel), and the potential timing for doing so. Any future ability to collect patient-level data via EHR technology would allow CMS to validate the accuracy of the data and also link data for patients over time to assess patient outcomes of care related to treatment.

Comment: A few commenters recommended that if CMS finalizes new chart-abstracted measures in the Hospital OQR Program, CMS should not collect patient-level data through EHR technology for these measures; rather, CMS should limit data collection to aggregate data. Many commenters did not support patient-level data collection specifically due to EHR system concerns. These commenters supported collecting aggregate data because the EHR environment is not mature. One commenter stated that a group of its stakeholder hospitals are in the early stages of adopting EHR systems and encouraged CMS to delay requiring patient-level data where their infrastructure is not ready to collect patient information.

Some commenters do not support patient-level data collection using EHR technology due to concerns about protecting the privacy of EHR data. One commenter believed that until CMS can ensure patients' records can be securely maintained and transmitted, CMS should not collect patient-level data via EHR technology.

Response: We appreciate the comments we received on whether we should collect patient-level data via certified EHR technology on the four

proposed chart-abstracted measures and the potential timing for doing so.

We agree with commenters that chart-abstracted measure data collected in aggregate form is currently the most appropriate collection method, and we are finalizing the aggregate mode of data collection for the three new chart-abstracted measures in section XIII.H.2.f. of this final rule with comment period.

We will consider these commenters' concerns in proposing future updates to the program and updates or expansions to the Hospital OQR Program measures. Specifically, we will continue to consider the maturity of EHR systems in future proposals to collect HOPD data via EHR technology. We understand the need for additional infrastructural development on the part of hospitals and CMS and the adoption of standards for capturing, formatting, and securely transmitting the data elements that make up measures. Once these activities are accomplished, the adoption of many measures that rely on data obtained directly from EHRs will enable us to expand the Hospital OQR Program measure set with less cost and burden to hospitals.

Comment: A few commenters did not support aggregate data collection for the proposed chart-abstracted measures, and suggested that CMS only adopt measures where a validation strategy is in place. These commenters pointed out that the use of aggregate data in lieu of patient-level data does not allow for validation of data accuracy. The commenters believed that without validation, there is no opportunity for robust field-testing to ensure that electronic and chart-abstracted measures provide comparable results.

Response: We interpret these commenters' views as being in support of patient-level data collection and data collection via EHR technology. We likewise support the future adoption of measures with patient-level data collection, via EHR technology, and where submitted data may be validated. We have not, to date, proposed measures for the OQR Program with the EHR mode of data collection. In this final rule with comment period, we have finalized three measures that are chart-abstracted with aggregate data submission via the Web-based tool. We cannot validate the data that is submitted in this manner. We agree with commenters that validation is a way to measure the accuracy of data submitted, and hope to be able to accomplish validation using EHR technology to collect data sometime in the near future.

Comment: Some commenters pointed out that CMS' collection of aggregate data might not actually have the effect of reducing burden. These commenters believed this would be the case if hospitals must first perform a patient-level review for each medical record in order to compile the aggregate data. Commenters were generally concerned about burden, and some commenters favored both an emphasis on adoption of claims-based measures and measures that do not require chart abstraction.

Response: We appreciate the commenters' concerns about the burden that can be involved in collecting aggregate-level data. We sought public comment on whether we should collect patient-level data via certified EHR technology on the four proposed chart-abstracted measures (this would not apply to the one HAI measure, Influenza Vaccination Coverage among Healthcare Personnel), and the potential timing for doing so. We interpret these commenters as being in favor of collecting patient-level data when it is feasible. We will take these comments into consideration in future rulemaking.

These comments are similar to comments we received related to how hospitals should gather information to report on our most recent proposed measures. We refer readers to section XIII.H.2.f of this final rule with comment period where we address these comments.

Comment: Many commenters offered views generally applicable to data collection in the Hospital OQR Program, but not specific to the proposed measures described in section XIII.E of the CY 2014 OPPTS/ASC proposed rule (78 FR 43647). Commenters voiced commitment to: (1) providing data to measure quality of care; (2) supporting CMS' alignment of measures and requirements across data reporting and value based purchasing programs whenever possible and as early as possible in the implementation phases of new programs; (3) allowing stakeholders to meet Meaningful Use (MU) standards through submission of data to the Hospital OQR Program; and, (4) adopting future EHR measures that are fully endorsed, tested, and specified by CMS. Many commenters asked CMS to consider technology barriers to efficient and accurate EHR-based quality reporting, including the need for widely adopted standards, information models, and vocabularies to support EHR-based reporting. Many commenters also asked CMS not to adopt aggressive timelines for EHR data submission and recommended specific policies and timelines related to electronic submission. Some commenters urged

CMS to carefully consider confidentiality, privacy, and security regulations, and to consider State-based regulations before implementing EHR measures for use by Partial Hospitalization Programs (PHPs) in HOPDs. Finally, several commenters suggested that CMS should convene a work group that includes the hospital industry to collaborate on how best to collect the data needed to accurately capture the care provided in off-campus provider-based departments.

Response: We will take these comments into consideration for future rulemaking for our quality reporting programs.

Each of the proposed measures is described in greater detail below.

1. Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)

The proposed measure assesses the percentage of healthcare personnel (HCP) who have been immunized for influenza. Rates of serious illness and death resulting from influenza and its complications are increased in high-risk populations such as persons over 50 years or under four years of age, and persons of any age who have underlying conditions that put them at an increased risk. HCP can acquire influenza from patients and can transmit influenza to patients and other HCP. Many HCP provide care for, or are in frequent contact with, patients with influenza or patients at high risk for complications of influenza. The involvement of HCP in influenza transmission has been a long-standing concern.^{1 2 3}

Vaccination is an effective preventive measure against influenza, and can prevent many illnesses, deaths, and losses in productivity.⁴ HCP are considered a high priority for expanding influenza vaccine use. Achieving and sustaining a high rate of influenza vaccination coverage among HCP is intended to help protect HCP and their patients in hospital settings and reduce disease burden and healthcare costs. Due to the potentially significant impact of HCP influenza vaccination on patient outcomes, we believe this measure is

¹ Maltezou, H.C., Drancourt, M.: Nosocomial influenza in children. *Journal of Hospital Infection* 2003; 55:83–91.

² Hurley, J.C., Flockhart, S.: An influenza outbreak in a regional residential facility. *Journal of Infection Prevention* 2010; 11:58–61.

³ Salgado, C.D, Farr, B.M., Hall, K.K., Hayden, F.G.: Influenza in the acute hospital setting. *The Lancet Infectious Diseases* 2002; 2:145–155.

⁴ Wilde, M.A., McMillan, J.A., Serwint, J., Butta, J., O'Riordan, M.A., Steinhoff, M.C.: Effectiveness of influenza vaccine in health care professionals; a randomized trial. *The Journal of the American Medical Association* 1999;281:908–913.

appropriate for measuring the quality of care in hospital outpatient departments.

We proposed to adopt this process measure for the CY 2016 payment determination and subsequent years. We also proposed that Hospital OPDs use the NHSN infrastructure and protocol to report the measure for Hospital OQR Program purposes. Hospitals currently submit data to NHSN to comply with the requirements of the Hospital IQR Program and those requirements will be unchanged for data submission to NHSN for the Hospital OQR Program. The measure numerator is: HCP in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year: (a) received an influenza vaccination administered at the healthcare facility, or reported in writing (paper or electronic) or provided documentation that influenza vaccination was received elsewhere; (b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other component(s) of the vaccine, or history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination; (c) declined a vaccination; or (d) persons with unknown vaccination status or who do not otherwise meet any of the definitions of the above-mentioned numerator categories. The measure denominator is: the number of HCP who are working in the healthcare facility for at least 1 working day between October 1 and March 31 of the influenza season, regardless of clinical responsibility or patient contact. The specifications for this measure are available at <http://www.qualityforum.org/QPS/QPSTool.aspx?Exact=false&Keyword=0431>.

In its 2013 Pre-Rulemaking Report, (http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx), the MAP supported inclusion of this measure in the Hospital OQR Program and noted that the measure would address a measure type that is not adequately represented in the program measure set. Furthermore, the adoption of this measure will align with both the Hospital IQR Program, which adopted the measure for the FY 2015 payment determination and subsequent years, and the ASCQR Program, which adopted the measure for the CY 2016 payment determination and subsequent years.

In the CY 2012 OPPI/ASC proposed rule (76 FR 42323 through 42324), we proposed this measure for the CY 2015 payment determination. However, in the CY 2012 OPPI/ASC final rule with

comment period (76 FR 74470 through 74472), we decided not to finalize the measure (76 FR 74472) and, instead, decided to propose it in future rulemaking for the CY 2016 payment determination and subsequent years in order to address measure refinements in the denominator and operational issues. We believe that these refinements have since been made and that the operational issues have been resolved.

We have learned that many States are proactively aligning their reporting requirements for this measure to mirror the federal requirements in an effort to reduce burden on providers and suppliers. We also recently learned that the measure may soon be undergoing some minor updates and review by NQF. Consistent with our policy to use a subregulatory process to adopt nonsubstantive changes to measures arising out of the NQF process stated in the CY 2009 OPPI/ASC final rule with comment period (73 FR 68766 through 68767), we would use this process to adopt the upcoming NQF revisions for this measure, if the revisions are nonsubstantive.

We refer readers to section XIII.H.2. of the proposed rule for a detailed discussion of data collection (78 FR 43656). We invited public comment on this proposal.

Comment: Several commenters opposed this measure and contended that the measure is duplicative of the Influenza vaccination measure in the Hospital IQR Program. Commenters stated that it is burdensome to report the same measure for both settings. A few commenters requested clarifications for the measure inclusions for both hospital inpatient and outpatient settings. Some commenters noted that hospital staff may float between different hospital inpatient and outpatient locations on different days and they requested clear guidelines to identify staff working at different hospital locations. A few commenters recommended allowing hospitals to report by attesting through the Hospital IQR Program that both their inpatient and outpatient healthcare personnel are vaccinated.

Response: We recognize that the current measure specifications may lead to some redundancy in data collection and data submission of this measure in both the inpatient and outpatient settings. We are aware that some HCP may work across both of these settings. We also realize that it may be difficult for hospitals to accurately attribute HCP using current instructions to report accurate data for both the Hospital IQR and Hospital OQR Programs.

After considering the public comments we received and our

discussion with the CDC's NHSN, we plan to address the commenters' concerns by providing clear instructions on the appropriate attribution of HCP working in the outpatient setting. We intend to provide these instructions in time for the first data collection period beginning in October 2014 and before the data submission deadline on May 15, 2015. The instructions will be included in the measure specifications in our planned December 2013 addendum to the Hospital OQR Specifications Manual, which will be available on the QualityNet Web site (<https://www.qualitynet.org>).

We also intend to separately clarify HCP definitions for the inpatient setting with respect to the Hospital IQR Program in the Hospital IQR Specifications Manual, which we anticipate will be published on April 1, 2014 to cover the discharges dated October 1, 2014–June 30, 2015. In addition, as the measure steward, the CDC's NHSN plans to set up the capability to clearly differentiate reporting on its Web site for the hospital inpatient and outpatient settings.

Comment: One commenter believed that this measure may not be necessary as many hospitals already require the influenza vaccination as a condition for employment. Another commenter requested a waiver for States with legislation prohibiting healthcare providers from requiring employees to obtain influenza vaccination as a condition for employment.

Response: We believe that this proposed measure is necessary for achieving high levels of vaccination in HCP and that this new measure provides useful information to consumers of healthcare services. We note that a recent report by CDC (Morbidity and Mortality Weekly Report 2013; 62(38):781–786) found that during the 2012–2013 influenza season, 30 percent of HCP worked in settings where influenza vaccination was required, 46 percent worked in settings where it was promoted but not required, and 24 percent worked in settings where it was neither required nor promoted. Vaccination adherence at facilities with a contingency requirement for employment was 96.5 percent. Rates were lower in facilities that promoted, but did not require vaccination (76.9 percent) and lower still in facilities that neither required nor promoted vaccination (50.4 percent). Thus, there is wide variation in workplace programs for the influenza vaccination and in vaccine coverage among HCP. Therefore, we believe that tracking influenza vaccination coverage is pivotal to raise vaccination adherence to

higher and more uniform levels across the Nation.

We acknowledge the commenter's concern regarding State laws prohibiting providers from requiring that healthcare workers get an influenza vaccination. We want to clarify that the numerator of the population of this measure includes more than just HCPs who received an influenza vaccination administered at the healthcare facility, or who reported in writing (paper or electronic) or provided documentation that they received an influenza vaccination elsewhere. The numerator population also includes HCP who: (a) have a medical contraindication/condition of severe allergic reaction to eggs or to other components of the vaccine; (b) have a history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination; (c) declined a vaccination; (d) have an unknown vaccination status or do not otherwise meet any of the other definitions in the numerator categories. We believe that these last three categories encompass HCP who may not have been vaccinated and cannot be required to comply with a vaccination requirement under State law. Therefore, we do not believe that a waiver is needed for States where legislation prohibits providers from requiring that HCPs get influenza vaccinations as a condition of employment. Regardless of whether requiring the influenza vaccination with employment is prohibited by the State, HOPDs can still take actions to improve their vaccination rates.

Comment: One commenter asked whether CMS would publicly report this measure separately for the Hospital OQR Program, instead of reporting a hospital-wide rate, which includes hospital inpatient units and off-campus clinics, among others.

Response: In the upcoming CY 2015 OPPS/ASC proposed rulemaking, we will provide detailed proposals regarding the public reporting of this measure as stated above.

After consideration of the public comments we received, we are finalizing as proposed the measure OP-27: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) for the Hospital OQR Program for the CY 2016 payment determination and subsequent years.

For the proposed rule, we received many general comments applicable to the four proposed chart-abstracted measures. We have organized this preamble by first summarizing and responding to these general comments applicable to these four measures, summarizing and responding to

measure-specific comments, and then describing our final policy.

Comment: A few commenters supported adopting all four proposed chart-abstracted measures. However, many other commenters opposed all four proposed chart-abstracted measures based on their claims that follow-up visits and assessments are performed in places other than in HOPDs. Thus, HOPDs may not be able to access other patient records or they may not be able to track down the patients who may go elsewhere for follow-up. The commenters stated that HOPDs merely provide a facility for physicians to perform certain procedures, but follow-up visits are performed at physician offices. Many commenters viewed the four proposed chart-abstracted measures as "Clinician Office" setting measures designed to measure, for example, ophthalmologist and other physician performance and not HOPD performance. Commenters stated that, for example, ophthalmologists assess post-operative visual function and patient outcomes, and determine additional surgical procedures as necessary in their respective offices and not in the HOPD. Likewise, physicians perform colonoscopy at HOPDs, but follow-up colonoscopy intervals are determined by the physician and documented in medical records kept in the physician's office.

Some commenters asserted that measures for the outpatient setting should be geared towards tracking the care of patients during their HOPD visits. Patients who receive some type of care in the HOPD do not always receive the majority of their care in HOPDs, because they are most likely to be followed by their primary care physicians for other medical care. Therefore, it is generally not practical to have the HOPD tracking the long-term follow-up care of its patients.

The commenters recommended that because CMS wishes to eventually align the hospital and physician quality programs, CMS must design measures that recognize that there are differences in how facilities and physicians collect information, report quality measures, and interact with patients.

Many commenters concluded that these four measures are more appropriate as Physician Quality Reporting System (PQRS) measures, because physicians are better suited to track and follow-up patients (PQRS is a voluntary reporting system that provides an incentive payment to identified individual eligible physicians). Commenters asserted that the measures are duplicative as both

PQRS measures and Hospital OQR Program measures.

Some commenters expressed concerns that the measures are neither NQF-endorsed for the HOPD setting nor field-tested.

Response: We thank those commenters who expressed support for the measures. While these measures are suitable for clinician office settings, as indicated by commenters, we also believe they are suitable for settings that supply services to the same target populations for the measures, such as HOPDs. The intent of the measures is to promote accountability for Medicare beneficiaries, improve the coordination of services, reduce fragmented care, encourage redesigned care processes for high quality and efficient service delivery, and incentivize higher value care. These measures focus on the patient and encourage physicians, such as ophthalmologists, to collaborate, communicate, and share information with HOPDs. We hope this new mode of coordination will become the common practice in healthcare delivery.

HOPDs provide care without the higher cost associated with inpatient hospitalization. More and more procedures are done safely and effectively on an outpatient basis and we expect this trend will continue. Therefore, we believe that assessing care coordination is a very important aspect of evaluating the overall quality of care furnished by HOPDs. We stress that true clinical integration is evidenced by effective patient coordination of care across health care settings, providers, and suppliers and is best shown when there is a structure in place that is patient-focused and where clinicians collaborate on best practices in an effort to furnish higher quality care that they likely would not achieve if working independently.

We do not believe these measures are duplicative of PQRS measures because, even though the measures' indicators are the same, the level of analysis is different (facility versus physician). We plan to make nonsubstantive tweaks to the measure, such as updating and modifying HCPCS codes, in order to better fit the measure for a HOPD level of analysis. We hope to set new milestones in the integral coordination and collaboration of care across outpatient provider types and facilities, as spurred by these measures. Regarding the comments that the proposed chart-abstracted measures have not been field-tested, we note that all three measures that we are finalizing (as discussed below) 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) Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).

We are finalizing the same three chart-abstracted measures in both the Hospital OQR Program and ASCQR Program for the CY 2016 payment determination and subsequent years.

Finalizing these measures for the Hospital OQR Program would further align measures across outpatient hospital and ambulatory settings, which furnish many similar services to beneficiaries. The availability of identical outcome measures at HOPDs and ASCs will enable beneficiaries to compare facilities and make informed decisions.

In addition, we believe the measures are appropriate for the HOPD setting, because the services assessed by these measures are frequently performed in HOPDs. Also, all three of the chart-abstracted measures that we are finalizing are NQF-endorsed for the Ambulatory Care: Clinician Office/Clinic setting, which we have historically interpreted as including the HOPD setting.

Comment: Some commenters noted that an initial cataract surgery or colonoscopy may be performed at a different HOPD. This situation would make retrieving data burdensome. Some commenters believed that obtaining office visit records and surgical outcome data from other physician offices is an intrusive violation of patient privacy.

Response: There may be some instances in which a HOPD may have great difficulty in obtaining information from other HOPDs, and some additional information may need to be obtained directly from patients for these measures. But as a general matter, our overarching goal for adopting the three proposed measures is to encourage the coordination of care across health care settings, providers, and suppliers as often as possible. We would like to see HOPDs, ophthalmologists and other physicians actively and routinely engaged in exchanging information to better communicate and coordinate the care of patients.

We note that there are a variety of ways to collect patient-related data and, at times, it may be appropriate for HOPDs to obtain data directly from the ophthalmologist or other physician who

either ordered a procedure for a patient or performed that procedure. HOPDs may have professional and commercial relationships with these ophthalmologists or other physicians. As such, an HOPD may have the ability to develop the means to obtain follow-up information including using contractual requirements to share such information with HOPDs.

We also note that HOPDs and referring physicians are generally subject to the HIPAA Privacy, Security, and Breach Notification Rules, and are required to protect the privacy and confidentiality of their patients' protected health information as required by those rules. We expect that HOPDs and physicians would adhere to any applicable requirements in providing and obtaining this information in order to prevent any violations of patient privacy.

We believe that our implementation strategy for these measures will minimize collection and reporting burden. We detail the data submission procedures for the measures in section XIII.H.2. of this final rule with comment period.

Comment: Many commenters asserted that it is extremely burdensome to retrieve timely the data from physician offices and that the data would be difficult to validate. A few commenters strongly believed that the huge reporting burden from the four proposed chart-abstracted measures could be diminished if claims are used as the data source.

Response: We appreciate commenters' concerns that it could be difficult or burdensome for hospitals to retrieve from physician offices the data they will need for the chart-abstracted measures in a timely manner. We believe such problems are more likely to occur in the early phases of establishing these measures, when hospitals and physicians have not yet set up effective infrastructures to routinely exchange information. In order to accommodate these concerns, we have taken several steps that we believe should alleviate some of this burden. The Web-based collection strategy we are finalizing for the measures and subsequent release of specifications and implementation guidance in the Hospital OQR Specifications Manual will address some of the concerns about feasibility of data collection raised by the commenters. To further reduce burden, we are also finalizing a low case threshold exemption and a sampling methodology for hospitals with a high volume of cases covered by the new measures. We believe that these provisions should together significantly

reduce burden for the three chart-abstracted measures we are finalizing. We have discussed these modifications in more detail in section XIII.H.2.f of this final rule with comment period.

We do not include chart-abstracted measures submitted via the Web-based tool in our validation procedures and, therefore, we will not be validating these measures at this time. Although some commenters would prefer that we use claims as the source for this data, we believe these measures will have the positive effect, in a number of instances, of requiring providers to communicate with each other. Using these kinds of measures will help us capture HOPDs' efforts at care coordination, which is something we want to measure, and that we do not believe we can measure with claims. We are also not aware of any applicable coding to capture this communication and coordination of patient care.

We received specific comments on the individual proposed chart-abstracted measures and they are discussed below.

2. Complications Within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures (NQF #0564)

The proposed measure assesses the percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power intraocular lens (IOL), retinal detachment, or wound dehiscence.

Although complications that may result in a permanent loss of vision following cataract surgery are uncommon, this outcome measure seeks to identify those complications from surgery that can reasonably be attributed to the surgery. It focuses on patient safety and monitoring for events that, while uncommon, can signify important issues in the care being provided. Advances in technology and surgical skills over the last 30 years have rendered cataract surgery safer and more effective. An analysis of Managed Care Organization data demonstrated that the rate of complications for this measure were 1 to 2 percent. However, with an annual volume of 2.8 million cataract surgeries in the United States, many of which are performed in hospital surgical outpatient departments, a 2-percent rate is a significant number of

surgeries associated with complications.⁵

The measure numerator is: patients who had one or more specified operative procedures for any of the following major complications within 30 days following cataract surgery: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence. The measure denominator is: all patients aged 18 years and older who had cataract surgery and no significant pre-operative ocular conditions impacting the surgical complication rate. This measure excludes patients with certain comorbid conditions impacting the surgical complication rate. The specifications for this measure are available at <http://www.qualityforum.org/QPS/0564>.

In its 2013 Pre-Rulemaking Report, (http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx), the MAP supported this measure and noted that the measure addresses a high impact condition that is not adequately addressed in the Hospital OQR measure set. Currently the NQF endorsement is time-limited.

We refer readers to section XIII.H.2. of the proposed rule for a detailed discussion of data collection. We invited public comment on this proposal.

Comment: Many commenters noted that this measure is unnecessary as complications from cataract surgery are rare and data collection would be very burdensome, since the volume of cataract surgery performed is huge. Commenters added that this measure requires very detailed information about not only specific complications that may have occurred, but also data on any additional follow up surgical procedures to accurately report data for this measure.

Response: As discussed in the proposed rule (78 FR 43649), a large number of complications from cataract surgery occur even though the percentage of complications from cataract surgery is small. The MAP indicated that the measure addresses a high impact condition that is not adequately addressed in the Hospital OQR measure set. Therefore, we believe that complications following cataract surgery which would require additional surgical procedures are important to measure.

However, unlike the other three measures we proposed, we agree that a HOPD would incur significant additional burden to collect the detailed information about specific complications and required additional surgical procedures to accurately report this measure. This would far exceed the burden we believe accompanies the other chart-abstracted measures that we proposed in the proposed rule. We have emphasized that we believe that care coordination between providers and practitioners is an essential element of appropriate, high quality care, and that the element of coordination cannot be measured using a claims-based or other form of measure.

Nonetheless, this is one instance in which we believe the burden involved in collecting the data required for chart-abstractation far outweighs the benefits in measuring care coordination.

We have based our conclusion on the fact that a HOPD would be required to acquire far more information than the more fundamental follow up information that accompanies the other measures we proposed (such as the patient survey data for OP-31, which basically involves collecting a patient's perceptions about visual improvement following cataract surgery). In contrast, there is far more information necessary for OP-28 and the nature of that information is more detailed, complicated, and very likely much more difficult for an HOPD to acquire. We agree with the commenters that this measure requires very detailed information about not only specific complications that may have occurred, but also data on specific additional follow up surgical procedures to accurately report data for this measure.

Because we continue to believe this is an important area to measure quality of care, we plan to explore other ways to collect this data, including the potential development of a claims-based risk-adjusted outcome measure of cataract complications, which would address the same quality issues as this measure, but minimize the burden associated with measurement to the greatest degree possible. Further, we anticipate that the new measure would be applicable to both the ASC and HOPD settings. We have previously developed a robust methodology for using claims to identify surgical complications for patients who have had total hip and knee replacements, and therefore, we believe that it may be possible to do so for cataract surgeries as well. This is not the case with the other three measures, which do not measure surgical complications.

After consideration of the public comments we received, and in light of the above reasons, we are not finalizing this proposed measure for the Hospital OQR Program at this time.

3. Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)

The proposed measure assesses the percentage of patients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.

In the average-risk population, colonoscopy screening is recommended in current guidelines at 10-year intervals.⁶ Our analysis indicated that about 25 percent of surgeries/procedures performed in HOPDs and ASCs are colonoscopies. Performing colonoscopy too frequently increases patients' exposure to procedural harm. This measure aims to assess whether average risk patients with normal colonoscopies receive a recommendation to receive a repeat colonoscopy in an interval that is less than the recommended amount of 10 years.

The measure numerator is: patients who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report. The measure denominator is: all patients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy. This measure excludes patients with documentation of medical reason(s) for recommending a follow-up interval of less than 10 years (for example, an above-average risk patient or inadequate prep). The specifications for this measure are available at: <http://www.qualityforum.org/QPS/0658>.

In its 2013 Pre-Rulemaking Report, (http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx), the MAP supported the direction of the measure. Currently the NQF endorsement is time-limited.

We refer readers to section XIII.H.2. of the proposed rule for a detailed discussion of data collection. We

⁵ National Quality Measures Clearing House. Agency for Healthcare Research and Quality. Available at <http://qualitymeasures.ahrq.gov/content.aspx?id=27981&search=complications+within+30+days+following+cataract+surgery>.

⁶ Davila RE, Rajan E, Baron TH, Adler DG, Egan JV, Faigel DO, Gan SI, Hirota WK, Leighton JA, Lichtenstein D, Qureshi WA, Shen B, Zuckerman MJ, VanGuilder T, Fanelli RD, Standards of Practice Committee, American Society for Gastrointestinal Endoscopy. ASGE guideline: colorectal cancer screening and surveillance. *Gastrointest Endosc* 2006 Apr;63(4):546-57. <http://www.ncbi.nlm.nih.gov/pubmed/16564851?dopt=Abstract>.

invited public comment on this proposal.

Comment: One commenter interpreted the MAP's recommendation of "Support Direction," to mean that a measure was not, in the MAP's opinion, ready for implementation in the Hospital OQR Program. Commenters stated that CMS should only finalize measures fully supported by the MAP.

Response: We take into account all MAP input when deciding on which measures to adopt for the program. We note that in addition to MAP input, we also consider feedback that we receive from many other stakeholders such as providers, specialty societies, measure developers, patients, and their caregivers during the rulemaking public comment period in evaluating whether to finalize measures. We continuously review and revise the measures in our programs to ensure that only the highest caliber measures are selected. We stress, however, that we are only required to consider the input provided by the MAP. The ultimate decision on whether to include a measure for the program rests solely with the Secretary. Although, ideally, we would want the MAP to fully support all measures for our programs, we recognize that it is not always possible. A "support direction" recommendation by the MAP indicates "measures, measure concepts, or measure ideas that should be phased into the program measure set over time, after specific issues are addressed." The MAP's reasons for supporting the direction of a measure can vary greatly, from measure to measure. In some instances, for example, the MAP might simply believe that a measure should first receive NQF endorsement.

We believe that this measure addresses the critical issue of colonoscopies potentially performed too frequently and potentially increasing patients' exposure to procedural harm. Because the procedure is performed often at HOPDs, we believe that this measure is necessary for the Hospital OQR Program.

After consideration of the public comments we received, we are finalizing this measure for the CY 2016 payment determination and subsequent years as proposed.

4. Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659)

This measure assesses the percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings who had a follow-up interval of 3 or more

years since their last colonoscopy documented in the colonoscopy report.

Colonoscopy is the recommended method of surveillance after the removal of adenomatous polyps, because it has been shown to significantly reduce subsequent colorectal cancer incidence. The timing of follow-up colonoscopy should be tailored to the number, size, and pathologic findings of the adenomatous polyps removed. A randomized trial of 699 patients showed that after newly diagnosed adenomatous polyps have been removed by colonoscopy, follow-up colonoscopy at 3 years detects important colonic lesions as effectively as follow-up colonoscopy at both 1 and 3 years.^{7 8}

The measure numerator for the proposed measure is: patients who had an interval of 3 or more years since their last colonoscopy. The measure denominator is: all patients aged 18 years and older receiving a surveillance colonoscopy with a history of a prior colonic polyp in a previous colonoscopy. This measure excludes patients with: (1) Documentation of medical reason(s) for an interval of less than 3 years since the last colonoscopy (for example, last colonoscopy incomplete, last colonoscopy had inadequate prep, piecemeal removal of adenomas, or last colonoscopy found greater than 10 adenomas); or (2) documentation of a system reason(s) for an interval of less than 3 years since the last colonoscopy (for example, unable to locate previous colonoscopy report, previous colonoscopy report was incomplete). The specifications for this measure are available at <http://www.qualityforum.org/QPS/0659>.

In its 2013 Pre-Rulemaking Report, (http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx), the MAP supported the direction of the measure. A "support direction" recommendation by the MAP indicates "measures, measure concepts, or measure ideas that should be phased into the program measure set over time, after specific issues are addressed" (for example, obtaining NQF endorsement).

⁷ National Quality Measures Clearing House. Agency for Healthcare Research and Quality. Available at <http://qualitymeasures.ahrq.gov/content.aspx?id=27981&search=complications+within+30+days+following+cataract+surgery>.

⁸ Davila RE, Rajan E, Baron TH, Adler DG, Egan JV, Faigel DO, Gan SI, Hirota WK, Leighton JA, Lichtenstein D, Qureshi WA, Shen B, Zuckerman MJ, VanGuilder T, Fanelli RD, Standards of Practice Committee, American Society for Gastrointestinal Endoscopy. ASGE guideline: colorectal cancer screening and surveillance. *Gastrointest Endosc* 2006 Apr;63(4):546–57. <http://www.ncbi.nlm.nih.gov/pubmed/16564851?dopt=Abstract>.

Currently the NQF endorsement is time-limited.

We refer readers to section XIII.H.2. of the proposed rule for a detailed discussion of data collection. We invited public comment on this proposal.

Comment: One commenter interpreted the MAP's "Support Direction" recommendation to mean that a measure was not, in the MAP's opinion, ready for implementation in the HQQR Program. Commenters stated that CMS should only finalize measures fully supported by the MAP.

Response: We refer readers to our response above to the same MAP recommendation concerns expressed with respect to the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) measure.

We believe that this measure addresses the critical area of timely following-up colonoscopies to detect important colonic lesions after newly diagnosed adenomatous polyps have been removed by colonoscopy. Proper timing can be effective in reducing the incidence of subsequent colorectal cancer. Because colonoscopy is so commonly performed at HOPDs, and because this measure addresses a significant gap in the Hospital OQR Program, we believe that this measure is necessary for the Hospital OQR Program. We also note that NQF recently lifted its time-limited endorsement and the measure is now fully-endorsed by NQF. We expect that this change will appear on the NQF Web site in the near future.

After consideration of the public comments we received, we are finalizing this measure, without modification, for the Hospital OQR Program as proposed.

5. Cataracts—Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (NQF #1536)

The proposed measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery.

Cataract surgery is performed to improve a patient's vision and associated functioning. This outcome is achieved consistently through careful attention to the accurate measurement of axial length and corneal power and the appropriate selection of an IOL. Failure to achieve improved visual functioning after surgery in eyes without comorbid ocular conditions that could impact the success of the surgery

would reflect care that should be assessed for opportunities for improvement. Evidence suggests that visual improvement occurs in about 86–98 percent of surgeries in eyes without comorbid conditions. However, with an annual volume of 2.8 million cataract surgeries in the United States, many of which are performed in hospital outpatient surgical departments, the impact could affect a significant number of patients per year.⁹

We proposed to adopt this measure for the CY 2016 payment determination and subsequent years. The measure numerator is: 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 a pre-operative and post-operative visual function instrument. The measure denominator is: all patients aged 18 years and older in sample who had cataract surgery. There are no exclusions. The specifications for this measure are available at <http://www.qualityforum.org/QPS/1536>. Additional information for the measure specifications can be found in the NQF Measure Evaluation available at <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=68317>.

In its 2013 Pre-Rulemaking Report, (http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx), the MAP supported the inclusion of the measure in the Hospital OQR Program and noted that the measure addresses a high impact condition not adequately addressed in

the program measure set. The MAP added that this measure, which addresses outcomes, falls under a category of measures inadequately represented in the program measure set. It also meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is NQF-endorsed. We refer readers to section XIII.H.2. of the proposed rule for a detailed discussion of data collection. We invited public comment on this proposal.

Comment: One commenter stated that the measure requires patients to complete a pre-operative and a post-operative visual function questionnaire. The follow-up survey may occur in intervals of one day, two weeks or one month post-op. The pre- and post-surgery surveys are conducted in the physician office and they are compared for analysis. The commenter noted it takes a third-party administrator to process the questionnaire in order to prevent the introduction of bias (such as how a physician characterizes a patient's progress) and this administrative cost would impose a new burden for HOPDs.

Response: We note that the pre-operative and post-operative surveys can be done in person at the HOPD or physician's office or via phone, email, or mail. The two surveys can be analyzed by the physician or the HOPD. However, given that this measure collects standard clinical follow-up information, we would expect physicians and HOPDs to already have standard operating procedures in place in order to conduct these visual assessments or for HOPDs to acquire them from patients' physicians in order to properly follow up by comparing pre- and post-operative surveys. Therefore, we do not believe this measure should impose undue additional burden.

Also, while a HOPD may want to utilize a third party administrator to process survey information, we do not believe one should be necessary. We believe that including this measure in the Hospital OQR Program is important because, as the MAP stated and we believe, this measure falls under a category of measures inadequately represented in the Hospital OQR Program measure set, and the measure exemplifies patient reported outcomes in the delivery of care.

In response to the comments we have received on the burden associated with the chart-abstracted measures we are finalizing, we have modified our implementation strategy in a manner that we believe will significantly minimize collection and reporting burden. We detail the data submission procedures for this measure and others in section XIII.H.2. of this final rule with comment period.

After consideration of the public comments we received, we are finalizing this measure for the CY 2016 payment determination and subsequent years as proposed.

In summary, we are finalizing four new measures (one CDC/NHSN measure and three chart-abstracted measures): (1) Influenza Vaccination Coverage among Healthcare Personnel; (2) Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients; (3) Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and (4) Cataracts—Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery for the CY 2016 payment determination and subsequent years.

⁹National Quality Measures Clearing House. Agency for Healthcare Research and Quality. Available at <http://www.qualitymeasures.ahrq.gov/content.aspx?id=27982>.

NQF#	Finalized Measures for the CY 2016 Payment Determination and Subsequent Years
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 Patient
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

The finalized measure set (a total of 28 measures) for the Hospital OQR Program for the CY 2016 payment

determination and subsequent years is listed in the table below.

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Finalized Hospital OQR Program Measure Set for the CY 2016 Payment Determination and Subsequent Years	
NQF#	Measure Name
0287	OP-1: Median Time to Fibrinolysis
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes
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
0270	OP-6: Timing of Antibiotic Prophylaxis
0268	OP-7: Prophylactic Antibiotic Selection for Surgical Patients
0514	OP-8: MRI Lumbar Spine for Low Back Pain
--	OP-9: Mammography Follow-up Rates
--	OP-10: Abdomen CT – Use of Contrast Material
0513	OP-11: Thorax CT – Use of Contrast Material
0489	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
--	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*
0491	OP-17: Tracking Clinical Results between Visits
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
--	OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional
0662	OP-21: Median Time to Pain Management for Long Bone Fracture
--	OP-22: ED- Patient 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
--	OP-25: Safe Surgery Checklist Use
--	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

Finalized Hospital OQR Program Measure Set for the CY 2016 Payment Determination and Subsequent Years	
NQF#	Measure Name
	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***

* Public reporting for OP-15 continues to be deferred at the time of this CY 2014 OPPS/ASC final rule with comment period.

** 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.

*** New measures finalized for the CY 2016 payment determination and subsequent years.

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F. Possible Hospital OQR Program Measure Topics for Future Consideration

The current measure set for the Hospital OQR Program includes measures that assess process of care, imaging efficiency patterns, care transitions, ED throughput efficiency, the use of Health Information Technology (HIT) care coordination, patient safety, and volume. We anticipate that as EHR technology evolves and more infrastructure is put into place, we will have the capacity to accept electronic reporting of many clinical chart-abstracted measures that are currently part of the Hospital OQR Program using certified EHR technology. We are working diligently toward this goal. We believe that this progress, at a near future date, would significantly reduce the administrative burden on hospitals under the Hospital OQR Program to report chart-abstracted measures. We recognize that considerable work needs to be done by measure owners and developers to make this possible with respect to the clinical quality measures targeted for electronic specifications (e-specifications). This includes completing e-specifications for measures, pilot testing, reliability and validity testing, and implementing such specifications into certified EHR technology to capture and calculate the results, and implementing the systems.

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, through future rulemaking, we intend 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, including partial hospitalization programs (PHPs) that are part of HOPDs.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43651), we indicated that we are considering the following measure domains for future measures: Clinical quality of care; care coordination; patient safety; patient and caregiver experience of care; population/community health; and efficiency. We believe this approach will promote better care while bringing the Hospital OQR Program in line with other established quality reporting programs such as the Hospital IQR Program and the ASCQR Program, all of which are targeting the same broad measure domains for future expansion.

We invited public comment on this approach and on our suggestions and rationale for possible measure topics for future consideration in the Hospital OQR Program.

Comment: Commenters presented the following as possible future measure topics:

- A patients' experience of care measure
- A core patient safety measure set or a serious hospital-acquired infection composite measure that includes Central Line Bundle Compliance, *Clostridium difficile* (C-difficile), catheter-associated urinary tract infection (CAUTI), and MRSA Bacteremia (MRSA)
- Clinician-level measures that can be applied appropriately in the hospital outpatient setting for conditions such as diabetes, coronary artery disease, and COPD
- Patient-Reported Outcomes Measures

Response: We thank the commenters for the feedback and will take it into consideration for future measures.

In addition, we solicited comments on the following potential quality measure topics for partial hospitalization programs (PHPs) that are part of HOPDs. Some of these measure topics are currently part of the IPFQR Program, and some of them we are currently considering for the IPFQR Program: Polyp-therapy with antipsychotic medications; Post-discharge of continuity of care; Alcohol screening; Alcohol and drug use; Tobacco use assessment; and Follow-up after hospitalization for mental illness. These measure topics would advance our goal of aligning measurement of PHPs in HOPDs with that of the IPFQR Program over time.

Comment: One commenter recommended that CMS not propose any of the measures topics for PHPs in HOPDs for the Hospital OQR Program until such measures are specified and tested in the PHP setting, and NQF-endorsed and reviewed by the MAP. The commenter was concerned about the need for more infrastructure support for additional measures.

Response: We thank the commenter for the suggestions. We will take these comments into account when considering whether to propose the measures for PHPs in future rulemaking.

Comment: Some commenters made specific recommendations for new measure proposals for PHPs. Commenters believed that with appropriate modification, the adoption of some of the IPFQR Program measures for PHPs could promote enhanced care coordination between PHPs and IPFs.

Specifically, the commenters recommended modifying two pairs of IPFQR measures for the PHP setting: Hospital-Based Inpatient Psychiatric Services (HBIPS) 4 and 5 (multiple antipsychotics); and HBIPS 6 and 7 (continuity of care). According to the

commenters, HBIPS 4 requires the identification of patients who are discharged on two or more antipsychotic medications, while HBIPS 5 reports the number of patients discharged on multiple antipsychotic medications with appropriate justification. Antipsychotics are important tools in managing behavior, but often have significant side effects, especially when multiple antipsychotic medications are used concurrently. It is often appropriate to reduce (or “taper”) the number of antipsychotics given to patients, but the tapering of drugs cannot always be completed during an inpatient hospitalization. Based on the information they presented, commenters contended it would be appropriate to measure PHPs on HBIPS 4 and 5 because antipsychotic medication tapering can and often does continue in PHPs. Furthermore, commenters stated that using setting-appropriate versions of HBIPS 4 and 5 in both IPFs and PHPs might encourage better coordination of the use of antipsychotic medications across these two settings.

Commenters also noted that similarly, HBIPS 6 measures whether a post-discharge continuing care plan is created, while HBIPS 7 measures whether the post-discharge continuing care plan is transmitted to the next level of care provider. A plan of care provides the next provider with a summary of a patient’s course of treatment, discharge medications and any recommendations for ongoing care. Whenever a patient changes care settings, the transmission of a plan of care equips the new health care team with important information to shape a patient’s treatment plan. Based on the commenters’ understanding of the measures they described, they asserted that assessing both IPFs and PHPs on these measures could reinforce the need for ongoing, two-way communication across a patient’s behavioral health care team.

Response: We thank the commenters for the detailed recommendations for future measures for PHPs. We will take them into consideration when we develop measures for PHPs.

G. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2014 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. All other hospitals paid under the OPSS that meet the reporting requirements receive the full OPSS payment update without the reduction. For a more detailed discussion of how the payment reduction for failure to meet the administrative, data collection, and data submission requirements of the Hospital OQR Program was initially implemented, we refer readers to the CY 2009 OPSS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPSS equal the product of the OPSS conversion factor and the scaled relative weight for the APC to which the service is assigned. The OPSS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPSS payment rate for services with the following status indicators (listed in Addendum B to this final rule with comment period, 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 proposed to delete status indicator “X” as described in sections II.A.3. and XI. of the proposed rule. We also note that we proposed to develop status indicator “J1” as part of the proposed comprehensive APC discussed in section II.A.2.e. of the proposed rule. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for applicable hospitals, with the exception of services assigned to New Technology APCs with assigned status indicator “S” or “T.” We refer readers to the CY 2009 OPSS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy.

We did not receive any public comments on the CY 2014 OPSS status

indicators to which the payment reduction to OPSS payment rates would apply, for hospitals who fail to meet the OQR reporting requirements. We note that the “J1” status indicator would not apply in the CY 2014 OPSS, due to the delay in implementation of the comprehensive APC policy, which is discussed in section II.A.2.e. of this final rule with comment period. We also note that status indicator “X” was not deleted, because the packaging proposal for ancillary services was not finalized for the CY 2014 OPSS, as discussed in section II.A.3. of this final rule with comment period. Therefore, the reporting ratio would continue to apply to services with status indicator “X.”

The OPD fee schedule increase factor is an input into the OPSS conversion factor, which is used to calculate OPSS payment rates. To implement the requirement 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 OPSS 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 OPSS relative weights by the reduced conversion factor. To determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPSS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPSS/ASC final rule with comment period by the CY 2010 OPSS final reporting ratio of 0.980 (74 FR 60642).

In the CY 2009 OPSS/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 those 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 in those cases 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. We believe that these adjustments continue to be equally applicable to payments for hospitals that do not meet the Hospital OQR Program requirements. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when the 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. This policy conforms to current practice under the IPPS. 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 the proposed rule.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2014

In the CY 2014 OPPS/ASC proposed rule (78 FR 43652), 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

2014 annual payment update factor. For the CY 2014 OPPS, the proposed reporting ratio was 0.980, calculated by dividing the proposed reduced conversion factor of \$71.273 by the proposed full conversion factor of \$72.728. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2014 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 proposed to delete status indicator "X" as described in sections II.A.3. and XI. of the proposed rule. We also note that we proposed to develop status indicator "J1" as part of the proposed comprehensive APC discussed in section II.A.2.e. of the proposed rule 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 invited public comment on these proposals.

Comment: One commenter suggested that OPPS outlier payments for hospitals that failed to meet the Hospital OQR Program requirements be calculated based on the full adjusted payment as if they met the requirements. The commenter believed that otherwise, hospitals could potentially receive an outlier payment as a result of failing to comply with the quality reporting requirements.

Response: In the CY 2009 OPPS/ASC final rule with comment period (78 FR 68772), we described how failure to meet the Hospital OQR Program requirements would affect certain OPPS payment adjustments. For the OPPS outlier payment calculation, we finalized a policy to calculate OPPS outliers using payments with the

Hospital OQR Program reduction already applied. This application of the quality reporting payment reduction in calculating the OPPS outliers is similar to how this issue is handled under the IPPS.

After consideration of the public comment we received, we are finalizing our proposal to apply the Hospital OQR Program reduction in the manner described above and, therefore, are finalizing our proposal, with modification to reflect the CY 2014 OPPS status indicators to which the adjustment would apply.

As a result, for the CY 2014 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 "P," "Q1," "Q2," "Q3," "R," "S," "T," "U," "V," or "X" 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 of Hospital OQR Data for the CY 2015 Payment Determination and Subsequent Years

1. Administrative Requirements for the CY 2015 Payment Determination and Subsequent Years

To participate successfully in the Hospital OQR Program, hospitals must meet administrative, data collection and submission, and data validation requirements (if applicable). Hospitals that do not meet Hospital OQR Program requirements, as well as hospitals not participating in the program and hospitals that withdraw from the program, will not receive the full OPPS payment rate update. Instead, in accordance with section 1833(t)(17)(A) of the Act, those hospitals will receive a reduction of 2.0 percentage points to their OPD fee schedule increase factor for the applicable payment year.

We established administrative requirements for the payment determination requirements for the CY 2013 payment update and subsequent years in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74479 through 74487). In the CY 2013 OPPS/

ASC final rule with comment period (77 FR 68480 through 68481), we modified these requirements by extending the deadline for certain hospitals to submit a participation form. For the CY 2014 payment determination and subsequent years, we modified the deadline for hospitals that are not currently participating in the Hospital OQR Program and wish to participate, provided they have a Medicare acceptance date before January 1 of the year prior to the affected annual payment update. For example, 2013 would be the year prior to the affected CY 2014 annual payment update, and we are referring to an acceptance date before January 1, 2013. The hospitals must submit a participation form by July 31 rather than March 31 of the year prior to the affected annual payment update in order to participate in the Hospital OQR Program for purposes of the CY 2014 payment update. In the example, the deadline would be July 31, 2013.

The Hospital OQR Program procedural requirements are unchanged from those adopted in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68480 through 68481). In the CY 2014 OPPS/ASC proposed rule (78 FR 43653), we proposed to codify these procedural requirements at § 419.46(a). To participate in the Hospital OQR Program, a hospital—as defined in section 1886(d)(1)(B) of the Act and that is reimbursed under the OPPS—must:

- Register with QualityNet before beginning to report data.
- Identify and register a QualityNet security administrator as part of the registration process located on the QualityNet Web site (<http://www.QualityNet.org>);
- Complete and submit an online participation form available at the QualityNet Web site if this form has not been previously completed, if a hospital has previously withdrawn, or if the hospital acquires a new CMS Certification Number (CCN). For Hospital OQR Program purposes, hospitals that share the same CCN are required to complete a single online participation form. Once a hospital has submitted a participation form, it is considered to be an active Hospital OQR Program participant until such time as it submits a withdrawal form to CMS or no longer has an effective Medicare provider agreement.

Deadlines for submitting the notice of participation form are based on the date identified as a hospital's Medicare acceptance date:

- If a hospital has a Medicare acceptance date before January 1 of the

year prior to the affected annual payment update, the hospital must complete and submit to CMS a completed Hospital OQR Notice of Participation Form by July 31 of the calendar year prior to the affected annual payment update.

- If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must submit a completed participation form no later than 180 days from the date identified as its Medicare acceptance date.

Hospitals may withdraw from participating in the Hospital OQR Program and the procedural requirements for this are unchanged from those adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 77480). In the CY 2014 OPPS/ASC proposed rule (78 FR 43653), we proposed to codify these procedural requirements at § 419.46(b). Under these procedures, a participating hospital may withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet Web site. The hospital may withdraw any time from January 1 to November 1 of the year prior to the affected annual payment update. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under § 419.43(h), and is required to submit a new participation form in order to participate in any future year of the Hospital OQR Program.

We invited public comment on this proposal.

Comment: One commenter supported codifying administrative requirements for the Hospital OQR Program.

Response: We thank the commenter for this support.

Comment: One commenter requested clarification regarding whether the proposed regulations apply to a hospital provider-based free standing emergency department that is not located on the campus of a hospital.

Response: Hospital OQR Program reporting is by CMS Certification Number (CCN), not by the physical location of clinical services provided. If the hospital has a free standing location that is included in a hospital CCN governing its eligibility to bill Medicare claims via OPPS, then services provided at that location should be included in the Hospital OQR Program reporting, along with all activity reported for that CCN. A hospital may refer to the Web site (<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=Qnet>

[Public%2FPages%2FQnetTier2&cid=1191255879384](https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPages%2FQnetTier2&cid=1191255879384)) for technical and educational support including contact information for questions on how to participate in the Hospital OQR Program to successfully receive a full APU.

After consideration of the public comments we received, we are finalizing as proposed, our proposal to codify certain Hospital OQR Program procedural requirements at § 419.46.

2. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

a. Background

We refer readers to the following OPPS/ASC final rules with comment period for a history of measures adopted for the Hospital OQR Program, including lists of: 11 measures finalized for the CY 2011 payment determination in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60637); 15 measures finalized for the CY 2012 payment determination in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72083 through 72084); 23 measures finalized for the CY 2013 payment determination in the CY 2011 OPPS/ASC final rule with comment (75 FR 72090); 26 measures finalized for the CY 2014 and CY 2015 payment determination in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74469 and 74473) and no additional measures finalized for the CY 2015 payment determination in the CY 2013 OPPS/ASC final rule with comment (77 FR 68476 through 68478). In the CY 2013 OPPS/ASC final rule with comment period, we confirmed the removal of one measure for the CY 2013 payment determination and subsequent years (77 FR 68473 through 68474), confirmed the suspension of one measure for the CY 2014 payment determination (77 FR 68474 through 68476), and finalized the deferred data collection for one measure (77 FR 68476).

In this final rule with comment period, we are finalizing four additional new measures. For a full list of current Hospital OQR measures, we refer readers to the table in section XIII.H.2.f. of this final rule with comment period.

b. Effects of Changes on Data Submission for CY 2015 and CY 2016 Payment Determinations and Subsequent Years

In section XIII.C.2.a. of the CY 2014 OPPS/ASC proposed rule (78 FR 43646 through 43647), we proposed to remove OP-19 for the CY 2016 payment determination and subsequent years. In section XIII.H.2.b. of the CY 2014 OPPS/

ASC proposed rule (78 FR 43653), however, we referred to the removal of OP-19 as being proposed for removal for CY 2015 and subsequent years. We intended for the proposal language in these two sections to match; specifically, we intended that the removal of OP-19 should begin with the CY 2015 payment determination and continue forward into subsequent years. Our proposal to remove OP-19 from the Hospital OQR Program beginning with the CY 2015 payment determination (this is our earliest opportunity to remove the measure from the Hospital OQR Program) would not require a participating hospital to take any new action, because we previously suspended OP-19 effective with January 1, 2012 encounters, and we have not used OP-19 data to meet requirements for any payment determination under the Hospital OQR Program or in public reporting.

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43646 through 43647) in section XIII.C.2.a, we proposed to remove OP-24 from the Hospital OQR Program for the CY 2016 payment determination and subsequent years. In section XIII.H.2.b. of the CY 2014 OPPTS/ASC proposed rule (78 FR 43653), however, we referred to the removal of OP-24 as being proposed for removal for the CY 2015 payment determination and subsequent years. We intended for the proposal language in these two sections to match; specifically, we intended that the removal of OP-24 should begin with the CY 2015 payment determination and continue forward into subsequent years. Our proposal to remove OP-24 from the Hospital OQR Program beginning with the CY 2015 payment determination (this is our earliest opportunity to remove the measure from the Hospital OQR Program) would not require a participating hospital to take any new action, because to date, we have not required hospitals to submit data for OP-24.

For the CY 2016 payment determination and subsequent years, in section XIII.E. of the proposed rule, we proposed to add five additional measures to the program, but we are only finalizing four of the five as additional new measures.

The four finalized, new measures are:

One measure that requires hospitals to submit data annually via an online tool located on the CDC's NHSN Web site:

- OP-27: Influenza Vaccination Coverage among Healthcare Personnel.

Three remaining measures that require hospitals to submit data annually via the QualityNet Web site:

- OP-29: Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients;
- OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and
- OP-31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

We refer readers to section XIII.E. for a discussion about these new finalized measures, and our decision not to finalize measure OP-28: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures.

In section XIII.H.2.f below, we discuss proposed and finalized requirements for data collection for each of the four new measures by mode of data submission.

c. General Requirements

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43654), we did not propose to make any changes to the Hospital OQR Program procedural requirements that we discussed and adopted in the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74480 through 74482). We proposed to codify the policy that, to be eligible to receive the full OPD fee schedule increase factor for any payment determination, hospitals that participate in the Hospital OQR Program must submit to CMS data on measures selected under section 1833(17)(C) of the Act in a form and manner, and at a time specified by CMS. This means that hospitals must comply with our submission requirements for chart-abstracted data, population and sampling data, claims-based measure data, and Web-based quality measure data. In the CY 2014 OPPTS/ASC proposed rule (78 FR 43654), we proposed to codify these general submission requirements at § 419.46(c).

Submission deadlines by measure and data type are posted on the QualityNet Web site. In general, deadlines for patient-level data submitted directly to CMS would be approximately 4 months after the last day of each calendar quarter. For example, the submission deadline for data for services furnished during the first quarter of CY 2014 (January–March 2014) would be on or around August 1, 2014. We proposed to codify language at § 419.46(c)(2) stating our practice of posting actual submission deadlines by measure and by data type on the QualityNet Web site (<http://www.QualityNet.org>).

We proposed to codify our policies for initial data collection periods and submission deadlines for a hospital that

did not participate in the previous year's Hospital OQR Program in § 419.46(c)(3) of our regulations. We refer readers to our previously finalized policy in the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68481) to establish data collection and submission requirements for the CY 2014 payment determination and subsequent years. To determine when a hospital that did not participate in a previous year's payment determination must begin collecting and submitting data to meet Hospital OQR Program requirements for a full annual payment update, we continue to use the January 1 Medicare acceptance date. If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must collect data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update, in addition to submitting a completed Hospital OQR Notice of Participation Form. If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must collect data for encounters beginning with the first full quarter following submission of the completed Hospital OQR Notice of Participation Form. All hospitals, whether the Medicare acceptance date is before or after January 1 of the year prior to an affected annual payment update, must follow data submission deadlines as specified on the QualityNet Web site.

We invited public comment on these proposals.

Comment: One commenter supported codifying procedural requirements for the Hospital OQR Program.

Response: We thank this commenter for support.

Comment: Commenters expressed concerns regarding the 30 day preview period for a hospital to preview data that will be posted on the *Hospital Compare* Web site and made available to the public. Commenters question the adequacy of this preview period to correct errors.

Response: While we appreciate these concerns, because these comments are outside the scope of our proposed rule, we will take the comments into consideration for future rulemaking.

After consideration of the public comments we received, we are finalizing as proposed our proposal to codify general submission requirements at § 419.46(c): (1) our practice of posting actual submission deadlines by measure and by data type on the QualityNet Web site (<http://www.QualityNet.org>) at § 419.46(c)(2); and (2) our policies for

initial data collection periods and submission deadlines for a hospital that did not participate in the previous year's Hospital OQR Program in § 419.46(c)(3) of our regulations.

d. Chart-Abstracted Measure Requirements for the CY 2015 Payment Determination and Subsequent Years

The following chart-abstracted measures in the Hospital OQR Program require data submission for the CY 2015 payment determination and subsequent years:

- OP-1: Median Time to Fibrinolysis;
- OP-2: Fibrinolytic Therapy Received Within 30 Minutes;
- OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention;
- OP-4: Aspirin at Arrival;
- OP-5: Median Time to ECG;
- OP-6: Timing of Antibiotic Prophylaxis;
- OP-7: Prophylactic Antibiotic Selection for Surgical Patients;
- OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients;
- OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional;
- OP-21: ED—Median Time to Pain Management for Long Bone Fracture;
- OP-22: ED Patient Left Without Being Seen; and
- 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.

The form and manner for submission of one of these measures, OP-22: ED Patient Left Without Being Seen, is unique, and is detailed in section XV.G.2.f. of the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68484). As discussed above, we did not propose any new chart-abstracted measures where patient-level data is submitted directly to CMS in the proposed rule.

e. Claims-Based Measure Data Requirements for the CY 2015 Payment Determination and Subsequent Years

The table in section XIII.D. of the proposed rule includes measures that the Hospital OQR Program collects by accessing electronic Medicare claims data submitted by hospitals for reimbursement.

We did not propose any new claims-based measures in the proposed rule. Therefore, the following 6 existing claims-based measures will be included for the CY 2015 payment determination and subsequent years:

- OP-8: MRI Lumbar Spine for Low Back Pain;

- 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; and
- OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).

In the CY 2012 OPPTS/ASC final rule with comment period, we deferred the public reporting of OP-15, a claims-based measure (76 FR 74456). We did not propose any changes to this policy. As discussed in the CY 2014 OPPTS/ASC proposed rule (78 FR 43654), public reporting for OP-15 continues to be deferred, and this deferral has no effect on any payment determinations at this time.

We will continue our policy of calculating the measures using hospitals' Medicare claims data as specified in the Hospital OQR Specifications Manual; therefore, no additional data submission is required for hospitals. In the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74483), we stated that for the CY 2014 payment update, we would use paid Medicare FFS claims for services furnished from January 1, 2011 to December 31, 2011.

In the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68482 through 68485), for the CY 2015 payment determination, we finalized our proposal to use paid Medicare FFS claims for services from a 12 month encounter period from July 1, 2012 through June 30, 2013 for the calculation of the claims-based measures. This is a departure from the previous deadlines used for these measures. Prior to the CY 2013 final rule, the time period for encounters for the CY 2014 payment determination was January 1, 2011 to December 31, 2011. Under the policy finalized in the CY 2013 OPPTS/ASC final rule with comment period, for the CY 2015 payment determination, we are using the encounter period July 1, 2012 to June 30, 2013. As stated in that final rule with comment period, we adopted this period in order to align the data period for inpatient and outpatient claims based measures reported on the *Hospital Compare* Web site, and also to be able to post more recent data for claims-based measures on the Web site. This modification brings our claims data six months more current effective with the CY 2015 payment determination.

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43655), we proposed, for the

CY 2016 payment determination and subsequent years, to continue this approach and to use paid Medicare FFS claims for services from a 12 month period from July three years before the payment determination through June of the following year. For the CY 2016 payment determination, this 12 month period for calculation of claims-based measures would be from July 1, 2013 through June 30, 2014. We invited public comment on this proposal.

Comment: One commenter believed that the recent changes in the IPPS rulemaking regarding the two midnight benchmarks for Medicare Part A payment will result in more bills that are "split" bills (denied Medicare Part A inpatient, but allowed to bill Medicare Part B outpatient services). The commenter expressed concern that these billing situations would pose a problem for under-submission in the Hospital OQR Program and would like to understand how these billing types will be handled in the outpatient "core measures" program such that hospitals do not have to identify up to hundreds of outpatient bills that were intended to be inpatient for the purpose of accurately meeting the submission requirements. The commenter appeared to be concerned that, at the time chart-abstraction happens, the hospital's universe of claims may not be complete as it would exclude Part B outpatient claims that are created and billed at some future point in time pursuant to a Part A inpatient claim denial. The commenter believes the chart abstractor might be at risk of "under-submission" (failing to sample or submit data corresponding to a sufficiently high enough number of cases to meet Hospital OQR Program requirements).

Response: We believe this commenter is referring to our policies finalized in the FY 2014 IPPS/LTCH PPS final rule regarding hospital Part B billing following reasonable and necessary Part A hospital inpatient claim denials (78 FR 50908 through 50938). Specifically, in the final rule we provided that if a Medicare Part A claim for inpatient hospital services is denied because the inpatient admission was not reasonable and necessary, or if a hospital determines under § 482.30(d) or § 485.641 (utilization review) after a beneficiary is discharged that the beneficiary's inpatient admission was not reasonable and necessary, the hospital may bill Medicare for the Part B inpatient services (furnished after the time of inpatient admission) that would have been reasonable and necessary if the beneficiary had been treated as a hospital outpatient rather than admitted as an inpatient, provided the beneficiary

is enrolled in Medicare Part B. These services must be submitted on a Part B inpatient claim. We also provided that for beneficiaries treated as hospital outpatients prior to an inpatient admission who are enrolled in Medicare Part B, hospitals may continue to bill Part B for hospital outpatient services that were furnished in the 3-day (1-day for non-IPPS hospitals) payment window prior to the inpatient admission. These services must be submitted on a Part B outpatient claim. When billing Part B following this type of Part A hospital inpatient claim denial, hospitals cannot change a beneficiary's patient status from inpatient to outpatient. The beneficiary was formally admitted as an inpatient and there is no provision to change a beneficiary's status after he or she is discharged from the hospital. Therefore, the beneficiary is considered an outpatient for services billed on the Part B outpatient claim, and is considered an inpatient for services billed on the Part B inpatient claim. For Part A claims with dates of admission on or after October 1, 2013, timely filing applies such that hospitals must submit the Part B claims within 12 months of the date of service in order to receive payment (78 FR 50922 through 50924).

Under the Hospital OQR Program, hospitals are required to submit data on quality measures for hospital outpatient services furnished within a given timeframe (encounter dates). A hospital's claims data supports two types of OQR measures of quality: claims based measures and chart-abstracted measures (claims data can be used to identify cases eligible for chart-abstractation). With regard to claims-based measures, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68483), we described that, for the upcoming CY 2015 payment determination, we will use paid, FFS claims for services during the time period from July 1, 2012 through June 30, 2013. We would like to clarify that these paid, FFS claims are Part B outpatient claims. Inpatient services are excluded, so all Part B inpatient claims are excluded. However, we will include paid Part B outpatient claims for services furnished in the 3-day (1-day for non-IPPS hospitals) payment window prior to an inpatient admission, along with other paid Part B outpatient claims, if they are paid prior to the cut-off date for claims inclusion of September 30, 2013. For the CY 2015 payment determination, we note that hospitals have a longer timeframe (beyond the usual timely filing deadline) to submit certain rebilled Part

B outpatient claims for services furnished during the Hospital OQR reporting period of July 1, 2012 through June 30, 2013 (78 FR 50935 through 50936). Part B outpatient claims for these dates of service that are processed and paid after the claims inclusion cut-off of September 30, 2013 will not be included in the Hospital OQR Program CY 2015 payment determination.

As it relates to chart-abstracted data, the hospital is responsible for submitting complete data that are available at the submission deadline for each measure of quality, and we will assess submitted data. If a claim is not timely available for the associated medical record's inclusion in the chart-abstractor's universe of records, the chart-abstractor cannot include data from that record in data submitted to CMS.

After consideration of the public comments we received, we are finalizing as proposed our proposal to continue to use paid Medicare FFS claims from a 12-month period from July 1st of the 3 years before the payment determination through June 30th of the following year.

f. Data Submission Requirements for Measure Data Submitted Via Web-Based Tool for the CY 2016 Payment Determination and Subsequent Years

In previous rulemaking, we have referred to measures where data are submitted via a Web-based tool on a CMS Web site under our quality data reporting programs as structural measures (measures concerned with attributes of where care occurs, such as material resources, human resources, and organizational structure.¹⁰ For example, the Hospital OQR measure OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data is a structural measure. However, because measures where data is submitted in this manner may or may not be structural, for example, the Hospital IQR chart-abstracted, process of care measure PC-01: Elective Delivery Prior to 39 Completed Weeks Gestation, we have refined our terminology and now refer to the mode of data submission as Web-based.

Thus, the previously finalized Web-based measures where data is entered on a CMS Web site that we require for the CY 2015 payment determination and subsequent years are listed below:

- OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data;
- OP-17: Tracking Clinical Results Between Visits;
- OP-22: ED Patient Left Without Being Seen;
- OP 25: Safe Surgery Check List Use; and
- OP 26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.

Measure OP-22: ED Patient Left Without Being Seen, is included in this list because, while patient-level data for this measure is collected via chart-abstractation, HOPDs submit aggregate data using an online tool. Thus, the same schedule for encounter periods and data submission deadlines applies to OP-22.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68483 through 68484), we finalized that, for the CY 2014 payment determination, hospitals are required to submit data on all Web-based measures between July 1, 2013 and November 1, 2013 with respect to the time period from January 1, 2012 to December 31, 2012.

We also finalized in the CY 2013 OPPS/ASC final rule with comment period for the CY 2015 payment determination, that hospitals are required to submit data on all Web-based measure data between July 1, 2014 and November 1, 2014 with respect to the time period from January 1, 2013 to December 31, 2013.

In the CY 2014 OPPS/ASC proposed rule, we proposed to apply a similar schedule for the CY 2016 payment determination and subsequent years. We proposed that hospitals would be required to submit data between July 1 and November 1 of the year prior to a payment determination with respect to the time period of January 1 to December 31 of two years prior to a payment determination year. Thus, for example, for the CY 2016 payment determination, hospitals would be required to submit data between July 1, 2015 and November 1, 2015 with respect to the time period of January 1, 2014 to December 31, 2014.

We also proposed to apply the same mode of data collection and deadlines to the following proposed chart-abstracted measures.

- OP-28: Complications within 30 days Following Cataract Surgery Requiring Additional Surgical Procedures (this measure was not finalized and will not be implemented);
- OP-29: Endoscopy/Polyp Surveillance: Appropriate follow-up

¹⁰ Maintz, J. Defining and Classifying Clinical Indicators for Quality Improvement. *Inter J Quality Health Care* (2003) 15(6), 523-530.

interval for normal colonoscopy in average risk patients;

- OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and

- OP-31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

Specifically, for data collection, we proposed that hospitals submit aggregate-level data through the CMS Web-based tool (the QualityNet Web site). As with OP-22, a chart-abstracted measure that is submitted once annually via the Web-based tool, hospitals would submit the data required for these newly proposed measures for a particular program year once annually during the data submission window proposed for Web-based measures as stated above, and would do so via the Outpatient section on the QualityNet secure Web site. While we proposed submission deadlines with an annual frequency, the data input forms on the QualityNet Web site for such submission will require hospitals to submit aggregate data represented by each separate quarter. We proposed to use the Web-based collection tool and collect aggregate-level data because we believe these options are less burdensome to hospitals than patient-level reporting.

While this proposal applies to the CY 2016 payment determination and subsequent years, in the CY 2014 OPPI/ASC proposed rule (78 FR 43656), we summarized for the proposed and existing chart-abstracted measures collected via the Web-based tool, data collection periods and deadlines as they apply to just the CY 2016 payment determination.

We recognize that aggregate-level reporting has the potential to result in less accurate measure rates than patient-level reporting. However, to reduce burden for hospitals, we believe that an aggregate data submission approach is the preferable approach at this time.

We invited public comment on these proposals.

In section XIII.E of this final rule with comment period, we describe that, in the CY 2014 OPPI/ASC proposed rule (78 FR 43647 through 43648) we sought public comment on whether we should collect patient-level data via certified EHR technology on the four proposed chart-abstracted measures (this would not apply to the one HAI measure, OP-27: Influenza Vaccination Coverage among Healthcare Personnel), and the potential timing for doing so. We refer readers to section XIII.E of this final rule with comment period for a discussion of the related public comments.

Comment: Several commenters raised general questions about the two colonoscopy measures CMS proposed without making a distinction between the two measures. Commenters expressed concern about determining the appropriate interval between colonoscopies if a patient had his or her last colonoscopy in a different HOPD or other facility. Another commenter was concerned about how HOPDs should be collecting the pre-procedure information necessary to make these determinations, noting that it would require significant system changes to achieve accurate data collection. The commenter described as an example having to set up a system with an NP or RN collecting a sufficient amount of accurate colonoscopy history from a patient during the patient's pre-procedure visits. The commenter believed that such a system would be necessary to determine whether an additional colonoscopy is necessary based on recommended frequency guidelines. The commenters also pointed out that many colonoscopies are performed at a facility that is not within the same entity as the ordering physician's practice, making it difficult for the HOPD to acquire medical records that are in the physician's possession.

Response: We appreciate these comments. We expect that, to address these measures, HOPDs will need to either ask patients about their colonoscopy history and polyp status, or acquire that information from such sources as the patient's physician or the facility that performed the most recent colonoscopy. This data will be critical for HOPDs attempting to determine an appropriate interval between colonoscopies.

Pre-procedure information can include a patient's history, perhaps in the form of a medical record or as obtained through verbal communication with the patient. We believe this information, which includes how recently patients had their previous colonoscopy and any other factors that might affect a HOPD's determination of an appropriate interval, is essential to a HOPD's decision about when to perform a follow-up colonoscopy. Acquiring this information may mean that some HOPDs must gather more information than they may be accustomed to.

We believe that HOPDs that perform certain procedures must manage the risk of procedural harm to patients and coordinate care by improving the communication between the HOPD, its patients, specialist physician offices, ASCs, surgeons performing procedures, and other outpatient departments. We expect some providers will need to

adopt new processes to effectively gather this information in order to manage the risk of procedural harm, and to report data for this measure. For example, HOPDs may in some cases need to establish some form of pre-procedure interaction with patients in order to establish their procedural history, either by using an NP or RN, as one commenter suggested, by using a survey form, or by some other method. There may be some concern that, despite HOPDs managing risk of procedural harm to the best of their abilities, patients may not always be able to accurately represent their polyp history during direct interactions with caregivers. In these instances, patients can authorize the release of medical information from one provider or practitioner to another.

Comment: One commenter recommended that CMS require reporting of data that is included in validation.

Response: We believe this commenter would like the Hospital OQR Program to restrict data collection to measures that are also subject to validation processes. We refer readers to section XIII.E.1. above for a discussion of this issue.

Comment: Many commenters believed that these measures are burdensome and the data is not easily attained in the outpatient setting. Many commenters argued that CMS' proposed requirement to collect aggregate-level data to report through the Web-based tool would actually increase the burden on hospitals. These commenters point out that the hospital must perform patient-level reviews to report aggregate-level data. One commenter believed that the submission of aggregate data using the Web-based tool required time spent manually entering data into QualityNet and made it more burdensome for a hospital to work with a vendor.

The commenters stated that, unless CMS intends to release full specifications, including clear and complete measure numerator, denominator, exclusion criteria, and algorithms, hospitals will experience burden in having to review and interpret NQF specifications for each of the new measures. One commenter stated that there are difficulties with CMS' infrastructure, and the commenter believes that any additional measures are likely to cause operational difficulties with data collection via the QualityNet Web site.

Response: We understand all new measures impose some burden on hospitals to gather and report data. We also appreciate that many commenters favor CMS adopting claims-based measures into the Hospital OQR

Program whenever possible, as we discuss in section XIII.E.1 above. However, we believe that the measures we are adopting are important indicators of the quality of care HOPDs provide and that any effort in acquiring data and burden in reporting that data is appropriate based on the importance of measuring the quality of care.

Regarding the burden imposed by Web-based reporting, we would like to clarify that the Hospital OQR Program requires entering aggregate data via the Web-based tool, not patient-level data or detail. A hospital is required to populate one numerator and one denominator field for the applicable measures onto QualityNet. However, hospitals would still be required to perform a patient-level review of medical records to compile aggregate data. Hospitals would abstract data for new measures OP-29, OP-30, and OP-31 the same way they have been abstracting data for all other previously finalized chart-abstracted measures; this process involves identifying their total aggregate sums for the numerator and denominator.

For the new measures (OP-29, OP-30, and OP-31), it should not be difficult for a hospital to use the Web-based tool to enter aggregate data, making a vendor unnecessary. In fact, we are not aware that any hospitals currently use a vendor to submit data for measure OP-22. However, if a hospital does choose to use a vendor, we do not see any reason why finalizing these new measures would necessarily make working with a vendor more difficult. Vendors routinely provide services to hospitals, submitting large amounts of detailed, and often complex, data to CMS on the hospitals' behalf.

We believe that reporting the aggregate-level data required by the new measures via the Web-based tool is less burdensome to hospitals than reporting patient-level data. We believe that the ease with which hospitals can submit their aggregate counts using our Web-based tool (the QualityNet Web site) reduces the burden of reporting. As we noted above, this process is the same process we finalized for OP-22 and similar to the process we finalized for a quality measure in the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537).

We will provide full, in-depth specifications for OP-29, OP-30, and OP-31 in the upcoming December 2013 addendum to the Hospital OQR Specifications Manual. We note that numerators, denominators, and exclusions have been established and made public as shown on the NQF Web site. The Hospital OQR Specifications Manual includes instructions for

identifying a measure's population (for example, using specific data elements), an algorithm for each measure in both diagram and narrative form, and sampling methodology for measures as applicable. The Hospital OQR Specifications Manual also includes information on the rationale for each measure, how each measure is publicly reported, how improvement is noted, etc., and it identifies references to Medical or other scientific journals that include discussion of a measure's focus. We would like to clarify that we are finalizing that a hospital would submit aggregate numerators, denominators, exclusion counts, and total populations and sample sizes for the new measures (OP-29, OP-30, and OP-31) according to the measure specifications.

However, we are sensitive to commenters' concerns regarding burden, and as such, we are addressing it in two ways—applying a sampling scheme and a low case threshold exemption. We intend to decrease burden and facilitate data reporting for these measures by allowing random sampling of cases when volume is high, instead of collecting information for all eligible patients. In our December 2013 addendum to the Hospital OQR Specifications Manual, we will publish a sampling methodology for these new measures that will take into account the burden that these new measures may place on hospitals during the CY 2014 encounter period. Specifically, we will employ the same sampling requirements for these measures that are currently used for the ED Throughput measure set (that is, measures OP-18/NQF 0496, OP-20/NQF 0498, and OP-22/NQF 0499). Sampling is a process of selecting a representative part of a population in order to estimate the hospital's performance, without collecting data for its entire population. In this way, using a statistically valid sample, a hospital can measure its performance in an effective and efficient manner. We describe how to obtain a statistically valid sample and the current sampling methodology and requirements for ED Throughput Measure Set within "Section 4—Population and Sampling Specifications" of the Hospital OQR Specifications Manual, v7.0 at the QualityNet Web site (<https://www.qualitynet.org>). There, the ED Throughput Sampling requirement is located in Table 3. A hospital should follow the same methodology for new measures OP-29 (NQF 0658), OP-30 (NQF 0659), and OP-31 (NQF 1536). In the upcoming release of the addendum to the Hospital OQR Specifications Manual (available at the QualityNet

Web site <https://www.qualitynet.org>), we will include information that the ED Throughput Sampling requirements at Table 3 are also applicable to new measures OP-29, OP-30, and OP-31.

We will adjust the sampling requirement based on our experience with collecting this data in the first year.

In addition, we are implementing a low case threshold exemption for newly finalized measures OP-29, OP-30, and OP-31. To reduce the burden on hospitals that treat a low number of patients, this exemption excludes hospitals that perform 20 or fewer relevant procedures per measure in any year from having to submit data for that year for measures OP-29, OP-30, and OP-31. This low case threshold exemption is consistent with our practice for chart-abstracted measures in the Hospital IQR Program (73 FR 48617), but annualized to be consistent with the Hospital OQR Program's single annual reporting requirement for these three measures. Because data for OP-29, OP-30, and OP-31 are to be submitted once annually via Web-based tool, we will not require hospitals that perform 20 or fewer cases per year per measure to submit this data annually.

We agree our data collection system experiences malfunctions, and we work to resolve system issues as quickly as we are able to through our contractors. However, the system functionality to report aggregate data using the Web based tool is stable at this time and our contractors assure us that the system will be able to collect aggregate data for OP-29, OP-30, and OP-31 by the first deadline for measure submission.

After consideration of the public comments we received, we are finalizing our proposal, for the CY 2016 payment determination and subsequent years, that hospitals will be required 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 two years prior to a payment determination year. For example, for the CY 2016 payment determination, the encounter period is January 1, 2014 to December 31, 2014 and the data submission window is July 1, 2015 through November 1, 2015. The CY 2014 encounter data is scheduled to be displayed on *Hospital Compare* in December 2015.

We also are finalizing our proposals: (1) To apply a uniform mode of data collection and deadlines to the new measures OP-29, OP-30, and OP-31; (2) that hospitals submit aggregate-level data through the CMS Web-based tool (the outpatient section of the QualityNet Web site); and, (3) that hospitals submit

all aggregate-level data required for a particular program year once annually during the data submission window.

In addition, we are finalizing a sampling scheme and low case threshold exemption. We will publish a sampling scheme for newly finalized measures in the upcoming December

2013 addendum to the Hospital OQR Specifications Manual. For the low case threshold exemption, we are finalizing that any hospital that performs 20 or fewer procedures annually for a particular new measure, will not be required to submit any data for that new measure.

Set out below are the finalized data collection requirements for chart-abstracted measures that are collected annually via the Web-based tool illustrating how these policies will apply to just the CY 2016 payment determination.

Illustrative Data Collection Requirements for the CY 2016 Payment Determination for Hospital OQR Program Web-Based Measures that are also Chart-Abstracted Measures

Measure	Encounter Dates	Data Submission Timeframe	Public Reporting
OP-22: ED Patient Left Without Being Seen*	January 1, 2014 – December 31, 2014	July 1, 2015 – November 1, 2015	Quarterly (April, July, October, December)
OP-29: Endoscopy/polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients**	January 1, 2014 – December 31, 2014	July 1, 2015 – November 1, 2015	CY 2014 encounter data to be published December 2015.
OP-30: Endoscopy/polyp surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use**	January 1, 2014 – December 31, 2014	July 1, 2015 – November 1, 2015	CY 2014 encounter data to be published December 2015.
OP-31 -- Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery**	January 1, 2014 – December 31, 2014	July 1, 2015 – November 1, 2015	CY 2014 encounter data to be published December 2015.

* Previously finalized with payment determination beginning CY 2013.

** Finalized for the CY 2016 payment determination and subsequent years.

g. Data Submission Requirements for a Measure Reported Via NHSN for the CY 2016 Payment Determination and Subsequent Years

As discussed in section XIII.E.1. of this final rule with comment period, we are finalizing the addition of OP–27: Influenza Vaccination Coverage among Healthcare Personnel to the Hospital OQR Program measure set. We proposed to use the data submission and reporting standard procedures set forth by the CDC for NHSN participation for submission of this measure to NHSN. Hospitals currently submit data to NHSN to comply with the requirements of the Hospital IQR Program and those requirements will be unchanged for data submission to NHSN for the Hospital OQR Program. We refer readers to the CDC's NHSN Web site (<http://www.cdc.gov/nhsn>) for detailed data submission and reporting procedures. We believe that these procedures are feasible because they are already widely used by over 4,000 hospitals reporting HAI data using NHSN. Our proposal seeks to reduce hospital burden by aligning our data submission and reporting procedures with NHSN procedures currently used by hospitals who participate in the reporting requirements for the Hospital IQR Program as well as hospitals in the 30 States and the District of Columbia that mandate HAI reporting via NHSN.

We proposed to adopt the NHSN HAI measure data collection timeframe of October 1 through March 31st, as previously finalized in the Hospital IQR Program (76 FR 51631 through 51633), which links data collection to the time period in which influenza vaccinations are administered during the influenza season. Because data for this measure would be collected seasonally, we proposed that hospitals submit their data for this measure to NHSN for purposes of the Hospital OQR Program by May 15th of the calendar year in which the vaccination season has ended. For example, for vaccinations given from October 1, 2014 (or when the vaccine becomes available) to March 31, 2015, the submission deadline would be May 15, 2015. This data submission deadline corresponds to that finalized by the Hospital IQR Program in the FY 2014 IPPS/LTCH final rule (78 FR 50821).

We invited public comment on these proposals.

Comment: One commenter expressed concern regarding whether the NHSN system will be overwhelmed if a large number of independent HOPDs began to submit data on the influenza measure. The commenter urged that prior to

implementation of any HOPD measures in the NHSN, CMS and CDC must work together to find the necessary resources to sustain and expand the reporting capabilities of the NHSN.

The commenter also stated that hospitals are having difficulty in obtaining reports from the NHSN system and when this problem is reported to NHSN, hospitals either receive no response or a generic response with no expected correction date provided. The commenter voiced concerns that this limits hospitals' ability to use NHSN data for performance improvement efforts, and that the concerns raised by the lack of system reliability must be mitigated through appropriate funding and quality control.

Response: We thank the commenter for the feedback. We believe this commenter is referring to the availability of feedback, in report form, to indicate whether a hospital has successfully reported HAI data to NHSN for purposes of meeting payment determination requirements for the Hospital IQR Program. The Hospital OQR Program has not, to date, required reporting to the NHSN system. HOPDs will report to the CDC using their CCN. Since hospitals have a single CCN, hospitals that already report data to the CDC's NHSN Web site for purposes of the Hospital IQR Program will not need to reenroll or get a new account, because they have already established their CCN identity. Where hospitals currently report data for the HCP vaccination rate for the inpatient setting, the CDC will add a drop-down option for hospitals to distinguish the reporting of data for the outpatient setting. The CDC will capture and transmit this outpatient data to CMS using the existing infrastructure for capturing and transmitting data for the inpatient setting.

The Hospital IQR Program has experienced problems with HAI feedback reports generated from CDC data in the past due to programming issues which have been corrected as they are identified. These experiences with the Hospital IQR Program report will be leveraged in the CMS outpatient feedback report, called the Provider Participation Report. The existing Provider Participation Report will be modified to include a column to indicate whether a facility has successfully reported the HCP influenza vaccination measure data for purposes of the Hospital OQR program.

NHSN has addressed and corrected previous issues with system strain and slow data-set generation due to high volume requests for data and reports. NHSN continues to closely monitor the Web site for any new potential issues

and strives to respond immediately. In light of these changes, we do not believe that it is likely that the NHSN system will be overwhelmed by this proposed reporting. The proposed reporting relies on making modest extensions to the existing NHSN infrastructure where the reporting is parallel to existing HCP data capture for the inpatient setting.

Comment: Several commenters asked how we will require reporting of students and volunteers at the hospital for this measure. One commenter would like clarification on how to gather data for personnel who were immunized outside of the reporting hospital. Commenters point out that it is a strain on resources to collect data on these categories of vaccinated personnel.

Response: We believe that hospitals are well equipped to report these categories of vaccinated personnel, since they already report these categories for personnel working in hospital inpatient departments in the Hospital IQR Program. CMS and CDC believe that only small modifications are necessary to report these categories of vaccinated personnel for hospital outpatient departments, since many hospitals use the same human resource system to collect relevant information on both hospital inpatient and outpatient department personnel. The CDC will collaborate with CMS on refining and publishing specifications for how to attribute workers by setting. CMS will refer to the CDC's specifications in the December 2013 addendum to the Hospital OQR Specifications Manual that will be available on the Quality Net Web site (<https://qualitynet.org>).

The numerator of the population of this measure includes personnel who received an influenza vaccination administered at the healthcare facility, or reported in writing (paper or electronic) or provided documentation that influenza vaccination was received elsewhere. The numerator also includes those who were determined to have a medical contraindication or particular allergy or immune status, who declined the influenza vaccination, or who have an unknown vaccination status or do not meet other NQF numerator categories (to review the NQF Measure Description and Numerator and Denominator Statements, please refer to the NQF Web site at <http://www.qualityforum.org/Home.aspx>). We believe the numerator categories will alleviate some of the difficulty a hospital may have in tracking down the vaccination status of some categories of HCW. We recognize the challenge for hospitals in collecting data for students, volunteers, and offsite personnel. We

nonetheless believe that the benefit of reducing influenza in hospitals outweighs any burden incurred by screening all staff, volunteers, students, and offsite personnel. We believe that this burden should, by and large, amount to gathering information about immunization during initial worker orientation and during flu vaccine season for existing workers, providing vaccines when appropriate, and keeping track of who has been vaccinated.

After consideration of the public comments we received, we are finalizing as proposed our proposal to use the data submission and reporting standard procedures set forth by the CDC for NHSN participation in general and for submission of data for this measure to NHSN. We are also finalizing our proposal to adopt the NHSN HAI measure data collection timeframe of October 1st through March 31st for this measure. The first deadline for hospitals to submit this data will be May 15, 2015 with respect to the October 1, 2015 through March 31, 2015 encounter period.

h. Population and Sampling Data Requirements for the CY 2015 Payment Determination and Subsequent Years

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484), for the CY 2014 payment determination and subsequent years, we continued our policy that hospitals may submit voluntarily on a quarterly basis, aggregate population and sample size counts for Medicare and non-Medicare encounters for the measure populations for which chart-abstracted data must be submitted, but they will not be required to do so. Where hospitals do choose to submit this data, the deadlines for submission are the same as those for reporting data for chart-abstracted measures, and hospitals may also choose to submit data prior to these deadlines. The deadline schedule is available on the QualityNet Web site. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72101 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of these policies.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43656), we did not propose any changes to this policy.

3. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2015 Payment Determination and Subsequent Years

a. Selection of Hospitals for Data Validation of Chart-Abstracted Measures for the CY 2015 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 74487 and 77 FR 68484 through 68487) 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 2014 OPPS/ASC proposed rule (78 FR 43656 through 43657), we did not propose any changes to this policy.

However, we proposed to codify at § 419.46(e) of our regulations the existing policy that we may validate one or more measures selected under section 1833(17)(C) of the Act by reviewing documentation of patient encounters submitted by selected participating hospitals. Upon written request, a hospital must submit to CMS or its contractor supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 45 days of the date identified on the written request, in the form and manner specified in the written request. A hospital meets the validation requirement with respect to a fiscal year if it achieves at least a 75-percent reliability score, as determined by CMS.

We invited public comment on our proposal to codify these requirements. *Comment:* One commenter supported codifying Hospital OQR procedures.

Response: We appreciate this commenter's support.

Comment: One commenter was opposed to the Hospital OQR Program using any threshold for establishing a passing rate of reliability for validation as criteria for a hospital achieving a full annual payment update. The commenter stated that, due to the complexity of the measures and the fact that there has been no evidence facilities submit inaccurate data to give the appearance of higher quality of care on the *Hospital Compare* Web site, the Hospital OQR Program should only look at whether a facility submits records when and as

requested. The commenter believed that successful submission of records should be sufficient to assure data integrity.

Response: We disagree. While we appreciate the commenter's perspective that hospitals are not motivated to submit data that inaccurately represents their care to appear to have higher quality of care on the *Hospital Compare* Web site, we nevertheless remain committed that all hospitals are responsible for submitting accurate data. All reporting hospitals are subject to selection for validation each payment determination year, which provides an additional incentive to maintain data quality. The validation process assesses overall data accuracy using data abstracted by CMS from hospital medical record copies, as compared to the data that a hospital submits to CMS. This process is intended to ensure that hospitals submit high quality and accurate data to CMS. We believe the opportunity for a hospital to be selected for validation is a motivator for the hospital to maintain stringent chart abstraction and data submission standards.

However, we believe that requiring hospitals to meet a reliability score serves a purpose beyond deterring hospitals from manipulating their data for display purposes. We believe that requiring a reliability score also motivates hospitals: (1) To continuously improve their internal operations to accurately capture the high quality care they provide; (2) to obtain data that can be measured and compared meaningfully across peer hospitals; and, (3) to report data to support our movement away from reimbursement for volume of care provided and toward reimbursement for quality of care. We appreciate the work hospitals do to refine processes to improve the quality of care they provide to patients and to report data reliably on measures of quality.

After consideration of the public comments we received, we are finalizing our proposal to codify at § 419.46(e) of our regulations our existing policies regarding validation of patient encounters at selected participating hospitals.

b. Targeting Criteria for Data Validation Selection for the CY 2015 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 2014 OPPS/ASC proposed rule (78 FR 43657), we did not propose any changes to this policy.

c. Methodology for Encounter Selection for the CY 2015 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 2014 OPPS/ASC proposed rule (78 FR 43657), we did not propose any changes to this policy.

d. Medical Record Documentation Requests for Validation and Validation Score Calculation for the CY 2015 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 procedures for requesting medical record documentation for validation and validation score calculation. In the CY 2014 OPPS/ASC proposed rule (78 FR 43657), we did not propose any changes to our procedures regarding medical record requests.

However, we proposed to codify these procedures at §§ 419.46(e)(1) and (e)(2) as summarized below:

- CMS may validate one or more measures selected under section 1833(17)(C) of the Act by reviewing documentation of patient encounters submitted by selected participating hospitals.
- Upon written request by CMS or its contractor, a hospital must submit to CMS supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 45 days of the date identified on the written request, in the form and manner specified in the written request.
- A hospital meets the validation requirement with respect to a fiscal year if it achieves at least a 75-percent reliability score, as determined by CMS.

We invited public comment on our proposal to codify these procedures.

We did not receive any public comment on our proposal to codify medical record documentation requests and validation and validation score calculation procedures. Therefore, we are finalizing our proposal to codify these procedures at §§ 419.46(e)(1) and (e)(2).

I. Hospital OQR Reconsideration and Appeals Procedures for the CY 2015 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487) for a discussion of our reconsideration and appeals procedures.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43657 through 43658), we proposed one change to the reconsideration request procedures to ensure our deadline for reconsideration requests will always fall on a business day. We also proposed to codify the process, including our proposal to change the deadline by which participating hospitals may submit requests for reconsideration at § 419.46(f) of our regulations.

A hospital seeking reconsideration would submit to CMS, via the QualityNet Web site, a Reconsideration Request form that will be made available on the QualityNet Web site. Where we have required that this form must be submitted by February 3 of the affected payment year (for example, for the CY 2014 payment determination, the request was required to be submitted by February 3, 2014), we proposed to modify this requirement so that the Reconsideration Request form would be required to be submitted on the first business day in February of the affected payment year instead. As proposed, the Reconsideration Request form for the CY 2014 payment determination would be required on February 3, 2014, which is a Monday, because this is the first business day in February; however, the form for the CY 2015 payment determination would be required on February 2, 2015, which is also a Monday, and the first business day in February. We note that while we use the CY 2014 and 2015 payment determinations as examples, we proposed this policy for the CY 2014 payment determination and subsequent years. The other requirements of the form would remain unchanged. We requested public comment on this proposal.

We also proposed to codify this process by which participating hospitals may submit requests for reconsideration, including our proposal to change the reconsideration request deadline at § 419.46(f). Under these proposed procedures, the hospital must submit to CMS via QualityNet, a reconsideration request via the QualityNet Web site, no later than the first business day in the month of February of the affected payment year containing the following information:

- The hospital's CMS Certification Number (CCN);
- The name of the hospital;
- The CMS-identified reason for not meeting the requirements of the affected payment year's Hospital OQR Program, as provided in any CMS notification to the hospital;
- The hospital's basis for requesting reconsideration. The hospital must identify its specific reason(s) for believing it should not be subject to the reduced annual payment update;
- The hospital-designated personnel contact information, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).
- The hospital-designated personnel's signature;
- A copy of all materials that the hospital submitted to comply with the requirements of the affected Hospital OQR Program payment determination year; and
- If the hospital is requesting reconsideration on the basis that CMS has determined it did not meet an affected payment determination year's validation requirement, the hospital must provide a written justification for each appealed data element classified during the validation process as a mismatch. Only data elements that affect a hospital's validation score are eligible to be reconsidered.

We also proposed to codify 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.

While we did not propose to codify the following process, we note that, after receiving a request for reconsideration, CMS—

- Provides an email acknowledgement, using the contact information provided in the reconsideration request, to the designated hospital personnel notifying them that the hospital's request has been received.
- Provides a formal response to the hospital-designated personnel, using the contact information provided in the reconsideration request, notifying the hospital of the outcome of the reconsideration process.

• Applies policies regarding the scope of our review when a hospital requests reconsideration, because it failed our validation requirement.

These policies are as follows:

- If a hospital requests reconsideration on the basis that it disagrees with a determination that one or more data elements were classified as mismatches, we only consider the

hospital's request if the hospital timely submitted all requested medical record documentation to the CMS contractor each quarter under the validation process.

- If a hospital requests reconsideration on the basis that it disagrees with a determination that one or more of the complete medical records it submitted during the quarterly validation process was classified as an invalid record selection (that is, the CMS contractor determined that one or more of the complete medical records submitted by the hospital did not match what was requested), thus resulting in a zero validation score for the encounter(s), our review is initially limited. We will review only to determine whether the medical documentation submitted in response to the designated CMS contractor's request was the correct and complete documentation. If we determine that the hospital did submit correct and complete medical documentation, we abstract the data elements and compute a new validation score for the encounter. If we conclude that the hospital did not submit correct and complete medical record documentation, we do not further consider the hospital's request.

- If a hospital requests reconsideration on the basis that it disagrees with a determination that it did not submit the requested medical record documentation to the CMS contractor within the 45 calendar day timeframe, our review is initially limited to determining whether the CMS contractor received the requested medical record documentation within 45 calendar days, and whether the hospital received the initial medical record request and reminder notice. If we determine that the CMS contractor timely received copies of the requested medical record documentation, we abstract data elements from the medical record documentation submitted by the hospital and compute a validation score for the hospital. If we determine that the hospital received two letters requesting medical documentation but did not submit the requested documentation within the 45 calendar day period, we do not further consider the hospital's request. (We note that in the proposed rule (78 FR 43658), we inadvertently referred to 30 calendar days, instead of 45 calendar days in this bulleted item. We used the correct 45 day timeframe in our discussion of Hospital OQR Program validation requirements in section XIII.H.3. of the proposed rule (78 FR 43656) and in proposed § 419.46(e)(1) (78 FR 43704).

If a hospital is dissatisfied with the result of a Hospital OQR reconsideration decision, the hospital is able to file an appeal under 42 CFR Part 405, Subpart R (PRRB appeal), as we have provided in our codification at § 419.46(f)(3).

We invited public comment on these proposals.

Comment: Several commenters supported CMS' proposed change to the reconsideration request procedures to ensure our deadline for reconsideration requests will always fall on a business day.

Response: We appreciate these commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to: (1) Change the deadline by which participating hospitals may submit requests for reconsideration; and, (2) codify this deadline and our procedural requirements for requesting a reconsideration at § 419.46(f) of our regulations.

J. Extraordinary Circumstances Extension or Waiver for the CY 2014 Payment Determination and Subsequent Years

In our experience, there have been times when facilities have been unable to submit information to meet program requirements due to extraordinary circumstances that are not within their control. It is our goal to not penalize such entities for such circumstances and we do not want to unduly increase their burden during these times. We refer readers to the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68489) for a complete discussion of our extraordinary circumstances extension or waiver process under the Hospital OQR Program.

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43658), we proposed one change to our process for hospitals to request and for CMS to grant extensions or waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the hospital. Specifically, we proposed that we may grant a waiver or extension to hospitals if we determine that a systemic problem with one of our data collection systems directly or indirectly affected the ability of hospitals to submit data. Because we do not anticipate that such systemic errors will happen often, we do not anticipate granting a waiver or extension on this basis frequently.

We also proposed to codify language for the general requirements for our extension or waiver process including the proposal for systemic errors at § 419.46(d) as described below:

CMS may grant an extension or waiver 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 waiver as follows:

- Upon request by the hospital. Specific requirements for submission of a request for an extension or waiver are available on the QualityNet Web site.
- At the discretion of CMS. CMS may grant waivers or extensions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

For the hospital to request consideration for an extension or waiver of the requirement to submit quality data or medical record documentation for one or more quarters, a hospital would follow specific requirements for submission of a request available on QualityNet. While we did not propose to codify the following process, we note that the following information must appear on the request form:

- Hospital CCN;
- Hospital Name;
- CEO or other hospital-designated personnel contact information, including name, email address, telephone number, and mailing address (must include a physical address, a post office box address is not acceptable);
- Hospital's reason for requesting an extension or waiver;
- Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the hospital believes it would again be able to submit Hospital OQR data and/or medical record documentation, and a justification for the proposed date.

The request form must be signed by the hospital's designated contact, whether or not that individual is the CEO. A request form is required to be submitted within 45 days of the date that the extraordinary circumstance occurred.

Following receipt of such a request, CMS would—

- (1) Provide an email acknowledgement using the contact information provided in the request notifying the designated contact that the hospital's request has been received; and,

- (2) If we make the determination to grant a waiver or extension to hospitals that have not requested them, because we determine that an extraordinary

circumstance has occurred in a region or locale, we would communicate this decision to hospitals and vendors through routine communication channels, including but not limited to emails and notices on the QualityNet Web site.

We invited public comment on these proposals.

Comment: Several commenters supported CMS' proposal to waive requirements where we have systemic errors.

Response: We appreciate these commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to include a waiver or extension for CMS' systemic errors and to codify language for the general requirements for our extension or waiver process, including our systemic errors waiver/extension policy at § 419.46(d).

XIV. Hospital Value-Based Purchasing (VBP) Program Updates

A. Background

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing program (the Hospital Value-Based Purchasing (VBP) Program) under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

B. Additional CMS Appeals Review Process

1. Statutory Basis

Section 1886(o)(11)(A) of the Act requires the Secretary to establish a process by which hospitals may appeal the calculation of a hospital's performance assessment with respect to the performance standards (section 1886(o)(3)(A) of the Act) and the hospital's performance score (section 1886(o)(5) of the Act).

Under section 1886(o)(11)(B) of the Act, there is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following: (1) The methodology used to determine the amount of the value-based incentive payment under section 1886(o)(6) of the Act and the determination of such amount; (2) the determination of the amount of funding available for the value-based incentive payments under section 1886(o)(7)(A) of the Act and the

payment reduction under section 1886(o)(7)(B)(i) of the Act; (3) the establishment of the performance standards under section 1886(o)(3) of the Act and the performance period under section 1886(o)(4) of the Act; (4) the measures specified under section 1886(b)(3)(B)(viii) of the Act and the measures selected under section 1886(o)(2) of the Act; (5) the methodology developed under section 1886(o)(5) of the Act that is used to calculate hospital performance scores and the calculation of such scores; or (6) the validation methodology specified in section 1886(b)(3)(B)(XI) of the Act.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53581), we finalized an administrative appeals process and codified that process at 42 CFR 412.167.

2. Independent CMS Review

In the CY 2014 OPPI/ASC proposed rule (78 FR 43659), for the Hospital VBP Program, we proposed to implement an independent CMS review that will be an additional appeal process available to hospitals, beyond the existing review and corrections process (77 FR 53578 through 53581 and 76 FR 74544 through 74547) and appeal process codified at § 412.167. We proposed that a hospital would be able to request this additional independent CMS review only if it first completes the appeal process at § 412.167(b) and is dissatisfied with the result. We stated our belief that our proposal to require hospitals to complete the existing appeal process at § 412.167(b) before they can request an additional independent CMS review will facilitate the efficient resolution of many disputed issues, thus decreasing the number of independent CMS reviews that are requested. We stated our intent to provide hospitals with our independent review decision within 90 calendar days following the receipt of a hospital's independent review request. We also proposed to codify this policy in our regulations at § 412.167 by redesignating the existing paragraph (c) as paragraph (d), and inserting a new paragraph (c).

We invited public comments on these proposals.

Comment: Numerous commenters supported the proposed independent review process, including the proposed 90-day limit on independent review requests. Some commenters suggested that CMS include the proposed 90-day time limit for hospitals to request the independent review process in the regulation text. One commenter also urged CMS to align the Hospital VBP Program with the Physician Value-Based Payment Modifier Program,

including the appeals and independent review process.

Response: We appreciate the commenters' support and note that our intention is to provide hospitals with a decision on an independent review request as quickly as possible. We also appreciate the commenters' suggestion that we include the 90-day timeframe for independent CMS reviews in our regulation text. While we will strive to complete those reviews within 90 days, we do not believe that it is appropriate at this time to incorporate a firm deadline into our regulations. We recognize that the number and complexity of these reviews will impact the actual completion timeframe. We also strongly encourage hospitals to request this additional independent CMS review within 30 days after they receive a decision on an appeal submitted under the regulations at § 412.167(b).

With respect to the commenters' suggestion that we align the Hospital VBP Program with the Physician Value-Based Payment Modifier Program, we are currently examining how we might be able to align various quality reporting and pay-for-performance programs.

After consideration of the public comments we received, we are finalizing the independent CMS review process as proposed. We also are finalizing our proposal to codify this policy at § 412.167 by redesignating existing paragraph (c) as paragraph (d), and inserting a new paragraph (c).

C. Performance and Baseline Periods for Certain Outcome Measures for the FY 2016 Hospital VBP Program

As described in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50681 through 50687), we have adopted the CLABSI, CAUTI, and SSI measures, which are reported to CDC's National Healthcare Safety Network (NHSN), for the FY 2016 Hospital VBP Program. However, when we proposed to adopt these measures in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27610 through 27611), we inadvertently did not make FY 2016 performance and baseline period proposals for these proposed measures. In the CY 2014 OPPI/ASC proposed rule (78 FR 43659), we proposed to adopt FY 2016 performance and baseline periods for these measures so that we would have enough time to consider and respond to public comments before the proposed start of the performance periods.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53597 through 53598), we finalized an 11-month performance period for the CLABSI measure for the FY 2015 Hospital VBP Program

(February 1, 2013 through December 31, 2013), with a corresponding baseline period of January 1, 2011 through December 31, 2011. While we adopted an 11-month performance period for the CLABSI measure for FY 2015 based on its posting date on the *Hospital Compare* Web site, beginning with FY 2016, we proposed to align the NHSN measures' performance and baseline periods with other domains' performance and baseline periods, where possible, and with the calendar year. As we have stated with regard to other domains, a 12-month performance period provides us more data on which to score hospital performance, which is an important goal both for CMS and for stakeholders.

Therefore, we proposed to adopt CY 2014 (January 1, 2014 through December 31, 2014) as the performance period for the CLABSI, CAUTI, and SSI measures for the FY 2016 Hospital VBP Program, with CY 2012 (January 1, 2012 through December 31, 2012) as the baseline period. We invited public comments on these proposals.

Comment: Numerous commenters supported the proposed performance and baseline periods, but argued that CMS should not adopt the CAUTI and CLABSI measures for the Hospital VBP Program because they have been finalized for the HAC Reduction Program. Commenters stated that it is inappropriate to penalize hospitals more than once for the same measure, and that two programs adopting the same measures may be confusing for hospitals and patients, especially because the two programs calculate performance differently. Other commenters opposed any measures that are not NQF-endorsed or risk-adjusted, and suggested that CMS suspend the CLABSI and SSI measures from the Hospital VBP Program.

Response: We appreciate the commenters' input. However, the proposals in the CY 2014 OPPS/ASC proposed rule were limited to the FY

2016 performance and baseline periods for the CAUTI, CLABSI, and SSI measures, not the adoption of the measures themselves. We adopted these measures for the FY 2016 Hospital VBP Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50686 through 50687), and responded to public comments on the substance of those measures in the same final rule (78 FR 50683). Accordingly, we view the public comments we received on the substance of these measures to be outside the scope of the CY 2014 OPPS/ASC proposed rule.

Comment: Some commenters noted that the CAUTI, CLABSI, and SSI measures underwent changes between the proposed baseline period of CY 2012 and the proposed performance period of CY 2014. The commenters noted that these changes may be confounding as CMS attempts to assess hospital performance on the measures. Commenters also noted that CDC may make additional definition changes to the CAUTI measure in CY 2014, and urged CMS to consider data instability when comparing data collection periods.

Response: We appreciate the commenters' suggestion. The changes to the CAUTI, CLABSI, and SSI measures cited by the commenters were changes the CDC made to standardize the process hospitals use to identify healthcare-associated infections (HAIs) and reflect operational practices already widely used for identifying those infections. Specifically, the change to the definition of "HAI" that applies to each of these measures improves each measure's objectivity and promotes greater standardized reporting. The CDC has informed CMS that it does not expect those changes to significantly impact the measure rates. In addition, our own clinically based qualitative review of the measure definition changes indicate that these measure definition refinements will not

substantially change national and hospital performance rates used in our FY 2016 measure rate and score calculations using CY 2012 and CY 2014 data. In this clinically based review, we assessed the clinical consistency of measure definitions across time, hospital adherence to current clinical guidelines, and relevant clinical outcomes associated with these infections. Our review found that the overall measure definitions for each of these measures remained consistent from a clinical perspective, and supported consistent and valid measurement of relevant clinical outcomes in CY 2012 and CY 2014.

We will continue to closely monitor the impact of the definitional changes made to the CAUTI, CLABSI, and SSI measures between CY 2012 and CY 2014 as we continue to collect data in these measures.

As we stated in prior rulemaking, we believe strongly that hospitals must be encouraged through the Hospital VBP Program to minimize infection events that present significant health risks to patients. We also believe that the CAUTI, CLABSI, and SSI measures provide information critical to this quality improvement effort by tracking infection events.

Comment: Numerous commenters supported the proposals and stated that adopting the calendar year makes more sense than the finalized 11-month performance period for the CLABSI measure for FY 2015.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing the FY 2016 performance and baseline periods for the CAUTI, CLABSI, and SSI measures as proposed.

The finalized performance and baseline periods for the CAUTI, CLABSI, and SSI measures for the FY 2016 Hospital VBP Program appear in the following table.

Finalized Performance and Baseline Periods for CAUTI/CLABSI/SSI under the FY 2016 Hospital VBP Program		
Domain	Baseline Period	Performance Period
Outcome ● CAUTI / CLABSI / SSI	● January 1, 2012 – December 31, 2012	● January 1, 2014 – December 31, 2014

XV. 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 ASC Quality Reporting (ASCQR) Program

We refer readers to section XIV.K.1. of the CY 2012 OPPTS/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

In the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66875), the CY 2009 OPPTS/ASC final rule with comment period (73 FR 68780), the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60656), and the CY 2011 OPPTS/ASC final rule with comment period (75 FR 72109), we did not implement a quality data reporting program for ASCs. We determined that it would be more appropriate to allow ASCs to acquire some experience with the revised ASC payment system, which was implemented for CY 2008, before implementing new quality reporting requirements. However, in these rules, we indicated that we intended to implement a quality reporting program for ASCs in the future. In preparation for proposing a quality reporting program for ASCs, in the CY 2011 OPPTS/ASC proposed rule (75 FR 46383), we solicited public comment on 10 measures.

In addition to CMS preparing to propose implementation of a quality reporting program for ASCs, HHS developed a plan to implement a value-based purchasing (VBP) program for payments under title XVIII of the Act for ASCs, and submitted a report to Congress entitled “Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan” that details this plan. The plan and the report to Congress were required under section 3006(f) of the Affordable Care Act as added by section 10301(a) of the Affordable Care Act. The report is found on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/Downloads/C_ASC_RTC-2011.pdf.

Currently, we do not have express statutory authority to implement an ASC VBP program.

In the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized our proposal to implement the ASCQR Program beginning with the CY 2014 payment determination. We adopted quality measures for the CY 2014, CY 2015, and CY 2016 payment determinations and subsequent years, and finalized some data collection and reporting timeframes for these measures. We also adopted policies with respect to the maintenance of technical specifications and the updating of measures, publication of ASCQR Program data and, for the CY 2014 payment determination, requirements for the claims-based measures. For a discussion of these final policies, we refer readers to the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74492 through 74517).

In the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74515), we indicated our intent to issue proposals for administrative requirements, data validation and completeness requirements, and reconsideration processes in the FY 2013 IPPS/LTCH PPS proposed rule, rather than in the CY 2013 OPPTS/ASC proposed rule, because the FY 2013 IPPS/LTCH PPS proposed rule was scheduled to be finalized earlier and prior to data collection for the CY 2014 payment determination, which was to begin with services furnished on October 1, 2012. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53636 through 53644), we issued final policies for administrative requirements, data completeness requirements, extraordinary circumstances waiver or extension requests, and a reconsideration process. For a complete discussion of these policies, we refer readers to the FY 2013 IPPS/LTCH PPS final rule.

In the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68492 through 68500), we issued final policies regarding our approach to selecting quality measures, reporting requirements, and payment reductions for ASCs that fail to meet the ASCQR Program requirements.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPTS/ASC final rule with comment

period (77 FR 68493 through 68494) for a detailed discussion of the considerations we use for the selection of ASCQR Program quality measures.

Comment: A few commenters recommended that CMS ensure that the proposed measures are specified to provide an opportunity for stakeholders input.

Response: We note that all the proposed measures are fully specified and we provide the links to the detailed measure specifications which were submitted to NQF by the measure stewards. We believe that these measure specifications provided the detailed information needed for the public to understand the measures being proposed and to be able to provide meaningful comments on the proposed measures during the rulemaking process. Proposed measures are not included in the ASCQR Specifications Manual (Specifications Manual) because we generally incorporate specifications for measures to be used in the ASCQR Program into the Specifications Manual, along with implementation guidance, after publication of the rule, but prior to implementation. As mentioned in section XV.B.5. of this final rule with comment period, which discusses maintenance of technical specifications, our general policy is to provide six months lead time between Specifications Manual publication and the start date of collection so that ASCs have adequate time to prepare for new reporting requirements.

2. ASCQR Program Quality Measures Adopted in Previous Rulemaking

In the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized our proposal to implement the ASCQR Program beginning with the CY 2014 payment determination and adopted measures for the CY 2014, CY 2015, and CY 2016 payment determinations. In an effort to streamline the rulemaking process, we also finalized our policy that, when we adopt measures for the ASCQR Program, these measures are automatically adopted for all subsequent years payment determinations unless we propose to remove, suspend, or replace the measures (76 FR 74494, 74504, 74509, and 74510).

The quality measures that we have previously adopted are listed below.

ASC Program Measurement Set Adopted in Previous Rulemaking	
ASC-1: Patient Burn*	
ASC-2: Patient Fall*	
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant*	
ASC-4: Hospital Transfer/Admission*	
ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing*	
ASC-6: Safe Surgery Checklist Use**	
ASC-7: 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: Influenza Vaccination Coverage among Healthcare Personnel ***	

*New measure for the CY 2014 payment determination.

** New measure for the CY 2015 payment determination.

***New measure for the CY 2016 payment determination.

3. Additional ASCQR Program Quality Measures for the CY 2016 Payment Determination and Subsequent Years

In the CY 2014 OPPS/ASC proposed rule (78 FR 43661 through 43664), we proposed quality measures for the CY 2016 payment determination and subsequent years based on our approach for future measure selection and development finalized in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494), which includes, among other considerations, aligning the ASCQR Program measures with our efforts in other clinical care settings and taking into account the views of the Measures Application Partnership (MAP).

We stated that we believe that ASCs and HOPDs are similar in their delivery of surgical and related nonsurgical services. Therefore, we seek to propose quality measures that can be applied to both HOPDs and ASCs to the extent possible because many of the same surgical procedures are performed in both of these settings. Measure harmonization assures that quality of care for similar services is measured in a comparable manner across settings. This approach would provide meaningful information for Medicare beneficiaries to make informed decisions.

Section 3014 of the Affordable Care Act added section 1890A of the Act establishing a pre-rulemaking process, which, among other steps, requires the Secretary to take into consideration the input from multi-stakeholder groups in selecting certain categories of quality and efficiency measures described in section 1890(b)(7)(B) of the Act. As part of the pre-rulemaking process, the consensus-based entity that CMS must contract with under section 1890 of the Act (currently NQF) convened the multi-stakeholder groups, referred to as the MAP. The MAP is a public-private partnership created for the primary purpose of providing input to HHS on the selection of the categories of measures in section 1890(b)(7)(B) of the Act, which includes measures for use in certain specific Medicare programs, measures for use in reporting performance information to the public, and measures for use in health care programs other than for use under the Act.

After we selected quality measures that we might propose for the ASCQR Program based on our established policies regarding the approach to selecting quality measures in CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494), we included the measures in a publicly

available document entitled “List of Measures Under Consideration for December 1, 2012” in compliance with section 1890A(a)(2) of the Act, and the measures were reviewed by the MAP in its “MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS,” which has been made available on the NQF Web site at: http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx. We considered the input and recommendations provided by the MAP in selecting measures to propose for the ASCQR Program.

As part of the MAP's input and recommendations in its 2013 Pre-Rulemaking Report, the MAP also supports: (1) HHS' efforts to move toward greater alignment across the Hospital OQR and ASCQR Programs; and (2) the inclusion of ASCs within a broader approach to measuring performance and improving care that is aligned across health care settings (page 35, MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS).

For the CY 2016 payment determination and subsequent years, we proposed to adopt four measures for the ASCQR Program, all of which were reviewed by the MAP and three of which are NQF-endorsed for the ASC setting (NQF #0564 being the exception): (a) Complications within 30 Days following Cataract Surgery Requiring Additional Surgical Procedures (NQF #0564); (b) Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients (NQF #0658); (c) Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659); and (d) Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).

For purposes of the ASCQR Program, sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, read together, require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) 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. The proposed measures are described in greater detail below.

We proposed that data collection for these four measures would begin in CY 2014. We referred readers to section XV.D. of the proposed rule for detailed discussion of data collection and submission time frames. We proposed to collect aggregate data (numerators, denominators, and exclusions) on all ASC patients for these four proposed chart-abstracted measures via an online Web-based tool that would be made available to ASCs via the QualityNet Web site. This online Web-based tool is currently in use in the ASCQR Program for ASC-6 (Safe Surgery Checklist Use) and ASC-7 (ASC Facility Volume Data on Selected ASC Surgical Procedures). We invited public comment on these proposals. More information regarding this proposed method of collection was provided in section XV.D.5.c. of the proposed rule.

To advance our efforts to collect high quality data on all ASC patients for the ASCQR measures while minimizing burden for ASCs, we also sought public comment on alternative data collection strategies for these four proposed measures. In particular, we sought comment on collection of patient-level data through registries or other third party data aggregators, and via certified electronic health record (EHR) technology, along with the potential timing for doing so.

Comment: Some commenters believed that CMS should allow ASCs to meet the requirements of the ASCQR Program using registry-based reporting and urged CMS to propose a registry-based reporting option that would allow ASCs to fulfill all program requirements through a single mechanism to simplify and streamline the process of data submission. Other commenters urged CMS to focus on options to reduce reporting burden associated with data submission through multiple portals (claims-based, QualityNet, and NHSN), suggesting instead the use of registries or electronic health records.

Response: We thank the commenters 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 in this program. Should registry-based

reporting of the ASC quality measures 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. In addition, if such measures do exist, we would need to understand the current state of EHR adoption by ASCs before proposing them. In a previous environmental scan, which included an assessment of the readiness of ASC to electronically report quality data, we found low levels of EHR use by ASCs. We are in the process of updating the environmental scan of ASCs, which will include an analysis of EHR adoption and an assessment of ASCs' abilities to report quality data via EHR systems. We believe that ASCs continue to be slow to adopt EHRs because many of them are small facilities and there has been no incentive program to encourage such adoption, but we intend to assess this position based upon the results of our updated environmental scan.

For the proposed rule, we received many general comments that are applicable to all four proposed measures. We have organized the document by first summarizing and responding to these general comments that are applicable to all the four proposed measures, and then summarizing and responding to measure-specific comments and describing our final policy.

Comment: Many commenters stated that ASCs only render the facility for ophthalmologists to perform cataract surgery and that follow-up visits, post-operative visual assessments and tracking of complications are performed at the ophthalmologists' offices. Likewise, physicians perform colonoscopies at ASCs, but follow-up colonoscopy intervals are determined and documented by the physician in medical records kept in the physicians' offices. Commenters noted that ASCs do not have long term relationships with patients and Federal regulations do not permit ASCs to provide postoperative follow-up care; therefore, the patient would not visit the ASC, but rather another site, for post-operative care and identification of complications. Many commenters perceived the four proposed chart-abstracted measures as "Clinician Office" setting measures designed to measure ophthalmologist and other physician performance and not ASC performance. Commenters gave as examples ophthalmologists who

assess post-operative visual function and patient outcomes, and determine whether additional surgical procedures are necessary, and physicians who receive pathology reports and determine the colonoscopy intervals for their patients. Therefore, commenters believed these four measures are better suited as Physician Quality Reporting System (PQRS) measures. Commenters considered the measures as duplicative of the PQRS measures.

Some commenters expressed concerns that the measures are neither NQF-endorsed nor field tested for the facility setting. Other commenters stated that CMS must re-specify, test, and obtain NQF endorsement of these measures at the facility level of analysis before they can be adopted for the ASCQR Program.

Some commenters believed that the four proposed measures require ASCs to expend resources engaged in quality reporting activities that would have no direct impact on facility performance improvement efforts.

Response: As noted above, for purposes of the ASCQR Program, sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, read together, require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs. As stated in the CY 2014 OPPI/ASC proposed rule (78 FR 43661 through 43664), we believe these measures are appropriate for measuring the quality of care in the ASC setting. Further, the three measures that we are finalizing (as discussed below) are NQF-endorsed for the "Ambulatory Care: Ambulatory Surgery Center (ASC)" setting. Therefore, we respectfully disagree with the commenters and continue to believe that these quality measures are appropriate for the ASC setting. With respect to the commenters who stated that the proposed chart-abstracted measures should be re-specified and field-tested, we note that all three measures that we are finalizing (as discussed below) were specified for the ASC setting and field tested at the ASC facility setting level by the measure steward.

Further, we do not believe these measures are duplicative of PQRS measures because even though the measure indicators are the same, the level of analysis (facility versus physician) is different. The measure indicators for the ASCQR Program will reflect the HCPCS codes for the ASC facility level of analysis. As we stated in the CY 2013 OPPI/ASC final rule with comment period (77 FR 68493), in implementing the ASCQR Program, one

of our principles is that measures should be aligned across Medicare and Medicaid public reporting and incentive payment systems to promote coordinated efforts to improve quality. We hope to set new milestones in the intrinsic coordination and collaboration of hand-off care across outpatient providers and suppliers, as reflected in these measures.

We also do not agree that the four proposed measures would have no direct impact on facility performance improvement efforts. Rather, we believe that these measures promote accountability for the care provided to Medicare beneficiaries, improve the coordination and collaboration of services, reduce fragmented care, encourage redesigned care processes for high quality and efficient service delivery, and incentivize higher value care.

ASCs provide care without the higher costs associated with hospitalization. More and more procedures are done safely and effectively in an ambulatory care setting and we expect such trend will continue. Hence, we believe that assessing care coordination is a very important aspect of evaluating the overall quality of the care furnished by ASCs. We stress that real clinical integration is evidenced by effective patient coordination of care across health care settings, providers, and suppliers and is best shown when there is a structure in place that is patient-focused and where clinicians collaborate on best practices in an effort to furnish higher quality care that they likely would not achieve if working independently.

As discussed in detail in sections XIII.E.3., 4., and 5. of this final rule with comment period and below, we are finalizing the same chart-abstracted measures for the Hospital OQR Program as we are for the ASCQR Program for the CY 2016 payment determination and subsequent years: (1) Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; (2) Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and (3) Cataracts—Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery. The adoption of these measures in the hospital outpatient and ASC settings will further align measures across outpatient and ambulatory settings which furnish many similar services to beneficiaries. The availability of identical outcome measures at HOPDs and ASCs enable

beneficiaries to compare facilities and make informed decisions.

Comment: Some commenters believed that obtaining patient data from the ophthalmologist's or other physician's office is not always feasible. Commenters also noted that the initial and subsequent surgical cataract and colonoscopy procedures due to complications may occur at two different ASCs. In addition, commenters also believed that obtaining patient information from the ophthalmologist's or other physician's office would be an intrusive violation of patient privacy.

Response: Our overarching goal for adopting the three proposed measures is to encourage the coordination of care across health care settings, providers, and suppliers as frequently as possible. We would like to see ASCs, ophthalmologists, and other physicians actively and routinely engaged in exchanging information to better communicate and coordinate the care of patients.

We note that ASCs have professional and commercial relationships with the ophthalmologists or other physicians that perform procedures and are paid for services rendered at their facilities. As such, ASCs have the ability to develop the means to obtain follow-up information that include, but are not limited to, inclusion of contractual requirements to supply such information to the ASC. The availability of follow-up information from physicians performing procedures at an ASC is further discussed in section XVI.D.5.c. of this final rule with comment period.

Regarding the issue of patient privacy, we note that ASCs and referring physicians are generally subject to the HIPAA Privacy, Security, and Breach Notification Rules, and are required to protect the privacy and confidentiality of their patients' protected health information as required by those rules. We expect that ASCs and physicians would adhere to any applicable requirements in providing and obtaining this information and would not violate patient privacy.

We believe that our implementation strategy for these measures will minimize collection and reporting burden, as discussed in section XV.D.5.c. of this final rule with comment period.

Comment: Many commenters expressed concern that it is extremely burdensome for ASCs, which do not widely use EHRs, to retrieve outcome data from ophthalmologist and other physician offices.

Response: We appreciate commenters' concerns that it could be difficult or

burdensome for ASCs to retrieve from physician offices the data they will need for the chart-abstracted measures. We believe such problems are more likely to occur in the early phases of establishing these measures, when ASCs and physicians have not yet set up effective infrastructures to routinely exchange information. In order to accommodate these concerns, we have taken steps that we believe should alleviate some of this burden. The Web-based collection strategy we are finalizing for the measures and subsequent release of specifications and implementation guidance in the ASCQR Specifications Manual will address some of the concerns about feasibility of data collection raised by the commenters. To further reduce burden, we are finalizing a sampling methodology for ASCs. We believe that this should significantly reduce burden for the three chart-abstracted measures that we are finalizing. We discuss these steps designed to reduce burden in more detail in section XV.D.5.c. of this final rule with comment period.

We recognize that EHR technology currently may not be widely used in ASCs. However, with the ongoing progress of EHR technology in healthcare delivery, we expect more ASCs will have EHR technology at their disposal in the future. As mentioned previously, we will be conducting an environmental scan to assess EHR implementation in ASCs and readiness for electronic reporting in the future. We will take these factors into account before including an EHR-based reporting mechanism for the ASCQR Program.

We received specific comments on the individual proposed measures and they are discussed below in the sections addressing each of the proposed measures.

a. Complications Within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures

It is uncommon to have complications that may result in a permanent loss of vision following cataract surgery. Cataract surgery has become safer and more effective due to advances in technology and surgical skills over the last 30 years. Based on an analysis of Managed Care Organization data, it is estimated that the annual volume for cataract surgeries is 2.8 million in the U.S with the rate of cataract surgery complications being 1 to 2 percent. However, with an annual volume of 2.8 million cataract surgeries in the United States, a 2 percent rate is significant and

translates to over 36,000 surgeries associated with complications.¹¹

Therefore, for the CY 2016 payment determination and subsequent years, we proposed to adopt the Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures measure, which assesses the "[p]ercentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence." This outcome measure seeks to identify those complications from surgery that can reasonably be attributed to the surgery. It focuses on patient safety and monitoring for events that, while uncommon, can signify important issues in the care being provided. The numerator for this measure is the number of "[p]atients who had one or more specified operative procedures for any of the following major complications within 30 days following cataract surgery: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence." The denominator for this measure is the total number of "[p]atients aged 18 years and older who had cataract surgery and no significant pre-operative ocular conditions impacting the surgical complication rate." This measure excludes patients with certain "comorbid conditions impacting the surgical complication rate." The measure specifications can be found at: <http://www.qualityforum.org/QPS/0564>. This measure has been endorsed by NQF for the "Ambulatory Care: Clinic" setting (NQF #0564) but, currently, is not NQF-endorsed for the ASC setting.

We believe this measure meets the statutory requirements discussed above. This measure is not NQF-endorsed in the ASC setting and we could not find any other comparable measure that is specifically endorsed for the ASC setting. However, 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

¹¹ National Quality Measures Clearing House. Agency for Healthcare Research and Quality. Available at <http://qualitymeasures.ahrq.gov/content.aspx?id=27981&search=complications+within+30+days+following+cataract+surgery>.

being provided in ASCs. Further, this measure reflects consensus among affected parties as it has been endorsed by NQF for the “Ambulatory Care: Clinic” setting. We believe that this consensus also applies to the same surgeries that are performed in other ambulatory settings, such as ASCs and HOPDs. Given the high volume of cataract surgeries performed in ambulatory care settings and the potential 2 percent complication rate, we believe it is important for us to include this measure in the ASCQR Program measure set, and that this is an appropriate application of NQF #0564 to the ASC setting.

We note that section 1833(t)(17) of the Act does not require that each measure we adopt be endorsed by a national consensus building entity. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act applies to the ASCQR Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures. In its 2013 Pre-Rulemaking Report, the MAP supported inclusion of this measure in the ASCQR Program and noted that this measure “[a]ddresses a high impact condition not adequately addressed in the program measure set.” Currently, the NQF endorsement for this measure is time-limited.

We invited public comment on this proposal.

Comment: Many commenters believed that this measure is not a good measure to include in the ASCQR Program measure set because complications from cataract surgery are rare, data collection would be very burdensome, and the volume of cataract surgery performed at ASCs is huge. Commenters added that this measure requires very detailed information about not only specific complications that may have occurred, but also data on any additional follow-up surgical procedures to accurately report data for this measure. A few commenters stated that subsequent surgical procedures due to complications from the previous cataract surgery may not occur at the same ASC. ASCs also would need to determine if a patient who experienced any of the above-listed complications then underwent any of a list of 39 specified operative procedures (identified by a list of CPT codes) within the 30-day period following the index surgery.

Response: As discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 43661) and in this final rule with comment period, a large number of complications from cataract surgery occur even though the percentage of

complications from cataract surgery is small. Therefore, we believe that complications following cataract surgery which would require additional surgical procedures are important to measure. However, after consideration of the public comments we received, we agree that this measure as specified imposes a significant burden on an ASC to collect the required data that far exceeds the burden we believe accompanies the other chart-abstracted measures that we proposed in the CY 2014 OPPS/ASC proposed rule. We have emphasized that we believe that care coordination between ASCs and practitioners is an essential element of appropriate, high quality care, and that the element of coordination cannot be measured using a claims-based or other form of measure.

Nonetheless, this is one instance in which we believe the burden involved in collecting the data required for chart-abstracted data outweighs the benefits in measuring care coordination. That is because an ASC would be required to acquire far more information than the more fundamental follow up information that accompanies the other measures (such as the patient survey data for ASC-11, which basically involves collecting information on a patient's perceptions about visual improvement following cataract surgery). In contrast, there is far more information necessary for this measure and the nature of that information is more detailed, complicated and very likely much more difficult for an ASC to acquire. We agree with the commenters that this measure requires very detailed information about not only specific complications that may have occurred, but also data on specific additional follow up surgical procedures to accurately report data for this measure.

Because we continue to believe this is an important area to measure quality of care, we plan to explore ways to collect these data, including the potential development of a claims-based risk-adjusted outcome measure of cataract complications, which would address the same quality issues as this measure, but minimize the burden associated with measurement to the greatest degree possible. Further, we anticipate that the proposed new measure would be applicable to the ASC and HOPD settings. For these reasons, we have decided not to finalize this particular measure of cataract surgery complications.

After consideration of the public comments we received, we are not finalizing this measure for the ASCQR Program for the CY 2016 payment determination and subsequent years.

b. Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)

The American Cancer Society's current guidelines recommend colonoscopy screening at 10-year intervals¹² for the average risk population (<http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/colorectal-cancer-early-detection-aacs-recommendations>).

For the CY 2016 payment determination and subsequent years, we proposed to adopt the Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients measure, which assesses the “[p]ercentage of patients aged 50 years and older receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.” Performing colonoscopy too frequently increases a patients' exposure to procedural harm. This measure aims to assess whether average risk patients with normal colonoscopies receive a recommendation to receive a repeat colonoscopy in an interval that is less than the recommended amount of 10 years. This measure is NQF-endorsed for the ASC setting. The numerator for this measure is the number of “[p]atients who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.” The denominator for this measure is the total number of “[p]atients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy.” The measure excludes patients whose medical records contain reason(s) for recommending a follow up interval of less than 10 years. The specifications for this measure can be found at: <http://www.qualityforum.org/QPS/0658>.

We believe this measure meets the statutory requirements discussed above. This measure is appropriate for the measurement of quality of care furnished by ASCs because colonoscopy screening is commonly performed in ASCs and this measure was developed

¹² Davila RE, Rajan E, Baron TH, Adler DG, Egan JV, Faigel DO, Gan SI, Hirota WK, Leighton JA, Lichtenstein D, Qureshi WA, Shen B, Zuckerman MJ, VanGuilder T, Fanelli RD, Standards of Practice Committee, American Society for Gastrointestinal Endoscopy. ASGE guideline: colorectal cancer screening and surveillance. *Gastrointest Endosc* 2006 Apr;63(4):546–57. <http://www.ncbi.nlm.nih.gov/pubmed/16564851?dopt=Abstract>.

to specifically measure quality of care furnished by ASCs. We also believe it meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is NQF-endorsed for the ASC setting.

In its 2013 Pre-Rulemaking Report, the MAP supported the direction of this measure. Currently, the NQF endorsement for this measure is time-limited.

We invited public comment on this proposal.

Comment: One commenter asserted that the MAP's "Support Direction," recommendation means the measure was not, in the MAP's opinion, ready for implementation in the ASCQR Program. Commenters stated that CMS should only finalize measures fully supported by the MAP.

Response: We take into account all MAP input when deciding on which measures to adopt for the program. We note that in addition to MAP input, we also consider feedback that we receive from many other stakeholders such as suppliers, specialty societies, measure developers, patients, and their caregivers during the rulemaking public comment period in evaluating whether to finalize measures. We continuously review and revise the measures in our programs to ensure that only the highest caliber measures are selected. We stress, however, that we are only required to consider the input provided by the MAP. The ultimate decision on whether to include a measure for the program rests solely with the Secretary.

We believe that this measure addresses a critical area of colonoscopies being performed too frequently, which may increase patients' exposure to procedural harm. The procedure is performed often at ASCs; therefore, we believe the measure is important for the ASCQR Program. Further, we believe that the Web-based collection strategy we are finalizing for the measures along with the release of specifications and implementation guidance in the Specifications Manual will address concerns about feasibility of data collection raised by the MAP.

After consideration of the public comments we received, we are adopting this measure for the CY 2016 payment determination and subsequent years as proposed.

c. Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients With a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659)

According to the American Cancer Society, in patients with increased or

high risk of colorectal cancer, colonoscopy screening is recommended based on risk factors. One such factor is a history of adenomatous polyps. The frequency of colonoscopy screening varies depending on the size and amount of polyps found; however, the general recommendation is a 3 year follow-up (<http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/colorectal-cancer-early-detection-acsc-recommendations>).

A randomized trial of 699 patients showed that after newly diagnosed adenomatous polyps have been removed by colonoscopy, follow-up colonoscopy at 3 years detects important colonic lesions as effectively as follow-up colonoscopy at both 1 and 3 years.¹³

For the CY 2016 payment determination and subsequent years, we proposed to adopt the Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use measure, which assesses the "[p]ercentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report" This measure is NQF-endorsed for the ASC setting. The numerator for this measure is the number of "[p]atients who had an interval of 3 or more years since their last colonoscopy." The denominator for this measure is the total number of "[p]atients aged 18 years and older receiving a surveillance colonoscopy with a history of a prior colonic polyp in a previous colonoscopy." This measure excludes patients with: (1) Documentation of medical reason(s) for an interval of less than 3 years since the last colonoscopy (for example, last colonoscopy incomplete, last colonoscopy had inadequate prep, piecemeal removal of adenomas, or last colonoscopy found greater than 10 adenomas); or (2) documentation of a system reason(s) for an interval of less than 3 years since the last colonoscopy (for example, unable to locate previous colonoscopy report, previous colonoscopy report was incomplete).

¹³ Davila RE, Rajan E, Baron TH, Adler DG, Egan JV, Faigel DO, Gan SI, Hirota WK, Leighton JA, Lichtenstein D, Qureshi WA, Shen B, Zuckerman MJ, VanGuilder T, Fanelli RD, Standards of Practice Committee, American Society for Gastrointestinal Endoscopy. ASGE guideline: colorectal cancer screening and surveillance. *Gastrointest Endosc* 2006 Apr;63(4):546–57. <http://www.ncbi.nlm.nih.gov/pubmed/16564851?dopt=Abstract>.

The specifications for this measure can be found at: <http://www.qualityforum.org/QPS/0659>.

We believe this measure meets the statutory requirements discussed above. This measure is appropriate for the measurement of quality of care furnished by ASCs because colonoscopy is commonly performed in ASCs and this measure was developed to specifically measure quality of care furnished by ASCs. We also believe it meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is NQF-endorsed for the ASC setting.

In its 2013 Pre-Rulemaking Report, the MAP supported the direction of this measure. While this measure had been endorsed by the NQF for a limited time period, recent communications with NQF have revealed that this measure is now fully endorsed; it is expected that this status update will be reflected on the NQF Web site in the near future.

We invited public comment on this proposal.

Comment: Some commenters asserted that the MAP's "Support Direction" recommendation means the measure is not, in the MAP's opinion, ready for implementation in the ASCQR Program. Commenters stated that CMS should only finalize measures fully supported by the MAP.

Response: We refer readers to our response above to the same MAP recommendation concerns expressed with respect to the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) measure. We believe that Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use measure addresses a critical area of timely follow-up colonoscopy to detect important colonic lesions effectively in reducing subsequent colorectal cancer incidence, after newly diagnosed adenomatous polyps have been removed by colonoscopy. Because colonoscopies are performed so often at ASCs, the measure is important for the ASCQR Program. Further, we believe that the Web-based collection strategy we are finalizing for the measures and subsequent release of specifications and implementation guidance in the Specifications Manual will address concerns about feasibility of data collection raised by the MAP.

After consideration of the public comments we received, we are adopting this measure for the CY 2016 payment determination and subsequent years as proposed.

d. Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (NQF #1536)

Cataract surgery is performed to improve a patient's vision and associated functioning. This outcome is achieved consistently with careful attention to the accurate measurement of axial length and corneal power and the appropriate selection of an intraocular lens (IOL). Failure to achieve improved visual functioning after surgery in eyes without comorbid ocular conditions that could impact the success of the surgery would reflect care that should be assessed for opportunities for improvement. Evidence suggests that visual improvement occurs in about 86 to 98 percent of surgeries in eyes without comorbid conditions. However, with an annual volume of 2.8 million cataract surgeries in the U.S., an improvement rate from 86 to 98 percent could impact a significant number of patients per year.¹⁴

For the CY 2016 payment determination and subsequent years, we proposed to adopt the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure, which assesses the "[p]ercentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery." This measure is NQF-endorsed for the ASC setting. The measure numerator is the number of "[p]atients 18 years and older in sample who had improvement in visual function achieved within 90 days following cataract surgery, based on completing a pre-operative and post-operative visual function instrument." The measure denominator is the total number of "[p]atients aged 18 years and older in sample who had cataract surgery." There are no exclusions. The specifications for this measure are available on the Web site at: <http://www.qualityforum.org/QPS/1536>. Additional information for the measure

specifications can be found in the NQF Measure Evaluation available on the Web site at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=68317>.

We believe this measure meets the statutory requirements discussed above. This measure is appropriate for the measurement of quality of care furnished by ASCs because cataract surgery is commonly performed in ASCs and this measure was developed to specifically measure quality of care furnished by ASCs." It also meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is NQF-endorsed for the ASC setting.

In its 2013 Pre-Rulemaking Report, the MAP supported the inclusion of this measure in the ASCQR Program and noted that this measure "[a]ddresses a high-impact condition not adequately addressed in the program measure set."

We invited public comment on this proposal.

Comment: One commenter stated that the measure requires patients to complete a pre-operative and a post-operative visual function questionnaire. The follow-up survey may occur in intervals of one day, two weeks or one month post-op. The pre- and post-surgery surveys are conducted in the physician office and they are compared for analysis. The commenter noted it takes a third-party administrator to process the questionnaire in order to prevent the introduction of bias and this administrative cost would impose a new burden for ASCs.

Response: This measure collects standard clinical follow-up information. We would expect that physicians responsible for post-operative cataract surgery care to have standard operating procedures in place under which physicians would conduct these visual assessments. We do not believe a third party administrator to process survey information for ASC interpretation is necessary because we expect that ASCs would obtain the outcome information necessary for this measure from the physician that performed the surgery (as discussed in section XVI.D.5.c. of this final rule with comment period, all

physicians involved in co-management of a cataract surgery patient should have these results). We believe that no bias would be introduced or associated administrative cost imposed because outcome interpretation would not be done at the ASC. Finally, we believe that including this measure in the ASCQR Program is important because, as the MAP stated and we believe, this measure falls under a category of measures inadequately addressed in the ASCQR Program measure set, and the measure serves to drive coordination of care.

In response to the comments we have received on the burden associated with the chart-abstracted measures we are finalizing, we have modified our implementation strategy in a manner that we believe will significantly minimize collection and reporting burden. We detail these procedures for and further discuss the issue of obtaining data for this measure in section XV.D.5.c. of this final rule with comment period.

After consideration of the public comments we received, we are adopting this measure for CY 2016 payment determination and subsequent years as proposed.

In summary, we are finalizing our proposals for the CY 2016 payment determination and subsequent years to adopt three chart-abstracted measures: (1) Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients; (2) Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and (3) Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. We will collect aggregate data (numerators, denominators, and exclusions) on all ASC patients for these three finalized chart-abstracted measures via an online Web-based tool that will be made available to ASCs via the QualityNet Web site. Data submission requirements for these three measures are discussed in section XV.D.5.c. of this final rule with comment period.

¹⁴ National Quality Measures Clearing House. Agency for Healthcare Research and Quality. Available at <http://www.qualitymeasures.ahrq.gov/content.aspx?id=27982>.

NQF#	Newly Finalized ASCQR Measures for the CY 2016 Payment Determination and Subsequent Years
0658	ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patient
0659	ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use
1536	ASC-11: Cataracts- Improvement in Patient's Visual Function within 90 days Following Cataract Surgery

The finalized measure set (a total of 11 measures) for the ASCQR Program for the CY 2016 payment determination

and subsequent years is listed in the table below.

	ASC Program Measure Set for the CY 2016 Payment Determination and Subsequent Years
	Measure Name
ASC-1	Patient Burn*
ASC-2	Patient Fall*
ASC-3	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant*
ASC-4	Hospital Transfer/Admission*
ASC-5	Prophylactic Intravenous (IV) Antibiotic Timing*
ASC-6	Safe Surgery Checklist Use**
ASC-7	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	Influenza Vaccination Coverage among Healthcare Personnel ***
ASC-9	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients ***
ASC-10	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use***
ASC-11	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery***

*New measure for the CY 2014 payment determination and subsequent years.

** New measure for the CY 2015 payment determination and subsequent years.

***New measure for the CY 2016 payment determination and subsequent years.

4. ASCQR Program Measure Topics for Future Consideration

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 ASC setting. Through future rulemaking, we intend to propose new measures that address

clinical quality of care, patient safety, care coordination, patient experience of care, surgical outcomes, surgical complications, complications of anesthesia, and patient reported outcomes of care. We invited public comment on these measurement topics.

Comment: Commenters presented the following suggestions for future measure topics:

- Equipment Reprocessing;
- Sedation Safety;
- Post-Discharge Emergency Department Visit within 72 Hours of ASC Procedure;
- Hospital admission following discharge from an ASC;
- Normothermia;
- Venous Thromboembolism; and
- Surgical Site Infection.

Response: We thank the commenters for their feedback and will take the suggestions into considerations for future measure topics for the ASCQR Program.

5. Technical Specification Updates and Data Publication

In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures (76 FR 74513 through 74514), including the subregulatory process for making updates to the adopted measures. We believe that a measure can be updated through this subregulatory process provided it is a nonsubstantive change. We make the determination of what constitutes a substantive versus a nonsubstantive change on a case-by-case basis.

Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure. We believe that non-substantive changes may include updates to any measure based upon changes to guidelines upon which the measures are based. We will revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We also will post the updates on the QualityNet Web site at: <https://www.QualityNet.org>. We will provide sufficient lead time for ASCs to implement the changes where changes to the data collection systems would be necessary. We generally release the Specifications Manual every 6 months and release addenda as necessary. This release schedule provides at least 3 months of advance notice for nonsubstantive changes such as changes to ICD-10, CPT, and HCPCS codes, and at least 6 months of advance notice for changes to data elements that would require significant systems changes.

We will continue to use rulemaking to adopt substantive updates. Examples of changes that we might generally consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example, changes in acceptable timing of medication, procedure/process, or test administration). Again, we make the determination of what constitutes a substantive versus a nonsubstantive change on a case-by-case basis.

We believe that this policy adequately balances our need to incorporate nonsubstantive updates to ASCQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change a measure that it is no longer the same measure that we originally adopted. We also note that the NQF endorsement process incorporates an opportunity for public comment and engagement in the measure maintenance process. These policies regarding what is considered substantive versus nonsubstantive apply to all measures in the ASCQR Program.

As noted above, we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74513 through 74514). We also provided additional clarification regarding the ASCQR Program policy in the context of the previously finalized Hospital OQR program policy in the CY 2013 OPPS/ASC final rule with comment period. We refer readers to the CY 2013 OPPS/ASC final rule with comment period for a discussion of the process for updating the ASCQR Program quality measures (77 FR 68496 through 68497).

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we also 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.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43664), we did not propose any changes to these policies.

Comment: One commenter noted that the conversion of a measure to use ICD-10-CM/PCS should be considered as a substantive change that follows current proposed rulemaking processes. The commenter requested clarification regarding the publication, preview, and comment period for ICD-9-CM to ICD-10-CM/PCS mappings for all value sets for diagnoses and procedures used by measures specified in this rule.

Response: None of the current ASCQR measures utilize ICD-9 codes to define numerators, denominators, exclusions, and other data elements for the measures. To the extent that we adopt any future ASCQR measures that utilize ICD-9 codes in measure data elements, we will crosswalk those ICD-9 codes to ICD-10 prior to including the measures in the ASCQR Specifications Manual to

inform data collection. We note that we do not consider updating codes from ICD-9 to ICD-10 a substantive change to a measure because doing so does not change the intent or meaning of the measure.

Comment: Some commenters stated that ASCs should be allowed to review their data. These commenters also believed that ASCs should have the ability to correct any errors prior to the data being made publicly available because a few errors could cause extreme differences in actual versus publicly reported rates.

Response: We thank the commenters for raising these issues. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we finalized a policy to make data that an ASC submitted for the ASCQR Program publicly available on a CMS Web site after providing an ASC an opportunity to review the data to be made public. We will address processes for public reporting in further detail in future rulemaking.

C. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

Section 1833(i)(2)(D)(iv) of the Act states that the Secretary may implement the revised ASC payment system "in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7)." Paragraph (7) contains subparagraphs (A) and (B). Subparagraph (A) of paragraph (7) states the Secretary may provide that an ASC that does not submit "data required to be submitted on measures selected under this paragraph with respect to a year" to the Secretary in accordance with this paragraph will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year. It also specifies that this reduction applies only with respect to the year involved and will not be taken into account in computing any annual increase factor for a subsequent year. Subparagraph (B) of paragraph (7) makes many of the provisions of the Hospital OQR Program applicable to the ASCQR Program "[e]xcept as the Secretary may otherwise provide." Finally, section 1833(i)(2)(D)(v) of the Act states that, in implementing the revised ASC payment system for 2011 and each subsequent year, "any annual update under such system for the year, after application of clause (iv) [regarding the reduction in the annual update for failure to report

on quality measures] shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).” Section 1833(i)(2)(D)(v) of the Act also states that the “application of the preceding sentence may result in such update being less than 0.0 for a year, and may result in payment rates under the [revised ASC payment system] for a year being less than such payment rates for the preceding year.”

2. Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for Each 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 would be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction would apply 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 OPPTS/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 OPPTS 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 non-facility PE RVU-based amounts and the standard ASC ratesetting methodology. We finalized our proposal that the standard ASC ratesetting methodology for this 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 an office-based or radiology procedure 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, we finalized our proposal in the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68500) 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.

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. 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 OPPTS/ASC proposed rule (78 FR 43664 through 43665), we did not propose any changes to these policies.

D. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Administrator

a. Background for the CY 2014 and CY 2015 Payment Determinations

A QualityNet account is required to submit quality measure data to the QualityNet Web site via a Web-based tool and, in accordance with CMS policy, a QualityNet security administrator is necessary to set-up such an account for the purpose of submitting this information to the QualityNet Web site. In previous rulemaking, we referred to this role as the QualityNet administrator; we are referring to this role in this rulemaking as the QualityNet security administrator, which emphasizes the security function of this role and aligns terminology for the ASCQR Program with the Hospital IQR and OQR Programs. While the main purpose of a QualityNet security administrator is to

serve as a point of contact for security purposes for quality reporting programs, we believe from our experience that a QualityNet security administrator typically fulfills a variety of tasks related to quality reporting, such as creating, approving, editing, and terminating QualityNet user accounts within an organization, and monitoring QualityNet usage to maintain proper security and confidentiality measures. Therefore, we highly recommend that ASCs have and maintain a QualityNet security administrator.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53638 through 53639), we did not require that ASCs do so for the CY 2014 payment determination because ASCs are not required to submit data directly to the quality data warehouse for the CY 2014 payment determination (76 FR 74504) and we do not want to unduly burden ASCs by requiring ASCs to have a QualityNet security administrator. We note that a QualityNet account is not necessary to access information that is posted to the QualityNet Web site, such as the Specifications Manual and educational materials.

As finalized in the CY 2012 OPPI/ASC final rule with comment period (76 FR 74504 through 74509), for the CY 2015 payment determination, we required ASCs to submit quality measure data for two quality measures (safe surgery checklist use and ASC facility volume data on selected ASC surgical procedures) collected from services provided during the January 1, 2012 to December 31, 2012 timeframe via an online tool located on the QualityNet Web page. As set forth in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53638 through 53639), to enter these data into our data system, we required that ASCs identify and register a QualityNet security administrator who followed the registration process located on the QualityNet Web site and submitted the information as specified on this site. Because submission of these data was not required until the July 1, 2013 to August 15, 2013 time period, we required that ASCs have a QualityNet security administrator at the time ASCs submit Web-based measure data in 2013 for the CY 2015 payment determination, which was no later than August 15, 2013. ASCs could have had a QualityNet security administrator prior to this date, but it was not required.

We noted that there are necessary mailing and processing procedures that must be completed in order to have a QualityNet security administrator which are separate from completion of the forms by the ASC that can require significant time to complete. We

strongly cautioned ASCs to not wait until the deadline to apply; instead, we recommended allowing a minimum of 2 weeks, and strongly suggested allowing additional time prior to the deadline to submit required documentation in case of unforeseen issues. We did not require that ASCs maintain a QualityNet security administrator after the entry of their data via an online tool located on the QualityNet Web site in 2013 for the CY 2015 payment determination.

We also noted that QualityNet users must complete a user enrollment process, which is part of the registration process, to ensure access to the Secure QualityNet Portal beginning July 1, 2013. Portal access will be required for ASCs submitting data under the ASCQR Program using an online tool located on the QualityNet Web site.

b. Requirements for the CY 2016 Payment Determination and Subsequent Years

In the CY 2014 OPPI/ASC proposed rule (78 FR 43666), for the CY 2016 payment determination and subsequent years, we proposed that, similar to the requirement for the CY 2015 payment determination, ASCs would be required to have a QualityNet security administrator for the purposes of setting up a QualityNet account for the purpose of entering data via an online tool located on the QualityNet Web site if this had not been completed previously, or the current user accounts lapsed or were discontinued. If an ASC does not already have a QualityNet account, the facility would need to identify and register a QualityNet security administrator who follows the registration process located on the QualityNet Web site and submits the information as specified on this site. A QualityNet security administrator is not required for submitting data. A QualityNet security administrator is required to set up user accounts and for security purposes and a current user account is required for submitting data. Therefore, an ASC would need to acquire a QualityNet security administrator only if no current QualityNet account exists for the ASC. An ASC would be required to have an active account by any specified data entry deadline. For example, the deadline would be August 15, 2014 for the CY 2016 payment determination. Although we highly recommend that ASCs have and maintain a QualityNet security administrator, we believe that requiring an ASC to maintain a QualityNet administrator throughout the year would unnecessarily increase burden on ASCs.

As noted previously, there are necessary mailing and processing procedures for having a QualityNet security administrator assigned by CMS separate from completion of the forms by the ASC that can require significant time to complete and we strongly caution ASCs to not wait until any data entry deadline to apply. While we previously recommended allowing a minimum of 2 weeks, based upon recent experience, we strongly suggest allowing 4 to 6 weeks prior to any data submission deadline to submit required documentation for processing and in case of unforeseen issues. Also, QualityNet users must complete a user enrollment process, which is part of the registration process, to ensure access to the Secure QualityNet Portal. Portal access is required for ASCs submitting data under the ASCQR Program to meet CMS IT security requirements. The legislative source for this requirement originates in the Federal Information Security Management Act of 2002 which was amended by the Cybersecurity Act of 2012. The Document Library on the <http://www.idmanagement.gov> Web site contains documentation related to identity management including the Federal Identity, Credential and Access Management (FICAM) Roadmap and Implementation Guidance (version 2, 12/08/2011).

We invited public comment on these proposals.

We did not receive any public comments regarding our proposals on QualityNet account and security administrator requirements under the ASCQR Program. Therefore, we are finalizing our proposals that ASCs will be required to have a QualityNet security administrator for the purposes of setting up a QualityNet account for the purpose of entering data via an online tool located on the QualityNet Web site if this had not been completed previously or no current user accounts were available and that ASCs will be required to have an active account by any specified data entry deadline in order to submit required data for the CY 2016 payment determination and subsequent years.

2. Requirements Regarding Participation Status

a. Background for the CY 2014 Payment Determination and Subsequent Years

We finalized in the CY 2012 OPPI/ASC final rule with comment period (76 FR 74516) a policy to consider an ASC as participating in the ASCQR Program for the CY 2014 payment determination if the ASC includes Quality Data Codes

(QDCs) specified for the ASCQR Program on their CY 2012 claims relating to the finalized measures.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53639 through 53640), we stated that once an ASC submits any quality measure data, it would be considered to be participating in the ASCQR Program. Further, once an ASC submits any quality measure data and is considered to be participating in the ASCQR Program, an ASC would continue to be considered participating in the ASCQR Program, regardless of whether the ASC continues to submit quality measure data, unless the ASC withdraws from the Program by indicating on a participation form that it is withdrawing, as discussed below. For example, if an ASC includes any QDCs on its claims for the CY 2014 payment determination, it would be considered participating in the ASCQR Program for the CY 2014 payment determination and for each subsequent year's payment determination unless the ASC withdraws.

Likewise, if an ASC did not submit any QDCs for the CY 2014 payment determination, but submitted quality measure data for the CY 2015 payment determination, the ASC would be considered participating in the ASCQR Program starting with the CY 2015 payment determination and continuing for each subsequent year's payment determination unless the ASC withdraws from the ASCQR Program.

In the FY 2013 IPPS/LTCH PPS rulemaking (77 FR 28103, 53639), we considered whether to require that an ASC complete and submit a notice of participation form for each year's payment determination to indicate that the ASC is participating in the ASCQR Program as we require for hospitals, but decided against this approach because we were concerned about the burden on ASCs. We believe these requirements will reduce burden on ASCs while accomplishing the purpose of notifying us of an ASC's participation in the ASCQR Program.

We stated that any and all quality measure data submitted by the ASC while participating in the ASCQR Program could be made publicly available. This policy allows us to provide information on the quality of care provided to Medicare beneficiaries which promotes transparency.

Once an ASC submits quality measure data indicating its participation in the ASCQR Program, an ASC must complete and submit an online form indicating withdrawal in order to withdraw from the ASCQR Program. This form is located on the QualityNet Web site. We also require that an ASC indicate on the

form the initial payment determination year to which the withdrawal applies. We established a different process for ASCs to withdraw from participation than the process we established for an ASC to participate in the ASCQR Program because of the payment implications of withdrawal. We stated that, in withdrawing from the ASCQR Program, the ASC would incur a 2.0 percentage point reduction in its annual payment update for that payment determination year and any subsequent payment determinations in which it is withdrawn.

We stated that we will not make quality measure data publicly available for that payment determination year and any subsequent payment determinations for which the ASC is withdrawn from the ASCQR Program.

We established that an ASC would continue to be deemed withdrawn unless the ASC starts submitting quality measure data again. Once an ASC starts submitting quality measure data, the ASC would be considered participating unless the ASC withdraws, as discussed above. We believe that these policies reduce the burden on ASCs by not having to notify us as to when they are participating.

We established that an ASC can withdraw from the ASCQR Program at any time up to August 31, 2013 for the CY 2014 payment determination. We anticipated that this would be the latest date possible to allow an ASC to withdraw before payment determinations affecting CY 2014 payment are made. We established that an ASC can withdraw from the ASCQR Program at any time up to August 31, 2014 for the CY 2015 payment determination. We clarified in the CY 2014 OPPTS/ASC proposed rule (78 FR 43667) that these deadlines mean up to and including August 31 in each of these respective years.

We stated that these program requirements would apply to all ASCs designated as open in the CASPER system before January 1, 2012 for the CY 2014 payment determination. Because ASCs were not required to include QDCs on claims until October 2012 for the CY 2014 payment determination, an ASC designated as open in the CASPER system before January 1, 2012 was operating for at least 10 months before having to report any data. We believe this is a sufficient amount of time for ASCs to be established to report quality data for the CY 2014 payment determination.

For the CY 2015 payment determination, we established that program requirements would apply to all ASCs designated as open in the

CASPER system for at least 4 months prior to January 1, 2013. We believe that this date and length of operations experience would provide new ASCs sufficient time before having to meet quality data reporting requirements after the ASCQR Program's initial implementation year.

b. Requirements for the CY 2016 Payment Determination and Subsequent Years

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43667), for the CY 2016 payment determination and subsequent years, we proposed that an ASC can withdraw from the ASCQR Program at any time up to and including August 31 of the year preceding a payment determination. We anticipate that this will be the latest date possible to allow an ASC to withdraw before payment determinations affecting the next calendar year's payment are made. Therefore, for example, for the CY 2016 payment determination, an ASC would be able to withdraw from the ASCQR Program at any time up to and including August 31, 2015. Once an ASC has withdrawn for any payment determination year, it would have a 2.0 percentage point reduction in their annual payment update and it would not be possible to reinstate participation status for that year.

For the CY 2016 payment determination and subsequent years, we proposed that all program requirements would apply to all ASCs designated as open in the CASPER system at least 4 months prior to the beginning of data collection for a payment determination. Therefore, for the CY 2016 payment determination, data collection begins with January 1, 2014 services; these program requirements would apply to all ASCs designated as open in the CASPER system for at least 4 months prior to January 1, 2014 (that is, an open date of September 1, 2013 or earlier). We believe that this date and length of operations experience would provide any new ASCs sufficient time before having to meet quality data reporting requirements.

We invited public comment on these proposals.

We did not receive any comments regarding participation status under the ASCQR Program and we are finalizing our proposals without modification. Specifically, we are finalizing that, for the CY 2016 payment determination and subsequent years, an ASC can withdraw from the ASCQR Program at any time up to and including August 31 of the year preceding a payment determination, and all ASCQR Program requirements would apply to all ASCs designated as open in

the CASPER system at least 4 months prior to the beginning of data collection for a payment determination.

3. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures for the CY 2014 Payment Determination and Subsequent Years

In the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74496 through 74511), we adopted five claims-based measures for the CY 2014, CY 2015, and CY 2016 payment determinations and subsequent years. We also finalized that, to be eligible for the full CY 2014 ASC annual payment update, for the claims-based measures, an ASC must submit complete data on individual quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims (76 FR 74515 through 74516). Further, we finalized the data collection period for the CY 2014 payment determination, as the Medicare fee-for-service ASC claims submitted for services furnished between October 1, 2012 and December 31, 2012. ASCs will add the appropriate QDCs on their Medicare Part B claims, using the Form CMS-1500 or associated electronic data set submitted for payment, to submit the applicable quality data. A listing of the QDCs with long and short descriptors is available in Transmittal 2425, Change Request 7754 released March 16, 2012 (<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Transmittals-Items/ASC-CR7754-R2425CP.html>). Details on how to use these codes for submitting numerator and denominator information are available in the Specifications Manual located on the QualityNet Web site (<https://www.QualityNet.org>).

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53640), we adopted a policy that only claims for services furnished between October 1, 2012 and December 31, 2012 paid by the administrative contractor by April 30, 2013 would be included in the data used for the CY 2014 payment determination. We believe that this claim paid date allowed ASCs sufficient time to submit claims while allowing sufficient time for CMS to complete required data analysis and processing to make payment determinations and to supply this information to administrative contractors.

In the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68497 through 68498), we finalized a data collection and processing period for the CY 2015 payment determination and subsequent years. For the CY 2015

payment determination and subsequent years, an ASC must submit complete data on individual claims-based quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims. The data collection period for such claims-based quality measures is the calendar year 2 years prior to a payment determination year. Only claims for services furnished in each calendar year paid by the administrative contractor by April 30 of the following year of the ending data collection time period would be included in the data used for the payment determination year. Therefore, for example, only claims for services furnished in CY 2013 (January 1, 2013 through December 31, 2013) paid by the administrative contractor by April 30, 2014 would be included in the data used for the CY 2015 payment determination.

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43667 through 43668), we did not propose any changes to these policies.

4. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

a. Background for the CY 2014 Payment Determination and Subsequent Years

In the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74516), we finalized our proposal that data completeness for claims-based measures for the CY 2014 payment determination be determined by comparing the number of claims meeting measure specifications that contain the appropriate QDCs with the number of claims that would meet measure specifications, but did not have the appropriate QDCs on the submitted claims.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53641), we finalized our policy for the CY 2014 and CY 2015 payment determination years that the minimum threshold for successful reporting be that at least 50 percent of claims meeting measure specifications contain QDCs. We believe that 50 percent is a reasonable minimum threshold for the initial implementation years of the ASCQR Program because ASCs are not familiar with how to report quality data under the ASCQR Program and because many ASCs are relatively small and may need more time to set up reporting systems. We stated in that final rule that we intend to propose to increase this percentage for subsequent years' payment determinations as ASCs become more

familiar with reporting requirements for the ASCQR Program.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53641), we stated that, because private payers would not have QDCs in their required HCPCS data files until January 1, 2013, claims with QDCs received prior to January 1, 2013 could be rejected for invalid codes. Because it is not possible for ASCs to submit differing codes on primary versus secondary payer claims for at least some payers, we specified that only claims where Medicare is the primary payer—not the secondary payer—will be used in the calculation of data completeness for the CY 2014 payment determination.

We also finalized our proposal in the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68498 through 68499) that data completeness for claims-based quality measures for the CY 2015 payment determination and subsequent years will be determined by comparing the number of Medicare claims (where Medicare is the primary or secondary payer) meeting measure specifications that contain the appropriate QDCs with the number of Medicare claims (where Medicare is the primary or secondary payer) that would meet measure specifications, but did not have the appropriate QDCs on the submitted claims for the CY 2015 payment determination and subsequent years. We made this change based on the fact that private payers had QDCs in their required HCPCS data files beginning January 1, 2013.

b. Requirements for the CY 2016 Payment Determination and Subsequent Years

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43668 through 43669), for the CY 2016 payment determination and subsequent years, we proposed to continue our policy that the minimum threshold for successful reporting be that at least 50 percent of claims meeting measure specifications contain QDCs. We believe that 50 percent is a reasonable minimum threshold for the initial implementation years of the ASCQR Program. Because ASCs cannot re-submit claims for the sole purpose of adding QDCs (such claims are rejected by administrative contractors as duplicate claims), we believe maintaining this minimum as the program matures is reasonable. We intend to propose to increase this percentage for future payment determinations as ASCs, administrative contractors, and billing clearing houses become more familiar with reporting requirements for the ASCQR Program and the program itself becomes more established.

As finalized in the FY 2013 IPPS/LTCH PPS final rule, data completeness for claims-based quality measures will be determined by comparing the number of Medicare claims (where Medicare is the primary or secondary payer) meeting measure specifications that contain the appropriate QDCs with the number of Medicare claims (where Medicare is the primary or secondary payer) that would meet measure specifications, but did not have the appropriate QDCs on the submitted claims for the CY 2015 payment determination and subsequent years.

In our initial implementation of claims-based measures, we determined that some ASCs have relatively small numbers of Medicare claims. Therefore, for the CY 2016 payment determination and subsequent years, we proposed a minimum case volume of 240 Medicare claims (primary plus secondary payer) per year (which is an average of 60 per quarter). ASCs that have fewer than 240 Medicare claims per year during a reporting period for a payment determination year would not be required to participate in the ASCQR Program for the subsequent reporting period for that subsequent payment determination year. For example, if an ASC had 200 Medicare claims during the calendar year of January 1, 2013 to December 31, 2013 (data submitted on claims during this year would be applied to CY 2015 payment determinations), the ASC would not be required to participate in the ASCQR Program for the CY 2016 payment determination (which would use data submitted on claims during the January 1, 2014 to December 31, 2014 calendar year). We proposed a minimum case threshold to exempt smaller facilities where program implementation can be overly burdensome. We have selected 240 Medicare claims per year because 10 percent of ASCs have less than 240 Medicare claims per year so this policy would exempt only those ASCs with the fewest number of Medicare claims. If an ASC exceeds this 240 Medicare claim threshold in any given calendar year, the ASC would be required to participate in the ASCQR Program the subsequent calendar year and would be subject to all program requirements.

We invited public comment on this proposal.

Comment: Many commenters supported CMS' proposal that ASCs must have a minimum of 240 Medicare claims (primary plus secondary payer) or otherwise be exempt from ASCQR Program requirements.

Response: We thank the commenters for their support. We agree that a minimum case threshold for program

participation to alleviate burden on small facilities and for those with few Medicare claims is appropriate.

Comment: Many commenters stated that while they appreciated that a claims-based reporting mechanism can lessen the burden of data collection and reporting, they were concerned that the current measures using the QDC reporting mechanism were not specified, tested, or NQF-endorsed for claims-based reporting.

Response: We thank the commenters for their understanding of how the use of QDCs can limit burden and that this is an important consideration. Regarding the use of QDCs submitted on claims for ASC-1 through ASC-5, the NQF has endorsed ASC-1 through ASC-5 as appropriate for the ASC setting and data collection of case information has been tested in this setting. Further, for all of these measures which count rare, adverse events, it is expected that the number of cases for any ASC would be very small. Therefore, while ASCs would garner the information from patient records, the QDC reporting mechanism is the way ASCs report the collected data. The measures using the QDCs for reporting and the QDCs are specified and contained in the Specifications Manual which is available on the QualityNet Web site. Based upon our initial data collection for encounters occurring during October 1, 2012 to December 31, 2012, the vast majority of ASCs are able to successfully submit data for these measures using QDCs. In addition, QDCs are successfully used for data collection for other CMS quality programs, including the PQRS and e-Prescribing Incentive Program. Therefore, we do not see a need to also test the ability of ASCs to submit data for these measures via QDCs placed on Medicare claims.

Comment: Several commenters suggested that measure-level exemptions for ASC-5, Prophylactic Intravenous (IV) Antibiotic Timing would be appropriate. These commenters argued that single-specialty ASCs that provide gastrointestinal endoscopies or ophthalmic procedures do not administer IV prophylaxis and that not having an exemption method created undue burden. Suggested exemption methods included an attestation form or the development of a QDC indicating non-use.

Response: We thank the commenters for these ideas and agree that single specialty ASCs would rarely, if at all, use IV prophylaxis. We have investigated using administrative claims data as a means to exclude ASCs from having to report data for this measure

based on procedures billed as well as examined QDC-data reported to date. Unfortunately, we have not yet been able to identify a method to exclude ASCs based on these data and are reluctant to allow a blanket exemption from reporting measure data based upon the completion of a form or one-time reporting of a QDC without any ability to assess the veracity of the basis for exemption. At issue is a means to independently verify that an ASC does not ever administer IV prophylaxis. We remain open to various means of reducing burden, including the potential use of measure-level exemptions if an evidence-based solution can be developed. However, we note that this particular measure does not place any more burden on ASCs compared to any of the other finalized measures where data are reported via QDCs because all of the current ASCQR Program measures reported using QDCs are expected to have low numbers of events.

Comment: Some commenters agreed with the proposal to have a minimum case volume, but indicated that it was not clear how the 240-claim threshold correlates to the 10 percent of ASCs submitting the lowest volume of Medicare claims. These commenters' review of the CMS Limited Data Set file accompanying the CY 2014 OPPI/ASC proposed rule suggested the 10 percent target would be reached with a lower claim threshold. Some commenters agreed that implementation of a minimum threshold policy was important, but expressed concern that some ASCs may "fall in and out" of being required to participate and encouraged CMS to issue annual reminders of this policy. Some commenters also believed that any ASC eligible for the exemption that wishes to report for reasons other than receiving a payment should be able to do so.

Response: We thank these commenters for supporting our proposal while requesting clarification of the basis for the selected threshold value. In selecting the 240-claim threshold, we utilized the October 1, 2012 to December 31, 2012 claims data submitted for the CY 2014 payment determination. Based upon this analysis, approximately 10 percent of ASCs fell below the 60 claims per quarter, which we extrapolated to 240 claims per year threshold. We will continue to monitor these data and, if adjustment in the claims volume threshold appears necessary, we will make proposals in future rulemaking.

Regarding ASCs that may have claims volume such that they would be required to participate one year and not

the next, we would encourage ASCs to monitor their claims volume via CMS-supplied reports. We agree that annual reminders of the policy would be useful and intend to issue such reminders via listserv and postings on the QualityNet Web site.

Regarding the ability of an ASC eligible for the exemption that wished to report data, though not being required to do so for ASCQR Program purposes, we did not make any proposals that would prohibit ASCs from reporting data. Therefore, we clarify here that, if any Medicare-certified ASCs wish to report data under the ASCQR Program, they may do so, however, they must follow all program requirements for submitting data and any data reported could be made publicly available unless the ASC withdraws using the process outlined in section XV.D.2.a. of this final rule with comment period. We clarify here that ASCs that are exempt from all requirements due to low Medicare case volume would not be subject to a reduction in their annual payment update if they voluntarily report data.

After consideration of the public comments we received, we are finalizing our proposals without modification. Specifically, for the CY 2016 payment determination and subsequent years, we are finalizing our proposal that the minimum threshold for successful reporting be that at least 50 percent of claims meeting measure specifications contain QDCs. We also are finalizing that an ASC must have a minimum case volume of 240 Medicare claims (primary plus secondary payer) per year (which is an average of 60 per quarter) to be required to participate in the ASCQR Program. ASCs that have fewer than 240 Medicare claims per year during a reporting period for a payment determination year will not be required to participate in the ASCQR Program for the subsequent reporting period for that subsequent payment determination year.

5. Requirements for Data Submitted via a CMS Online Data Submission Tool

a. Background for the CY 2015 Payment Determination and Subsequent Years

In the CY 2012 OPPS/ASC final rule with comment period, we finalized two measures with data submission required using an online measure submission Web page available at <http://www.qualitynet.org> beginning with the CY 2015 payment determination: Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures (76 FR 74509). In that final rule with comment period, we finalized that, for the CY 2015 payment

determination, ASCs would report data for these two measures between July 1, 2013 and August 15, 2013 for services furnished between January 1, 2012 and December 31, 2012.

b. Requirements for the CY 2016 Payment Determination and Subsequent Years for Measures Currently Finalized

In the CY 2014 OPPS/ASC proposed rule (78 FR 43669), for the CY 2016 payment determination and subsequent years, we proposed for the Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures for which data will be submitted via a using an online data submission tool available on <http://www.qualitynet.org>, that the data collection time periods would be for services furnished during the calendar year two years prior to the payment determination year and that data would be submitted during the January 1 to August 15 time period in the year prior to the payment determination. Therefore, for the CY 2016 payment determination, the data collection time period for these measures would be calendar year 2014 (January 1, 2014 to December 31, 2014) and the data submission time period would be January 1, 2015 to August 15, 2015. We proposed these changes to increase the timeframe for allowing data submission for these measures and to align the data collection time periods for the claims-based and Web-based measures. This alignment has the additional benefit of providing more current data for these Web-based measures for a payment determination and would prevent the need for retrospective data collection by ASCs, which can be burdensome.

Under this proposal, no data would be collected for calendar year 2013 (January 1, 2013 to December 31, 2013) for the Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures because the CY 2015 payment determination will use data from services performed in the January 1, 2012 to December 31, 2012 time period and, under our proposal, the CY 2016 payment determination would use data from services performed in January 1, 2014 to December 31, 2014. (In the proposed rule (78 FR 43669), although we stated that data collection time periods would be for services furnished during the calendar year two years prior to the payment determination year, we inadvertently stated that the time period for the CY 2016 payment determination was "January 1, 2014 to December 1, 2014.")

We invited public comment on these proposals.

Comment: Several commenters agreed that moving the data collection period ahead one year and expanding the data submission timeframe to begin January 1 through August 15 for the CY 2016 payment determination and subsequent years rather than July 1 through August 15 as finalized previously for the CY 2015 payment determination are appropriate and beneficial changes for the Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures measures. Some of these commenters cautioned that, while they supported the shifting of the data collection time period, they believed the alignment will result in a significant amount of confusion and that extensive educational outreach would be necessary.

Response: We thank the commenters for their support of our proposals; we agree that aligning data collection periods and data submission time frames for these measures across payment determination years are appropriate and beneficial changes for the ASCQR Program. We appreciate the cautioning of possible confusion with the data collection timeframes. We believe that, since there will be a year of not having to collect these data, there will be sufficient time to provide educational outreach on this matter.

After consideration of the public comments we received, we are finalizing our proposals regarding data collection and submission requirements for the Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures measures for the CY 2016 payment determination and subsequent years. Specifically, for these measures for which data will be submitted via an online data submission tool available on <http://www.qualitynet.org>, we are finalizing that the data collection time periods would be for services furnished during the calendar year two years prior to the payment determination year and that data would be submitted during the January 1 to August 15 time period in the year prior to the payment determination. These changes provide a longer timeframe for allowing data submission for these measures compared to the CY 2015 payment determination, align the data collection time periods for the claims-based and Web-based measures, and result in data not being collected for calendar year 2013 (January 1, 2013 to December 31, 2013) for the Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures measures. No data will be collected for calendar year 2013 (January 1, 2013 to December 31, 2013) for the Safe Surgery

Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures measures because the CY 2015 payment determination will use data from services performed in the January 1, 2012 to December 31, 2012 time period and the CY 2016 payment determination will use data from services performed in January 1, 2014 to December 31, 2014.

c. Requirements for the CY 2016 Payment Determination and Subsequent Years for New Measures With Data Submission via a CMS Web-Based Tool

In the CY 2014 OPPI/ASC proposed rule (78 FR 43669), we proposed to adopt four additional chart-abstracted measures for the ASCQR Program and proposed 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.

These measures are: (1) Complications within 30 Days following Cataract Surgery Requiring Additional Surgical Procedures; (2) Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients; (3) Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and (4) Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. We describe our timeframes and process for measure specifications in section XV.B.5. of this final rule with comment period.

In the CY 2014 OPPI/ASC proposed rule (78 FR 43669), we wished to clarify that, while we have referred to measures where data are submitted via a Web-based tool on a CMS Web site under our quality data reporting programs by the type of measure, that is, structural measures (measures concerned with attributes of where care occurs, such as material resources, human resources, and organizational structure),¹⁵ not all quality measures where data are submitted via a Web-based tool on a CMS Web site are structural measures. For example, the four proposed new measures proposed are not structural measures. Therefore, we have refined our terminology and now refer to the mode of data submission, Web-based, rather than the type of measure.

We proposed that data collection and reporting for these measures would

begin with the CY 2016 payment determination.

In addition, we proposed for these measures, and any future measures for the ASCQR Program where data are submitted via an online measure submission Web page available on <http://www.qualitynet.org>, that beginning with the CY 2016 payment determination:

- 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;
- 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.

Therefore, for the CY 2016 payment determination, the data collection time period would be January 1, 2014 to December 31, 2014 and the data submission time period for the collected data would be January 1, 2015 to August 15, 2015. We stated that these proposals are in alignment with proposals in section XV.D.5. of the proposed rule regarding data collection and submission time frames for measures already adopted for the ASCQR Program where data is submitted via an online data submission tool available on the Web site at: <http://www.qualitynet.org>.

We invited public comment on these proposals.

Comment: Many commenters did not support collection of aggregate data for the four proposed measures because they did not support the addition of these measures to the ASCQR Program.

Response: We discuss the adoption of three of the four proposed new measures for the ASCQR Program in section XV.B.3. of this final rule with comment period.

Comment: Some commenters stated that the collection of follow-up data for the proposed measures would be burdensome because ASCs would have data related only to the procedures performed at the ASC and not for procedures performed off-site. Many commenters asserted that it is extremely burdensome to retrieve timely the data from the physician or ophthalmologist offices and such data would be difficult to validate. Other commenters stated that given the high volume of cataract surgery, it would be extremely burdensome to extract data from medical records. In addition, commenters noted that the initial and subsequent surgical cataract and colonoscopy procedures due to complications may occur at more than one facility. Some commenters strongly believed that the huge reporting burden from the four proposed chart-abstracted

measures could be diminished if claims are used as the data source.

Response: We appreciate the commenters' concerns and acknowledge that the adoption of the three new measures we are finalizing will result in some additional burden to ASCs. However, we do not believe that this will be an undue or insurmountable burden. Regarding the ability to obtain follow-up information, we believe that ASCs have professional and commercial relationships with the physicians that perform surgical procedures and are paid for those services rendered at their facilities. The newly adopted measures are concerned only with the procedures performed at the ASC.

For the three measures being adopted in this final rule with comment period, the physician performing and billing for the procedure would have or is expected to have the information necessary to report on the measure. For the Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patient measure, standard medical practice is that the physician performing the procedure would make the determination of whether the results were normal and would make the appropriate recommendation that would be documented in the patient's medical record. For the Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use measure, the physician performing the procedure would have the information of whether a patient had a history of adenomatous polyps and for Medicare claims, this is reflected on the claim by including HCPCS code G0105 which indicates a colonoscopy on an individual at high risk. In the case of the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure, patients undergoing cataract surgery are often co-managed with preoperative care, intraoperative services, and post-operative care (90 days) stages identified by Medicare. Co-management of cataract care requires a written transfer agreement between the surgeon and receiving doctor(s) with all physicians involved retaining the results of the first post-operative visit as part of the patient's medical record.

Although we believe this approach is reasonable and not unduly burdensome, after consideration of the many comments we received on this issue regarding the burden of collecting this information, in this final rule with comment period we are permitting ASCs to collect information on a sample of eligible patients, with minimal case

¹⁵ Maintz, J. Defining and Classifying Clinical Indicators for Quality Improvement, *Inter J Quality Health Care* (2003) 15(6), 523–530.

number requirements, instead of requiring the collection of information on all eligible patients. Sampling is a process of selecting a representative part of a population in order to estimate the ASC's performance, without collecting data for its entire population. In this way, using a statistically valid sample, an ASC can measure its performance in an effective and efficient manner. Sampling will reduce burden significantly for ASCs with high volume because the number of cases that must have data reported will be significantly reduced. We have provided the option of sampling in other quality reporting programs when we have determined that it would be appropriate, including the Hospital IQR and OQR Programs. As with our other quality reporting programs, sampling specifications for the new ASCQR Program quality measures, which describe how to obtain a statistically valid sample and the current sampling methodology and requirements for these measures, will be included in the ASCQR Specifications Manual, which will be made available on the QualityNet Web site in December 2013. We believe that the improved clinical patient outcomes that can result from these measures outweigh any remaining burden that ASCs may incur from data collection associated with them.

Regarding the use of claims data as the information source for the three measures being adopted, we agree that this data collection mechanism can be used to reduce burden. However, we are not aware of coding for claims payment that could be used to specify the new measures being adopted for the ASCQR Program.

Comment: Several commenters expressed concern about the limited amount of time that ASCs would have to respond to and prepare for any new measures finalized in the rulemaking process. Because the CY 2014 OPPI/ASC final rule with comment period will likely be published in November 2013, ASCs would have only 2 months to become aware of and versed in the new quality measures finalized in the rule, to develop and implement the changes in daily processes and operational systems needed to collect the required data, and to initiate data collection making this timeline inadequate in length. These commenters believed that implementing a new measure is more challenging than revising an existing measure; as such, a minimum of 6 months of advance notice should be extended for any new measures. In addition, these commenters suggested that if any of the proposed measures are adopted in this

rulemaking, the data collection period should be modified to January 1, 2015 through December 31, 2015 with data submission in 2016, for use toward the CY 2017 payment determination.

Response: We thank the commenters for their well-thought out suggestions regarding data collection, submission, and use for new measures. However, due to the importance of the new measures being finalized in this rulemaking, we believe the proposed timeframes for these activities are justifiable and adequate because, although the data would be collected for services furnished during the CY 2014 timeframe, data would not need to be submitted until 2015, providing additional time from finalization of this final rule with comment period to time when the data would actually have to be submitted.

After consideration of the public comments we received, we are finalizing our proposal without modification for data submission and timeframes on three new measures for the ASCQR Program being adopted in this final rule with comment period. The new measures we are adopting are: (1) Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients; (2) Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and, (3) Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. Specifically, we are finalizing that ASCs must submit aggregate data (numerators, denominators, and exclusions) for these three measures on all ASC patients and that these data will be collected via an online Web-based tool that would be made available to ASCs via the QualityNet Web site. However, as discussed above, we are permitting ASCs to collect information on a sample of eligible patients, with minimal case number requirements, instead of requiring the collection of information on all eligible patients. The sampling specifications for the new ASCQR Program quality measures will be included in the ASCQR Specifications Manual, which will be made available on the QualityNet Web site in December 2013.

We are also finalizing, as proposed without modification, that beginning with the CY 2016 payment determination (and for all subsequent payment determination years), the data collection time period will be the calendar year (January 1 to December 31) 2 years prior to the affected payment determination year, and the data

collected will be submitted during the time period of January 1 to August 15 in the year prior to the affected payment determination year. Therefore, for the CY 2016 payment determination, the data collection time period will be January 1, 2014 to December 31, 2014, and the data submission time period will be January 1, 2015 to August 15, 2015.

6. Data Submission Requirements for a Measure Reported via the National Healthcare Safety Network (NHSN) for the CY 2016 Payment Determination

a. Background for the CY 2016 Payment Determination

For the CY 2016 payment determination, we finalized the adoption of the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), a process of care, healthcare-associated infection (HAI) measure, in the CY 2012 OPPI/ASC final rule with comment period (76 FR 74510). We specified that data collection for the influenza vaccination measure would be via the NHSN from October 1, 2014 to March 31, 2015 and that details for data submission would be made in future rulemaking.

b. Requirements for the CY 2016 Payment Determination

In the CY 2014 OPPI/ASC proposed rule (78 FR 43670), we proposed to use the data submission and reporting standard procedures that have been set forth by 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://sdn.cdc.gov> (data certificate installation is required to access this site))). We stated in the proposed rule that we believed that ASCs would know and be comfortable with these procedures because these procedures are already used by many ASCs to fulfill State-mandated reporting of HAI data through the NHSN in at least 17 States. However, based on public comments we received, ASCs may not be as familiar with NHSN reporting as we previously believed.

We separately 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 proposed an August 15, 2015 deadline because this date is the latest date possible for data entry that will provide sufficient

time for CMS to make the CY 2016 payment determinations. Further, this date aligns the data entry deadline with the deadline for the measures entered via the CMS online tool. We believe this data submission deadline allows ASCs to have sufficient time to collect and compile the necessary data while taking into account ASCQR Program considerations.

We invited public comment on these proposals.

Comment: Several commenters protested that ASCs are entirely unfamiliar with NHSN. These commenters pointed out that, while a number of States have mandated NHSN reporting, many of those State requirements do not include ASCs and though some States mandate NHSN reporting for ASCs, the surgical procedures being monitored for reporting purposes are not often performed in the ASC setting. Thus, ASCs generally do not have data to report to NHSN. These commenters cautioned that CMS and CDC should plan to make significant investments of time, personnel, and other resources to support initial enrollment and reporting to ensure successful implementation of NHSN reporting by ASCs. These commenters also suggested that revisions in the CDC's NHSN site to reduce confusion for ASCs, such as revising documentation to include ASCs, replace the term "hospital" with "facility", simplifying set-up instructions, and continuance of the planned elimination of the digital certificate requirement for NHSN access could facilitate ASC participation.

Response: We thank the commenters for voicing these concerns and providing constructive suggestions. We note that CDC estimates that only 285 ASCs are currently enrolled and reporting in the NHSN. We agree that resources will be required to ensure successful implementation of ASC reporting to the NHSN to meet ASCQR Program requirements. CMS and CDC are working together in this endeavor and will be considering the comments received that are aimed at improving the NHSN site and will be implementing educational efforts for ASCs.

Because we believe CMS' and CDC's efforts will address many of the commenters' concerns, we are finalizing our proposal to use the data submission and reporting standard procedures without modification; that is, to use those procedures that have been set forth by CDC for NHSN participation in general and for submission of this measure to NHSN. We believe ASCs have sufficient time to set up NHSN accounts and to become familiar with

all reporting procedures to be able to successfully report data because we intend to propose a 2015 data submission deadline.

Comment: Several commenters supported CMS' proposal of an August 15, 2015 deadline as alignment of submission deadlines within the ASCQR Program was a sensible approach that would limit confusion. Some of these commenters noted that an earlier deadline served no useful ASCQR Program purpose. Other commenters supported an August 15, 2015 deadline for ASCs to submit their 2014–2015 influenza season data because, while this date is not consistent with the deadline for other quality reporting programs that enter data for this measure via NHSN, the ASCQR Program is already quite complex, featuring three different data submission methods for the CY 2016 payment determination. Given this complexity, a consistent data submission deadline could help minimize confusion across the NHSN and QualityNet data entry systems.

Several commenters disagreed with an August 15, 2015 data submission deadline for ASCs as it differed from the May 15th deadline proposed for two other CMS quality data reporting programs, the Hospital IQR and Hospital OQR Programs. Some of these commenters believed that providing ASCs with a later deadline would provide an unfair advantage because ASCs would have longer to submit their data. Other commenters believed that having a differing date for ASCs than other facilities would be confusing to ASCs, thereby, disadvantaging ASCs.

Response: We thank the commenters for their thoughts regarding an August 15, 2015 deadline for ASCs to submit their 2014–2015 influenza vaccination data (October 1, 2014 through March 31, 2015). We generally try, when feasible, to align requirements across quality reporting programs, but program requirements are tailored to individual quality reporting program needs. Due to issues raised by commenters regarding our proposed August 15, 2015 deadline, we are not finalizing a data submission deadline for 2014–2015 influenza vaccination and instead intend to issue proposals regarding a 2015 data submission deadline for this measure in the CY 2015 OPPS/ASC proposed rule.

After consideration of the public comments received, we are finalizing our proposal to use the data submission and reporting standard procedures set forth by CDC for NHSN participation for the ASCQR Program without modification. As stated above, we are not finalizing our proposal regarding an

August 15, 2015 data submission deadline for ASC–8 due to concerns expressed by commenters. We intend to issue proposals regarding a 2015 data submission deadline for this measure in the CY 2015 OPPS/ASC proposed rule which is scheduled to be finalized in late CY 2014.

7. ASCQR Program Validation of Claims-Based and CMS Web-Based Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53641 through 53642), consistent with other CMS quality reporting programs, we did not require validation of claims-based measures (beyond the usual claims validation activities conducted by our administrative contractors) or structural (Web-based) measures for the ASCQR Program. We also do not require validation of claims-based or Web-based measures under the Hospital IQR and OQR Programs.

We noted that with regard to the current ASCQR Program claims-based measures, the number of events expected to be reported is small because most of the measures are for adverse or rare events. In this situation, any random selection of cases would require a burdensome sample size. Further, we expect the accuracy for reported adverse events to be high. We stated that, because we do not believe at this time that any results that could be obtained justify the burden associated with a data validation process which would necessitate an independent validation effort, we also are not requiring a data validation process for our current claims-based measures, and we continue to believe so.

We stated that as we gain more experience with the ASCQR Program, we will reassess whether a data validation process for claims-based and measures where aggregate data is reported via an online tool is needed. 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.

8. Extraordinary Circumstances Extensions or Waivers for the CY 2014 Payment Determination and Subsequent Years

a. Background

In our experience, there have been times when facilities have been unable to submit information to meet program requirements due to extraordinary circumstances that are not within their

control. It is our goal to not penalize such entities for such circumstances and we do not want to unduly increase their burden during these times. Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53642 through 53643), we established procedures for extraordinary circumstance extension or waiver requests for the submission of information required under the ASCQR Program. We refer readers to that rule for a complete discussion of the process.

b. Additional Criterion for Extraordinary Circumstance Waivers or Extensions for CY 2014 and Subsequent Years

In the CY 2014 OPPS/ASC proposed rule (78 FR 43670), we proposed that, starting in CY 2014, we may grant a waiver or extension to ASCs for data submission requirements if we determine that a systematic problem with one of our data collection systems directly or indirectly affected the ability of ASCs to submit data. Because we do not anticipate that such systematic errors will happen often, we do not anticipate granting a waiver or extension on this basis frequently. If we make the determination to grant a waiver or extension, we proposed to communicate this decision through listserv notice and posting via our QualityNet Web site (<https://www.qualitynet.org>) as we have done in the past with CMS-issued waivers where a geographic location was affected by adverse weather.

We invited public comment on this proposal.

Comment: Several commenters supported and expressed their appreciation for CMS' proposal to grant waivers or extensions for data submission requirements if we determine a systematic problem with any data collection system directly or indirectly affected the ability of ASCs to submit data.

Response: We thank the commenters for supporting our proposal.

After consideration of the public comments we received, we are finalizing our proposal without modification to grant waivers or extensions to ASCs for data submission requirements if we determine that a systematic problem with any part of our data collection system directly or indirectly affected the ability of ASCs to submit data. If we make the determination to grant a waiver or extension, we will communicate this decision through listserv notice and posting via our QualityNet Web site (<https://www.qualitynet.org>).

9. ASCQR Program Reconsideration Procedures for the CY 2014 Payment Determination and Subsequent Years

We have established similar processes by which participating hospitals can submit requests for reconsideration of quality reporting program payment determinations for the Hospital IQR Program and the Hospital OQR Program. We believe these reconsideration processes have been effective in the hospital quality reporting programs and such a process would be effective for ASC quality reporting. Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 through 53644), we adopted an informal reconsideration process for the ASCQR Program for the CY 2014 payment determination and subsequent years modeled after the reconsideration processes we implemented for the Hospital IQR and Hospital OQR Programs. We refer readers to that rule for a complete discussion of our procedures.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43670), we did not propose any changes to this informal reconsideration process. However, we clarified some aspects of the informal reconsideration review process that we established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 to 53644). As we stated in that rule, we intend to complete any reconsideration reviews and communicate the results of these determinations within 90 days following the deadline for submitting requests for reconsideration. For those ASCs that submit a reconsideration request, the reconsideration determination would be the final ASCQR Program payment determination. For those ASCs that do not submit a reconsideration request or do not submit a reconsideration request as specified in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 through 53644), for example, the request was not submitted by the deadline, the CMS determination would be the final payment determination. There would be no appeal of any final ASCQR Program payment determination.

XVI. Final Rule: Changes to the Conditions for Coverage (CfCs) for Organ Procurement Organizations (OPOs) (42 CFR Part 486, Subpart G)

A. Background

The Organ Procurement Organization Certification Act of 2000 (section 701 of Pub. L. 106–505) amended section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) and directed the Secretary to establish regulations governing the certification and/or recertification of Organ Procurement

Organizations (OPOs). Among other things, section 371(b)(1)(D)(ii) of the Public Health Service Act requires that regulations be established for the certification and/or recertification process, which (1) “rely on outcome and process performance measures that are based on empirical evidence obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations,” and (2) “use multiple outcome measures as part of the certification process.” Payment under the Medicare and Medicaid programs for organ procurement costs may be made only if, among other requirements, the OPO is certified or recertified as meeting the standards to be a qualified OPO under section 371(b) of the Public Health Service Act and meets the performance-related standards prescribed by the Secretary, as provided for in section 1138(b) of the Social Security Act.

The final rules implementing these statutory requirements and setting out the Conditions for Coverage (CfCs) for OPOs (OPO CfCs) were published in the **Federal Register** on May 31, 2006 (71 FR 30982). The OPO CfCs are codified at 42 CFR Part 486 and set forth the certification and recertification processes for OPOs. OPOs are required to meet their CfCs, which include both outcome and process performance measures.

In general, with the exception of OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, or possessions, the three outcome measures are: (1) A donation rate of eligible donors as a percentage of eligible deaths; (2) an observed donation rate as compared to the expected donation rate; and (3) a yield measure, which requires that two of the following three outcome measures be met: (i) The number of organs transplanted per standard criteria donor, (ii) the number of organs transplanted per expanded criteria donors, and (iii) the number of organs used for research per donor. For OPOs that operate exclusively in noncontiguous States, Commonwealths, Territories, and possessions, the three outcome measures are: (1) A donation rate of eligible donors as a percentage of eligible deaths; (2) an observed donation rate as compared to the expected donation rate; and (3) a yield measure, which requires that two of the following three outcome measures be met: (i) the number of kidneys transplanted per standard criteria donor; (ii) the number of kidneys transplanted per expanded criteria donors; and (iii) the number of organs used for research per donor. All of the yield measures include pancreata

used for islet cell transplantation as required by section 371(c) of the Public Health Service Act (42 U.S.C. 273(c)). The first and third outcome measures are compared to a national mean. The second outcome measure is calculated by the Scientific Registry of Transplant Recipients (SRTR).

B. Regulatory Changes

In the CY 2014 OPPS/ASC proposed rule (78 FR 43534), we proposed to modify the regulations so that all of the OPOs must meet two out of the three outcome measures to be recertified. We were concerned about the requirement to automatically decertify OPOs if they fail to meet all three of the outcome measures. We believed that the requirement that each OPO meet all three outcome measures as set forth in § 486.318 was unnecessarily stringent. For that reason, we proposed to modify the outcome measure requirement so that OPOs would be required to meet two of the three outcome measures. We noted that the majority of OPOs were meeting all three of the outcome measures. Based on our experience, we observed that many of the OPOs that were failing to meet all three outcome measures were meeting two of the three measures and were in compliance with all of the other requirements in the OPO CfCs; that is, the process performance measures set forth at §§ 486.320 through 486.348. We believe these OPOs were performing satisfactorily and should not be decertified based solely on their failure to meet one outcome measure. This belief was based not only on our observation and monitoring of these OPOs' performance, but also on some concerns with the outcome measures, which we discussed in detail in the proposed rule (78 FR 43671 through 43672).

Specifically, we proposed to revise paragraphs (a)(1) and (b) of §§ 486.316 and the introductory text of paragraphs (a) and (b) of § 486.318 of the regulations to require that OPOs meet at least two out of the three outcome measures instead of the requirement to meet all three outcome measures. We also asked for public comments on any other potential empirically based outcome measures for OPOs that might be used in the future. Most of the commenters opposed this proposal. The commenters indicated that the proposal did not address the problems with the current outcome measures and recommended that CMS develop a different strategy for the upcoming recertification cycle. Some of the commenters expressed concerns about the outcome measures and requested additional changes so that an OPO

could be recertified even if it failed to meet any of the outcome measures. A summary of the public comments and our responses follow.

Comment: Some commenters acknowledged the thought that CMS had put into the proposal and the challenges CMS would face in revising the outcome measures. Commenters also acknowledged that the proposal would have a beneficial effect on some of the OPOs that would otherwise be decertified under the current outcome measures requirement.

Response: We appreciate these comments. We believe that modifying the outcome measure requirement so that OPOs must now meet two out of the three outcome measures will benefit both the OPOs and the potential recipients on the waiting lists by avoiding the decertification of OPOs that are performing satisfactorily.

Comment: Other commenters indicated that the proposed revisions were insufficient to address their numerous concerns about problems that the commenters believed were inherently related to the existing outcome measures.

Response: As we noted in the proposed rule, we have received feedback from various members of the OPO community regarding these concerns, which are addressed in more detail below. We acknowledge that the provisions set forth in this final rule do not address all of the specific concerns raised by commenters. Despite the critical comments relating to the current measures, no commenters suggested any empirically based outcome measures that could be used in the future, except for a few commenters that suggested using the OPTN yield measure. However, other commenters were also critical of that measure.

OPOs perform an important role in the health care system, and we understand the challenge OPOs face in developing relationships with hospitals and health care professionals, as well as in obtaining consent from families to procure organs. However, Congress required the Secretary to create outcome and process performance measures to encourage OPOs to improve their performance. The OPO CfCs are designed to encourage OPOs to be more efficient in procuring organs in order to save more lives. We also note that the current outcome measures were largely based upon public comments we received to the OPO proposed rule (CMS-3064-P), and that many of the concerns relating to the outcome measures were not raised during prior rulemaking (71 FR 30999 through 31005). We believe that the vast

majority of the 58 OPOs will be able to meet two out of the three outcome measures. We also believe that the outcome measures continue to provide a fair basis for comparing OPOs' performance.

Comment: Several commenters suggested that, instead of proposing a modification to the outcome measures requirement, CMS take a two-part approach concerning the outcome measures and recertification. First, the commenters suggested a revision to 42 CFR 486.312(c) to state that CMS "may" voluntarily not renew an OPO's agreement if it failed to meet the performance measures. The commenters suggested that the CfCs be modified so that CMS has the discretion to renew the agreement despite an OPO's failure to meet all three of the outcome measures, essentially changing the regulatory language from "will not voluntarily renew" the agreement with an OPO to "may renew" the agreement. Second, the commenters recommended that CMS be allowed to work with OPOs that failed to meet the performance measures to develop corrective action plans, or a similar improvement process, comparable to the process currently used for transplant centers.

Response: We appreciate the concerns expressed by the commenters. However, we believe that the commenters' recommended approach would be inconsistent with section 1138(b)(1)(C) of the Act that permits payment for organ procurement costs "only if" the OPO meets "performance-related standards prescribed by the Secretary." In addition, we note that the Organ Procurement Organization Certification Act of 2000 required the Secretary to establish through rulemaking multiple outcome measures based upon empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified OPOs and that these measures must be used as part of the recertification process. Consistent with the statute, the Secretary developed the standards through notice and comment rulemaking and the final standards reflect public input. The outcome measures constitute an empirically based standard that is applied to all of the OPOs and allow a comparison of an OPO's performance to the performance of its peers. We believe that changing "will not" to "may" in the regulations would effectively render this empirically based standard a nullity and would eliminate any meaningful empirically based standards for the recertification process. We believe that the suggested change would be contrary to the plain language of the relevant

statutes; therefore, we are not able to adopt the suggested change. We also believe that it would be contrary to Congress' express intent to recertify an OPO that failed to meet the outcome and performance measures during the past performance period. OPO performance is a critical element of the organ transplantation system in the United States. An OPO that is efficient in procuring organs and delivering them to recipients will save more lives than an ineffective OPO. Replacing an OPO that failed to meet the performance measures with an alternative organization that has been successful in the past is likely to increase the supply of organs available to patients on the organ transplant waiting lists.

Comment: Several commenters expressed concerns about the "limited appeals process" available to OPOs that are decertified due to the outcome measures. The commenters also indicated that "CMS noted repeatedly that no appeal on 'substantive' issues may be allowed."

Response: The OPO CfCs set forth at 42 CFR 486.314 specifically state that "the OPO may appeal the decertification on substantive and procedural grounds." Therefore, the OPO CfCs do not "limit" the grounds upon which an OPO can appeal a decertification. In addition, we will consider exercising our enforcement discretion, including consideration of outcome measures, on a case-by-case basis when appropriate as part of the review process.

Comment: Many commenters indicated that the proposed revisions were insufficient to address their numerous concerns about problems that the commenters believed were inherently related to the existing outcome measures. Some commenters asserted that the measures are flawed because there were significant problems with how the outcome measures were initially developed and the validity of the outcome measures has not been established. They also stated that CMS had acknowledged that the current outcome measures are flawed or have significant problems.

Response: We disagree with the comment. The outcomes measures were developed through a public process, using notice and comment rulemaking. We made significant changes to our proposed standards based on the comments and recommendations of the OPOs, including the national association that represents all OPOs (71 FR 30999). The first outcome measure allows us to assess an OPO's conversion rate of potential donors to actual donors so that we can determine how an OPO

has performed in regard to donor potential in its own designated service area as well as how it has performed compared to other OPOs. The second outcome measure uses the statistical methodology developed by the SRTR for determining an expected donation rate for each OPO, allowing an assessment of how an OPO has performed in view of its expected performance. Our third measure is comprised of three individual measures for organs transplanted per donor and organs used for research per donor. This third measure allows us to assess how well an OPO fulfills its ultimate mission—recovering viable organs and placing them with transplant centers for transplantation—as well as its commitment to placing organs for research (71 FR 31000).

In the preamble to the proposed rule, we acknowledged that we had some concerns about the outcome measures due to input we had received from the OPO community. We also indicated that we believe that OPOs should not be decertified based solely on their failure to meet one outcome measure because our experience with the OPOs indicated that the OPOs that were failing one of the outcome measures were performing satisfactorily. In addition, we noted that the majority of OPOs are meeting all three outcome measures and we expect that only a small number of OPOs would not be able to meet at least two of the outcome measures. If the current outcome measures were fundamentally flawed or had significant problems, we would anticipate that the number of OPOs that would not successfully meet this requirement would be much higher. Therefore, while we acknowledge that there are concerns with the current outcome measures, we believe the current measures are a valid means of measuring OPO performance in keeping with the statutory requirements. Each measure is empirical; that is, based upon observation or statistically derived from data.

Comment: Some commenters believe the existing regulatory standards are flawed because the data upon which the outcome measures are based are self-reported and are not verified by another source; therefore, the accuracy of the data cannot be verified.

Response: We disagree with the commenters' premise that the reported information cannot be verified. All OPOs are required to provide specific information to the OPTN, the SRTR, and CMS (42 CFR 486.328). This information includes, but is not limited to, the number of eligible deaths; the number of eligible donors; the number of organs transplanted, by organ type;

and the results of death record reviews. In addition, the data that are to be used for recertification purposes must be reported to the OPTN of all deaths in all hospitals and critical access hospitals (CAHs) in the OPO's DSA, unless a particular hospital or CAH has been granted a waiver and is working with another OPO (42 CFR 486.328(c)). We are able to independently audit the hospital's records. Moreover, if an OPO determines that any data was incorrect, through death record reviews or any other means, it has 30 days to report the accurate data to the OPTN (42 CFR 486.328(d)). Therefore, if any OPOs are not reporting accurate data, they are not in compliance with this condition and could be subject to regulatory sanctions, up to and including decertification. Thus, we believe that there are sufficient tools to verify the reported information.

Comment: Some commenters suggested that the definitions of "eligible death" and "donor" are being interpreted and clinically implemented in an inconsistent manner among the OPOs, which could negatively impact some of the OPOs' performance on the outcome measures.

Response: We agree that data should be accurately and consistently reported, and we established these definitions to standardize the terms to the greatest extent possible. We expect that all of the OPOs will interpret and implement all of the CfCs, including the definitions, and report their data in good faith. We adopted the definition of "eligible deaths" using the OPTN definition of that term in response to public comments (71 FR 30985). We note that the commenter does not criticize the definitions per se, but instead focuses on how some OPOs are applying those definitions. Considering the very divergent circumstances present with donors, we acknowledge that there may be times that different OPOs would disagree about whether a particular individual's death should be classified as an "eligible death" and subsequently whether the donor is an "eligible donor." While some variation is possible, we believe that these cases should be rare. If there are questions or concerns about how to interpret and implement any of the requirements or report data, those questions or concerns should be communicated to CMS or OPTN so they can be addressed.

We are disturbed by the commenters' suggestion that some OPOs may be interpreting certain requirements and reporting their data in a way designed to gain an unfair advantage over other OPOs in their performance on the outcome measures. Despite these

comments, we have not been given any specific evidence that the alleged practice is actually occurring. We also note that we evaluate OPOs for their compliance with the applicable CfCs, including the condition for reporting of data at 42 CFR 486.328. An OPO could face decertification if it is found in violation of those rules. We will scrutinize the data to assess for any unfair actions taken by an OPO.

Comment: Some commenters suggested that the outcome measures provide a disincentive to organ procurement, which is resulting in fewer, rather than more, organs being recovered for transplantation. One commenter gave the example of a potential donor with multiple comorbidities for whom the OPO could only expect to be able to procure the liver for transplant. The commenter stated that if an OPO is concerned about the third outcome measure, which, among other things, measures the organs transplanted per donor (yield measurement), there is a disincentive to pursue that donor because they would likely only recover a single organ.

Response: We disagree. While our empirically based outcome measures do measure various aspects of the OPOs performance, the measures specifically encourage OPOs to fulfill their ultimate mission, which is the recovery of transplantable organs and placement with transplant centers for transplantation for patients, as well as for research purposes.

Comment: Some commenters suggested that there are conflicts between the OPO CfCs and the transplant center (TC) Conditions of Participation (CoPs). The commenters stated that the OPO CfCs incentivize OPOs to pursue as many donors as possible and procure as many transplantable organs as possible. However, the commenter added, the TC CoPs require transplant centers to meet specific outcome measures for graft and patient survival. For example, the commenter stated that concerns related to these outcome measures may cause some transplant surgeons to decide not to transplant certain types of organs, such as organs procured from Donors after Cardiac Determination of Death (DCDD). The commenter believed that this could result in some organs procured by OPOs not being transplanted, which would negatively impact the third (yield) measure.

Response: As explained in the proposed rule and in the background section above, our regulations with respect to outcomes measures for OPOs reflect the specific standards Congress required the Secretary to develop for

measuring OPO performance under the Organ Procurement Organization Certification Act of 2000. Our rules are fully consistent with those statutory directives. Transplant centers, in contrast, are not required to meet regulatory standards that are based on the OPO statute. However, we will examine our standards in an attempt to determine if greater synergy is possible in the future.

Comment: Many commenters noted that they agreed with the DHHS Secretary's Advisory Committee on Organ Transplantation's (ACOT) Recommendation 55 that was made in August 2012 (<http://www.organdonor.gov/legislation/acotreccs55.html> accessed on November 18, 2013), which, among other things, includes a recommendation that the DHHS Secretary direct CMS and the Health Resources and Services Administration (HRSA) to confer with the OPO community to conduct a comprehensive review of the regulatory requirements for OPOs and transplant centers and promulgate regulatory and policy changes to OPO requirements, including, but not limited to, "a statistically sound method for yield measures for OPOs" (<http://www.organdonor.gov/legislation/acotreccs55.html>).

Response: We are interested in continuing to improve our standards and are currently conducting a comprehensive review of the OPO CfCs and will consider these public comments in any future rulemaking. However, we believe it would be unfair to OPOs to develop new standards at this time and to apply those standards retroactively for past periods.

After consideration of the public comments we received, we are finalizing as proposed the revisions to §§ 486.316 and 486.318 of our regulations by modifying the current outcome measures requirement to require that OPOs must meet two out of the three outcome measures instead of all three outcome measures.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43672), we also solicited public comments on any other potential empirically based outcome measures for OPOs that might be used in future rulemaking. We stated that we would especially appreciate public comments on the new yield measure that was produced by the SRTR and is being used by the OPTN. The OPTN recently adopted this new yield measure, which calculates the expected number of organs transplanted for each donor based on multiple donor risk factors. The measure uses more extensive risk factors that mitigate the differences in

the donor pool of the each DSA. This may allow an OPO's performance to be measured in terms of the expected outcomes for the DSA based upon the expected outcomes for individual donors within the DSA and not against a national average. In the proposed rule, we stated that when comparing OPOs currently identified to be below expected performance levels by the OPTN matrix and the OPOs identified as below expected performance levels by the CMS measures, we had noted that the lists are not the same. We stated that if the new OPTN measure proves to be a more accurate reflection of performance as measured by the organs transplanted for each donor in each individual DSA (as it is accepted by HRSA and the OPO community), this may provide an alternative outcome measure that could be adopted in the future. We referred readers to the SRTR Web site at http://www.srtr.org/csr/current/Tech_notes.aspx for specific details on the risk adjustment models used for this measure.

Comment: A few of the commenters noted the the OPTN yield measure was an improvement over the current outcome measures and that it should be considered by CMS. However, these commenters also noted that there were issues with this measure. One commenter noted that the OPTN measure was "too new" and "needs some vetting before it can be accurately used to define performance." Another commenter noted that the measure "requires further revision."

Response: We are currently conducting a comprehensive review of the OPO CfCs. We will consider these public comments concerning the current outcome measures and the new OPTN yield measure if we proceed with future rulemaking.

XVII. Final Rule: Revisions of the Quality Improvement Organization (QIO) Regulations

A. Legislative History

The Utilization and Quality Control Peer Review Program was originally established by sections 142 and 143 of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982 (Pub. L. 97-248). The name of the individual organizations covered under the program was "Peer Review Organizations." In a final rule with comment period published in the **Federal Register** on May 24, 2002 (67 FR 36539), we revised the regulatory references to these organizations to "Quality Improvement Organizations" (QIOs)—without changing the definition or functions of the QIOs—to reflect the

program's shift from a compliance-oriented focus to one emphasizing quality improvement. There have been a number of amendments to the QIO statute over the years, but they have not resulted in any substantial changes in how the program operates. However, in section 261 of the recently enacted Trade Adjustment Assistance Extension Act of 2011 (TAAEA) (Pub. L. 112–40), Congress authorized numerous changes to the original legislation that modernize and improve the QIO Program and included additional flexibility for the Secretary in the administration of the QIO Program. This legislation also updated the nomenclature from the Peer Review Organization Program to the QIO Program and included amendments to update the terminology of the program (replacing “peer review organization” and “utilization and quality control peer review organization” with “quality improvement organization” in relevant provisions of the Act).

Specifically, section 261 of the TAAEA increased the flexibility available to the Secretary by updating the statutory definition of the organizations that can contract with CMS as QIOs (as described in section 1152 of the Act), changing certain contract terms and processes by which the Secretary contracts with QIOs (as described in section 1153 of the Act), and broadening the Secretary's authority to delineate the scope of work for QIOs (as described in section 1154 of the Act).

The regulations that implement sections 1152 and 1153 of the Act are codified at 42 CFR Part 475; Subpart C of Part 475 includes provisions that specifically govern the types of organizations eligible to become QIOs. The regulations that implement section 1154 of the Act and much of the work performed by QIOs are codified at 42 CFR Part 476. Section 1154 of the Act states that much of the work QIOs will perform is subject to the terms of their contracts with CMS. We note that, consistent with this provision, the contracts and requests for proposals (RFPs) used to contract with QIOs include significant detail on the work performed by the QIOs. Our proposal did not include changes to this approach to the QIO Program and was intended to provide a framework to guide the contracting process by establishing minimum eligibility criteria, direction for how CMS will determine that the minimum criteria are met, and a basic process for how awards are made.

B. Basis for Proposals and Finalized Policies

Section 261 of the TAAEA eliminated certain limitations specified in sections 1152 and 1153 of the Act that appear in several existing provisions in Part 475. In order to eliminate these limitations in the regulations and fully utilize the flexibility provided as a result of the statutory changes, in the CY 2014 OPPS/ASC proposed rule (78 FR 43672 through 43678 and 43705 through 43706), we proposed regulatory changes to implement the statutory amendments. These changes involve, among other things, changing the eligibility standards for an entity to be awarded a QIO contract and defining specific terms that will be used to describe QIOs and their work. We proposed to change the terminology related to the geographic area in which a QIO must perform its different functions. As amended, the statute authorizes the establishment of “such local, State, regional, national or other geographic areas as the Secretary determines appropriate” for QIO contract awards. We also proposed revisions to existing regulation text regarding the eligibility of a health care facility association to be a QIO and revisions to eliminate provisions at § 475.106 regarding the eligibility of payor organizations to be QIOs based on the proposed revisions to eliminate obsolete text and to codify the eligibility provisions for payor organizations in a different section. The statutory amendments also include a change in the contract period for a QIO, extending it from 3 to 5 years. Therefore, we proposed to include in § 475.107 language to reflect the TAAEA amendment to section 1153(c) of the Act, which modified the statutory 3-year QIO contract term to a 5-year contract term. Although we did not previously update this regulation with a prior statutory change in the QIO contract term from 2 years to 3 years, we included the 5-year time period in the proposed rule as a technical correction in order to make the regulation consistent with the amended statute. We believe that these changes would be instrumental in improving aspects of the QIO's review activities and would enable us to improve the program by ensuring that QIOs are better able to meet the needs of Medicare beneficiaries. We stated in the preamble to our proposal that the proposed revisions to §§ 475.101 through 475.107 were intended to allow organizations that currently perform QIO work to compete for new QIO contracts, while expanding eligibility to additional entities under the new authority granted

by the TAAEA. We stated that we will focus contract determinations on the ability of organizations to perform QIO functions as stated in the RFP. In the proposed rule, we solicited public comments on whether our proposed regulation text for Subpart C of Part 475 sufficiently meets this goal as well as our explained goal to implement the flexibility provided by Congress in the TAAEA amendments. In addition, we proposed in § 475.1 and § 476.1 a technical correction to redesignate paragraphs (a) through (d) in the definition of “Five percent or more owner” as paragraphs (1) through (4). The specific proposed changes and corrections are explained in more detail in the following sections.

QIOs work at the grassroots level of American health care delivery systems in all 50 States, the District of Columbia, and most U.S. Territories in order to improve care for Medicare beneficiaries. QIOs originally reviewed Medicare services to determine whether they were reasonable and medically necessary, met professionally recognized standards of care, and were provided in the appropriate setting. However, the QIO contract has evolved over the course of the years as the literature supports the concept that defects in the health care process are rarely related to the performance of one individual but to a system of care with multiple opportunities for failure. Attempts to improve quality through inspection methods, that is, by performing one chart review at a time, are less likely to yield the systemic improvements in care for Medicare beneficiaries that can come from analyzing aggregate data in order to identify problems, developing a plan of action, monitoring the result through data driven processes, and making changes as needed based on those results.

The qualifications and expertise required to execute these quality improvement initiatives have evolved to now include expertise from disciplines such as physicians, nurses, other clinicians, health care leaders, experts in statistics and health care system reengineering, and many other kinds of professionals. As we discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 43673), we interpret our proposed regulation so as not to prohibit the use of professionals in the health care industry that are not licensed physicians or certified practitioners in connection with quality improvement initiatives or other activities that do not, by law, require use of licensed physicians or certified practitioners. We anticipate that these other professionals may offer valuable insight to QIOs on

ways to enhance the performance of their QIO functions, as well as provide services designed to help QIOs maximize their impact. We proposed to adopt this approach to further our goal that the regulations under 42 CFR Part 475 reflect a multidisciplinary approach to the performance of QIOs. Therefore, we intended that the proposed standards would not be a barrier to the inclusion of any other nonphysician or nonpractitioner professional that CMS or the QIO deems appropriate for the successful performance of QIO functions. Patients and their families also play a critical role in the success of quality improvement initiatives. Amendments to the Act made by the TAAEA would accommodate the evolution of quality improvement and would allow CMS the flexibility to expand the types of organizations eligible to provide multidisciplinary support in quality improvement. As indicated in the CY 2014 OPPTS/ASC proposed rule (78 FR 43673), we sought with this proposal to ensure that the regulations governing QIO eligibility reflect the increased flexibility afforded by the TAAEA. This will help us ensure that we can administer the QIO Program in a manner that reflects contemporary practices and allows us to include the appropriate individuals and entities in working toward improving care processes.

As described in section 1154 of the Act, QIOs perform many specific review functions that are necessary to ensure the quality of care provided to Medicare beneficiaries. The addition of section 1154(a)(18) by the TAAEA explicitly provides the Secretary with the broad authority to require that QIOs perform any additional activities the Secretary determines may be necessary for the purpose of improving the quality of Medicare services. Based on this authority, QIOs will, as a general matter, be required to represent CMS as “change agents” that work at local levels in their individual QIO geographic areas. The TAAEA also amended section 1154(a) of the Act to permit QIOs to perform one or more QIO functions instead of all QIO functions listed in the statute. Different QIOs might now be required to work on one or more different tasks within a QIO area; that is, all QIOs might no longer be required to handle the complete and broad range of QIO activities within their respective geographic areas but to focus on particular tasks of QIO work. For example, one QIO might be required to offer to a variety of stakeholders the knowledge and resources for improving health quality, efficiency, and value

designed to improve the care provided to Medicare beneficiaries, while another QIO is required to perform case review in the same area.

As under the current program, QIOs will be required to base their work on clinical evidence and some may be required to generate reliable data about clinical performance. QIOs may also serve as independent, objective, and collaborative partners that support CMS’ mission to improve health care quality in the Medicare program (which, in turn, has the potential to greatly benefit the broader health care community) by leveraging the best efforts of all health care stakeholders, including beneficiaries and their families. While the goal of the QIOs is to benefit Medicare beneficiaries, the work of the QIOs may also, as a secondary matter, benefit other patients and residents who receive medical care. In this context, we are seeking to ensure that the regulations governing QIO eligibility reflect contemporary practices and permit the inclusion of organizations that can help to improve care processes for Medicare beneficiaries. We proposed to do so by removing restrictions that are no longer statutorily mandated and including requirements that reflect the current goals of the QIO Program.

One such contemporary practice is the inclusion of patients and families in health care quality improvement. As a result, we proposed the addition to the QIO requirements of a new focus on patient and family engagement and patient and family inclusion in case reviews and quality improvement initiatives.

We believe that the TAAEA legislation allows us a great deal of flexibility in how we restructure the work that QIOs perform and the types of organizations qualified to perform that work. We intend to continually examine methods for providing care to beneficiaries in a way that maximizes efficiency, eliminates waste, decreases harm, lowers costs through improvement, and engages patients more effectively. One way to continue improving the quality, efficacy, and efficiency of care in the Medicare program is to reconsider how QIOs provide services to determine whether the current longstanding contract structure and eligibility requirements best fit the continually evolving science related to driving quality improvement. The changes we proposed and are adopting as final are intended to ensure that we have the flexibility we need to reconsider as necessary certain aspects of the QIO Program structure in response to experience and changes in research findings and the health care

community’s approach to quality improvement.

The regulatory proposals in the CY 2014 OPPTS/ASC proposed rule (78 FR 43672 through 43678) focus on the primary functional responsibilities of a QIO as a basis for determining eligibility. These responsibilities are case review (which includes the statutory minimum standards) and quality improvement initiatives. As stated in the proposed rule, we believe that the eligibility and contracting standards proposed for QIOs focus on the necessary minimum requirements for successful operation of the QIO Program.

C. Changes to the Nomenclature and Regulations Under 42 CFR Parts 475 and 476

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43673 through 43678), we set forth proposals for updating the nomenclature and the definition of physician in both 42 CFR Parts 475 and 476 and for the partial deletion and revision of the regulations under 42 CFR Part 475. Part 475 includes definitions and standards governing eligibility and the award of contracts to QIOs. We proposed to replace nomenclature that has been amended by the TAAEA; revise the existing definition in Part 475, Subpart A and Part 476, Subpart A of the term “physician;” add new definitions to Part 475, Subpart A as necessary to support proposed new substantive provisions in Part 475, Subpart C; and revise, add, and replace some substantive provisions in Part 475, Subpart C.

We have summarized the public comments we received and our responses below, using the regulation sections as headings to guide the discussion. In some cases, we have summarized and discussed issues raised by commenters in connection with the substantive issue rather than the regulation section identified by the commenter in order to better discuss each topic. For example, we have addressed comments about the need for objectivity and neutrality from all QIOs in connection with our discussion below in § 475.101 below, although some commenters raised this issue in connection with § 475.105.

Comment: As a general matter about the proposal, one commenter urged CMS to postpone proposed changes to the QIO Program until “the pace of healthcare reform is less frenetic, physician practices are more stable,” and “CMS has a clearer sense of how the proposed changes would impact the quality and costs of patient care.”

Response: Although there have been many changes made through health care reform since 2010, there have been very few programmatic changes made in this particular area of health care quality improvement. The science of quality improvement has changed significantly over the last few decades and we believe that these proposed regulatory changes, which allow flexibility for any number of possible configurations, are long overdue. Further, the substantial changes made by the TAAEA are generally effective with QIO contracts awarded after January 1, 2012. As we approach the conclusion of the current QIO contracts and consider awarding QIO contracts after the enactment of the TAAEA, we believe that these changes are best accomplished now. As we move forward, we hope to capitalize on past successes of the QIO Program as well as improve the program by establishing a more flexible, efficient, patient-centered and family-centered model.

1. Nomenclature Changes

In order to align the regulations with the nomenclature changes made by section 261 of the TAAEA, we proposed nomenclature changes where necessary in 42 CFR Part 475. For example, we proposed to revise the heading of Subpart C of Part 475 to read “Subpart C—Quality Improvement Organizations” and to replace the term “peer review” with “quality improvement”. In each proposed provision in Part 475, Subpart C, we used the new nomenclature where appropriate.

In addition, Part 476 is currently entitled “Utilization and Quality Control Review,” and Subpart C of Part 476 is entitled “Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations (QIOs),” both of which reflect the terminology used before enactment of the TAAEA. In order to reflect the nomenclature changes made by the TAAEA, we proposed to revise the title of Part 476 to read: “Part 476—Quality Improvement Organization Review” and the title of Subpart C of Part 476 to read: “Subpart C—Review Responsibilities of Quality Improvement Organizations (QIOs).”

Comment: One commenter asserted that CMS’ proposed change of the term “peer review” to “quality improvement” is vague and its impact is unclear.

Response: We have made changes to the nomenclature throughout Parts 475 and 476 consistent with the changes made to nomenclature in the title and text of the statute at sections 1151, 1152, 1153 and 1154 of the Act. As we

mention above, similar changes to the regulatory references to these organizations have been made in the past. However, the prior nomenclature changes were made without changing the definition or function of the QIOs. We have made changes in this final rule to reflect the program’s shift from a compliance-oriented focus to one emphasizing quality improvement in addition to completing the nomenclature changes made by the TAAEA, modernizing and improving the QIO Program, and changing the eligibility requirements for QIOs.

After consideration of the public comment we received on the nomenclature changes, we are finalizing these proposed changes to Parts 475 and 476 without modification.

2. Addition and Revision of Definitions

In the CY 2014 OPPS/ASC proposed rule (78 FR 43674), we proposed changes to §§ 475.101 through 475.107 to reflect new eligibility standards for an entity to be awarded a QIO contract and to use specific terms that will be used to describe QIOs and their quality improvement work. In connection with these changes, we proposed to add definitions of “case review”, and “QIO area,” add cross-references to definitions in § 476.1 of “practitioner” and “quality improvement initiative”, and revise the definition of “physician” under § 475.1 and § 476.1, as discussed below. Further, we proposed a technical revision to the definition of “Five percent or more owner” in Part 475. In the proposed rule, we solicited public comments on our proposed definitions and revisions.

We proposed to define “case reviews” to mean “the different types of reviews that QIOs are authorized to perform. Such reviews include, but are not limited to: (1) Beneficiary complaint reviews; (2) general quality of care reviews; (3) Emergency Medical Treatment and Labor Act (EMTALA) reviews; (4) medical necessity reviews, including appeals and DRG validation reviews; and (5) admission and discharge reviews.” We provided this list to illustrate the range and scope of case reviews but we noted in the proposed rule that the Act and other provisions in Chapter IV of Title 42 of the Code of Federal Regulations require additional reviews and that the Secretary, pursuant to section 1154(a)(18) of the Act, may require additional reviews under the contracts awarded to QIOs.

We did not receive any public comments on the proposed definition of “case review” and proposed amendments to the definition of “five

percent or more owner”. We are finalizing the technical revision to the definition of “five percent or more owner”. We are finalizing the proposed definition of “case review” with one slight modification to eliminate the word “including” in paragraph (5) to avoid the suggestion that appeals and DRG validation reviews are the only types of medical necessity review. As with the proposed definition, the final rule provides a nonexhaustive list of types of case reviews.

We proposed to expand the definition of “physician” beyond the existing definition under § 475.1 and § 476.1 to reflect the definition in section 1861(r) of the Act, as well as to cover several additional characteristics that are unique to the QIO Program. We proposed the following definition of physician for both Parts 475 and 476: Physician means “(1) A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatry, a doctor of optometry, or a chiropractor as described in section 1861(r) of the Act; (2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice as a doctor as described in paragraph (1) above; and (3) An individual licensed to practice as a doctor as described in paragraph (1) above in any Territory or Commonwealth of the United States of America.” We stated our belief that the proposed revisions are necessary to eliminate references in paragraphs (1) and (2) of the existing definition to physicians licensed in the State in which the QIO is located, in order to reflect the fact that a QIO’s contract area may no longer be limited to one State. In addition, we proposed to amend paragraph (3) of the existing definition so that it no longer applies to only American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands. We proposed to enlarge this part of the definition to apply to physicians licensed to practice in all U.S. Territories and Commonwealths to more closely align with the Secretary’s flexibility in awarding QIO contracts granted by the TAAEA. In the proposed rule, we solicited public comments on whether our proposed definition is sufficiently inclusive and appropriate to achieve these goals.

In addition, we proposed to define the terms “practitioner” and “quality improvement initiative” for purposes of Part 475 by cross-referencing the existing definitions for these terms at § 476.1.

Comment: A few commenters supported the proposed changes to the definition of “physician”, and one

commenter supported the expanded definition of “physician” which the commenter believed better reflected the definition contained in the TAAEA. Several other commenters suggested that CMS’ proposed change to expand the definition of “physician” may lead to review of the actions of doctors of medicine and osteopathy by other “limited” licensed practitioners and recommended that physicians should only be subject to review by other physicians, preferably practicing physicians in the same specialty or a peer level match. Commenters requested that CMS clarify that the proposed changes are not intended to replace peer review by QIOs with reviews of physicians’ decisions by nonphysician providers. Another commenter was concerned with the potential impact the broad definition of “physician” will have with respect to its use in § 476.98.

Response: We appreciate the commenters’ responses on this issue. While we believe that the requirements in section 1154(d) of the Act and the regulations at § 476.98(a) make it clear that QIOs are, except in limited circumstances, required to use a peer-to-peer match when performing reviews, we understand that the expansion of the definition of “physician” may mean that the peer conducting the review may not always be licensed in the same State where the care took place but must be licensed where the physician is working. We note that section 1154(d) of the Act provides that no QIO shall use the services of an individual who is not a duly licensed doctor of medicine, osteopathy, dentistry, optometry, or podiatry to make final determinations of denial of services provided by such physicians. In addition, we understand the commenters concern that the expanded definition of “physician” may lead to review of the action of physicians by physicians practicing in another specialty. We would like to clarify that, despite one commenter’s suggestion in support of the proposed definition, the TAAEA does not include a definition of physician. It remains unclear why some commenters believed that our broadening of the definition of “physician” would lead to care provided by physicians being reviewed by nonphysicians. We reiterate that there are safeguards in the statute and regulations to ensure that, during case review, there is a peer-to-peer match whenever possible and that physician decisions will not be reviewed by nonphysician providers. We also note that our subregulatory guidance, such as the definition of “peer reviewer” in the QIO Manual, emphasizes the

requirement to use a specialty match whenever possible. The QIO Manual can be found on our Web site at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/qio110c05.pdf>. The QIO Manual stipulates that a peer reviewer is “a reviewer who is either a physician or other practitioner who matches, as closely as possible, the variables of licensure, specialty, and practice setting of the physician or practitioner under review” and that only in “cases in which there is no peer match available, the QIO can use another physician reviewer without the same expertise.”

After consideration of the public comments we received, we are finalizing, without modification, our proposal to revise the definition of “physician” under § 475.1 and § 476.1.

In connection with our proposal to revise the requirements that an entity must meet to serve as a QIO, we also proposed to define, in § 475.1, the terminology related to the geographic area in which a QIO must perform its different functions. Before our proposal in the CY 2014 OPPS/ASC proposed rule, the regulations in Part 475 did not define this area but did refer to a QIO’s “review area” in a number of places in existing text at §§ 475.102 and 475.103, and “QIO area” in §§ 475.1, 475.105(a), and 475.107(a) and (d). The term “review area” was used to refer to the geographic area in which each QIO performs its review functions under its contract with CMS while the term “QIO area” was used to refer to the geographic area covered by the contract. We proposed to define and use the term “QIO area” to mean “the defined geographic area, such as the State(s), region(s), or community(ies), in which the CMS contract directs the QIO to perform.” We stated that our proposal to add this definition was meant to reflect the flexibility afforded to us by the TAAEA to establish a QIO area as the geographic area we believe will be most effective in accomplishing the goals of a particular QIO contract. In addition, we also stated that the change in terminology from “QIO review area” to “QIO area” is intended to emphasize that the term can encompass more than just “review” functions. With this proposed change, we stated our intent to not only broaden the scope for choosing an appropriately sized geographic area, but also to identify capability and functionality as the primary way to identify the appropriate organization to perform specific QIO contract functions.

We note that, on May 2, 2013, a Request for Information (RFI) was distributed seeking information about the methods we may use to assign work

to QIO contractors. In the RFI, we stated that “to accomplish our goal of further improving care for Medicare beneficiaries, CMS intends to restructure how it administers the Program.” In addition, we solicited “comments about four potential options the Agency may use to divide work among a varying number of QIO contractors across the country.” Many of the commenters who responded to the proposed rule appear to have been aware of the RFI and many seem to have been addressing the regional proposals in the RFI as part of their comments on the proposed rule.

Under the current QIO Program, although there are State-based contract awards, some QIOs share corporate parents and several QIOs subcontract to other QIOs for QIO work. The regulatory proposal was not to regionalize QIOs but to adopt a definition of “QIO area” that would apply if the contracts were awarded on a regional basis or a State-by-State basis and to implement statutory flexibility that does not mandate specific geographic areas for QIO contracts nor prohibit regional contracts.

The RFP process will be the process through which the contract’s geographic areas are defined. We would like to make clear that it is our intent that the regulation as proposed, and as finalized, permits flexibility in terms of designing the work and the geographic area for each QIO. The contracting process will finalize the details of the program’s structural changes, if any.

Comment: One commenter supported CMS’ proposed changes in terminology from “QIO review area” to “QIO area” in order to emphasize that this term may encompass more than “review” functions. One commenter supported the expansion of a greater geographic area and stated that the proposed definition of “QIO area” versus “QIO review area” emphasizes that the proposed term encompasses more than “review” functions which may provide a broader scope for choosing an appropriately sized geographic area and may assist in identifying the capability and functionality as a means to identify organizations to perform specific QIO contract functions. Some commenters stated that this proposed definition allows for more flexibility and will allow for the designation of QIOs that are best equipped to provide a specific set of services. Other commenters indicated that the rapidly changing requirements make it increasingly difficult for every QIO to have the requisite expertise and specialization in order to be a subject matter expert on all QIO initiatives and activities. These

commenters stated that a regional QIO approach has great potential to ensure every State has the same level of expert support and is consistently receiving the same information.

Response: We appreciate the comments in support of the expanded definition of “QIO area” and the general approach underpinning our proposal that would allow specific QIOs to focus and develop expertise in a single area of quality improvement. The QIO Program has expanded beyond case reviews and the changes proposed reflect the array of tasks that QIOs are currently performing. We agree that the increased flexibility is beneficial and plan to, wherever possible, create efficiencies of scale to pool expertise in the interests of establishing and spreading best practices. We would like to clarify that a regional approach to the QIO Program structure is one option that we are considering. However, we have a variety of geographic options available under the statute and the regulation as finalized in this final rule.

Comment: Several commenters stated that many practicing physicians have spent years building relationships with their local QIOs and suggested that these State-based QIOs have a degree of credibility with local Medicare beneficiaries and providers. In addition, commenters stated that the State-based QIOs are better able to identify problems in their local communities, design appropriate solutions, and identify local physician leaders to initiate projects. The commenters also stated that they have had “long and fruitful collaboration” with their respective State-based QIO and indicated that this relationship has resulted in sustained quality improvements for their Medicare beneficiaries. These commenters further stated that valuable time and resources would be lost as relationships and trust would need to be forged again to ensure provider engagement in educational opportunities. One commenter stated that, although some function-specific QIOs may address unmet needs, these QIOs should not be established at the expense of State-based QIOs. This commenter recommended that a cost effective alternative would be for CMS to give high-performing existing QIOs the option to expand their portfolio of quality improvement activities during contract renegotiations.

Response: The proposed rule and this final rule do not require regionalization but rather permit the creation of contract areas other than on a State-by-State basis. In determining how to best implement the flexibility afforded to the Secretary by the statutory changes made through the TAAEA, we will consider

several factors. For example, under the current structure of the QIO Program, there already exists a multi-State subcontracting structure for the appeal case reviews. There also are several multi-State corporate QIO management structures that have operated successfully for many scopes of work. These structures have been able to capitalize on the strengths and the expertise of particular entities.

In addition, we believe that, for some functions, QIO contracts that cross State lines would create economies of scale and standardization of processes and eliminate duplicative administrative and management overhead. This potential structure would improve communication between CMS and the QIOs and decrease the contracting and administrative burden currently faced by both entities. Further, to the extent that quality improvement initiatives are designed in connection with nationwide quality measurements or quality improvement programs, QIOs would not be hampered by serving larger QIO areas. We are aware that many providers have established strong relationships with local QIO staff, and we understand the importance of preserving these ties. We expect to maintain in future QIO contracts the type of local “on the ground” involvement, which is tailored to meet the needs of communities and longstanding relationships that have been built between providers and QIO staff under the existing structure.

We believe that the proposed changes to the definition of “QIO area” will enable flexibility and targeting of program expertise in the best interests of beneficiaries and are consistent with our efforts to continually strive to make the QIO Program more efficient. In addition, we note that in §§ 475.102 and 475.103, discussed in more detail below, we proposed and are finalizing provisions to take into account the geographic location of an organization applying for a QIO contract. Those provisions do not list exhaustive factors for consideration in awarding QIO contracts and we may include additional factors where and when necessary.

Comment: One commenter supported CMS’ proposal to define “QIO area” and believed that it would be in the best interest of Medicare beneficiaries. In addition, the commenter encouraged CMS to take advantage of the opportunity for flexibility provided when contracting with QIOs. Some commenters supported CMS’ proposed QIO Program changes by affirming that greater standardization and nationally recognized expertise are advantageous for activities such as assistance with education and data submission for

quality measurement programs, and technical advice related to quality measurement specifications. One commenter asserted that the proposed QIO Program changes may result in reduced spending by approximately \$330 million based upon Congressional Budget Office estimates by demonstrating more cost effective strategies for delivering services. This commenter also supported CMS’ proposal to expand the definition of a QIO area that would allow a QIO to serve in more than one State. The commenter indicated that regional QIOs (formed by more than one single-State QIO contract held by a single corporate entity) already currently exist and believed that having regional QIOs is logical from an economy of scale perspective. One commenter stated that it recognizes that economies of scale and efficiencies may occur but indicated its concern that a “dramatic change to mandated multi-State [QIO] contracts” would introduce the possibility that some States may be left without a local source for quality improvement technical assistance.

Some commenters recognized the efficiencies and effectiveness that may be achieved to the QIO Program and recommended that, in situations where successful work has been demonstrated through QIOs that cover multiple States (formed by more than one single-State QIO contract held by a single corporate entity), CMS use these collaborations to test the feasibility and effectiveness of the expanded “QIO area” definition as a first phase in restructuring the QIO contracts and QIO areas.

However, some commenters asserted that it would be difficult to maintain the “local perspective” in a regionalized QIO structure, that they did not see evidence for “radical, untested” changes to the State-based nature of the QIO Program and stated that CMS’ proposed changes seem to have been undertaken with little consultation with either the national or local practitioner community of their respective States. Some commenters maintained that the proposed changes in the QIO Program would cause the current State-based QIO experience and expertise to be “sacrificed.” One commenter also believed that long-term care providers may be held responsible to increase their administrative duties in order to interact with a separate organization for each function. One commenter stated that a single-State QIO may be better able to understand and focus on the Medicare beneficiaries and providers being served for more densely populated States.

Response: We reiterate that the proposed rule and this final rule do not require regionalization but rather permit the creation of contract areas other than on a State-by-State basis. We appreciate the support for these regulatory provisions and agree that standardization and better targeting of subject-matter expertise will help increase the efficiency of the QIO Program and create better value for Medicare beneficiaries. While we did not propose in the proposed rule that we would establish a regional structure, we acknowledge that the proposed rule, once finalized, would accommodate that structure. We believe that having the flexibility to adopt a different QIO contract structure, if we choose to establish one, would enable the QIO Program to benefit from the lessons already learned through the multi-State corporate structure of many QIOs. There are currently 10 corporations that have coordinated separate QIO contracts to cover 26 States. In addition to the multi-State corporate structure, some QIOs have established subcontracting relationships with other QIOs for conflict of interest or administrative efficiency purposes that have also generated savings. Based on the QIO Program's history with these subcontracting and corporate structures that cross State lines, we believe that multi-State QIO structures have been successfully tested as a model for potential QIO structural changes. At the same time, we believe that this final rule makes it clear that the local involvement and expertise that is so important will be maintained. As an example, the requirements in § 475.102(a) of this final rule make it clear that, in determining eligibility for performing case review, we will take into consideration "the organization's proposed involvement of and access to physicians and practitioners in the QIO area with the appropriate expertise and specialization in the areas of health care related to case reviews" and "the organization's ability to take into consideration urban versus rural, local, and regional characteristics in the health care setting where care under review is provided." Furthermore, the RFI issued in May 2013 also generated significant comment, in some cases from providers and provider associations, which we intend to consider as part of the procurement process. Also, we received public comments on our regulatory proposal from practitioners and providers, which we considered as part of this rulemaking. In addition to these opportunities to comment and present their views, we anticipate that providers

and practitioners will provide us feedback on any changes that we will be implementing in the next QIO procurement and contract cycle so that we may continue to improve the QIO Program. In addition, §§ 475.102(b) and 475.103(b), as finalized, permit CMS to consider size and location of an organization as part of determining whether the organization has demonstrated the ability to perform case review or quality improvement initiatives as a QIO. We intend to interpret and apply the provisions in Part 475 as finalized in this rule to ensure local experience and expertise are available, maintained, and utilized by all QIOs in connection with case reviews and where necessary for quality improvement initiatives.

After consideration of the public comments we received, we are finalizing the proposed definition, without modification, of the term "QIO area" to mean "the defined geographic area, such as the State(s), region(s), or community(ies), in which the CMS contract directs the QIO to perform." This term appears throughout Part 475 and is used consistent with this definition.

We also proposed to add definitions of the terms "quality improvement initiative" and "practitioner" to Part 475 and to define them by cross referencing the definitions of the terms in § 476.1.

Comment: One commenter noted that CMS proposed to cross-reference the definition of "quality improvement initiative" in § 475.1 to § 476.1 and indicated that a definition of "quality improvement initiative" was not included in the proposed rule nor does the Code of Federal Regulations (October 1, 2012 Edition) include a definition of it. The commenter suggested that CMS provide a definition of "quality improvement initiative" that reflects the principles of contemporary quality improvement.

Response: The current definition of "quality improvement initiative" under § 476.1 was finalized in the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68559). The regulations as amended are accessible through the electronic Code of Federal Regulations at www.ecfr.gov.

We did not receive any public comments on the proposed cross-reference to the term "practitioner" and are finalizing that definition for Part 475 without modification. After consideration of the public comment we received regarding the term "quality improvement initiative," we also are finalizing this definition without modification.

3. Scope and Applicability of Subpart C of Part 475

We believe that the scope and applicability provision for 42 CFR Part 475, Subpart C should reflect that the statutory authority for the QIO Program was amended by the TAAEA. In the CY 2014 OPPTS/ASC proposed rule (78 FR 43674 through 43675), we proposed to replace the regulatory language in § 475.100 with new language that explicitly acknowledges that the regulations in Subpart C implement sections 1152 and 1153(b) and (c) of the Act as amended by section 261 of the TAAEA.

We did not receive any public comments on the proposed revisions to § 475.100, and we are finalizing these revisions as proposed without modification.

4. Eligibility Requirements for QIOs (§§ 475.101 Through 475.106)

We have interpreted and the regulations in Part 475 implement the statutory definition in section 1152 of the Act as setting minimum eligibility requirements for an entity to hold a QIO contract. Our regulatory proposal in the CY 2014 OPPTS/ASC proposed rule (78 FR 43675 through 43678 and 43705 through 43706) proposed to implement the changes in the QIO eligibility standards made by the TAAEA.

As a general matter, we recognize and appreciate the vital role of physicians in the work of the QIOs but also believe that some of the functions of the QIOs necessitate a multidisciplinary approach to quality improvement, inclusive of expertise from a wide breadth of disciplines. With the elimination of the requirement that a QIO be sponsored by or have access to physicians in a specific organizational structure, we proposed to delete the eligibility requirements in §§ 475.101 through 476.104 related to the concepts of "physician-sponsored organization" and "physician-access organization." In light of the current multidisciplinary approach to QIO activities, we believe that expanding the existing eligibility requirements beyond "physician-sponsored organizations" and "physician-access organizations" will both better reflect the flexibility Congress provided in the TAAEA amendments to section 1152 of the Act and be inclusive of the multidisciplinary approach that currently exists in contemporary quality improvement.

In the proposed rule, we solicited public comments on our focus on these primary QIO functions of case review and quality improvement initiatives and

how this functional approach would ensure that QIOs are appropriately selected for contract award. We proposed to vacate existing text at §§ 475.104 and 475.106 and reserve these two section numbers.

We respond to the public comments we received that are specific to each regulation topic below and address how we are finalizing §§ 475.101 through 475.106. We note that, while some commenters specifically identified regulation sections as part of the comment, we have grouped the comments by topic.

a. Eligibility To Be Awarded a QIO Contract (§ 475.101)

In the CY 2014 OPPS/ASC proposed rule (78 FR 43675 through 43676), we proposed that revised § 475.101 would no longer reference “physician-sponsored organizations” and “physician-access organizations,” would include a requirement that the governing body of the QIO include at least one consumer representative, and would include new eligibility standards for an organization to be awarded a QIO contract based on the TAAEA amendments to section 1152 of the Act. First, in paragraph (a), we proposed that a QIO must have a governing body that includes at least one representative of health care providers and one representative of consumers as required by sections 1152(2) and (3) of the Act as amended by the TAAEA. Second, in paragraph (b), we proposed to interpret and implement the amended language in section 1152(1) of the Act that an organization awarded a QIO contract must be able, as determined by the Secretary, to perform the functions under the Act consistent with the purposes of the QIO Program and the Medicare program by requiring that an organization demonstrate the ability to meet eligibility requirements and perform the functions of a QIO. Our proposal characterized the functions of a QIO as the activities that are built into the request for proposals used to award QIO contracts and the ability to perform case reviews and/or quality improvement initiatives as described in these regulations. We stated that, in our view, these broad categories encompass the work QIOs are required to perform under section 1154 of the Act. We stated our belief that our proposal reflects a different approach to structuring the QIO requirements than the current rule: We proposed to focus on the functions the organization performs under the QIO contract instead of the structure of the organization itself. As discussed in more detail below in connection with proposed §§ 475.102 and 475.103, this

function-focused approach also reflects both the important role of physicians and a multidisciplinary approach for the two primary functions of the QIO contracts, case reviews and quality improvement initiatives. These two primary functions are based on the statutory requirements for the functions QIOs must perform and our current approach of using quality improvement initiatives to improve the quality of care provided to Medicare beneficiaries. By referencing the contractual requirements set forth in the requests for proposals, we proposed to incorporate the flexibility provided in section 1154(a) of the Act to require a QIO to perform one or more of the listed QIO functions and section 1154(a)(18) of the Act for the inclusion of additional activities for QIOs to perform when such additional activities are determined necessary to improve the quality of care for Medicare beneficiaries.

Finally, in paragraph (c) of § 475.101, we proposed that a QIO must demonstrate the ability to actively engage beneficiaries, families, and consumers, as applicable, in case reviews and quality improvement initiatives. Although this is not a specifically required qualification for a QIO under sections 1152 and 1153 of the Act, we proposed this requirement because it reflects the multidisciplinary and multi-stakeholder approach to QIO functions that we intend to establish. Health care costs have doubled as a share of the economy over the past three decades, causing stress on beneficiaries, families, employers, and government budgets. We stated our belief that motivating beneficiaries to become involved in their own health care may reduce waste and ultimately improve the quality and efficiency of health care. We noted that one important way to accomplish this is by educating beneficiaries, their families, providers, and the public about the importance of identifying and pursuing value in health care. Value represents the best possible quality of health care at the most reasonable cost. A major component of a successful value initiative depends on a QIO’s understanding of patient and family goals, expectations, motivations, and aspirations. Our inclusion of the requirement that a QIO have the ability to actively engage beneficiaries, families, and consumers in health care decisions emphasizes our commitment to patient and family engagement as an essential component of the QIO Program.

In the proposed rule, we solicited public comments on whether our proposal sufficiently incorporated the statutory flexibility, identified the goals

of the QIO eligibility requirements, and provided guidance on how organizations will be determined eligible for QIO contracts.

Comment: One commenter suggested that these proposed changes may qualify as “lowering the standards to become a QIO” and therefore stated that providers may not be willing to engage with these entities and progress may cease.

Response: The commenter was not specific about how the proposal appeared to lower standards for QIOs. We recognize that our proposal would establish, in § 475.101, the “minimum level of resources and skills” an organization must have in order to demonstrate its capability to perform as a QIO. However, we do not intend for these factors to be the only criteria we use to evaluate organizations requesting QIO contracts. The RFPs will include detailed information that will be used in evaluating each offeror. The standards we proposed at §§ 475.102 and 475.103 are a description of the factors we may use and should not be interpreted as an exhaustive list.

Comment: One commenter stated that the proposed change in the definition of eligible organizations to remove from § 475.105 the restriction from contracting with an association of health facilities may not ensure that all providers have equal access to quality improvement efforts within a given region. The commenter indicated that all trade and professional associations do not represent all providers within a region and questioned how CMS will assure “equal access and assistance” will be provided to all providers, regardless of membership status in the potential association being responsible for or involved in working with providers on quality initiatives. This commenter believed that if a trade or professional association were to become a QIO, that QIO would show preference to those providers who are members of its trade or association.

Response: Although these comments were made in reference to proposed § 475.102 and § 475.103, we believe that all public comments concerning eligibility and our proposed changes to make some general requirement changes are best discussed together with the comments specifically addressing our proposed eligibility changes in § 475.101. We also appreciate the concern that, by amending § 475.105 to expand eligibility to associations of health care facilities, some providers may not receive treatment equal to those providers affiliated with the professional organization. We note that the TAAEA specifically amended the statutory prohibition on associations of

health care facilities serving as QIOs and that our proposal to change § 475.105 was designed to reflect the statutory change. In response to these concerns, we have added language to the QIO eligibility requirements in § 475.101(d) to emphasize that an organization must demonstrate its “ability to perform the functions of a QIO with objectivity and impartiality and in a fair and neutral manner.”

Comment: In the context of the definition of “QIO area”, some commenters stated that QIOs should have experience and a trusted relationship with practitioners when engaging in quality improvement initiatives, as these characteristics are necessary to ensure that patients are protected from errors, and that errors, when they occur, are corrected. These commenters also stated that QIOs must be able to demonstrate fairness to practitioners as well as a commitment to patient-centered care.

Response: We agree with the commenters who requested that we include a requirement that an organization be able to perform QIO quality improvement initiative functions in a fair and neutral manner. We also believe that this criterion should be applied to all QIO functions. We agree that an organization should be free from any conflicts of interest and be able to demonstrate fairness and serve as an objective party. To address these concerns, we have added final language at § 475.101(d), a requirement that QIO organizations be able to “Demonstrate the ability to perform the functions of a QIO with objectivity and impartiality and in a fair and neutral manner.”

Comment: Some commenters were concerned with CMS’ proposal in § 475.101(c) that, in order for organizations to qualify for QIO contracts, they must demonstrate the ability to actively engage beneficiaries, families and consumers, as applicable, in case reviews or quality improvement initiatives. These commenters asked for further clarification as to how CMS envisions incorporating patients and families into the case review function. Some commenters asserted that it is appropriate to consider how patients and families can be of assistance in areas such as patient perception of care, patient decision-making, patient safety, and quality. In addition, these commenters asserted that consumer engagement in health care is a relatively new field with a small body of research and evidence and believed that CMS may be challenged to assess whether QIO applicants are able to demonstrate the ability to actively engage beneficiaries in case reviews.

Response: We recently began a Patient and Family Engagement Campaign (PFEC), which has been implemented in 25 States. The purpose of this project is to support QIOs who propose fresh and original models to develop and implement a local PFEC that supports HHS’ and CMS’ goals of person-centeredness and family engagement. The underlying goals of this effort are to involve patients and families in decisions regarding health and healthcare in order to ensure consistency with patient preferences and priorities and empower them to take action for their own health care that could improve quality of life. We believe that this 1-year project will provide strategies and results that can be available for all QIOs to use. We also believe that the beneficiary complaint, and beneficiary appeal processes are excellent opportunities to incorporate patient and family engagement into case review activities. We expect to learn strategies from the PFEC that can be spread and utilized in future case review activities that involve direct communication with Medicare beneficiaries.

Although Patient and Family Engagement is a relatively new field, we believe that there is sufficient activity in the health care community to require that QIOs incorporate Patient and Family Engagement techniques in their contract proposals, strategies, and techniques. Because current information regarding evaluation and measurement of Patient and Family Engagement is limited, we intend use evaluation strategies and benchmarks successfully adopted by the Hospital Engagement Networks (HENs) to measure this new QIO activity. Outside of those measurement techniques tested by HENs and proposed by QIOs, we are not planning to be immediately prescriptive in our requirements for measuring QIOs’ tasks in this new field. We refer readers to the following CMS Web site for more information concerning HENs: <http://partnershipforpatients.cms.gov/about-the-partnership/hospital-engagement-networks/thehospitalengagementnetworks.html>.

Comment: Some commenters supported the proposed changes to separate the two primary functions of the QIO contracts, case reviews and quality improvement initiatives, and supported the focus on the functions the organization performs rather than the structure of the organization itself. One commenter expressed concern regarding the extent to which CMS may further delineate or separate work within the case review and quality improvement functions and cautioned CMS against

severe subdivision of work within each of the functions, as they believe this would require hospitals to potentially work with many different QIO contractors.

One commenter argued that bifurcating case review and quality improvement initiatives would increase administrative burden on providers and weaken the collaborative relationship with providers, QIOs, and other community stakeholders. This commenter urged CMS to retain an integrated approach to QIO work. Other commenters supported separating these functions, but requested that CMS not separate the case reviews so much so that a provider could be working with multiple QIOs for different types of cases, as this could prove confusing, burdensome, and expensive.

One commenter argued that the case review and quality improvement functions of QIOs should not be bifurcated because case review provides a QIO with the opportunity to identify, test, implement, and measure results in areas where providers need quality improvement assistance. The commenter also stated that fragmenting the functions would increase administrative burdens on providers because they would be required to act with multiple entities, and this would impede relationships between QIOs and facilities that are essential to quality improvement. Another commenter stated that CMS should consider a mechanism for linking quality improvement and case review contractors for the purpose of information sharing because, without this link, it is difficult to determine systemic and isolated issues. Another commenter stated that, if the two functions are bifurcated, there should be a plan for how these organizations will avoid giving conflicting, competing, or fragmented messages.

Response: We believe that a division of case review from quality improvement work would benefit the program by removing the tension and potential conflict of interest between performing case review of providers’ care and then attempting to engage those same providers in quality improvement initiatives to improve quality. As we have previously done, the QIO Program will continue and possibly expand its use of National Coordinating Centers (NCCs) to help with the coordination of case review and quality improvement work. Although providers may be asked to work with more than one QIO, allowing a single QIO to focus on a specific task will be beneficial to that QIO in becoming a stronger subject-matter

expert. The more expertise a QIO achieves, the more likely it will be that the QIO will effectively spread best practices in its engagement with providers. We believe that the flexibility to combine or separate these functions is best made during the contract process. Therefore, the regulation we are finalizing explicitly permits but does not require the division of these functions.

Comment: Some commenters supported CMS' proposal to ensure that QIO governance includes representatives of consumers and health care providers. The commenters believed that including these representatives would ensure that the CMS envisioned multidisciplinary and multi-stakeholder approach to QIO activities is implemented.

One commenter agreed with the importance of ensuring that essential voices have a role in the governance of the QIOs but suggested that CMS avoid specifying QIO governance requirements which may be viewed as too prescriptive and may result in token rather than meaningful representation.

Response: The requirement to have at least one consumer and one provider representative on the QIO's governance board is a statutory requirement from section 1152 of the Act. Therefore, we have no authority to eliminate this requirement in our regulations. We also believe that it is beneficial to the QIO Program to have both provider and consumer groups properly involved in QIO governance level decision-making. However, to ensure that we are not too prescriptive in our governance requirements, we did not propose additional requirements or details beyond the statutory mandate. For example, we did not require that beneficiaries also be represented as members of the board. Instead, in § 475.101(c), we chose to require that a QIO demonstrate its ability to actively engage these partners in case reviews and quality improvement initiatives.

Comment: One commenter expressed concern that the possible change where by regional review agents would no longer need to be local, physician-based organizations and could be for-profit entities was insulated from public comment in the recent RFI.

Response: We appreciate the public comments regarding our eligibility proposal in the proposed rule. The RFI was issued to solicit comments only on potential options for restructuring and dividing work among QIOs. Although some commenters believed that the RFI provided limited opportunity to comment on the overall changes CMS is considering, we knew that the public

would have ample opportunity to comment on our proposal for revisions to the regulations to implement the statutory amendments that were created by the TAAEA through this regulation comment process. We understand the commenters' concern that QIOs are no longer required to be physician-sponsored or physician-access organizations. However, as we discussed in the preamble to the proposed rule, we believe that contemporary quality improvement should involve a multidisciplinary team of practitioners. Although the revisions do allow for additional for-profit entities (health care associations) to be QIOs, there has never been a requirement that QIO organizations be nonprofit organizations.

Comment: One commenter expressed concern that because quality improvement initiatives require complete trust in the participating organizations, it may be difficult for providers to separate the potential conflict that would exist between a payor organization that is both paying for services and providing assistance in improving quality and efficiency. The commenter stated that providers would be placed in the position of determining whether activities are truly in the best interest of the beneficiary or in the best interest of the payor organization.

Some commenters requested that CMS revise the proposed regulatory language changes in the final rule to exclude provider and payor organizations from QIO eligibility criteria as either a prime contractor or as subcontractors, or to revise the proposed changes to reflect similar language to that of the State Medicaid agencies that are required to demonstrate that they can act with independence and objectivity from their own program. These commenters suggested that provider and payor organizations are advocates for their paying members and believed that there may be an unfair competitive advantage for other business opportunities where, for example, a State hospital association may be put in the position of reviewing and/or undertaking quality initiatives with its own members. In addition, the commenters stated that these proposed changes may undermine conflict-of-interest safeguards currently in place because these organizations have professional and financial relationships that they believe may hinder their ability to be independent and neutral.

Response: We agree with the commenters that impartiality and objectivity are keystones to QIO success; these commenters suggested that we revise our proposed changes to

§§ 475.102 and 475.103 to reflect similar language to that of proposed § 475.102(c), which requires that State Medicaid agencies demonstrate that they can act with independence and objectivity from their own program. We also understand that payor organizations may find themselves in a difficult position when working with the providers who receive payments from the organization. We appreciate the public comments cautioning us about potential conflicts of interest that may arise from our proposal in § 475.105 about the eligibility of payor organizations to serve as QIOs. We believe that all QIOs should be required to perform quality improvement initiatives in a fair and neutral manner and believe that this criterion should be applied to all QIO functions. We also agree that an organization should be free from any conflicts of interest and be able to serve as an objective party.

To address these concerns, we are finalizing proposed § 475.101 by adding a new paragraph (d) that requires all QIOs to "[d]emonstrate the ability to perform the functions of a QIO with objectivity and impartiality and in a fair and neutral manner." In addition, in this final rule, we have added language to § 475.105(a)(3) to make payor organizations ineligible for QIO contracts unless the payor organization "demonstrates to the satisfaction of CMS that, in performing QIO activities, the payor organization will act with complete objectivity and independence from its payor program."

After consideration of the public comments we received, we are adopting as final, with one minor technical modification, the proposed revised provisions of § 475.101(a) through (c) that contain the requirements that an organization must meet to be eligible for a QIO contract. In paragraph (c), we are finalizing a minor technical modification to the text to use "and/or" instead of "or" to be consistent with how paragraph (b)(2) treats eligibility standards for performing case review and quality improvement initiatives. We are finalizing a new paragraph at § 475.101(d) to add an objectivity and neutrality requirement as well.

b. Eligibility Requirements for QIOs to Perform Case Reviews and Quality Improvement Initiatives (§ 475.102 and § 475.103)

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43676), we proposed to list the various factors CMS may use to determine that an organization has demonstrated its ability to perform case reviews. We stated that we do not consider this list to be comprehensive, but an indication of the types of factors

we intend to focus on. The list of factors emphasizes the importance of QIOs having access to qualified physicians and practitioners for the purpose of performing case reviews.

Case reviews are concerned with care that was, should be, or should have been provided based on the facts of a particular case, concerning a particular episode of care or concerning a particular beneficiary, or both. By contrast, the vast majority of quality improvement initiatives are not initiated in the same manner as case reviews. Rather, quality improvement initiatives are based on patterns of care that reveal problems that are more systematic in nature, such as those that result in inefficiency, waste, or high cost, or that could potentially harm beneficiaries. These patterns of care can reflect problems that might impact large segments of the population or single episodes of care where the impact might affect fewer people, but the QIO is concerned about the health and safety of the public due to the severity of the quality of care issue. We proposed to revise §§ 475.102 and 475.103 to provide that CMS will determine if an organization is capable of performing case reviews and quality improvement initiatives, respectively, using an illustrative list of similar factors and including the same constraints on Medicaid agencies serving as QIOs (with the one additional requirement that these agencies demonstrate objectivity and independence from the Medicaid program). Because the proposals at §§ 475.102 and 475.103 are similar, we discuss these proposals, the public comments we received, and the final provisions together.

In § 475.102(a) and § 475.103(a), we proposed illustrative lists of the types of factors CMS may use to determine that an organization has demonstrated the ability to perform case reviews or quality improvement initiatives based on factors related to how the QIO work will be performed and the underlying capabilities necessary for performing well. We do not consider these lists to be comprehensive, but an indication of the kinds of factors on which we intend to focus. Under our proposals in § 475.102(a)(1) and (a)(2) and § 475.103(a)(1) and (a)(2), CMS would consider virtually identical factors such as: (1) The organization's proposed processes, capabilities, quantitative and/or qualitative performance objectives, and methodology for performing case reviews or quality improvement initiatives; and (2) the organization's proposed involvement of and access to physicians and practitioners in the QIO area with appropriate expertise and

specialization in the areas of health care related to case reviews or quality improvement initiatives.

Under § 475.102(a)(3) and (a)(4), with respect to performing case reviews, we proposed that CMS would consider the organization's ability to take into consideration urban versus rural, and regional characteristics in the health care setting where the care under review was provided; and the organization's ability to take into consideration evidence-based national clinical guidelines and professionally recognized standards of care. Under § 475.103(a)(3), with respect to performing quality improvement initiatives, we proposed that CMS would consider the organization's access to professionals with appropriate knowledge of quality improvement methodologies and practices. Our proposals at § 475.102(a)(5) and § 475.103(a)(3) included the use of virtually identical evaluation factors such as the organization's access to qualified information technology (IT) expertise. In the proposed rule, regarding § 475.102(a) and § 475.103(a), we solicited comment on whether the regulation text should incorporate the standards for QIOs that we proposed to use and the factors we intend to consider when determining whether those standards have been met. The comments received and our responses are set forth below.

Comment: One commenter suggested that, in determining QIO eligibility as a result of the proposed changes, CMS consider how case review types, such as beneficiary complaints and general quality of care reviews, may be more effective when carried out by a local QIO organization rather than a regional model. In addition, as noted above, several other commenters raised concerns about using regions rather than States as the service area for QIO contracts.

Response: We discuss above many of the public comments about regional QIO contracts in the context of our rule finalizing the definition of "QIO area." We also considered whether the success of case review types that involve direct contact with beneficiaries would suffer under a regional model. We believe that an established subcontracting relationship that one QIO currently has with 20 other QIOs to perform appeals work for them during the weekends serves as a model that has shown that this type of multi-State coordination can be done. In fact, this arrangement has been done seamlessly and with greater efficiency than the State-based model. This model allows those QIOs who have a low volume of appeals during their

weekend downtime to direct those cases to a single entity. This arrangement has generated savings in administrative overhead by redirecting the fragmented volume to one QIO for more efficient processing. We believe that the success of this existing model could be replicated under regional QIO contracts for case review functions. However, as we discuss above, we agree with commenters that sensitivity to and knowledge of the local health care area and issues are necessary for QIO success. Along these lines, we are finalizing § 475.102(a)(3) with the addition of the word "local" to clarify that this is one of the factors to be considered in determining whether an organization has demonstrated the ability to perform case reviews. In addition, we note that §§ 475.102(b) and 475.103(b) explicitly permit CMS to consider the geographic location of an organization as part of this determination about the ability to perform, respectively, case reviews and quality improvement initiatives.

Comment: Although some commenters supported CMS' proposed criteria, many commenters suggested additional or revised criteria for determining whether an organization has demonstrated the ability to perform case reviews. Some commenters indicated that CMS should add to its evaluation criteria whether an organization can conduct case reviews in a fair and neutral manner. One commenter suggested that CMS add: (1) Experience as a QIO; (2) whether the organization has a formal, internal quality management system; (3) whether the staff has quality credentials (for example, Certified Professional in Healthcare Quality, Certified Health Care Quality Management, and Six Sigma); and (4) whether the organization is free of actual or perceived organizational conflicts of interest and able to serve as an objective party. One commenter specifically requested guidance regarding CMS' statement that it will not "limit evidence an organization may present to demonstrate its capability to perform case reviews" when reviewing prior experience. Many commenters suggested additional or revised criteria for determining whether an organization has demonstrated the ability to perform quality improvement activities. These commenters suggested that CMS add: (1) Ability to foster a relationship of trust and engagement with clinicians and executive leaders; (2) demonstrated capability to convene and establish effective working relationship with various stakeholders, because QIOs

should support coordinated care and breaking down silos and building a more coordinated infrastructure; (3) demonstrated capacity to collect, analyze, and share data with providers that spurs improvement because data collection and sharing data are critical in quality improvement; (4) ability to complement and not duplicate quality improvement efforts already underway through State, regional, and Federal programs; (5) ability to access and include others, especially those with performance improvement experience; (6) experience with and an approach to change management because CMS has on many occasions stated that QIOs will be required to represent CMS as “change agents”; (7) demonstrated ability to be a neutral, independent organization and provide objective assistance to providers without favoritism or conflict of interest, specifically because failing to achieve quality metrics can lead to financial penalties; and (8) demonstrated ability to share best practices.

Response: As discussed above in connection with our final rule at § 475.101(d), we believe that whether an organization can conduct case reviews in a fair and neutral manner is an important consideration and that this criterion of neutrality and fairness should be applied to all QIO functions. In addition, we agree that this regulation should not limit the information and factors used to determine whether an organization applying to be a QIO has demonstrated its ability to perform case review and/or quality improvement initiatives. Because we are finalizing our proposal to expand criteria to qualify for QIO contracts beyond physician-sponsored and physician-access organizations and we intend to make our qualification criteria fair for all potential organizations who qualify, we will interpret and implement §§ 475.102 and 475.103 as providing illustrative and nonexhaustive criteria for consideration. We do not plan to unreasonably limit evidence an organization may present to demonstrate its capability to perform QIO functions to specific QIO experience and agree that information such as that identified by the commenters may be relevant. We particularly appreciate the recommendation that we require that all QIO organizations have a formal internal quality management system and a staff with quality credentials, and although the factors listed in paragraph (a) are not meant as an exhaustive list, we will take into consideration the requirements recommended by these

commenters and we may include them in our RFPs.

Comment: Commenters requested more information regarding how CMS will evaluate and weigh reasons for and against the award of contracts, and noted that CMS proposed nonexhaustive lists of types of factors without specifying the weight each would receive or what other factors CMS might consider.

Response: Although we proposed to establish the “minimum level of resources and skills” an organization must have in order to demonstrate its capability to perform as a QIO, we do not intend for the factors listed in the regulations to be the only criteria we use in our evaluation of organizations requesting QIO contracts. The RFP will include detailed information that will be used in evaluating each offeror and, if we decide to use a weighted evaluation methodology, the weights to be used in the evaluation of proposals.

Our proposals at § 475.102(b) and § 475.103(b) include the following virtually identical evaluation factors. In paragraph (b) of these sections, we proposed that CMS may consider characteristics such as the geographic location, size, and prior experience, that CMS finds relevant, of an organization in order to determine whether the organization has the capability to perform case review activities or quality improvement initiatives. A summary of the public comments we received on paragraph (b) of §§ 475.102 and 475.103 and our responses are set forth below.

Comment: Some commenters supported using a regional approach to conduct case reviews. However, the commenters urged CMS to make sure that contractors have mechanisms in place to ensure that they comprehend and consider regional characteristics of providers. Another commenter argued that case reviews would be more effective when done locally rather than by a centralized or regional organization because it is more effective for a local QIO to uncover breakdowns in systems and processes of care.

Response: In addition to the provisions in paragraph (a) of §§ 475.102 and 475.103 that address involvement and access to physicians with appropriate expertise and our addition of local characteristics to the list of what a QIO must be able to consider in performing case review, our proposal in paragraph (b) for both §§ 475.102 and 475.103 would permit CMS to consider the geographic location and size of organizations applying to be QIOs. As noted above, we believe that the current QIO tested subcontracting structure for handling appeals review

across State lines verifies that case review can be performed effectively and efficiently through a more regionalized structure. To the extent that the geographic location of an organization is a barrier or enhancement to successful performance, the regulation as proposed and as finalized would permit CMS to consider the location. The final rule provides the flexibility that is necessary to consider all relevant facts about the geographic location and size of an organization compared to the QIO area that will be served. Further, the addition of the term “local” to § 475.102(a) clarifies that we deem the consideration of local characteristics essential.

Comment: Another commenter stated that the second sentence proposed in § 475.103(b) should be revised so that CMS must consider prior experience in health care quality improvement and that such prior experience must include conducting quality improvement initiatives that achieved successful results.

Response: We agree with the recommendation that CMS should consider prior experience in health care quality improvement and whether that such prior experience achieved successful results. In response to this comment, we are finalizing § 475.103(b) with additional language to include the commenter’s suggestion that CMS consider relevant quality improvement initiative experience and whether it achieved successful results.

Finally, we proposed to include in a revised version of paragraph (c) of § 475.102 clarifications to the text that reflect the existing regulatory text at § 475.104(d), with some minor modifications. Section 475.104(d) currently includes requirements that a State government must meet in order to qualify as a QIO. Under our proposal, § 475.102 would be revised to apply this additional requirement in connection with case reviews. Similarly, as proposed, the provision at § 475.103(c) includes the requirements that a State government must meet to qualify as a QIO that performs quality improvement initiatives. While both §§ 475.102(c) and 475.103(c), with respect to State governments that administer a Medicaid program, maintain the substance of the existing rule, each of this makes it clear that the scope of the review will be limited to case review and quality improvement initiatives, respectively. In order to do this, in § 475.102(c), we proposed to replace the term “utilization and quality review functions” with the term “case review” and in § 475.103(c), we proposed to replace the same term with “quality improvement initiatives.” We proposed

to revise the language in § 475.102(c) and § 475.103(c) to clarify that the objectivity and independence mentioned in the existing regulation relate to objectivity and independence from the Medicaid program, as we believe there is an inherent conflict of interest that arises from the State's financial interest in the administration of that program. We did not receive any public comments on the proposed revisions to § 475.102(c) and § 475.103(c), and therefore are finalizing them as proposed.

We also received a number of public comments about §§ 475.102 and 475.103 generally rather than about specific paragraphs of those sections. We address those public comments below.

Comment: Commenters stated that QIOs should be permitted flexibility to offer different types of assistance to providers because many different approaches may be pursued by providers in a given jurisdiction.

Response: We appreciate this comment and do not plan to use this regulation to prohibit QIOs from offering technical assistance or to implement quality improvement initiatives through approaches and techniques if they are determined to be the best for the population in the QIO area.

Comment: Commenters suggested that CMS allow hospitals to work with multiple QIOs because different QIOs may have various types of subject-matter expertise. However, commenters also noted that managing multiple contracts may be difficult for small or resource-strapped hospitals, potentially limiting their involvement in quality improvement activities.

Response: We appreciate the support for separating some QIO functions to allow for QIO development of specialized expertise and will take this comment into consideration when developing the details in our RFPs. We also understand that working with multiple QIOs may be difficult, and we will include national coordination of QIO tasks through NCCs to aid providers in navigating the QIO contract structure.

Comment: One commenter stated that it is essential to quality improvement initiative work to have a local presence and understand contextual factors such as pressures and incentives of the community and its circumstances. Another commenter stated that the planned changes would make QIOs less focused on quality improvement at the community level and less able to forge partnerships with providers and patients to address challenges.

Response: We agree with the importance of a local presence as a means to forge important partnerships with providers and beneficiaries. We intend to spell out these requirements in detail in the RFPs. We believe that our intent is made clear in § 475.103 of the regulations which states that in determining eligibility for performing quality improvement initiatives, we will take into consideration “the organization’s proposed involvement of and access to physicians and practitioners in the QIO area with the appropriate expertise and specialization in the areas of health care concerning the quality improvement initiative” and that paragraph (b) permits us to consider the geographic location of a QIO as necessary. Our intent is to put in place safeguards to ensure there is local involvement during quality improvement initiatives. Although case review concerns care that was given at one specific place, quality improvement initiatives may address national or regional issues. We would like to reiterate that these characteristics are not an exhaustive list and that these factors can be considered in each procurement as necessary.

Commenters on the proposed revisions to § 475.102 and § 475.103 also raised the topic of objectivity and impartiality of the QIO. These public comments are addressed above in connection with the general eligibility requirements in § 475.101.

After consideration of the public comments we received, we are adopting proposed §§ 475.102 and 475.103 as final, with modifications. We are finalizing paragraph (a)(3) of § 475.102 with the addition of “local” to the list of characteristics that an organization must be able to take into consideration. We also are making minor revisions to the proposed text in finalizing § 475.103: (1) to change the wording in § 475.103(a)(2) and (a)(3) in order to mirror the language in § 475.102(a)(2) and to avoid any inadvertent ambiguity as to whether these provisions will be interpreted consistently; (2) to make technical edits to the text of § 475.103(a)(2) and (a)(3) to change “initiative” to “initiatives” and “methodologies” to “methodology” to improve readability of these paragraphs; (3) to create § 475.103(a)(4) to reorganize how we have included access to qualified information technology expertise as a factor; and (4) to revise § 475.103(b) to specify that CMS may consider whether quality improvement initiative experience “achieved successful results.”

c. Prohibitions on Eligibility as a QIO (§§ 475.105 and 475.106)

In the CY 2014 OPPS/ASC proposed rule (78 FR 43677), we proposed revisions to § 475.105(a)(2) to eliminate the prohibition against an association of health care facilities being awarded a QIO contract, to reflect a TAAEA amendment deleting this restriction from section 1153(b)(3) of the Act. We also proposed to move the existing provision covering the exclusion of health care facility affiliates in paragraph (a)(3) to paragraph (a)(2), and to create a revised paragraph (a)(3) that would include payor organizations as excluded entities unless they meet certain exception requirements identified in section 1153(b)(2)(B) of the Act. Prior to the TAAEA amendment, the statute imposed two prohibitions on CMS contracting with a payor organization to perform QIO functions: A prohibition applicable before November 15, 1984 and a prohibition with exceptions for periods of time after November 15, 1984. After November 15, 1984, a payor organization could perform as a QIO if the Secretary determined that there were no other entities available for a QIO area. These restrictions were implemented in the existing regulations codified at §§ 475.105(b) and 475.106. The TAAEA amendments left unchanged the prohibition in effect for the period of time before November 15, 1984, but revised section 1153(b)(2)(B) of the Act to add exceptions to the prohibition applicable after November 15, 1984. Section 1153(b)(2)(B) of the Act, as amended, permits the award of a QIO contract to a payor organization not only when the Secretary determines that there is no other entity available for an area, but also when the Secretary determines that there is a more qualified entity to perform one or more of the functions in section 1154(a) of the Act, if the entity meets all other requirements and standards in the QIO statute. We read this provision to mean that, when the Secretary determines that a payor organization is more qualified than a nonpayor organization in the QIO area to perform one or more of the functions in section 1154(a) of the Act, the payor entity can qualify as a QIO so long as all other eligibility criteria are met. We reflected this interpretation in the proposed rule as § 475.105(a)(3). As discussed in section XVII.C.4.a. of this final rule with comment period, after consideration of the public comments we received, we also are revising the final requirement under § 475.101(d) to impose a general objectivity requirement for all QIOs. In addition to

that, under § 475.105(a)(3), we are finalizing specific provisions for payor organizations that serve as QIOs which state that any payor organization meeting these requirements (now broken out and specified in § 475.105(a)(3)(i)) must also demonstrate to CMS' satisfaction that "in performing QIO activities," the payor organization will act with complete objectivity and independence from its payor program (now specified in § 475.105(a)(3)(ii)).

The existing paragraph (b) of § 475.105 prohibits payor organizations from being QIOs prior to November 15, 1984. Since that date has long passed, we believe this paragraph should be eliminated. We proposed to delete and reserve paragraph (b) of § 475.105 in its entirety. Paragraph (c) was proposed to remain largely unchanged except for a minor terminology update to clarify in the regulation text that the term "facility" is meant to refer to a "health care facility" and to change the term "conduct any review activities" to "perform any case review activities" to indicate our separation of case review functions from quality improvement initiatives. We stated that we do not believe that these proposed changes affect the underlying substance of the prohibitions.

As noted above, we proposed to delete and reserve all of § 475.106 in light of our proposed changes to § 475.105. We noted our belief that aspects of § 475.106 that we have not proposed to incorporate into § 475.105 are obsolete due to the passage of time.

Comment: Some commenters believed that health care affiliates should not conduct case reviews of health care facilities in the QIO area but also believed health care facility affiliates may be excellent organizations to lead the quality improvement functions of QIOs as evidenced through the achievements made through the HEN initiative. Therefore, the commenters requested that CMS revise the language of the proposed changes in the final rule so that health care facility affiliates would be eligible for QIO contracts that focus on quality improvement efforts. In addition, the commenters indicated that if CMS were not to make this suggested revision, then CMS would preclude some of the entities with whom CMS currently partners under the HEN initiative from becoming QIO contractors.

Response: We believe that implementing the additional flexibilities granted by the changes in the statute will improve the QIO Program. However, based on the authority being adopted with the revisions to §§ 475.101 through 475.103, we will cautiously

make changes that have been tested and that have appropriate safeguards to protect against any real or perceived conflict of interest among QIOs, providers, and beneficiaries. Section 1153(b)(3) of the Act expressly prohibits a health care facility or an affiliate of a health care facility from serving as a QIO in the area within the area served by the facility. The statute also specifies when an organization will not be considered to be affiliated with a health care facility in connection with this prohibition. We believe that the restriction under section 1153(b)(3) of the Act prohibits CMS from entering into QIO contracts with health care affiliates, as reflected in this final rule, means that some current quality contractors (such as some HENs participating in the Partnership for Patients initiative, for example) may not qualify as QIOs.

After consideration of the public comment we received, we are adopting, as final, proposed revised § 475.105 with one modification: We are adding language under paragraph (a)(3) and, in the process, splitting some of the text in paragraph (a)(3) into two paragraphs (i) and (ii), to specify that a payor organization will be considered ineligible for QIO contracts unless a payor organization is a more qualified entity to perform one or more of the functions of a QIO described in § 475.101(b), meets all the other requirements and standards of the part, and demonstrates to the satisfaction of CMS that, "in performing QIO activities, the payor organization will act with complete objectivity and independence from its payor program."

5. QIO Contract Awards (§ 475.107)

The existing regulations at 42 CFR Part 475 include requirements related to the establishment of QIO contracts and the assignment of bonus points. We proposed to delete the portions of existing § 475.107(c) pertaining to the assignment of up to 10 percent of available bonus points to physician-sponsored organizations, and the assignment of points in connection with the structure of the organization as "physician-sponsored" or "physician-access" because these provisions are obsolete in light of the changes to section 1152(1) of the Act and our proposals relating to the eligibility standards for an organization awarded a QIO contract. We also proposed to use cross-references in § 475.107(a) and (b) to the revised standards we proposed in §§ 475.101 through 475.103. We proposed to retain the regulatory language that requires CMS to identify proposals that meet the requirements of

§ 475.101 (proposed § 475.107(a)) and to identify those proposals that set forth minimally acceptable plans in accordance with the requirements of § 475.102 or § 475.103, or both as applicable (proposed § 475.107(b)).

In addition, we proposed to revise the regulatory language addressing the length of QIO contracts. The existing § 475.107(d) states that the contract for a given QIO area to the selected organization cannot exceed 2 years, which is inconsistent with the current statutory provision at section 1153(c)(3) of the Act. We proposed to redesignate this provision as paragraph (c) and to provide for a 5-year contract term as required by section 1153(c)(3) of the Act, as amended by section 261 of the TAAEA.

We received public comments related to these topics and discuss them below.

Comment: Some commenters stated that CMS' proposal that QIO contract awards be based on the selection of an organization from all proposals that set forth minimally acceptable plans may be construed to limit the contract award determination to a "lowest price technically acceptable standard" (LPTA). In addition, the commenters discouraged CMS from applying LPTA evaluation criteria and proposed that CMS continue its current policies and make selection based on a determination of best value using a "tradeoff" evaluation process in which technical quality is the primary consideration and all other evaluation factors are more important than cost/price.

One commenter also noted that ensuring the highest quality services should be considered the ultimate criterion in selecting a quality improvement organization. Another commenter noted the value of LPTA procurements, but suggested that, if CMS applies this approach to case reviews, it define "technically acceptable" to ensure adequate quality because ensuring the highest quality services should be considered the ultimate criterion in selecting a case review QIO. Some commenters further suggested that CMS clarify the proposed changes pertaining to past performance because they believed that, in the context of lowest price technically acceptable, an offeror whose experience is "unknown" is considered "acceptable" for contract award. These commenters asserted that CMS' proposed changes (to use lowest price technically acceptable and consider past performance) are conflicting and reiterates that, if prior experience/past performance is important, lowest price

technically acceptable bids are not an acceptable evaluation criterion.

Response: Although these commenters generally identified §§ 475.101, 475.102 and 475.103 as the basis for the comments, we discuss these comments here because they also address concerns about the process we proposed in § 475.107 for how to conduct the procurement for QIO contracts. Part of our proposal was meant to establish the “minimum level of resources and skills” that an organization must have in order to demonstrate its capability to perform as a QIO and we proposed at § 475.107(a) and (b) that CMS identify the proposals that meet the standards described in §§ 475.101 through 475.103. However, we did not intend for the factors listed in those sections to be the only criteria in our evaluation of organizations requesting QIO contracts or the ultimate decision to award a QIO contract. In addition to the minimum requirements listed in § 475.101, other standards we included in other sections are examples of the factors we may use and should not be interpreted as an exhaustive list.

We do not intend to change our evaluation methodology to begin using the lowest price technically acceptable standard and did not intend our proposal to suggest that. We will continue our current practice of making a selection based on a determination of best value that takes into consideration both technical quality and price. As the contracting process is a public one, with administrative processes for questions to be asked and answered, protests to be filed and addressed, and subject to oversight, we are confident that organizations applying to receive QIO contracts will be adequately informed of the evaluation criteria and methods used to award contracts and that it is in the best interest of the QIO Program for the regulatory standards to be flexible.

We are finalizing text at § 475.107(a) that we believe more clearly communicates that CMS will ensure compliance with the minimum standards described in §§ 475.101 through 475.105 without suggesting that CMS will award contracts to every entity that meets those minimum requirements. The text finalized in this final rule at § 475.107 makes it clear that CMS will ensure that all QIO awardees meet the requirements of §§ 475.101 through 475.103, subject to the restrictions at § 475.105. In addition, we believe that the text as finalized preserves the statutory flexibility provided for the contracting process consistent with the intent underlying our proposal. The finalized regulation at § 475.107(a) will ensure that QIO

contract awardees meet the requirements of §§ 475.101, 475.102, and 475.103, as applicable and subject to the prohibitions in § 475.105.

Comment: Many commenters supported CMS’ proposed changes of extending the contracting period from 3 years to 5 years. Some commenters stated that this proposal may allow for an improvement in the QIO’s review activities through sustained data collection. In addition, these commenters indicated that this proposed change would provide more time to focus on the assigned tasks rather than the demands of the contracting cycle.

One commenter stated that it would be prudent for CMS in awarding a contract to a new QIO organizational type to consider awarding a 2-year contract with 3 optional 1-year expansions in order to be certain that the new QIO organization is capable of performing the tasks in an acceptable manner.

Response: We appreciate the commenters’ support of the change in contract term to 5 years. We agree that the 5-year contract cycle will allow CMS and the QIOs to have a meaningful portion of the contract term to concentrate on program work and the assigned tasks rather than preparing for contract transition. We acknowledge the commenter’s suggestion that a shorter base period with option years may allow for us to make contract changes if a new organization is having difficulty with the contract requirements. However, section 1153(c)(3) of the Act requires that the contract “shall be for an initial term of five years and shall be renewable for terms of five years thereafter.” Therefore, we are finalizing the proposed language that extends the QIO contract term to 5 years.

After consideration of the public comments we received, we are adopting, as final, proposed § 475.107 with modifications. We are revising § 475.107 to make the language more succinct and to avoid any misinterpretation that this section might somehow restrict contracting procedures or otherwise limit the Agency’s flexibility. Further, we are finalizing, at paragraph (b) instead of at paragraph (c), the proposed language for the length of QIO contracts.

XVIII. Final Rule: Medicare Fee-for-Service Electronic Health Record (EHR) Incentive Program

A. Incentive Payments for Eligible Professionals (EPs) Reassigning Benefits to Method II CAHs

Section 1848(o)(1)(A) of the Act, as amended by section 4101(a) of the

HITECH Act, establishes the Medicare EHR Incentive Program, which provides for incentive payments to eligible professionals (EPs) who are meaningful users of certified EHR technology during the relevant EHR reporting periods. Section 1848(o)(1)(A)(i) of the Act provides that EPs who are meaningful EHR users during the relevant EHR reporting period are entitled to an incentive payment amount, subject to an annual limit, equal to 75 percent of the Secretary’s estimate of the Medicare allowed charges for covered professional services furnished by the EP during the relevant payment year. Under section 1848(o)(1)(B)(ii) of the Act, an EP is entitled to an incentive payment for up to 5 years. In addition, in accordance with section 1848(o)(1)(A)(ii) of the Act, there shall be no incentive payments made with respect to a year after 2016.

1. Background for Definition of EPs and EHR Incentive Payments to EPs

In accordance with section 1848(o)(5)(C) of the Act, in the final rule for Stage 1 of the EHR Incentive Program (75 FR 44442), we established a definition of the term “eligible professional” in the regulations at 42 CFR 495.100 to mean a physician as defined under section 1861(r) of the Act. Section 1861(r) of the Act defines the term “physician” to mean the following five types of professionals, each of which must be legally authorized to practice their profession under State law: A doctor of medicine or osteopathy; a doctor of dental surgery or dental medicine; a doctor of podiatric medicine; a doctor of optometry; or a chiropractor. As also discussed in that final rule (75 FR 44439), in accordance with section 1848(o)(1)(C) of the Act, hospital-based EPs are not eligible for an EHR incentive payment. The term “hospital-based EP” is defined in § 495.4 of the regulations as “Unless it meets the requirements of § 495.5 of this part, a hospital-based EP means an EP who furnishes 90 percent or more of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting in the year preceding the payment year, or in the case of a payment adjustment year, in either of the 2 years before such payment adjustment year.” Paragraphs (1)(i) and (1)(ii) of the definition specify how the percentage of covered professional services is calculated for Medicare for purposes of the payment years and payment adjustment years, respectively. We note a discrepancy between the regulation text for this definition and

the final policy we established in the preamble of the EHR Incentive Program Stage 2 final rule (77 FR 54102). Under the policy we finalized in that rule, we determine whether an EP is hospital-based for a payment adjustment year using either of the following Federal fiscal year's (FY) data: (1) The fiscal year before the year that is 1 year prior to the payment adjustment year (for example, FY 2013 data for payment adjustment year 2015); or (2) the fiscal year before the year that is 2 years prior to the payment adjustment year (for example, FY 2012 data for payment adjustment year 2015). If the data from either year result in a hospital-based determination, the EP would not be subject to the payment adjustments for the relevant year. In the definition under § 495.4 of the regulations, however, paragraph (1)(ii) incorrectly refers to the fiscal year preceding the payment adjustment year and the fiscal year 2 years before the payment adjustment year. The introductory text of the definition also incorrectly references either of the 2 years before such payment adjustment year. In the CY 2014 OPPI/ASC proposed rule (78 FR 43678), we indicated that we were taking this opportunity to make a technical correction to paragraph (1)(ii) and the introductory text of the definition of "hospital-based EP" at § 495.4 to conform to the policy stated in the preamble of the EHR Incentive Program Stage 2 final rule (77 FR 54102). We proposed to revise paragraph (1)(ii)(A) of the definition to read "The Federal fiscal year 2 years before the payment adjustment year; or" and paragraph (1)(ii)(B) of the definition to read "The Federal fiscal year 3 years before the payment adjustment year." We also proposed to revise the introductory text of the definition to reference, in the case of a payment adjustment year, either of the 2 years before the year preceding such payment adjustment year.

We did not receive any public comments on our proposal to make these technical corrections to the definition of "hospital-based EP" in § 495.4 of the regulations. Therefore, we are finalizing these technical corrections as proposed. Specifically, (1) paragraph (1)(ii)(A) of the definition of "hospital-based EP" in § 495.4 is revised to read "The Federal fiscal year 2 years before the payment adjustment year; or" and paragraph (1)(ii)(B) of the definition is revised to read "The Federal fiscal year 3 years before the payment adjustment year."; and (2) the introductory text of the definition is revised to reference, in the case of a payment adjustment year, either of the 2 years before the year

preceding such payment adjustment year.

Section 1848(o)(5)(A) of the Act defines covered professional services as having the same meaning as in section 1848(k)(3) of the Act; that is, services furnished by an eligible professional for which payment is made under, or is based on, the Medicare Physician Fee Schedule (MPFS). In accordance with section 1848(a)(1) of the Act, the Medicare allowed charge for covered professional services is the lesser of the actual charge or the MPFS amount established in section 1848 the Act. As specified under section 1848(o)(1)(A)(i) of the Act, the Secretary's estimate of allowed charges for EHR incentive payments is based on claims submitted to Medicare no later than 2 months following the end of the relevant payment year.

Section 1848(o)(1)(B)(i) of the Act sets forth the annual limits on the EHR incentive payments to EPs. Specifically, section 1848(o)(1)(B) of the Act provides that the incentive payment for an EP for a given payment year shall not exceed the following amounts:

- For the EP's first payment year, for such professional, \$15,000 (or \$18,000, if the EP's first payment year is 2011 or 2012);
- For the EP's second payment year, \$12,000;
- For the EP's third payment year, \$8,000;
- For the EP's fourth payment year, \$4,000;
- For the EP's fifth payment year, \$2,000; and
- For any succeeding year, \$0.

Under section 1848(o)(1)(B)(iv) of the Act, for EPs who predominantly furnish services in a geographic HPSA (as designated by the Secretary under section 332(a)(1)(A) of the Public Health Service Act), the incentive payment limitation amounts for each payment year are increased by 10 percent. Section 1848(o)(1)(B)(iii) of the Act also provides for a phased reduction in payment limits for EPs who first demonstrate meaningful use of certified EHR technology after 2013. Section 1848(o)(1)(D)(i) of the Act, as amended by section 4101(a) of the HITECH Act, provides that the incentive payments may be disbursed as a single consolidated payment or in periodic installments as the Secretary may specify. We make a single, consolidated, annual incentive payment to EPs. Payments are made on a rolling basis, as soon as we ascertain that an EP has demonstrated meaningful use for the applicable reporting period (that is, 90 days for the first year or a calendar year

for subsequent years), and reached the threshold for maximum payment.

Section 1848(o)(1)(A) of the Act provides that "with respect to covered professional services provided by an eligible professional," the incentive payment "shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6))." Section 1842(b)(6)(A) of the Act allows for reassignment of payments to an employer or entity with which the physician has a valid contractual arrangement allowing the entity to bill for the physician's services. Therefore, we provided that EPs would be allowed to reassign their incentive payments to their employer or an entity that they have a valid employment agreement or contract providing for such reassignment, consistent with all rules governing reassignments (75 FR 44445). Section 495.10(f) of the regulations permits EPs to reassign their incentive payments to an employer or to an entity with which they have a contractual arrangement, consistent with all rules governing reassignments, including 42 CFR Part 424, Subpart F. Section 495.10(f) also precludes an EP from reassigning the incentive payment to more than one employer or entity. To implement this requirement, we use the EP's Medicare enrollment information to determine whether an EP belongs to more than one practice (that is, whether the EP's National Provider Identifier (NPI) is associated with more than one practice). In cases where an EP is associated with more than one practice, the EP would select one tax identification number to receive any applicable EHR incentive payment.

2. Special Circumstances of EPs Reassigning Benefits to Method II CAHs

Since we implemented the EHR Incentive Program, we have received many requests from CAHs billing under Method II (Method II CAHs), members of Congress, and hospital associations requesting that we make it possible for EPs who assign their reimbursement and billing to a Method II CAH to participate in the program. Under section 1834(g)(2) of the Act, a CAH may elect to receive a cost-based payment for the facility costs of providing outpatient services, plus 115 percent of the fee schedule amount for professional services included within outpatient CAH services. CAHs that elect to receive both a facility payment and a professional payment for outpatient services are commonly referred to as Method II CAHs. The statute also provides that, as a condition for applying this provision, the

Secretary may not require that each physician or other practitioner providing professional services in a CAH must assign billing rights for such services to the CAH. Physicians and other practitioners who do not assign such rights to their Method II CAH continue to receive payment for their professional services directly under the appropriate professional fee schedule.

Since the inception of the EHR Incentive Program, we have been unable to account for the services furnished by EPs in Method II CAH outpatient departments (including emergency departments) due to limitations in our information systems. Specifically, our information systems have not been capable of receiving and storing line-level rendering EP identifying information for these Method II CAH claims for services furnished by EPs in outpatient departments. These claims are billed by the CAH on behalf of the EPs furnishing the services using the institutional claim form UB-04 or its electronic counterpart, the X12 837I format. Until a recent information systems change was implemented, we were unable to identify the NPI of the EP furnishing the service at the service line-level on the claim. While the information systems received and stored NPIs from each claim, the NPIs were not tied to the specific services furnished on the claim. This limitation made it impossible to take into account the services furnished by EPs in Method II CAH outpatient settings when we annually determined the hospital-based status of each EP for each payment year for purposes of the EHR Incentive Program. In addition, for those EPs who were determined to be not hospital-based and who successfully demonstrated meaningful use, we were unable to take into account such services in calculating the amount of an EP's EHR incentive payment for a payment year. Because the limitations in our information systems prevented us from identifying the NPIs of the EPs who furnished the services on the Method II CAH claims, we were unable to include those claims for purposes of the hospital-based determinations and EHR incentive payment calculations. However, it is important to note that these EPs could still participate in the EHR Incentive Program and qualify for an incentive payment based on their non-Method II CAH claims.

We began soon after the implementation of the EHR Incentive Program to develop the requisite changes so that our information systems would be able to receive and store line-level rendering EP identifying information for these Method II CAH

claims. We were able to implement these information systems changes effective for claims submitted on or after October 1, 2012 (in other words, on or after the start of FY 2013). Under the existing regulations at § 495.4, we determine an EP's hospital-based status for a payment year based on claims data from the fiscal year preceding the payment year. Thus, for purposes of the 2013 payment year, we determine whether an EP is hospital-based using claims data from FY 2012. However, as noted above, we are unable to take into account Method II CAH claims prior to the start of FY 2013. As a result, under the existing regulations, the hospital-based determinations for EPs for the 2013 payment year are based on FY 2012 claims data that do not include Method II CAH claims. The earliest that we would be able to include such claims under the existing regulations would be for the hospital-based determinations for the 2014 payment year, which are based on FY 2013 claims data.

As we discussed in the CY 2014 OPPI/ASC proposed rule (78 FR 43679), we want to avoid further delay in taking into account the services furnished by EPs in Method II CAH outpatient settings. Therefore, we proposed to add a provision to the definition of "hospital-based EP" at § 495.4 under new paragraph (3) to provide a special methodology for making hospital-based determinations for the 2013 payment year for EPs with services billed by Method II CAHs. We made this proposal solely in order to take into account the special circumstances of those EPs as described above. We stated that, under this proposal, we would be able to take into account Method II CAH claims when making hospital-based determinations for payment year 2013, one year before we would be able to do so under the existing regulations. Specifically, we proposed that, for payment year 2013 only, we would use a two-step process to make hospital-based determinations for EPs who furnish covered professional services billed by Method II CAHs. First, after we have accumulated the Method II CAH claims with the line-level furnishing EP identifying information for FY 2013 (October 1, 2012 through September 30, 2013), we would use that data to identify which EPs had Method II CAH service billings during that year, and we would make a special hospital-based determination for that subset of EPs for payment year 2013. Any EP determined to be nonhospital-based on the basis of FY 2013 claims data would be eligible to demonstrate meaningful use for the

relevant EHR reporting period and potentially qualify for an EHR incentive payment for payment year 2013. We indicated in the proposed rule that an EP who believes that he or she would be determined to be nonhospital-based under this proposed provision and wishes to qualify for the EHR incentive payment for payment year 2013 should not wait for the determination to implement Certified EHR Technology and begin meaningful use for an EHR reporting period in 2013. To qualify for an EHR incentive payment for payment year 2013, an EP will need to demonstrate meaningful use of Certified EHR Technology for an EHR reporting period in 2013. As is the case with other EPs that reassign their EHR incentive payments to another entity, these EPs may reassign their EHR incentive payments to the Method II CAH that bills on their behalf if the CAH is an employer or they have a contractual arrangement, consistent with the rules governing reassignments. Second, in the case of an EP determined to be hospital-based on the basis of FY 2013 claims data, we would check the hospital-based determination we have already for that EP under the existing regulation using the FY 2012 file. Any EP found to be nonhospital-based on the basis of the FY 2012 claims data (which do not include Method II CAH claims) would be held harmless to the determination made on the basis of FY 2013 claims data and considered nonhospital-based for payment year 2013. We believe that this second step of the proposed methodology is important to protect EPs who were initially determined nonhospital-based at the beginning of payment year 2013 under the existing regulation. We do not believe those EPs who were determined nonhospital-based under the existing regulation should have those determinations reversed by later (although more complete) FY 2013 claims data. This hold-harmless provision would preserve the prospectivity of nonhospital-based determinations for payment year 2013 that were made under the existing regulation and maintain the eligibility of those EPs to receive EHR incentive payments for payment year 2013. At the same time, the first step of our proposal would provide an opportunity for EPs who were determined to be hospital-based for payment year 2013 on the basis of FY 2012 data, which did not include the Method II CAH claims for their services, to establish their nonhospital-based status on the basis of the more complete FY 2013 data. We stated that it was important to note that, due to the systems limitations described

above, we were unable to propose any special method for making EHR incentive payments and hospital-based determinations for the payment years prior to payment year 2013. We lacked the ability to retrieve line-level furnishing EP identifying information for Method II CAH claims during the years prior to FY 2013. We invited public comments on this proposal.

Comment: Commenters were uniformly in favor of the proposal. Specifically, the commenters stated that they appreciated the agency's proposal to allow physicians who provide services in the outpatient departments of CAHs and have their services billed by the CAH under Method 2 to participate in the EHR incentive program in 2013. While the commenters noted that it is unfortunate that CMS' information systems have, until now, unfairly prevented these physicians from participating in the EHR Incentive Program because they could not use data from the UB-04 claims to identify services provided by the physician, they urged CMS to adopt both the proposed approach to identifying eligible physicians using 2013 claims data submitted on the UB-04 and the proposed hold harmless policy for those physicians who are determined to be eligible using the 2012 data, but not the new 2013 data. They also urged CMS to act as quickly as possible to provide detailed guidance on how physicians can take advantage of this policy change.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal concerning hospital-based determinations for certain EPs for the 2013 payment year. We will move as quickly as possible to provide detailed guidance on how EPs can take advantage of this policy change and to educate rural providers accordingly.

We are finalizing our proposal, without modification, to add a provision to the definition of "hospital-based EP" at § 495.4 under new paragraph (3) to provide a special methodology for making hospital-based determinations for the 2013 payment year for EPs with services billed by Method II CAHs. For payment year 2013 only, we will use a two-step process to make hospital-based determinations for EPs who furnish covered professional services billed by Method II CAHs.

First, after we have accumulated the Method II CAH claims with the line-level furnishing EP identifying information for FY 2013 (October 1, 2012 through September 30, 2013), we

will use that data to identify which EPs had Method II CAH service billings during that year, and we will make a special hospital-based determination for that subset of EPs for payment year 2013. Any EP determined to be nonhospital-based on the basis of FY 2013 claims data will be eligible to demonstrate meaningful use for the relevant EHR reporting period and potentially qualify for an EHR incentive payment for payment year 2013. As we indicated in the proposed rule, an EP who believes that he or she would be determined to be nonhospital-based under this proposed provision and wishes to qualify for the EHR incentive payment for payment year 2013 should not wait for the determination to implement Certified EHR Technology and begin meaningful use for an EHR reporting period in 2013. To qualify for an EHR incentive payment for payment year 2013, an EP will need to demonstrate meaningful use of Certified EHR Technology for an EHR reporting period in 2013. As is the case with other EPs that reassign their EHR incentive payments to another entity, these EPs may reassign their EHR incentive payments to the Method II CAH that bills on their behalf if the CAH is an employer or they have a contractual arrangement, consistent with the rules governing reassignments.

Second, in the case of an EP determined to be hospital-based on the basis of FY 2013 claims data, we will check the hospital-based determination we have already for that EP under the existing regulation using the FY 2012 file. Any EP found to be nonhospital-based on the basis of the FY 2012 claims data (which do not include Method II CAH claims) will be held harmless to the determination made on the basis of FY 2013 claims data and considered nonhospital-based for payment year 2013.

B. Cost Reporting Periods for Interim and Final EHR Incentive Payments to Eligible Hospitals

1. Background

In the July 28, 2010 final rule for Stage 1 of the EHR Incentive Program, we established the cost report periods from which we would draw the requisite data (for example, hospital acute care inpatient discharges and Medicare Part A acute care inpatient days) for determining interim and final EHR incentive payments to eligible hospitals (75 FR 44450). We specified in § 495.104(c)(2) of the regulations that we would use discharge and other relevant data from the hospital's most recently submitted 12-month cost report in order

to determine preliminary hospital EHR incentive payments. Similarly, we specified in § 495.104(c)(2) that we would make final EHR incentive payments to hospitals based on discharge and other relevant data from the hospital's first 12-month cost reporting period that begins on or after the first day of the payment year. (For purposes of EHR incentive payments for eligible hospitals, a payment year is a Federal fiscal year.) As we noted in the final rule (75 FR 44450 through 44451), section 1886(n)(2)(C) of the Act requires that a "12-month period selected by the Secretary" be employed for purposes of determining the discharge related amount. As we also stated in that final rule (77 FR 44452), we believe that the requirement for using 12-month cost reporting periods for purposes of determining preliminary and final payments is important to avoid the use of nonstandard cost reporting periods, which are often quite short (for example, 3 months) and therefore are "not likely to be truly representative of a hospital's experience, even if methods were to be adopted for extrapolating data over a full cost reporting period."

2. Special Circumstances

As we discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 43680), since the publication of the EHR Incentive Program final rule for Stage 1, we have become aware of circumstances in which the only cost reporting period for an eligible hospital that begins on or after the first day of a payment year is a nonstandard cost reporting period. For example, a hospital may be merging with another hospital under an arrangement in which its CCN, and therefore its existence as an identifiable hospital for Medicare EHR Incentive Program purposes, will not survive the merger. In such circumstances, the last cost reporting period for the hospital after its final payment year and prior to its merger into the surviving hospital may be a short period. In order to accommodate these situations, we proposed to revise § 495.104(c)(2) of the regulations to provide that, in cases where there is no 12-month cost reporting period that begins on or after the beginning of a payment year, we will use the most recent 12-month cost reporting period available at the time of final settlement in order to determine final EHR incentive payments for the hospital. We stated that we understood that, under this proposal, the last available cost reporting period that we would use for the final determination of EHR incentive payments may be the same 12-month cost reporting period that had been used for purposes of

determining the hospital's interim EHR incentive payments. We believe that this result is preferable to resorting to a nonstandard cost reporting period because a 12-month period is required by the statute to determine the discharge related amount and such periods tend, for reasons discussed in the EHR Incentive Program Stage 1 final rule, to be unrepresentative of the hospital's experience. We invited public comments on this proposal.

Comment: One commenter supported the proposal.

Response: We appreciate the commenter's support.

After consideration of the public comment we received, we are finalizing, without modification, the proposed revision to § 495.104(c)(2) of the regulations to provide that, in cases where there is no 12-month cost reporting period that begins on or after the beginning of a payment year, we will use the most recent 12-month cost reporting period available at the time of final settlement in order to determine final EHR incentive payments for the hospital.

XIX. Medicare Program: Provider Reimbursement Determinations and Appeals: Final Rule

A. Matters Not Subject to Administrative or Judicial Review (§ 405.1804)

1. Background

Section 1878(a) of the Act addresses appeals of certain Medicare payment determinations to the Provider Reimbursement Review Board (the "Board"). Below we briefly discuss the prospective payment system (PPS) under which payments for certain Medicare inpatient hospital services are made.

The Social Security Amendments of 1983 (Pub. L. 98–21) added section 1886(d) to the Act, which changed the method of payment for inpatient hospital services under Medicare Part A for short-term acute care hospitals. The method of payment for these hospitals was changed from a cost-based retrospective reimbursement system to a system based on prospectively set payment rates; that is, a PPS. Under Medicare's hospital inpatient prospective payment system (the hospital IPPS), payment is made at a predetermined rate for each hospital discharge.

The Social Security Amendments of 1983 also added section 1886(e)(1) to the Act, which required that, for cost reporting periods beginning in FYs 1984 and 1985, the IPPS result in aggregate program reimbursement equal to "what

would have been payable" under the reasonable cost-based reimbursement provisions of prior law; that was, for FYs 1984 and 1985, the IPPS would be "budget neutral." Section 1886(e)(1)(A) of the Act required that the projected aggregate payments for the hospital-specific portion should equal the comparable share of estimated reimbursement under prior law. Section 1886(e)(1)(B) of the Act required that projected aggregate reimbursement for the Federal portion of the prospective payment rates equal the corresponding share of estimated amounts payable prior to the passage of Pub. L. 98–21. In the 1983 IPPS interim final rule published in the **Federal Register** on September 1, 1983, we explained how the adjustment of the Federal portion of the prospective payment rate was determined, as well as the resulting adjustment factors for FY 1984 (48 FR 39887).

Under section 1878 of the Act and the regulations at Subpart R of 42 CFR Part 405, the Board has the authority to adjudicate certain reimbursement appeals by providers. The Board's decisions are subject to review by the Administrator of CMS under section 1878(f)(1) of the Act, as implemented by § 405.1875 of the regulations. A final decision of the Board, or any reversal, affirmance, or modification of a final Board decision by the Administrator, may be subject to review by a United States District Court.

2. Technical Conforming Change

As we discussed in the CY 2014 OPPTS/ASC proposed rule (78 FR 43680 through 43681), certain matters affecting payment to hospitals under the IPPS are not subject to administrative or judicial review. For example, section 1886(d)(7) of the Act precludes administrative and judicial review of the budget neutrality adjustment effected pursuant to section 1886(e)(1) of the Act. This preclusion of review is also reflected in section 1878(g)(2) of the Act (which states that "determinations and other decisions described in section 1886(d)(7) shall not be reviewed by the Board or any other court. . . ."). The existing regulatory text at § 405.1804(a) provides that there is no administrative or judicial review of "any budget neutrality adjustment in the prospective payment rates."

The language of § 405.1804(a) was promulgated as part of the implementing regulations (48 FR 39785 and 39835) for the hospital IPPS. Section 405.1804(a) was codified pursuant to section 1886(d)(7) of the Act. At the time of promulgation, section 1886(d)(7) of the Act specified only the budget neutrality adjustment in

section 1886(e)(1) of the Act. Additional budget neutrality adjustments under the IPPS were added by law and were not precluded from administrative or judicial review. For example, section 4410 of the Balanced Budget Act of 1997 (the BBA), Pub. L. 105–33, established the rural floor wage index budget neutrality adjustment, and did not preclude administrative or judicial review in the statute for this adjustment.

As we stated in the CY 2014 OPPTS/ASC proposed rule, we recognize that the language of the regulation at § 405.1804(a) is overly broad because it states that there is no administrative or judicial review of "any" budget neutrality adjustment in the prospective payment rates, and its terms are not limited to the budget neutrality adjustment specified in section 1886(e)(1) of the Act. We understand that the Board has relied on § 405.1804(a) to deny jurisdiction in appeals relating to budget neutrality adjustments other than the adjustment in section 1886(e)(1) of the Act. To the extent that the existing § 405.1804(a) refers to "any" budget neutrality adjustment, we believe that this regulatory text is not consistent with the current statute. Therefore, in the CY 2014 OPPTS/ASC proposed rule (78 FR 43681), we proposed to make a technical conforming change to § 405.1804(a) to conform the regulation to the current statute. This technical conforming change clarifies that there is no administrative or judicial review with respect to the budget neutrality adjustments enumerated in section 1886(e)(1) of the Act, and this preclusion of review does not apply to other budget neutrality adjustments under the IPPS.

We did not receive any public comments on this proposed technical conforming change. Therefore, for the reasons set out in the proposed rule, we are finalizing the proposed revisions to § 405.1804(a) without modification.

B. Clarification of Reopening of Predicate Facts in Intermediary Determinations of Provider Reimbursement (§ 405.1885)

A provider must submit an annual cost report to a fiscal intermediary (currently referred to as a Medicare Administrative Contractor (MAC)), as specified in regulations at 42 CFR 413.20(b) and 413.24(f). Through its review and settlement process, the intermediary determines the total amount of reimbursement due to a provider for its cost reporting period. This constitutes an "intermediary determination," as defined in § 405.1801(a). In accordance with

§ 405.1803, an intermediary determination is set forth in a notice of program reimbursement (NPR), which explains the intermediary's final determination of the total amount of program reimbursement due to the provider for the cost reporting period in question.

Section 405.1803(b) requires that the NPR explain any differences between the intermediary determination and the amount of program reimbursement claimed by the provider. Such differences may be attributable to specific provisions of the Medicare statute, regulations, CMS rulings, or program instructions. In addition, the intermediary determination may reflect specific findings of fact by the intermediary that differ from the provider's understanding of the facts.

The factual underpinnings of a specific determination of the amount of reimbursement due to a provider sometimes first arise in, that is, the pertinent facts occur or start during, or are reported by the provider and determined by the intermediary for, the same fiscal period as the cost reporting period under review. For example, the determination of whether a hospital subject to the inpatient prospective payment system (IPPS) should receive a payment adjustment for serving a significantly disproportionate share of low-income patients under section 1886(d)(5)(F) of the Act and § 412.106 of the regulations in a given fiscal period depends on the number of the hospital's patient days for the same period.

However, the factual underpinnings of a specific determination of the amount of reimbursement due to a provider may first arise in, or be determined for, a different fiscal period than the cost reporting period under review. We refer to these factual determinations as "predicate facts." Some of the factual underpinnings of determinations of reasonable cost reimbursement under section 1861(v) of the Act are subject to review for each cost report in which the provider claims the cost under the general principle that "payment is to be made on the basis of current costs of the individual provider, rather than costs of a past period" (42 CFR 413.5(a)). For example, reimbursement for a provider's bad debts arising from unpaid Medicare deductibles and coinsurance may be denied under 42 CFR 413.89 in the first fiscal period it is claimed because the collection effort on the account has not ceased and the account cannot yet be deemed worthless. However, the same bad debt may be deemed allowable in the following fiscal period, when the collection effort has ceased and the

account has been determined to be worthless. Similarly, interest expense is subject to review each fiscal period to determine whether it is allowable for each fiscal period during the life of the loan (42 CFR 413.153).

Other "predicate facts" are determined once, either in the first fiscal period in which they arise or are first determined, or in the first fiscal period that they are used as part of a formula for reimbursement, and then applied as part of that reimbursement formula for several fiscal periods thereafter. These facts are not reevaluated annually to determine whether they support a determination that a particular cost is reasonable because the formula is a proxy for reasonable costs. Instead, the formula itself will provide for changes in costs through an updating factor or otherwise. For example, the determination of an IPPS-exempt hospital's target amount (that is, per-discharge (case) limitation) or rate-of-increase ceiling under section 1886(b) of the Act and regulations at § 413.40 depends on: (1) The hospital's allowable net inpatient operating costs for a base period of at least 12 months before the first cost reporting period subject to the rate-of-increase ceiling; or (2) for later cost reporting periods, the target amount for the preceding 12-month cost reporting period. The hospital's allowable costs for its base period are "predicate facts" with respect to the first cost reporting period that is subject to the target amount because such base period costs figure in the determination of the hospital's first target amount. The target amount for each cost reporting period after the base period itself is a "predicate fact" for the following cost reporting period. We refer readers to section 1886(b)(3)(A) of the Act (for the first period, the target amount is calculated using "allowable operating costs of inpatient hospital services for the preceding 12-month cost reporting period"; the target amount for later cost reporting periods is calculated using the target amount for the preceding 12-month cost reporting period, increased by an applicable update factor).

A provider may challenge an intermediary determination by filing an appeal within 180 days of the NPR to the Board (under section 1878(a) of the Act and regulations at § 405.1835) or, if the amount in controversy is at least \$1,000 but less than \$10,000, to the intermediary hearing officer(s) (under § 405.1811). Alternatively, in accordance with § 405.1885, the provider may request that the intermediary reopen its NPR. In addition, the intermediary may reopen

the NPR on its own motion. Under § 405.1885(b), reopening must be requested by the provider, or initiated on the intermediary's own motion, within 3 years of the NPR, although there is no time limit for the reopening of an intermediary determination that was procured by fraud or similar fault of a party to such determination.

Appeal and reopening of an intermediary determination are both "issue-specific." In order to meet the jurisdictional requirements for appeal to the Board or to the intermediary hearing officer(s), the provider must establish its dissatisfaction with each specific matter in the intermediary determination that is appealed. We refer readers to section 1878(a) of the Act and current regulations at §§ 405.1835(a)(1) and (b) (Board appeals) and §§ 405.1811(a)(1) and (b) (intermediary hearing officer appeals). Similarly, § 405.1885(a)(1) provides that the intermediary determination may be reopened "for findings on matters at issue in a determination." We also refer readers to § 405.1887, which provides that a notice of reopening and any revised intermediary determination must specify the findings on matters at issue to be reopened and the particular findings to be revised through reopening, respectively, and § 405.1889(b), which provides that a provider's appeal rights after reopening are limited to the specific matters altered in the revised intermediary determination.

In many instances, when a factual matter arises in, or is determined for, the same fiscal period as the cost reporting period at issue, such a factual determination may be appealed or reopened as part of that period's intermediary determination. For example, if an IPPS hospital challenges the patient day count used to determine its DSH payment adjustment for its 2010 cost reporting period, the hospital must appeal its DSH patient day count within 180 days of the NPR for the 2010 cost reporting period (and meet the other jurisdictional requirements for appeal to the Board or to the intermediary hearing officer(s), as applicable). Similarly, the hospital would have to request, or the intermediary would have to initiate on its own motion, the reopening of the hospital's 2010 DSH patient day count within 3 years of the NPR for the 2010 cost reporting period.

When the specific matter at issue is a predicate fact that first arose in, or was determined for, an earlier fiscal period and that factual data then is used differently or applied to determine reimbursement in one or more later fiscal periods, our longstanding

interpretation and practice is that the pertinent provisions of the statute and regulations provide for review and potential redetermination of such predicate fact only by a timely appeal or reopening of: (1) The NPR for the cost reporting period in which the predicate fact first arose, or was first determined; or (2) the NPR for the period for which such predicate fact was first used or applied by the intermediary to determine reimbursement. For example, assuming base period costs calculated for the period consisting of the 12 months prior to the hospital's 2002 cost reporting period, that is, its 2001 cost reporting period, if an IPPS-exempt hospital challenges the determination of its 2008 cost reporting period target amount, the hospital could not appeal the determination of the *base period predicate facts* unless it was within 180 days of the NPR for the hospital's 2001 base period or its 2002 period (when the base year costs were first used to determine reimbursement). Similarly, the hospital would have to request, or the intermediary would have to initiate on its own motion, the reopening of the determination of the hospital's base period costs within 3 years of the NPR for the base year cost reporting period, that is, its 2001 or 2002 cost reporting periods. These are the only fiscal periods in which the hospital could or seek reopening of its base period costs. Of course, if the hospital's base period costs were later redetermined through appeal or reopening of its 2001 or 2002 NPRs, then the hospital could appeal or request reopening of those determinations. In addition, the hospital could appeal the determination of the *2008 cost reporting period target amount* within 180 days of the NPR for the 2008 cost reporting period. The hospital could also request the reopening of the determination of its 2008 cost reporting period target amount within 3 years of the NPR for its 2008 cost reporting period. However, the hospital could not revise the determination of its 2001 base year costs through an appeal or reopening of its 2008 target amount.

Many reimbursement formulas require the use of predicate facts, where data or a factual finding is taken from an earlier fiscal period and used to determine the amount of provider reimbursement in the fiscal period under review. As discussed above, we believe that these predicate facts should be subject to change only through a timely appeal or reopening for the fiscal period in which the predicate fact first arose or was first determined by the intermediary or the fiscal period in

which such fact was first used or applied to determine reimbursement. In some instances, a reimbursement statute may necessitate the use of data from a fiscal period that is not found in that period's cost report or NPR (such as "off the cost report," or underlying documentation). We believe that this kind of determination may be reviewed and redetermined through a timely appeal or reopening of the NPR for the cost reporting period in which the predicate fact was first used (or applied) by the intermediary to determine the provider's reimbursement pursuant to that reimbursement statute.

However, we recognize exceptions when a particular legal provision (of the Medicare statute, regulations, or CMS rulings) authorizes, as part of a specific reimbursement rule, the review and revision of a predicate fact after the expiration of the 3-year reopening period. For example, the reaudit regulation in § 413.77(a), promulgated to implement section 1886(h)(2) of the Act (which is related to the determination of the average per-resident amount used to calculate reimbursement for direct graduate medical education (GME) costs), authorizes intermediaries to modify base-period costs solely for purposes of computing the per resident amount after the hospital's base-period cost report is no longer subject to reopening under § 405.1885. We refer readers to the decision in *Regions Hospital v. Shalala*, 522 U.S. 448 (1998), which sustained the lawfulness of the reaudit regulation (then designated as § 413.86(e)).

As discussed above, we also recognize that not all facts occurring in prior fiscal periods are "predicate facts" in the same sense, because they are not determined once, but may be subject to review on an annual basis as part of the determination of a provider's reasonable cost reimbursement under section 1861(v) of the Act, such as the facts underpinning reimbursement for Medicare bad debts or allowable interest expense. Because these facts are subject to review each fiscal period by the intermediary, the intermediary's findings should also continue to be subject to review, either through an appeal or reopening.

As we stated in the CY 2014 OPPI/ASC proposed rule (78 FR 43683), we believe that the above-described interpretation of our rules regarding the appeal and reopening of predicate facts furthers the interests of both providers and the agency in maintaining the finality of intermediary determinations. The alternative, of allowing appeal and reopening of a predicate fact after the expiration of the 3-year reopening

period, may result in inconsistent intermediary determinations on a reimbursement matter recurring in different fiscal periods for the same provider. An alternative approach of allowing appeal and reopening of a predicate fact beyond the 3-year reopening period could also result in intermediary determinations that are contrary to Medicare law and policy regarding a specific reimbursement matter. As with the target amount example discussed above, reimbursement for various items is premised on a base period cost determination that could affect reimbursement for a given item for many cost reporting periods thereafter. If a provider disputes such a base period cost determination, it can appeal or request reopening of the NPR for the base period. However, unless such an appeal or reopening results in a different finding as to the predicate fact in question, reimbursement for a given provider's cost should not be based on one finding about a predicate fact in the base period and a different finding about the same predicate fact for purposes of determining reimbursement in later fiscal periods.

Under our longstanding interpretation and practice, once the 3-year reopening period has expired, neither the provider nor the intermediary is allowed to revisit a predicate fact that was not changed through the appeal or reopening of the cost report for the fiscal period in which such predicate fact first arose or for the fiscal period for which such fact was first determined by the intermediary. Further, the use or application of such facts is subject to change only through a timely appeal or reopening of the cost report for the fiscal period where the predicate fact was first used (or applied) by the intermediary to determine the reimbursement for the provider's cost in question. Accordingly, in the CY 2014 OPPI/ASC proposed rule (78 FR 43682 through 43683), we proposed to revise § 405.1885 to clarify that, absent a specific statute, regulation, or other legal provision permitting reauditing, revising, or similar actions changing predicate facts: (1) A predicate fact is subject to change only through a timely appeal or reopening of the NPR for the fiscal period in which the predicate fact first arose or the fiscal period for which such fact was first determined by the intermediary; and/or (2) the application of the predicate fact is subject to change through a timely appeal or reopening of the NPR for the fiscal period in which the fact was first used (or applied) by the intermediary to determine the

provider's reimbursement. As discussed earlier, this "first application" or "first use" of a predicate fact may involve underlying documentation that is "off the cost report."

We note that a recent court decision conflicts with our settled interpretation of the regulations for provider appeals and cost report reopenings. In *Kaiser Foundation Hospitals v. Sebelius*, 708 F.3d 226 (D.C. Cir. 2013), the court held that providers could appeal predicate facts used to determine their reimbursement in later fiscal periods even though such predicate facts were not timely appealed or reopened for the periods when they first arose or were determined by the intermediary, nor were such predicate facts timely appealed or reopened for the fiscal periods in which such facts were first used (or applied) by the intermediary to determine the providers' reimbursement. The predicate facts at issue in this case were the teaching hospitals' full-time equivalent (FTE) resident counts for their 1996 cost reporting periods, which, as required by section 1886(h)(4)(F)(i) of the Act, were used to calculate the statutory cap on residents for direct GME reimbursement for the first time in the hospitals' 1998 cost reporting periods. The providers could have challenged their FTE resident counts through timely appeals or reopening of their 1996 fiscal period NPRs, and they could have challenged the calculation of their resident caps through timely appeals or reopening of their 1998 fiscal period NPRs, the first time the caps were applied. Instead, the hospitals appealed their resident caps as applied to later cost reporting periods. The court held that the definition of "intermediary determination" under § 405.1801(a)(1), which is incorporated in the reopening rules at § 405.1885(a)(1), did not include factual findings, standing alone, where the providers made no attempt to challenge their direct GME reimbursement for their 1996 or 1998 fiscal periods due to the expiration of the 180-day appeal period and the 3-year period for reopening. Because the providers were not challenging the total amount of program reimbursement for their 1996 or 1998 fiscal periods, the court concluded that the intermediary determinations for those periods were not at issue and thus the 3-year limitation on reopening was not applicable.

We disagree with the court's decision, which we believe is contrary to our reopening regulations at § 405.1885(a), and the corresponding appeals regulations (discussed above), and which necessitates our proposed

clarification of the regulations. As noted above, we proposed to revise § 405.1885 to clarify that the specific "matters at issue in a determination" that are subject to the reopening rules include factual findings for one fiscal period that are predicate facts for later fiscal periods. The general 3-year reopening period applies to findings about such predicate facts and the reopening period is calculated separately for each finding about a predicate fact. We noted that this proposed revision of § 405.1885 would apply to *all* Medicare reimbursement determinations, and *not only* to direct GME payment, which was the particular issue in *Kaiser Foundation Hospitals v. Sebelius*. In the CY 2014 OPPS/ASC proposed rule (78 FR 43683 through 43684), we stated that, because the proposed revision clarifies longstanding agency policy, we were proposing that it be effective for any intermediary determination issued on or after the effective date of the final rule, and for any appeals or reopenings (or requests for reopening) pending on or after the effective date of the final rule, even if the intermediary determination (at issue in such an appeal or reopening) preceded the effective date of the final rule. We stated our view that the proposed revision was not impermissibly retroactive in effect because the proposal clarified longstanding agency policy and practice, and was procedural in nature. We referred readers, for example, to *Heimmermann v. First Union Mortgage Corp.*, 305 F.3d 1257, 1260–61 (11th Cir. 2002) (a rule clarifying the law, especially in an unsettled or confusing area of the law, is not a substantive change in the law, and thus the rule may apply to matters that preceded issuance of the rule).

However, if the proposed revision to § 405.1885 were deemed a retroactive application of a substantive change to a regulation, we referred readers to section 1871(e)(1)(A) of the Act, which permits retroactive application of a substantive change to a regulation if the Secretary determines that such retroactive application is necessary to comply with statutory requirements or that failure to apply the change retroactively would be contrary to the public interest. We have determined that retroactive application of the proposed revision to § 405.1885 is necessary to ensure compliance with various statutory provisions such as the target amount (under section 1886(b) of the Act) and the cap on residents for GME reimbursement (under section 1886(h)(4)(F)(i) of the Act); the 180-day period for filing appeals to the Board

(under section 1878(a)(3) of the Act); and the 3-year limit on reopening (under §§ 405.1885(b)(1), (2) of the regulations). We have further determined that it would be in the public interest to apply the proposed revision to intermediary determinations, appeals, and reopenings (including requests for reopening) that are pending on or after the effective date of the final rule. Not applying the proposed revisions to pending intermediary determinations, appeals, and reopenings would undermine the 3-year limit on reopening and the interests of both the Medicare program and Medicare providers in the finality of reimbursement determinations, and would be inconsistent with the statutory scheme.

Finally, although we proposed revisions only to § 405.1885, in order to clarify our regulations in accordance with this proposal, we stated that we were considering making similar changes regarding predicate facts to the regulations governing intermediary appeals at § 405.1811 and appeals to the Board at § 405.1835. We requested public comments with respect to amending the language of these additional regulations for appeals before the intermediary and the Board, but did not receive any timely comments on this point.

Comment: Two commenters opposed adoption of the proposed revisions because including findings of predicate facts in the reopening rule would undermine the accuracy of reimbursement determinations when a provider or the Medicare program learned of the inaccuracy after the 3-year period for reopening had expired. Other commenters opposed the change because it would prevent teaching hospitals from challenging their IME or direct GME resident caps if they have not already done so.

Response: We disagree with the commenters that the revisions to the reopening rules would materially undermine the accuracy of Medicare reimbursement because a provider could still seek revisions to a final intermediary determination by filing an appeal or requesting reopening and the intermediary could still initiate reopening on its own motion, and those appeal and reopening procedures are available over a lengthy period under the statute and regulations. Even before the appeal and reopening periods begin, providers have 5 months after the close of the cost reporting period to submit reports, and the intermediary is required to make its determination within a reasonable period of time thereafter. After a final intermediary determination

is issued, the Medicare statute authorizes appeal to the Board within 180 days of the final intermediary determination. The reopening regulations allow six times as long—3 years—for reopening of a final intermediary determination. Therefore, an NPR may be reopened many years after a fact arises during the cost reporting period at issue, depending on when the intermediary determination is issued. When a reopening results in a revised intermediary determination, the provider then may appeal or request reopening of the specific issue in the revised intermediary determination, resulting in review of the revised intermediary determination at an even more remote time. This reopening scheme, which the Supreme Court described as “generous” in *Your Home Visiting Nurse Services, Inc. v. Shalala*, 525 U.S. 449, 455 (1999), is intended to strike a balance between accurate reimbursement and administrative finality, in the interests of both the provider and the Medicare program. The proposed revisions merely clarify that a finding of predicate fact is also subject to reopening for a 3-year period. Moreover, the proposed revisions would not affect the exception to the 3-year reopening period for fraud or similar fault by a party to the final intermediary determination.

With respect to the IME and direct GME resident caps, we established in an August 1997 interim final rule that we would determine those caps in the course of settling cost reports starting on or after October 1, 1997 (for direct GME) or with discharges on or after October 1, 1997 (for IME), thereby putting teaching hospitals on notice that their caps would be determined at that time (62 FR 45966, 46003 through 46005 (August 29, 1997)). This is consistent with the resident cap statutory provisions (under section 1886(h)(4)(F) and section 1886(d)(5)(b)(v) of the Act), which require the use of the number of unweighted FTE residents for the cost reporting period ending on or before December 31, 1996, for cost reporting periods (or discharges, for IME) starting on or after October 1, 1997. We did not read this provision to allow for continuing challenges to this number of residents. Before the *Kaiser* decision, neither providers nor the Medicare program were allowed to challenge the 1996 FTE resident cap except through a timely appeal or reopening of the NPR for the 1996 base year or the first fiscal period in which the caps were applied. For example, we refer readers to *Hillcrest Riverside, Inc. v. Sebelius*, 680 F. Supp. 2d 30 (D.D.C. 2010); and

Swedish Am. Hosp. v. Sebelius, 773 F. Supp. 2d 1 (D.D.C. 2011). Indeed, many teaching hospitals challenged their NPRs for the 1996 fiscal period in order to correct perceived deficiencies in their caps. For example, we refer readers to *Henry Ford Health Sys. v. Dep’t of Health & Human Servs*, 654 F. 3d 660 (6th Cir. 2011); *Univ. of Chicago Med. Ctr. v. Sebelius*, 618 F.3d 739 (7th Cir. 2010); *Rhode Island Hosp. v. Leavitt*, 548 F.3d 29 (1st Cir. 2008); and *Riverside Methodist Hosp. v. Thompson*, No. C2–02–94, 2003 WL 22658129 (S.D. Ohio July 31, 2003). In our view, teaching hospitals have been allowed ample opportunity to correct their resident caps.

Comment: One commenter stated that it would support the proposed revisions if they bound CMS to accept as final a determination of predicate fact that had not been timely appealed or reopened, but which the provider now recognized had been determined inaccurately. According to the commenter, it was classified as a sole community hospital (SCH), but later realized that it was not the only like hospital within 25 miles. The then-applicable regulations for SCH status specified that the designation will be revisited if there is “a change in circumstance” and that “CMS will cancel the hospital’s classification as a sole community hospital effective with the date that the hospital no longer met the criteria for classification consistent with the provisions of § 405.1885” for the reopening of NPRs (42 CFR 412.92(b)(3)(iii) (2011)). The commenter asserted that, because it was not the only like hospital within 25 miles, it was appropriate to cancel its SCH designation, but it was not appropriate to recover reimbursement for past cost years because there had been no change in circumstances. The commenter asked whether the proposed revisions to the reopening rules, which apply to pending appeals, would govern its pending Board appeal challenging the recovery of reimbursement for past fiscal periods.

Response: Without passing judgment on the merits of the commenter’s pending Board appeal, this would appear to present a situation where, under the proposed revisions, the determination of a predicate fact (the provider’s distance from a like hospital) was beyond the 3-year reopening period. We note that in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53258, 53674), we amended § 412.92(b)(3) to require providers to disclose facts to CMS that would be material to initial SCH designations and if providers fail to disclose these facts, their SCH status will be cancelled.

Comment: One commenter asked if the proposed revisions would apply to determinations of successive predicate facts, such as the commenter’s Medicare Advantage days, total days, and education costs used in the Nursing and Allied Health Education (NAHE) Managed Care payment. The commenter also asked whether these predicate facts could be challenged by reopening the NPR for the fiscal period in which such facts are used to calculate payment, which is usually two fiscal periods afterward.

Response: As discussed in the example of the TEFRA target amount, predicate facts may arise in multiple years. The proposed revisions would permit reopening of the final determination of a provider’s Medicare Advantage days, total days, and NAHE payment for purposes of computing the NAHE Managed Care payment either in the fiscal period such costs and days were first determined, or in the fiscal period they were first used to calculate the NAHE Managed Care payment.

Comment: One commenter, noting that reopening of intermediary determinations is completely within the discretion of the intermediary, requested that CMS ensure that the intermediaries do not use this discretion to impair a provider’s ability to correct a predicate fact. The commenter suggested that if a provider’s request to reopen a predicate fact determination is denied, then recognition should be given to the timely filed reopening request in an appeal of the subsequent cost year, especially in situations where the first application of the predicate fact results in a reimbursement impact that is less than the jurisdictional amount for appeal to the Board.

Response: The regulations provide the fiscal intermediaries with unreviewable discretion as to whether to reopen specific findings on matters at issue in a final intermediary determination, and program manual instructions include guidance for the intermediary’s exercise of its discretionary reopening authority. We refer readers to the Provider Reimbursement Manual (CMS Pub. 15–1), Section 2931.2. We believe that the intermediary’s reopening authority has always encompassed specific findings about predicate facts, and we see no basis for limiting the intermediary’s discretion whether to reopen particular findings of predicate fact. As the Supreme Court recognized, reopening is provided by the grace of the Secretary (*Your Home*, 525 U.S. at 455). The Court found that the discretionary nature of reopening reflected the practical realities of the Medicare program where “the few dozen [intermediaries] often

need 3 years within which to discover overpayments in the tens of thousands of NPRs that they issue, while each of the tens of thousands of sophisticated Medicare-provider recipients of these NPRs is generally capable of identifying an underpayment in its own NPR within the 180-day time period specified in 42 U.S.C. 1395oo(a)(3)" for appeals to the Board (*Id.* at 455–56). If a provider wants to challenge a finding of predicate fact where the reimbursement impact is less than the statutory jurisdictional minimum of \$10,000 for Board appeals, § 405.1811 of the regulations gives the provider a right to appeal to the intermediary hearing officers if the amount in controversy is at least \$1,000 and the other requirements for intermediary hearing officer jurisdiction are satisfied. Thus, providers can appeal findings of predicate fact to the Board or the intermediary hearing officers within 180 days of a final intermediary determination, in addition to requesting reopening of a predicate fact within 3 years of such determinations.

Comment: One commenter suggested that application of the proposed revisions be limited to findings of fact that had not been appealed, instead of applying to issues on which the provider had received an adverse finding on the merits. For those issues, the commenter believed that it had the right to bring successive challenges to the finding of predicate fact after an adverse decision on the merits of a challenge to the finding of predicate fact in the first year it arose or was determined.

Response: We do not perceive a basis to limit the application of the proposed revisions to findings of predicate facts that have not been appealed. We believe that the proposed revisions should also apply to issues on which the provider has received an adverse final decision on the merits. Indeed, § 405.1803(d) of the regulations requires the intermediary to determine the effect of a final decision and issue any revised intermediary determination that proves necessary. Moreover, settled rules of issue preclusion, including the requirement that the issue be litigated on the merits by opposing parties, would apply to a final decision on the merits of the disputed predicate facts after exhaustion of administrative remedies and judicial review. We note that because appeals of an NPR sometime are not resolved finally before NPRs are issued for later fiscal periods, providers that wish to preserve their rights to administrative and judicial review sometimes will challenge predicate facts in successive appeals and actions for judicial review until the

first appeal is finally resolved. But upon final resolution of the first appeal, the parties usually do not relitigate the same finding of predicate facts in the appeals for later fiscal periods.

Comment: Several commenters opposed the proposed revisions to the reopening rules because the commenters were concerned that the Medicare program had reserved the right to create exceptions by regulation or Ruling that would benefit the program, but not Medicare providers. The commenters were also concerned that the Medicare program would interpret reimbursement provisions in the Medicare statute to authorize the revision of predicate facts only when it would result in reduced reimbursement to providers.

Response: In discussing the proposed revisions, we stated that the 3-year limit on reopening of a predicate fact might be countered by a statutory provision or a specific regulation on reimbursement of the matter at issue. This statement acknowledges that the proposed revisions cannot override a contrary statutory provision, and that revisions to the generally applicable reopening rules are not intended to trump the provisions of a specific reimbursement regulation. Instead, the proposed revisions to the reopening rules reflect the Medicare program's longstanding policy not to revisit predicate facts more than 3 years after the predicate fact arose or was first determined in a final intermediary determination. In cases where it has been necessary to adjust cost report data for use in later fiscal periods as a base year or cap after the 3-year reopening period has expired, the Medicare program has relied on statutory authority to make such adjustments and used notice and comment rulemaking to alert providers to the basis, purpose, and scope of the adjustments. For example, we refer readers to *Regions Hospital v. Shalala*, 522 U.S. 448 (1998) (sustaining the GME reaudit rule). These procedural protections would be reinforced by the proposed revisions to the reopening rules.

However, in light of the comments we received, we are limiting the scope of this final rule to "predicate facts" that are determined once and then used to determine payments for one or more fiscal periods after the fiscal period in which the facts arose or were determined. We are not applying these final provisions to facts that are subject to annual evaluation as part of the intermediary's final determination of reasonable cost reimbursement under section 1861(v) of the Act. We believe that narrowing the definition of "predicate facts" in this fashion will help allay commenters' concerns that

the proposed revisions will be subject to ad hoc exceptions that only serve to disadvantage providers. We note that the annual evaluation of certain predicate facts in the determination of reasonable cost reimbursement can increase the provider's reimbursement in later fiscal periods. For example, if a provider incurs a Medicare bad debt in 2002, but the debt is not deemed uncollectable until 2009, the bad debt would be reimbursable in 2009 if all the requirements of § 413.89 were satisfied.

Comment: Several commenters took issue with CMS' characterization of the proposed revisions as codifying longstanding policy. Instead, the commenters pointed to the decisions cited in the D.C. Circuit's *Kaiser Foundation Hospitals* decision as evidence that CMS has not taken a consistent position on when predicate facts can be reexamined, but instead has taken the position that benefits the program.

Response: We disagree with the commenters' assertion that the proposed revisions do not reflect our longstanding interpretation of the reopening regulations. The reopening rules, which were first promulgated in 1974, have always been interpreted and applied in an even-handed manner such that a given reopening might increase, decrease, or leave unchanged the provider's program reimbursement. The reimbursement effect of a specific reopening is determined by the governing law and the factual circumstances of the matter at issue.

Moreover, we disagree with the commenters' assertion that in certain cases we have reexamined predicate facts beyond the 3-year reopening period without authority for doing so. In three of these cases, a reimbursement regulation allowed reexamination of predicate facts so long as the underlying amount of reimbursement was not changed beyond the 3-year reopening period. For example, in proposing the GME reaudit rule that the Supreme Court later upheld in *Regions Hospital*, we acknowledged that "a special exception" to the general reopening rules was required to reexamine cost reports from the inpatient prospective payment system base year beyond the 3-year reopening period (53 FR 36592, September 21, 1988). In *Edgemont Hospital v. Mutual of Omaha Insurance Co.*, PRRB Dec. No. 95–D34, 1995 WL 933971 (Apr. 6, 1995), adjustments to the amount of operating costs considered in establishing the TEFRA target amount or rate-of-increase ceiling were authorized by § 413.40(g). If the Medicare program took the view that the reopening rules permitted the

reexamination of predicate facts beyond the 3-year reopening period, as the commenters suggested, then there would have been no need for the above-referenced regulations on GME reauditing and TEFRA limit adjustments to operating costs.

Contrary to the commenters' assertions, the Medicare program has applied its reopening rules to determinations of predicate facts to the benefit of providers. For example, when a provider received an adverse decision on its target amount for its first year, but the intermediary had failed to issue timely notices of reopening for the following fiscal periods, we instructed the intermediaries not to attempt to adjust those target amounts, which allowed the provider to retain reimbursement in excess of the cost ceilings calculated with the correct target amounts. Similarly, we have instructed intermediaries not to attempt to change incorrectly calculated high direct GME or IME resident caps for fiscal periods that were beyond the reopening period.

The other cases cited by commenters do not concern "predicate facts" as defined in the proposed revisions. *HealthEast Bethesda Lutheran Hospital & Rehabilitation Center v. Shalala*, 164 F.3d 415 (8th Cir. 1998), concerned interest expenses evaluated under § 413.153(b)(2). As we have discussed above, interest expense, when considered on a reasonable cost basis, is subject to reexamination in each fiscal period to determine whether the cost at issue qualifies as "necessary" interest expense for that fiscal period. We refer readers to § 413.5(a) of the regulations. The facts associated with these expenses, like bad debt arising from non-payment of Medicare deductibles and coinsurance, are not determined once and applied thereafter to determine reimbursement in subsequent fiscal periods. They are not within the scope of the proposed revisions, as we have revised it in response to the comments.

The remaining decision referenced by the commenters, *Mark Twain St. Joseph's Healthcare Corp. v. Leavitt*, 154 Fed. Appx. 651 (9th Cir. 2005), also does not support the commenters' view. In that case, the court held that recalculation of the provider's hospital specific rate did not violate the finality provisions of §§ 412.71 and 412.72; rather, the intermediary properly reopened the determination to correct an administrative error. If anything, the finality provisions of §§ 412.71(d) and 412.72(b) are consistent with our position that once a predicate fact, such as the hospital specific rate, is finally

determined, it is not subject to continuing requests for review or reopening beyond the 3-year reopening period at the instigation of either the intermediary or the provider.

Comment: Several commenters stated that CMS proposed to apply the revisions to the reopening rules retroactively, but that CMS had no authority to do so. Based on the D.C. Circuit's decision in *Kaiser Foundation Hospitals* and earlier decisions cited therein, the commenters stated that the proposed revisions to the reopening rules did not reflect longstanding Medicare policy, and thus the revisions did not clarify such policy. The commenters also stated that the proposed revisions would be contrary to the public interest in ensuring the accuracy of reimbursement determinations. One commenter also stated that it would be contrary to the public interest to apply the proposed revisions to pending appeals when providers have relied on the existing regulations.

Response: As explained in the proposed rule, we disagree with the D.C. Circuit's decision in *Kaiser Foundation Hospitals*, including the court's discussion of decisions in a few prior cases. As discussed above, we believe that the circumstances presented in those prior cases are not similar to those in *Kaiser*, and we also have narrowed the scope of the proposed revisions to address these concerns. In any event, in a program the size of the Medicare program, with thousands of providers submitting voluminous cost reports annually over the course of nearly 50 years, we do not believe that the few reimbursement decisions cited by the D.C. Circuit provide a reasonable basis for providers to forego their statutory right to appeal to the Board, and the regulatory process for reopening, by invoking an alleged right to seek revisions to predicate facts beyond the 3-year reopening period.

Nonetheless, we recognize that the D.C. Circuit rejected our interpretation of the reopening rules, and the court found that we had applied the rules differently in a few earlier cases. By amending the reopening rules now, our purpose is to articulate clearly what we had intended the regulations to say in the first place, so that the revised rules will be applied consistently by confining the reopening of predicate facts to the 3-year reopening period.

We continue to believe that application of the revised rules to intermediary determinations issued on or after the effective date of this final rule, and to appeals and reopenings (including requests for reopening) that

are pending on or after the same effective date, is not impermissibly retroactive in effect. Any finding of a predicate fact inherently has a degree of retroactivity because Congress (or the Medicare program) has assigned a future reimbursement consequence to provider actions that have already taken place, usually before the enactment of the relevant reimbursement statute. For example, when Congress enacted the direct GME and IME resident cap statute in 1997, and used a base year that ended no later than December 31, 1996, it assigned future consequences (the resident cap) to actions that were already completed (the provider's employment of residents during the 1996 cost reporting period).

We believe that this is a form of "secondary retroactivity" inasmuch as future consequences are attached to past actions, but such secondary retroactivity does not violate due process or, in the case of regulations, the Administrative Procedure Act, if the regulation is not unreasonable. For example, we refer readers to *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 203, 219–220 (1988) (Scalia, J., concurring); and *Nat'l Cable & Telecomms. Ass'n v. FCC*, 567 F.3d 659, 670–71 (D.C. Cir. 2009). Applying the proposed revisions to pending intermediary determinations, appeals, and reopenings will not affect the amount of reimbursement a provider received for the cost reporting period in which the predicate fact first arose or was determined. Nor would such application of the proposed changes to the reopening rules invalidate any revisions to predicate facts that were finalized prior to the effective date of this final rule. Instead, the revised reopening rules govern only the timing of permissible revisions to predicate facts, as of the effective date of this final rule, and thus the revisions to the reopening rules are procedural in nature.

The scope of applicability of the revised reopening rules also does not undermine providers' settled expectations. A provider cannot reasonably expect to be allowed to revise a predicate fact after the 180-day filing period for an appeal after the right has expired, when the only remaining means of securing such relief is through the discretionary reopening process. We refer readers to *Bergerco Canada v. U.S. Treasury Dept.*, 129 F.3d 189, 194–95 (D.C. Cir. 1997) (changes to discretionary licensing procedure made after plaintiff had filed request for license did not impair any rights of the plaintiff). After the 3-year period to request reopening has elapsed, a provider has no reasonable expectation

of securing revisions to predicate facts. While one of the commenters suggested that the *Kaiser* decision effectively established the governing law, the decision is of such recent vintage that few providers could have relied on it as a basis for changing predicate facts after expiration of the 3-year reopening period. Moreover, the strictures against retroactivity do not apply to procedural rules, which the reopening rules plainly are. We refer readers to *Combs v. Commissioner of Social Security*, 459 F.3d 640, 647 (6th Cir. 2006) (en banc).

In any event, if the revisions to the reopening rules were deemed a retroactive application of a substantive change to a regulation, we continue to believe that section 1871(e)(1)(A) of the Act permits retroactive application because it is necessary to ensure compliance with various statutory payment provisions such as the TEFRA target amount (under section 1886(b) of the Act) and the caps on residents for GME and IME reimbursement (under sections 1886(h)(4)(F) and 1886(d)(5)(B)(v) of the Act); the 180-day filing period for appeals to the Board (under section 1878(a)(3) of the Act); and the 3-year period for reopening (under §§ 405.1885(b)(1), and (b)(2) of the regulations). In addition, we continue to believe that retroactive application furthers the public interest in safeguarding the 3-year limit on reopening and the interests of both Medicare providers and the Medicare program in preserving the finality of reimbursement determinations.

Contrary to the commenter's assertion, the revised reopening rules still provide an avenue to correct predicate facts, thus promoting accuracy in reimbursement determinations. The revised reopening rules also protect the interests of administrative finality by ensuring that both Medicare providers and the Medicare program can close their books on a cost reporting period without worrying that the other party will invoke the *Kaiser* decision to make changes to predicate facts long after the close of the 3-year reopening period, when documents and witnesses may no longer be available.

After consideration of the public comments we received, we are adopting the proposed revisions to §§ 405.1885(a)(1) and (a)(2)(iv) to clarify that the specific "matters at issue in a determination" that are subject to the reopening rules include factual findings for one fiscal period that are predicate facts for later fiscal periods with the following modifications: We are adding language to paragraph (a)(1)(iii) that defines the "predicate facts" that are subject to the revisions as factual

findings for one cost reporting period that once determined are used in one or more subsequent cost reporting periods to determine reimbursement. We are adding language to paragraph (b)(2)(iv) to clarify that it does not apply to factual findings when made as part of a determination of reasonable cost under section 1861(v)(1)(A) of the Act. Paragraph (a)(1)(iv) also was reworded for clarity. Absent a specific statute, regulation, or other legal provision permitting reauditing, revising, or similar actions changing predicate facts: (1) A predicate fact is subject to change only through a timely appeal or reopening of the NPR for the fiscal period in which the predicate fact first arose or the fiscal period for which such fact was first determined by the intermediary; and/or (2) the application of the predicate fact is subject to change through a timely appeal or reopening of the NPR for the fiscal period in which the fact was first used (or applied), by the intermediary to determine the provider's reimbursement. The general 3-year reopening period applies to findings about such predicate facts and the reopening period is calculated separately for each finding about each predicate fact. At this time, we have decided not to make similar changes regarding predicate facts to the regulations governing intermediary appeals at § 405.1811 and appeals to the Board at § 405.1835.

XX. Files Available to the Public Via the Internet

In the CY 2014 OPPS/ASC proposed rule (78 FR 43684), we proposed to create new Addendum P—Proposed OPPS Items and Services That Will Be Packaged for CY 2014.

We did not receive any public comments related to the proposed creation of new Addendum P and are finalizing our proposal without modification.

The Addenda of the proposed rules and the final rules with comment period will be published and available only via the Internet on the CMS Web site. To view the Addenda of this final rule with comment period pertaining to CY 2014 payments under the OPPS, go to the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html> and select "1601-FC" from the list of regulations. All Addenda for this final rule with comment period are contained in the zipped folder entitled "2014 OPPS 1601-FC Addenda" at the bottom of the page.

To view the Addenda of this final rule with comment period pertaining to CY

2014 payments under the ASC payment system, go to the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html> and select "1601-FC" from the list of regulations. All Addenda for this final rule with comment period are contained in the zipped folders entitled "Addendum AA, BB, DD1 and DD2," and "Addendum EE" at the bottom of the page.

XXI. Collection of Information Requirements

A. Legislative Requirements for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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 2014 OPPS/ASC proposed rule (78 FR 43684), we solicited public comments on each of the issues outlined above for the information collection requirements discussed below.

B. Requirements in Regulation Text

1. Changes to the Outcome Measure Requirement for OPOs

In section XVI. of this final rule with comment period, we discussed our proposal to modify the outcome measures requirement for OPOs set forth at § 486.318. Currently, OPOs are required to meet all three outcome measures in that section or they are automatically decertified. We proposed to modify that requirement so that OPOs will meet the outcome measures requirement if they meet two out of the three outcome measures.

Based on our experience with OPOs and historical data concerning how many OPOs typically fail to meet one of the outcome measures, we believe that there would be about five OPOs that would fail to meet one of the outcome

measures. Our proposal would result in those five OPOs meeting the outcome measures requirement and not being automatically de-certified. Therefore, these five OPOs would not have to perform the ICRs under this section, which would be the time and resources needed to go through the appeals process in an attempt to secure a reversal of the decertification.

The ICRs that an OPO would be required to expend would depend upon how it chose to handle the decertification. An OPO may choose to not engage in the appeals process and merge with another OPO prior to the effective date of the decertification. Other OPOs would likely choose to take advantage of the appeals process, which would begin with reconsideration at the regional administrator level. It is likely that an OPO would expend considerable resources during the reconsideration and, if that was unsuccessful, a hearing before a CMS hearing officer. We believe both would require considerable time and other resources from the OPO's senior staff and legal counsel. We also believe that those OPOs that went onto a hearing would expend considerably more resources than those that received a reversal of their decertification at the reconsideration. While we do not have a reliable estimate on how much these OPOs would save due to the numerous unknown variables, we are confident that these OPOs would sustain a significantly positive effect from not being automatically de-certified as is currently required under the OPO CfCs. In addition, under 5 CFR 1320.3(c), a "collection of information" does not include requirements imposed on fewer than 10 entities. Therefore, the requirements of this section are not subject to the PRA.

2. Changes to the Medicare Fee-for-Service EHR Incentive Program

In section XVIII. of the CY 2014 OPPS/ASC proposed rule, we proposed to revise 42 CFR 495.4 to provide a special method for making hospital-based determinations for 2013 only in the cases of those EPs who reassign their benefits to Method II CAHs. We also proposed a minor clarification to the regulations at § 495.104(c)(2) concerning the cost reporting period to be used in determining final EHR payments for hospitals. We refer readers to the Stage 1 (75 FR 44517 through 44544) and Stage 2 (77 FR 54125 through 54135) final rules for the Medicare EHR Incentive Program for the discussions of the burden of the information collection requirements of the Medicare Fee-for-Service EHR Incentive Program. Our proposals in the proposed rule did not

modify or increase the information collection requirements of the program in any way.

After reviewing the public comments we received on the proposed rule, we are finalizing our proposals discussed in section XVIII. of this document. These final policies do not modify or increase the information collection requirements of the Medicare Fee-for-Service EHR Incentive Program in any way.

C. Associated Information Collections Not Specified in Regulatory Text

In the CY 2014 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. 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) and the CY 2013 OPPS/ASC final rule with comment period (77 FR 68527 through 68532) for detailed discussions of the Hospital OQR Program information collection requirements we have previously finalized.

a. Hospital OQR Program Requirements for the CY 2015 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68531) for a discussion on the burden of the information collection requirements of the previously adopted Hospital OQR Program measures for the CY 2015 payment determination. In the CY 2014 OPPS/ASC proposed rule, we did not propose to add any additional measures for the CY 2015 payment determination and subsequent years; therefore, there will not be an increase in our previous burden estimate.

We note that we had previously suspended data collection for the OP-19 measure and deferred data collection for the OP-24 measure. In this final rule with comment period, we are finalizing our proposal to remove the OP-19 and OP-24 measures from the Hospital OQR Program for the CY 2015 payment determination and subsequent years (78 FR 43646 through 43647, 78 FR 43653).

We refer readers to section XIII.C.2. of this final rule with comment period for our discussion of the removal of these measures. Because one of the measures was previously suspended and the other deferred, removing them will not impact our previous burden estimate and it remains unchanged.

In addition, we are finalizing our proposals to codify existing policies related to program participation and withdrawal, data submission, extraordinary circumstances extensions or waivers, data validation, and the reconsideration process. Because we are only codifying existing policies (including finalizing a clarification that we may grant extensions or waivers if systemic problems in our data collection systems directly or indirectly affect the ability of hospitals to submit data), we do not anticipate any additional burden to hospitals based on these proposals affecting the CY 2015 payment determination or subsequent years.

The Hospital OQR program has 3 types of measures that utilize different methods of data collection/ submission—chart-abstracted measures that require HOPDs to collected data from chart-abstraction, and submit that data directly to CMS, Web-based measures submitted via the QualityNet Web site (this includes some chart abstracted measures that are also submitted via the QualityNet Web site) and measures submitted via the CDC's NHSN Web site. In the CY 2014 OPPS/ASC proposed rule, there is only one section heading for all of these measures: "Web-based Measures for the CY 2016 Payment Determination and Subsequent Years" (78 FR 43685). We intended to include headings for the other two kinds of measures, but these were inadvertently deleted. For the new measures, this resulted in burden estimates for three chart-abstracted measures submitted directly to CMS via a Web-based tool, and one measure submitted via CDC's NHSN all appearing under a heading that refers to just one type of measure. In this final rule with comment period, we have corrected this error and separated the content appropriately using separate section headings for each of the different kinds of measures.

For the CY 2016 payment determination and subsequent years, the burden associated with Hospital OQR Program procedures consists of the time and effort associated with collecting and submitting data for the 3 different kinds of measures. Where we have chart-abstracted measures that are collected via Web-based tool, they are included below in section XXI.C.1.b., where their chart-abstraction burden is estimated,

and in section XXI.C.1.c., where we estimate their Web submission burden.

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 a particular payment determination. This burden would include, but not be limited to: maintaining familiarity with the Hospital OQR Program requirements (for example, participating in the monthly educational webinars, reading information available at the QualityNet Web site <https://qualitynet.org>, checking feedback reports to indicate a facility's current status or performance, reaching out to the Hospital OQR Program support contractor to make specific inquiries); staying up to date with system requirements (for example, updating passwords, maintaining a system that is fully functional in the QualityNet environment, etc.); and communicating how program requirements must be operationalized within the individual facility. For each hospital, we estimate burden as follows, for one annual cycle of the program:

- Program requirements (20 hours),
- System requirements (2 hours)
- Managing facility operations (20 hours)

The burden for one hospital is therefore the sum of these 3 areas above and therefore estimated at 42 hours. We calculate the total burden for the approximately 3,300 participating hospitals as 138,600 hours (42 hours multiplied by 3,300 facilities).

b. Chart-Abstracted Measures for the CY 2016 Payment Determination and Subsequent Years

We estimated, based on our past experiences with chart-abstracted measures, that there will be approximately 3,300 respondents per year and that each participating hospital will spend 35 minutes per case to collect and submit the data. As a result, the estimated burden associated with one case per hospital would be 1,924 hours (3,300 hospitals \times 0.583 hours per hospital). We estimated the financial burden for all hospitals to collect and submit data using our estimate of one case per hospital would be \$57,717 (3,300 hospitals \times \$30.00 per hour \times 0.583 hours). We note that this estimate is based on estimates of all of these measures being collected using the same methods of chart abstraction, but excludes estimates for data submission for measures that HOPDs will report via a Web-based tool.

Based upon the data submitted for the CY 2012 and CY 2013 payment determinations, we estimated there will

be a total of 1,679,700 cases per year, or approximately 509 cases per year per hospital. However, hospitals will vary greatly on the number of cases per HOPD due to specialization. Based on those numbers though, the estimated annual hourly burden associated with the aforementioned data submission requirements for the chart-abstracted data for all hospitals (excluding submission burden for measures submitted through the Web-based tool) is 979,265 hours (1,679,700 cases per year \times 0.583 hours per case). This estimate is based on data submitted previously and includes burden associated with measure OP-22, which is a chart-abstracted measure with Web-based submission.

For the CY 2016 payment determination, the three newly finalized measures (OP-29, OP-30, and OP-31) are chart-abstracted measures with Web-based submission. These three measures will add to the burden. In this rulemaking, we estimate the maximum burden, but in future rulemaking, we will update our burden estimate based on actual data we receive. To estimate maximum burden, we assume all facilities will have adequate volume to sample at the highest number of required cases. If a hospital is obligated to chart-abstract the highest number of cases from the instructions we provide to indicate appropriate sampling methodology based on hospital's volume, this is a basis for us to calculate a maximum burden estimate. Using the same sampling methodology we have used in the past, which can be found on Table 3 (ED Throughput) of "Section 4- Population, Sampling and Transmission" in the Hospital Outpatient Quality Reporting Specifications Manual, v7.0 available at <https://qualitynet.org>, we estimate that each of the approximately 3,300 responding hospitals will have volume adequate to support quarterly sample sizes of 96 cases, for a total of 384 cases (96 cases per quarter \times 4 quarters) to be abstracted by each hospital annually for one new measure.

Based on these assumptions for the three new measures, the total additional cases for one hospital to sample would be 1,152 (384 cases annually per measure \times 3 measures). We estimate that the time to chart abstract one case is 25 minutes. We estimate 25 minutes per case (or 0.417 hours per case) based on chart-abstraction time less the time to submit Web-based measures in aggregate (0.583 hours – 0.167 hours = 0.417 hours per measure). For the approximately 3,300 reporting hospitals, we therefore estimate the total maximum burden associated is

1,584,000 hours (3,300 hospitals \times 0.417 hours per hospital \times 1,152 cases). We estimate the maximum financial burden for all hospitals to collect and submit data via the Web-based tool for the three new measures to be \$47,520,000 (3,300 hospitals \times \$30.00 per hour \times 1,584,000 hours).

For chart-abstracted measures that HOPDs will *not* submit via a Web-based tool, HOPDs will incur a financial burden associated with chart abstraction and data submission for these non-Web-based measures, which requires that HOPDs submit patient-level data directly to CMS. We estimated the financial burden associated with these measures for all hospitals as \$29,377,953 (1,679,700 cases per year \times \$30.00 per hour \times 0.583 hours per case).

c. Web-Based Measures Submitted Directly to CMS for the CY 2016 Payment Determination and Subsequent Years

For the CY 2016 payment determination and subsequent years, we proposed to add five measures to the program. Of these five measures, four are chart-abstracted measures requiring that HOPDs submit patient-level data directly to CMS using a Web-based tool, with data collection beginning in CY 2014. Based on public comment we received regarding burden, we are not finalizing proposed measure OP-28 as part of the Hospital OQR Program measure set. Therefore, we are only finalizing three of the four chart-abstracted measures that we proposed. We refer readers to section XIII.E.2 of this final rule with comment period for a discussion of public comments regarding OP-28. We also refer readers to section XIII.G.2.f. of this final rule with comment period for our discussion of specific data collection requirements we finalized, which serves as the basis of our estimates of burden described.

For previously finalized Web-based measures (OP-12, OP-17, OP-25, and OP-26), our measurement methods are somewhat different from the methods we use for one existing measure and the three newly finalized Web-based measures (OP-29, OP-30, and OP-31). We estimated the burden of chart-abstraction for the subset of the four of these measures that are also chart-abstracted (OP-22, OP-29, OP-30, and OP-31). It is appropriate to consider this subset of four measures in both the section on chart-abstraction burden and in this section estimating Web-based measure burden because not all Web-based measures are also chart-abstracted. Our estimate in this section is based on the chart-abstraction for these four measures being complete by

the hospital at the time of Web-based entry. Each participating hospital would spend 10 minutes per measure per year to collect and submit the data. In the case of the subset of four chart-abstracted measures, the estimate here is only for the time associated with entering aggregate totals into our Web-based tool. The estimated annual burden associated with these measures is 4,409 hours (3,300 hospitals \times 0.167 hours per measure \times 8 measures per hospital) for the CY 2016 payment determination. This burden is based on a collection burden for OP-12, OP-17, OP-25, and OP-26 and a Web-based submission burden for all of the measures that are submitted via a Web-based tool.

HOPDs will incur a financial burden associated with identifying and submitting data for these eight Web-based measures. We estimated that the financial burden associated with these measures would be \$132,264 (3,300 hospitals \times \$30.00 per hour \times 0.167 hours per measure \times 8 measures). Of these eight measures, 4 are chart-abstracted. As noted above, we include the chart-abstraction burden for the subset of 4 chart-abstracted measures (1 previously finalized, 3 finalized in this rulemaking) submitted via Web-based tool in the section on chart-abstracted data collection above.

d. NHSN HAI Measure for the CY 2016 Payment Determination and Subsequent Years

For the NHSN HAI measure Influenza Vaccination Coverage among Healthcare Personnel (OP-27), the burden involved would be from gathering information either from existing reports or by other methods such as surveying the healthcare personnel population. In the CY 2014 OPPS/ASC proposed rule (78 FR 43685), we used an estimate of 10 vaccinations per outpatient hospital. Since then, we have obtained a more accurate estimate for the number of vaccinations per hospital and have reflected that in our calculations below. Using data from the United States Department of Labor Bureau of Labor Statistics, Occupational Employment Statistics Query System, and the total of all workers for Outpatient Care Centers Code 621400, the number of personnel for all hospitals is 640,360. We estimate 640,360 responses for a total burden of 106,940 hours (0.167 hours per response \times 640,360 responses).

HOPDs will incur a financial burden associated with data submission for this measure. Using the total of all Outpatient Care Center workers from the Bureau of Labor Statistics, as described above, we estimate that the financial

burden associated with this measure for all HOPDs would be \$3,208,203 (\$30.00 per hour \times 106,940 hours).

We invited public comment on the burden associated with the information collection requirements for the chart-abstracted measures, the Web-based measures submitted directly to CMS, and the measure submitted via CDC's NHSN. We did not receive any comments on the burden associated with information collection requirements. Therefore, we are finalizing our burden estimates.

e. Hospital OQR Program Validation Requirements for the CY 2015 Payment Determination and Subsequent Years

We use a sampling methodology, which involves establishing a particular 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. We do not validate measures submitted via Web-based tool or submitted to NHSN. The validation burden for a HOPD is the time and effort necessary to submit validation data to a CMS contractor. In the CY 2014 OPPS/ASC proposed rule, we did not propose any changes to our validation procedures. As a result, the burden associated with the validation procedures for the CY 2015 payment determination is the same as previously finalized for CY 2014 in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68531). We estimated that it would take each of the 500 sampled hospitals approximately 12 hours to comply with these data submission requirements. To comply with the requirements, we estimated each hospital would submit up to 48 cases for the affected year for review. All selected hospitals must comply with these requirements each year, which would result in a total of up to 24,000 charts being submitted by the sampled hospitals. The estimated annual burden associated with the data validation process for the CY 2015 payment determination is approximately 6,000 hours (500 selected hospitals \times 12 hours per hospital).

HOPDs will incur a financial burden associated with the required data abstraction and data submission for the validation process. We estimated that the financial burden associated with validation would be \$180,000 (\$30.00 per hour \times 6,000 hours).

These requirements were approved under OCN: 0938-1109. This approval expired on October 31, 2013.

We invited public comment on the burden associated with data validation

information collection procedures. We did not receive any public comments. Therefore, we are finalizing our burden estimates as proposed.

f. Hospital OQR Program Reconsideration and Appeals Procedures

In section XIII.I. of the proposed rule and this final rule with comment period, for the CY 2015 payment determination and subsequent years, we proposed and are finalizing a minor change to the reconsideration request process to ensure our deadline for these requests will always fall on a business day. We also proposed and are finalizing our proposal to codify our reconsideration request process at 42 CFR 419.46(h).

While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of the Paperwork Reduction Act of 1995 regulations excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, or appeals or all of these actions.

2. ASCQR Program Requirements

a. Claims-Based Measures for the CY 2014 Payment Determination

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532), we discussed the information collection requirements for the five claims-based measures (four outcome measures and one process measure) to be used for the CY 2014 payment determination. The five measures are: (1) Patient Burn (NQF # 0263); (2) Patient Fall (NQF # 0266); (3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF # 0267); (4) Hospital Transfer/Admission (NQF # 0265); and (5) Prophylactic Intravenous (IV) Antibiotic Timing (NQF # 0264). We collected quality measure data for the five claims-based measures using QDCs placed on submitted claims for services furnished from October 1, 2012 through December 31, 2012 that were paid by the contractor by April 30, 2013.

Approximately 71 percent of ASCs participated in Medical Event Reporting (the ASC Quality Collaboration's voluntary reporting program) (<http://www.ascquality.org>), which included reporting on the first four claims-based measures, which are outcome measures. Between January 1995 and December 2007, ASCs reported 126 events, an average of 8.4 events per year (Florida Medical Quality Assurance, Inc. and Health Services Advisory Group: Ambulatory Surgical Center Environmental Scan (July 2008) (Contract No. GS-10F-0096T)). We

estimated the burden to report QDCs for these 4 claims-based outcome measures to be nominal due to the small number of cases. Based on the data above, extrapolating from 71 percent to 100 percent of ASCs reporting, there would be an average of 11.8 events per year or less than 1 case per month per ASC.

For the claims-based process measure, Prophylactic IV Antibiotic Timing, we also estimated the burden associated with submitting QDCs to be nominal because few procedures performed by ASCs will require prophylactic antibiotic administration.

We invited public comment on the burden associated with these information collection requirements. We did not receive any public comments on our burden discussion in the CY 2014 OPPI/ASC proposed rule (78 FR 43686) regarding the five previously finalized claims-based measures for the CY 2014 payment determination.

b. Claims-Based and Web-Based Measures for the CY 2015 and CY 2016 Payment Determinations

In the CY 2013 OPPI/ASC final rule with comment period (77 FR 68532), we discussed the information collection requirements for the measures to be used for the CY 2015 and CY 2016 payment determinations. For the CY 2015 payment determination, we finalized the retention of the five measures we adopted for the CY 2014 payment determination, and we added two structural, Web-based, measures: Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures (76 FR 74504 through 74509). For the CY 2016 payment determination, we adopted the seven measures for the CY 2015 payment determination and added Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) (76 FR 74509).

Based on our data for CY 2014 payment determinations above for claims-based measures, extrapolating to 100 percent of ASCs reporting, there would be an average of 11.8 events per year. Therefore, we estimated the burden to report QDCs on this number of claims per year for the first four claims-based outcome measures to be nominal due to the small number of cases (approximately one case per month per ASC) for the CY 2015 and CY 2016 payment determinations. We estimated the burden associated with submitting QDCs for the fifth measure to be nominal as well, as discussed above.

For the CY 2015 payment determination, for the Web-based measures, ASCs will enter required information using a Web-based

collection tool between July 1, 2013 and August 15, 2013. For the Safe Surgery Checklist Use measure, we estimated that each participating ASC will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 878 hours (5,260 ASCs \times 1 measure \times 0.167 hours per ASC). For the CY 2015 payment determination, we estimated that, for the ASC Facility Volume Data on Selected ASC Surgical Procedures measure, each participating ASC would spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 878 hours (5,260 ASCs \times 1 measure \times 0.167 hours per ASC).

For the CY 2016 payment determination, in the CY 2014 OPPI/ASC proposed rule (78 FR 43669), we proposed, and are finalizing in this final rule with comment period, that ASCs would report data for the Safe Surgery Checklist Use measure and the ASC Facility Volume Data on Selected ASC Surgical Procedures measure between January 1, 2015 and August 15, 2015 for services furnished between January 1, 2014 and December 31, 2014. For the Safe Surgery Checklist Use measure for the CY 2016 payment determination, we estimated that each participating ASC would spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 878 hours (5,260 ASCs \times 1 measure \times 0.167 hours per ASC). For the CY 2016 payment determination, for the ASC Facility Volume Data on Selected ASC Surgical Procedures measure, we estimated that each participating ASC would spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 878 hours (5,260 ASCs \times 1 measure \times 0.167 hours per ASC).

For the CY 2016 payment determination, for the NHSN HAI measure: Influenza Vaccination Coverage among Healthcare Personnel, we estimated that the total annual burden associated with this measure for ASCs, including NHSN registration (5,260 ASCs \times 0.083 hour per facility = 437 hours) and data submission (5,260 ASCs \times 0.167 hour per response for 20 workers per facility = 17,568) would be 18,005 hours. This estimate is based upon burden estimates from the CDC (OMB No. 0920-0666) and reported numbers for the average number of workers per ASC.

For the CY 2016 payment determination, in the CY 2014 OPPI/ASC proposed rule (78 FR 43686), we

proposed to add four measures to the program with data collection to begin during CY 2014 and submission to be via a Web-based tool. As we discuss in section XV.B.3. of this final rule with comment period, we are finalizing the adoption of three of these four measures. For the chart-abstracted measures, we estimated that each participating ASC would spend 35 minutes per case to collect and submit the data, making the total estimated burden for ASCs with a single case per ASC of 3,067 hours (5,260 ASCs \times 0.583 hours per case per ASC). We expect that ASCs would vary greatly as to the number of cases per ASC due to ASC specialization.

In addition, in the proposed rule we stated that ASCs would incur a financial burden associated with chart abstraction and data submission for these four proposed measures. We estimated that ASCs (in the proposed rule (78 FR 43686), we erroneously referred to “for a chart-abstracted case, an ASC”) would incur costs of \$91,997 (5,260 ASCs \times \$30.00 per hour \times 0.583 hours). We solicited public comment on the impact of adding these measures and requiring data submission. We also invited public comment on the burden associated with these information collection requirements.

For the previously finalized Web-based Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures measures for the CY 2016 payment determination, we received public comments that increasing the data submission time period was an appropriate and beneficial change that did not increase burden. These comments are discussed in section XV.D.5.b of this final rule with comment period.

For the claims-based measures, we received public comments that data collection via claims was a way to reduce burden. These comments are discussed in sections XV.D.4 and XV.D.5. of this final rule with comment period.

We discuss public comments we received on burden associated with data collection for the NHSN HAI measure: Influenza Vaccination Coverage among Healthcare Personnel in section XV.D.6.b. of this final rule with comment period.

We discuss public comments we received on burden associated with the collection of aggregated data via a CMS Web-based tool in sections XV.B.3 and XV.D.5.c. of this final rule with comment period.

After consideration of the public comments received, we are finalizing our burden estimates related to claims-

based and Web-based measures for the CY 2015 and 2016 payment determinations as proposed.

c. Program Administrative Requirements and QualityNet Accounts; Extraordinary Circumstances Extension or Waiver Requests; Reconsideration Requests

In the CY 2012 OPPI/ASC final rule with comment period (76 FR 74516), we finalized our proposal to consider an ASC to be participating in the ASCQR Program for the CY 2014 payment determination if the ASC includes QDCs specified for the program on their CY 2012 claims relating to the finalized measures.

In the FY 2013 IPPS/LTCH PPS final rule, we finalized, for the CY 2015 payment determination and subsequent years, that once an ASC submits any quality measure data, it would be considered to be participating in the ASCQR Program. Once an ASC submits quality measure data indicating its participation in the ASCQR Program, in order to withdraw, an ASC must complete and submit an online form indicating that it is withdrawing from the program.

For the CY 2015 payment determination and subsequent years, if the ASC submits quality measure data, there is no additional action required by the ASC to indicate participation in the program. The burden associated with the requirements to withdraw from the program is the time and effort associated with accessing, completing, and submitting the online form. Based on the number of hospitals that have withdrawn from the Hospital OQR Program over the past 4 years, we estimated that 2 ASCs would withdraw per year and that an ASC would expend 30 minutes to access and complete the form, for a total burden of 1 hour per year.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53638 through 53639), we finalized for the CY 2015 payment determination the requirement that ASCs identify and register a QualityNet administrator in order to set up accounts necessary to enter structural measure data. We estimated that, based upon previous experience with the Hospital OQR Program, it would take an ASC 10 hours to obtain, complete, and submit an application for a QualityNet administrator and then set up the necessary accounts for structural measure data entry. We estimated the total burden to meet these requirements to be 52,600 hours (10 hours \times 5,260 ASCs). The financial burden associated with these requirements is estimated to

be \$1,578,000 (\$30.00 per hour \times 52,600 hours).

In the FY 2013 IPPS/LTCH PPS final rule, we adopted a process for an extension or waiver for submitting information required under the program due to extraordinary circumstances that are not within the ASC's control. We are requiring that an ASC would complete a request form that would be available on the QualityNet Web site, supply requested information, and submit the request. The burden associated with these requirements is the time and effort associated with gathering required information as well as accessing, completing, and submitting the form. Based on the number of ASCs that have submitted a request for an extension or waiver from the ASCQR Program over the past year, we estimated that 200 ASCs per year would request an extension or waiver and that an ASC would expend 2 hours to gather required information as well as access, complete, and submit the form, for a total burden of 400 hours per year. This estimate takes into account continued billing and claims processing issues.

We also adopted a reconsideration process that would apply to the CY 2014 payment determination and subsequent payment determination years under the ASCQR Program. While there is burden associated with an ASC filing a reconsideration request, the regulations at 5 CFR 1320.4 for the Paperwork Reduction Act of 1995 exclude data collection activities during the conduct of administrative actions.

We invited public comment on the burden associated with these information collection requirements.

We did not receive any public comments on our burden discussion in the proposed rule and are finalizing these burden estimates as proposed.

3. Hospital VBP Program Requirements

In section XIV. of the proposed rule, for the Hospital VBP Program, we proposed to allow hospitals to request an independent CMS review that would be an additional appeal process beyond the existing review and corrections process (77 FR 53578 through 53581 and 76 FR 74544 through 74547) and appeal process codified at 42 CFR 412.167.

While there is burden associated with a hospital requesting an independent CMS review, the regulations at 5 CFR § 1320.4 for the Paperwork Reduction Act of 1995 exclude collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, or appeals or all of these actions.

We invited public comment on the burden associated with these information collection requirements.

We did not receive any public comments on our burden discussion in the proposed rule.

XXII. 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.

XXIII. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of the final rule with comment period and the final rules in this document 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, the 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. In the CY 2014 OPPS/ASC proposed rule (78 FR 43687 through 43688), we solicited public comments on the regulatory impact analysis provided. 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 2014. 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, 2012, through and including December 31, 2012, and updated cost report information.

For CY 2014, we are continuing the current payment adjustment for rural SCHs, including EACHs. In addition, section 10324 of the Affordable Care Act, as amended by HCERA, authorizes a wage index of 1.00 for certain frontier States. Section 1833(t)(17) of the Act requires that subsection (d) hospitals that fail to meet quality reporting requirements under the Hospital OQR Program incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor. In this final rule with comment period, we are implementing these payment provisions.

This final rule with comment period is also necessary to update the ASC payment rates for CY 2014, 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 2014. Because the 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, because the services provided in ASCs are identified by HCPCS codes that are reviewed and revised either quarterly or annually, depending on the type of code, it is necessary to update the ASC payment rates annually to reflect these changes to HCPCS codes. 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. Sections 1833(i)(2)(D)(iv) and 1833(i)(7) of the Act authorize the Secretary to implement a quality reporting system for ASCs in a manner so as to provide for a reduction of 2.0 percentage points in any annual update with respect to the year involved for ASCs that fail to meet the quality reporting requirements. For CY 2014, we discuss the impacts associated with this payment reduction in section XV.C. of this final rule with comment period.

3. Overall Impacts for the OPPS and ASC Payment Provisions

We estimate that the effects of the final OPPS payment provisions will result in expenditures exceeding \$100 million in any 1 year. We estimate that the total increase from the changes in this final rule with comment period in Federal government expenditures under the OPPS for CY 2014 compared to CY 2013 will be approximately \$600 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate that the OPPS expenditures for CY 2014 will be approximately \$4.372 billion higher relative to expenditures in CY 2013. Because this final rule with comment period is economically significant as measured by the \$100 million threshold, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 55 displays the redistributive impact of the CY 2014 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 2014) will increase total OPPS payments by 1.7 percent in CY 2014. The changes to the APC weights, the changes to the wage indices, 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 2013 and CY 2014, 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 1.8 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 expenditures under the ASC payment system for CY 2014 compared to CY 2013 to be approximately \$143 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. Tables 56 and Table 57 of this final rule with comment period display the redistributive impact of the CY 2014 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 Final 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 2014 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 2014 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-1601-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 55 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 2014 OPPS/ASC proposed rule (78 FR 43687 through 43688), 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 this final rule with comment period that discuss the specific policies.

Comment: Numerous comments raised concerns about the lack of transparency created by introducing multiple policies into a complex payment system that was created by insufficient guidance on how proposed payment rates were developed, technical errors, insufficient policy details, and a lack of detailed impact analyses for each proposal.

Response: With regard to the lack of detailed impact analyses, we believe that our approach of modeling the overall impact of the payment system on classes of hospitals is one aspect of fostering transparency. However, assessing the impacts of a specific policy also relies on clear discussion of proposed changes and rationale, final modeled relative weights, summary data files and tables, and public use files. Overall impacts can allow a quick assessment of how multiple interacting policies combine to impact proposed payments, but can never provide the amount of additional detail that an individual commenter would desire for their specific product(s) or set of services.

We make numerous separate summary data files and public use files available, along with a discussion of our modeling processes, and we believe that this is the best means to foster robust public data-related comments on specific policies. We continuously examine ways in which the data process

could be simplified or made clearer, and we also welcome and appreciate public comment with regards to potential improvements. This year, we again received numerous thoughtful comments supported by detailed data analyses suggesting that commenters have modeled the data to draw detail on their specific policy interest. Finally, individual facilities have more recent internal data on the mix of services that they provide than the distribution of services in our claims data, and this should allow them to assess the impact on their facility along with discussion of the proposed policy in preamble text.

(2) Estimated Effects of OPPS Changes on Hospitals

Table 55 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 because we include CMHCs in our weight scaler estimate. We now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 55 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 2014, 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). We display separately the impact of our updates on CMHCs, and we discuss its impact on hospitals as part of our discussion of the hospital impacts.

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 final IPPS market basket percentage increase for FY 2014 is 2.5 percent (78 FR 50507). Section 1833(t)(3)(F)(i) of the Act reduces that 2.5 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.5 percentage points for FY 2014 (which is also the MFP adjustment for FY 2014 in the FY 2014 IPPS/LTCH PPS final rule (78 FR 51003); and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act further reduce the market basket percentage increase by 0.3 percentage points, resulting in the OPD fee schedule increase factor of 1.7 percent, which we are using in the calculation of the CY 2014 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 2014 estimates in Table 55.

To illustrate the impact of the CY 2014 changes, our analysis begins with a baseline simulation model that uses the CY 2013 relative payment weights, the FY 2013 final IPPS wage indices that include reclassifications, and the final CY 2013 conversion factor. Table 55 shows the estimated redistribution of the proposed increase in payments for CY 2014 over CY 2013 payments to hospitals and CMHCs as a result of the following factors: The independent effect of all relative weight changes between CY 2014 and CY 2013, resulting from final policies other than the packaging of outpatient laboratory services previously paid under the clinical laboratory fee schedule (CLFS) into the OPPS (Column 2); the marginal impact of the final policy to package clinical laboratory services (Column 3); the combined impact of the changes between CY 2013 and CY 2014 modeled in Columns 2 and 3 (Column 4: APC reconfiguration and recalibration for CY 2014 compared to CY 2013 payments, the combined effect of Columns 2 and 3); the final wage indices and the rural and cancer hospital adjustments (Column 5); the combined impact of all the changes described in the preceding columns plus the 1.7 percent OPD fee schedule increase factor update to the conversion factor (Column 6); the combined impact shown in Column 6 plus the CY 2014 frontier State wage

index adjustment (Column 7); and the estimated impact taking into account all payments for CY 2014 relative to all payments for CY 2013, including the impact of changes in estimated outlier payments and changes to the pass-through payment estimate (Column 8).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are not making any changes to the policy for CY 2014. 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 2014 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 2013 and CY 2014 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the final OPPS rates for CY 2014 will have a positive effect for providers paid under the OPPS, resulting in a 1.8 percent estimated increase in Medicare payments. 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 suggest that these changes will result in a 1.9 percent estimated increase in Medicare payments to all other hospitals. Those estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 55 shows the total number of facilities (4,068), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2012 hospital outpatient and CMHC claims data to model CY 2013 and CY 2014 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 2013 or CY 2014 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 (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 (3,905), 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 101 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration for Policies Other Than Outpatient Laboratory Test Packaging

Column 2 shows the estimated independent effect of all relative weight changes between CY 2013 and CY 2014 resulting from final policies other than packaging outpatient laboratory tests previously paid under the clinical laboratory fee schedule into the OPPS. These final policies include packaging drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (stress agents and Cysview), drugs and biologicals that function as supplies when used in a surgical procedure (skin substitutes), certain procedures described by add-on codes, and device removal procedures; new cost report data for estimating CT and MRI relative weights; and revisions to coding and APC structure for stereotactic radiosurgery. This column also reflects reclassification of services among APC groups due to updated CY 2012 hospital claims data and the most recent hospital cost report data available. Changes due to APC recalibration are less significant than in the CY 2014 OPPS/ASC proposed rule impact analysis, as several proposed policies were not finalized. Increases for rural hospitals are largely attributable to adoption of a single payment for clinic visits. Reductions for low volume hospitals, particularly rural hospitals, are attributable to reductions for certain

mental health services. Under the OPPS, payment for mental health services on a single day cannot exceed payment for partial hospitalization, and APC recalibration reduces the relative weight for partial hospitalization for CY 2014.

Column 3: APC Recalibration Due to Packaging Outpatient Laboratory Services

Column 3 shows the estimated impact of APC recalibration within the CY 2014 OPPS resulting from our packaging policy for outpatient laboratory services currently paid under the CLFS. This column compares the estimated CY 2014 OPPS payments with the addition of packaged laboratory services to CY 2014 OPPS payment in Column 2 plus payment for laboratory services at CY 2013 CLFS payment rates. Packaging laboratory services modestly reduces payment to rural hospitals who no longer receive separate payment for common laboratory tests. Relative weights for visits, x-rays, and the small set of common services furnished by rural hospitals (shown in Column 1) do increase with packaging, but this does not fully offset the impact of packaging laboratory tests. Packaging laboratory services also results in modest reductions to major teaching hospitals.

Column 4: APC Recalibration—All Changes

Column 4 shows the estimated combined effect of APC recalibration related to the policies modeled in Columns 2 and 3. Column 4 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 an increase of 0.1 percent, with the impact ranging from an increase of 0.4 percent to a decrease of 0.3 percent depending on the number of beds. Rural hospitals will experience a decrease of 0.4 percent, with the impact ranging from an increase of 0.5 percent to a decrease of 1.7 percent depending on the number of beds. Major teaching hospitals experience a decrease of 0.6 percent overall, largely attributable to packaging laboratory services. Packaging laboratory services also modestly reduces the relative weight for major teaching hospitals, while minor teaching hospitals and nonteaching hospitals experience modest increases.

Column 5: New Wage Indices and the Effect of the Rural and Cancer Hospital Adjustments

Column 5 demonstrates the combined budget neutral impact of APC recalibration; updating the wage indexes with the final fiscal year (FY) 2014 IPPS post-reclassification wage indexes; the rural adjustment; and the cancer hospital payment 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 indices for each year, and using a CY 2013 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indices. We also updated the list of counties qualifying for the section 505 out-migration adjustment.

Column 5 reflects the independent effects of the updated wage indices, 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 7. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are not making any changes to the policy for CY 2014. We are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2014, as described in section II.E. of this final rule with comment period.

We modeled the independent effect of updating the wage indices by varying only the wage indices, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2014 scaled weights and a CY 2013 conversion factor that included a budget neutrality adjustment for the effect of changing the wage indices between CY 2013 and CY 2014. Modest redistributions are the result of final FY 2014 wage policy.

The modeled differential between the CY 2013 cancer hospital payment adjustment and the CY 2014 cancer hospital payment adjustment had a minor effect on budget neutrality. We note that cancer hospitals receive about \$24 million less under the CY 2014 adjustment, which appears as a 0.1 increase for the general hospital population in row 2 of Column 5, All Hospitals (excluding cancer and children's hospitals, and CMHCs).

Column 6: All Budget Neutrality Changes Combined With the Market Basket Update

Column 6 demonstrates the combined impact of all the changes previously

described and the update to the conversion factor of 1.7 percent. It shows the estimated cumulative impact of the budget neutral adjustments from Columns 4 and 5 and the OPD fee schedule increase factor of 1.7 percent. With the exception of small rural hospitals and rural hospitals in the Middle Atlantic, we estimate that the addition of the 1.7 percent market basket alleviates negative impacts on payments for CY 2014 created by budget neutrality made in Columns 4 and 5 for payments made to most hospitals. Overall, these changes increase payments to urban hospitals by 1.9 percent and to rural hospitals by 1.1 percent. Most classes of hospitals will receive an increase in line with the 1.7 percent overall increase after the update is applied to the budget neutrality adjustments.

Column 7: All Adjustments With the Frontier State Wage Index Adjustment

This column shows the impact of all budget neutrality adjustments, application of the 1.7 percent OPD fee schedule increase factor, and the nonbudget neutral impact of applying the CY 2014 frontier State wage adjustment (that is, the frontier State wage index change in addition to all changes reflected in Column 6). This column differs from Column 6 solely based on application of the nonbudget neutral frontier State wage index adjustment. Rural hospitals in West North Central and Mountain States experience increases in payment of 3.2 and 2.3 percent, respectively, as a result of the frontier State wage index adjustment, while urban hospitals in those States experience increases of 3.6 and 2.1 percent, respectively.

Column 8: All Changes for CY 2014

Column 8 depicts the full impact of the CY 2014 policies on each hospital group by including the effect of all of the changes for CY 2014 and comparing them to all estimated payments in CY 2013. Column 8 shows the combined budget neutral effects of Column 4 and 5; the OPD fee schedule increase; the impact of the frontier State wage index adjustment; the impact of estimated OPDS 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 OPDS payments dedicated to transitional pass-through payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2013 update (and assumed, for modeling purposes, to be the same number for CY 2014), we included 52 hospitals in our model because they had both CY 2012 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2014 will increase payments to all providers by 1.8 percent for CY 2014. We modeled the independent effect of all changes in Column 8 using the final relative payment weights for CY 2013 and the final relative payment weights for CY 2014. We used the final conversion factor for CY 2013 of \$71.313 and the final CY 2014 conversion factor of \$72.672 discussed in section II.B. of this final rule with comment period.

Column 8 contains simulated outlier payments for each year. We used the one year charge inflation factor used in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50982) of 4.73 percent (1.0473) to increase individual costs on the CY 2012 claims, and we used the most recent overall CCR in the July 2013 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2013. Using the CY 2012 claims and a 4.73 percent charge inflation factor, we currently estimate that outlier payments for CY 2013, using a multiple threshold of 1.75 and a fixed-dollar threshold of \$2,025 will be approximately 1.1 percent of total payments. The estimated current outlier payments of 1.1 percent are incorporated in the comparison in Column 8. We used the same set of claims and a charge inflation factor of 9.69 percent (1.0969) and the CCRs in the July 2013 OPSF, with an adjustment of 0.9645, to reflect relative changes in cost and charge inflation between CY 2012 and CY 2014, to model the CY 2014 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of \$2,900.

We estimate that the anticipated change in payment between CY 2013 and CY 2014 for the hospitals failing to meet the Hospital OQR Program requirements will be negligible. Overall, we estimate that facilities will experience an increase of 1.8 percent under this final rule with comment period in CY 2014 relative to total spending in CY 2013. This projected increase (shown in Column 8) of Table 55 reflects the 1.7 percent OPD fee schedule increase factor, with 0.13 percent for the change in the pass-through estimate between CY 2013 and CY 2014, less 0.1 percent for the difference in estimated outlier payments

between CY 2013 (1.1 percent) and CY 2014 (1.0 percent), less 0.1 percent due to the frontier adjustment in CY 2013, plus 0.1 percent due to the frontier State wage index adjustment in CY 2014.

When we exclude cancer and children's hospitals (which are held harmless to their pre-BBA amount) and CMHCs, the estimated update increases is 1.9 percent after rounding. We estimate that the combined effect of all changes for CY 2014 will increase payments to urban hospitals by 2.0 percent.

Overall, we estimate that rural hospitals will experience a 1.1 percent

increase as a result of the combined effects of all changes for CY 2014. We estimate that rural hospitals that bill less than 5,000 lines of OPPS services will experience an increase of 2.2 percent and rural hospitals that bill 5,000 or more lines of OPPS services will experience increases ranging from 0.1 to 5.0 percent.

Among hospitals by teaching status, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 1.4 percent for major teaching hospitals and 1.8 percent for nonteaching hospitals.

Minor teaching hospitals will experience an estimated increase of 2.3 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 2.0 percent, proprietary hospitals will experience an increase of 2.0 percent, and governmental hospitals will experience an increase of 1.1 percent.

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TABLE 55.—ESTIMATED IMPACT OF THE CY 2014 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	APC Recalibration (Policies Other than Outpatient Laboratory Services) (%)	APC Recalibration (Outpatient Laboratory Services Packaging Policy) (%)	APC Recalibration (all changes) (%)	New Wage Index and Provider Adjustments (%)	Combined Cols 4, 5 with Market Basket Update (%)	Column 6 with Frontier State Wage Index Adjustment (%)	All Changes (%)
ALL FACILITIES *	4,068	0.0	0.0	0.0	0.0	1.7	1.8	1.8
ALL HOSPITALS	3,905	0.0	0.0	0.0	0.1	1.8	1.9	1.9
(excludes hospitals permanently held harmless and CMHCs)								
URBAN HOSPITALS	2,959	0.0	0.2	0.1	0.1	1.9	2.0	2.0
LARGE URBAN (GT 1 MILL.)	1,612	0.0	0.2	0.3	0.2	2.1	2.1	2.2
OTHER URBAN (LE 1 MILL.)	1,347	-0.1	0.1	0.0	0.0	1.7	1.9	1.7
RURAL HOSPITALS	946	0.4	-0.8	-0.4	-0.2	1.1	1.4	1.1
SOLE COMMUNITY	391	0.5	-0.5	0.0	-0.2	1.5	1.9	1.6
OTHER RURAL	555	0.3	-1.0	-0.8	-0.2	0.7	0.8	0.8
BEDS (URBAN)								
0 - 99 BEDS	1,037	-0.5	0.4	-0.1	0.0	1.7	1.8	1.7
100-199 BEDS	843	0.0	0.2	0.2	0.0	1.9	2.0	2.0
200-299 BEDS	458	0.0	0.3	0.3	0.1	2.1	2.3	2.2
300-499 BEDS	410	0.1	0.3	0.4	0.1	2.1	2.3	2.2
500 + BEDS	211	-0.1	-0.2	-0.3	0.2	1.6	1.6	1.6
BEDS (RURAL)								

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	APC Recalibration (Policies Other than Outpatient Laboratory Services) (%)	APC Recalibration (Outpatient Laboratory Services Packaging Policy) (%)	APC Recalibration (all changes) (%)	New Wage Index and Provider Adjustments (%)	Combined Cols 4, 5 with Market Basket Update (%)	Column 6 with Frontier State Wage Index Adjustment (%)	All Changes (%)
0 - 49 BEDS	363	0.9	-2.5	-1.7	-0.5	-0.5	-0.3	-0.6
50- 100 BEDS	346	0.6	-1.1	-0.5	-0.1	1.1	1.3	1.0
101- 149 BEDS	133	0.2	-0.2	0.1	-0.2	1.6	1.8	1.6
150- 199 BEDS	60	0.0	-0.6	-0.6	-0.1	1.0	1.5	1.0
200 + BEDS	44	0.1	0.4	0.5	0.0	2.1	2.1	2.3
VOLUME (URBAN)								
LT 5,000 Lines	523	-1.9	1.0	-0.9	0.0	0.9	1.1	0.6
5,000 - 10,999 Lines	124	-1.5	1.7	0.1	-0.2	1.6	2.1	1.7
11,000 - 20,999 Lines	121	-1.3	1.4	0.1	0.0	1.8	2.0	1.8
21,000 - 42,999 Lines	232	-0.5	1.6	1.1	-0.2	2.6	2.6	2.6
42,999 - 89,999 Lines	480	-0.2	1.4	1.2	0.1	3.0	3.0	3.0
GT 89,999 Lines	1,479	0.0	0.0	0.0	0.1	1.8	1.9	1.9
VOLUME (RURAL)								
LT 5,000 Lines	34	-1.0	1.8	0.8	-0.4	2.1	6.8	2.2
5,000 - 10,999 Lines	28	2.4	-2.8	-0.5	-0.8	0.4	0.4	0.1
11,000 - 20,999 Lines	54	6.5	-2.1	4.2	-0.8	5.1	5.1	5.0
21,000 - 42,999 Lines	163	1.0	-0.8	0.1	-0.2	1.6	2.4	1.5
GT 42,999 Lines	667	0.3	-0.8	-0.5	-0.2	1.1	1.3	1.1
REGION (URBAN)								
NEW ENGLAND	152	0.2	-1.2	-1.0	0.6	1.2	1.2	1.2
MIDDLE ATLANTIC	351	0.1	-0.9	-0.7	0.7	1.7	1.7	1.7
SOUTH ATLANTIC	453	-0.2	0.5	0.3	-0.3	1.7	1.7	1.9
EAST NORTH CENT.	474	0.3	-0.3	-0.1	-0.1	1.6	1.6	1.6
EAST SOUTH CENT.	176	-0.2	0.7	0.5	-0.2	2.0	2.0	2.1
WEST NORTH CENT.	198	0.1	1.1	1.2	-0.4	2.5	3.6	2.7
WEST SOUTH CENT.	519	-0.6	0.5	-0.2	-0.4	1.2	1.2	1.3
MOUNTAIN	198	-0.3	0.9	0.6	-0.6	1.7	2.1	1.8
PACIFIC	389	0.2	0.7	0.9	1.0	3.6	3.6	3.5

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	APC Recalibration (Policies Other than Outpatient Laboratory Services) (%)	APC Recalibration (Outpatient Laboratory Services Packaging Policy) (%)	APC Recalibration (all changes) (%)	New Wage Index and Provider Adjustments (%)	Combined Cols 4, 5 with Market Basket Update (%)	Column 6 with Frontier State Wage Index Adjustment (%)	All Changes (%)
PUERTO RICO	49	0.8	-0.8	0.0	0.5	2.1	2.1	2.2
REGION (RURAL)								
NEW ENGLAND	25	0.4	-1.0	-0.6	0.4	1.5	1.5	1.4
MIDDLE ATLANTIC	69	1.0	-3.6	-2.6	0.2	-0.7	-0.7	-0.8
SOUTH ATLANTIC	160	0.2	-0.1	0.1	-0.3	1.5	1.5	1.6
EAST NORTH CENT.	127	0.4	-1.6	-1.1	-0.3	0.3	0.3	0.4
EAST SOUTH CENT.	171	0.2	-0.2	0.1	-0.5	1.2	1.2	1.3
WEST NORTH CENT.	99	0.3	0.2	0.6	-0.2	2.1	3.2	2.1
WEST SOUTH CENT.	200	0.5	-0.6	-0.1	-0.5	1.1	1.1	1.2
MOUNTAIN	66	0.0	-1.2	-1.1	0.2	0.8	2.3	0.2
PACIFIC	29	0.5	0.3	0.8	1.1	3.6	3.6	3.5
TEACHING STATUS								
NON-TEACHING	2,885	0.0	0.1	0.1	0.0	1.7	1.8	1.8
MINOR	699	0.1	0.4	0.5	0.0	2.2	2.5	2.3
MAJOR	321	0.0	-0.6	-0.6	0.3	1.3	1.3	1.4
DSH PATIENT PERCENT								
0	11	2.8	1.3	4.1	0.1	5.9	5.9	5.6
GT 0 - 0.10	350	-0.6	0.1	-0.5	0.1	1.3	1.4	1.4
0.10 - 0.16	341	-0.1	-0.1	-0.2	0.1	1.6	1.7	1.7
0.16 - 0.23	685	0.2	-0.2	-0.1	0.1	1.7	1.8	1.8
0.23 - 0.35	1,080	0.0	0.3	0.3	0.0	2.0	2.2	2.1
GE 0.35	823	0.1	-0.1	0.0	0.1	1.8	1.9	1.8
DSH NOT AVAILABLE **	615	0.0	0.5	0.5	-0.1	2.1	2.1	2.4
URBAN TEACHING/DSH								
TEACHING & DSH	923	0.0	0.0	0.0	0.1	1.9	2.0	1.9
NO TEACHING/DSH	1,450	-0.1	0.4	0.3	0.0	2.0	2.0	2.0
NO TEACHING/NO DSH	11	2.8	1.3	4.1	0.1	5.9	5.9	5.6

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	APC Recalibration (Policies Other than Outpatient Laboratory Services) (%)	APC Recalibration (Outpatient Laboratory Services Packaging Policy) (%)	APC Recalibration (all changes) (%)	New Wage Index and Provider Adjustments (%)	Combined Cols 4, 5 with Market Basket Update (%)	Column 6 with Frontier State Wage Index Adjustment (%)	All Changes (%)
DSH NOT AVAILABLE**	575	-0.2	0.4	0.2	0.0	1.9	2.0	2.3
TYPE OF OWNERSHIP								
VOLUNTARY	2,040	0.1	0.0	0.1	0.1	1.9	2.1	2.0
PROPRIETARY	1,300	-0.5	0.9	0.4	-0.2	1.9	2.0	2.0
GOVERNMENT	565	0.3	-0.7	-0.5	-0.2	1.1	1.1	1.1
CMHCs	101	-1.3	1.8	0.4	-0.4	1.7	1.7	1.8

Column (1) shows total hospitals and/or CMHCs.

Column (2) shows the additional impact of changes resulting from the reclassification of HCPCS codes among APC groups and other data changes as a result of including the CY 2014 OPPS packaging policies (but excluding the packaging of outpatient laboratory services currently paid at CLFS rates).

Column (3) shows the additional impact of changes resulting from the reclassification of HCPCS codes among APC groups and other data changes as a result of including the CY 2014 OPPS policy to package outpatient laboratory services currently paid at CLFS rates.

Column (4) includes all CY 2014 OPPS proposals and compares those to the CY 2013 OPPS (which includes outpatient laboratory services previously paid at CLFS rates).

Column (5) shows the budget neutral impact of updating the wage index by applying the FY 2014 hospital inpatient wage index. The rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. Similarly, the differential in estimated cancer hospital payments for the adjustment is limited and thus results in a budget neutrality factor of 1.0005.

Column (6) shows the impact of all budget neutrality adjustments and the addition of the 1.7 percent OPD fee schedule update factor (2.5 percent reduced by 0.5 percentage points for the productivity adjustment and further reduced by 0.3 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).

Column (7) shows the nonbudget neutral impact of applying the CY 2014 frontier State wage index adjustment.

Column (8) 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 4,068 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs. Payments for laboratory services at CLFS rates, which we are packaging in the CY 2014 OPPS, are included in the columns where appropriate.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

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(3) Estimated Effects of OPPS Changes on CMHCs

The last line of Table 55 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization (PHP) services under the OPPS. In CY 2013, 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). In contrast, 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 reports for the provider type to which the APC is specific. For CY 2014, we are continuing the provider-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 2012 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.

Packaging outpatient laboratory tests results in a 1.8 percent payment increase to CMHCs, which is offset by a 1.3 percent decrease in payments from APC recalibration for policies other than packaging outpatient laboratory tests. Together with the market basket and all other changes, we estimate that CMHCs will experience an overall 1.8 percent increase in payments from CY 2013 (shown in Column 8).

Column 5 shows that the estimated impact of adopting the final FY 2014 wage index values will result in a small decrease of 0.4 percent to CMHCs. We note that all providers paid under the OPPS, including CMHCs, will receive a 1.7 percent OPD fee schedule increase factor. Column 6 shows that combining this OPD fee schedule increase factor, along with changes in APC policy for CY 2014 and the FY 2014 wage index updates, will result in an estimated increase of 1.7 percent. Column 7 shows that adding the frontier State wage index adjustment will result in no change to the cumulative 1.7 percent increase. Column 8 shows that adding the changes in outlier and pass-through

payments will result in an additional 0.1 percent increase in payment for CMHCs, for a total increase of 1.8 percent. This reflects all changes to CMHCs for CY 2014.

(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, the statute limits beneficiary liability for copayment for a procedure to the hospital inpatient deductible for the applicable year. The CY 2014 inpatient hospital deductible is \$1,216.

We estimate that the aggregate beneficiary coinsurance percentage will be 21.7 percent for all services paid under the OPPS in CY 2014. The estimated aggregate beneficiary coinsurance reflects the final policy to package laboratory services into the outpatient hospital services with which they are billed in addition to general system adjustments, including recalibration of the APC relative payment weights, change in the portion of OPPS payments dedicated to pass-through payments, and changes in the cancer hospital payment adjustment.

(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 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 \$600 million in additional program payments for OPPS services furnished in CY 2014. 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 XXIII.A. of this final rule with comment period.

(7) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we proposed and are making 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 proposed in section II.A.2.e. of the OPPS proposed rule to create 29 comprehensive APCs for CY 2014 to prospectively pay for device-dependent hospital outpatient services associated with 121 HCPCS codes. We proposed to define a comprehensive APC as a classification for the provision of a primary service and all adjunct services provided to support the delivery of the primary service. For services that trigger a comprehensive APC payment, the comprehensive APC would treat all individually reported codes on the claim as representing components of the comprehensive service, resulting in a single prospective payment based on the cost of all individually reported codes on the claim. For these APCs, we proposed to treat all previously individually reported codes as representing components of the comprehensive service, making a single payment for the comprehensive service based on all charges on the claim, excluding only charges for services that cannot be covered by Medicare Part B or that are not payable under the OPPS. This would create a single all-inclusive payment for the claim that is subject to a single beneficiary copayment, up to the cap set at the level of the inpatient hospital deductible.

We proposed this as a step that we believe will further improve the accuracy of our payments for these services where there is a substantial cost for a device that is large compared to the other costs that contribute to the cost of the procedure, and where the cost of the procedure is large compared to the adjunctive and supportive services delivered along with that procedure. We also believed the proposed policies would enhance beneficiary understanding and transparency for the beneficiary, for physicians, and for hospitals by creating a common reference point with a similar meaning for all three groups by using the comprehensive service concept that already identifies these services when they are furnished to a hospital inpatient.

We considered implementing this policy for CY 2014 as proposed, but in

response to public comments we received and because we are providing significantly greater detail on the comprehensive APC payment calculation methodology, we are delaying implementation of the policy for 1 year (we refer readers to section II.A.2.e. of this final rule with comment period). Although we are finalizing our comprehensive APC policy effective CY 2015, we also are inviting additional public comment because there is significant additional information on the comprehensive APC policy in the preamble of this final rule with comment period. We also believe that additional time to consider operational issues over a longer period of time is appropriate for this new payment methodology. We have published tables in this final rule with comment period to demonstrate how this policy would have been implemented in CY 2014, and we will 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.

In our final policy, we have revised some of our APC assignments to better align resource requirements in accordance with our usual 2 times rule adjustments and also to ensure that the resources required with certain complex subsets of procedures are similarly aligned with the other services in the APC. We have created a complexity adjustment to assign certain other subsets of complex procedures to different APCs than the simpler versions of those services. We have reassigned the composite cardiac ablation APC to the comprehensive APC for combined electrophysiology and cardiac ablation in order to remove an ambiguity in our proposed rule, and we have modified our proposal to base the APC assignment on the identification of the service with the greatest single service cost in the CY 2012 claims data rather than the proposed service with the greatest CY 2012 single service payment. Finally, we are not finalizing our proposal to include costs from certain inpatient room and board cost centers for comprehensive APC ratesetting because the outpatient costs associated with services in comprehensive APCs should not be reported in these inpatient cost centers. Also, we have removed the cost of brachytherapy seeds from comprehensive payment and specified that these seeds will be paid through unpackaged dedicated APC payments.

We considered but did not implement a number of other options. We considered implementing this policy for CY 2014 as proposed, but did not do so

because we believe we should provide an opportunity for additional public comment as well as a longer time period for operational implementation by CMS contractors and other stakeholders. We considered but did not implement comprehensive APCs as originally proposed. Although we believe that an averaged payment system similar to the IPPS with a single payment for a primary or comprehensive service is our goal and would be feasible, we agreed with commenters that the sudden transition from component payments to comprehensive payments could potentially create some economic challenges for some hospitals. Although we noted that a single payment for single and multiple component procedures, including short stay procedures, has worked well in the IPPS for almost 30 years, we determined that a complexity adjustment as recommended by commenters could reduce the spread of costs and ease the transition as hospitals explore mechanisms to increase efficiencies if their mean costs of a specific complex procedure exceed the average cost.

We considered but did not implement recommendations to eliminate certain proposed APCs from conversion to comprehensive payments. All of the proposals for exclusion were based on multiple component payments or on coding changes. We considered excluding the different APCs where commenters expressed concerns. However, after analysis of each APC, after applying our usual processes of modeling coding changes, and after developing and applying a complexity adjustment for high volume complex services with a high cost variance from the mean payment, we determined that these processes applied equally well to the various APCs and no sets of services stood out as inappropriate for conversion on the basis of coding changes or the basis of multiple component procedures that could not have any potential adverse impact mitigated.

We considered but did not implement a multiple procedure adjustment to the comprehensive APC payment. As an alternative to the complexity adjustment, we considered a multiplier to be applied when two or more individual procedures were performed during the same comprehensive service. However we did not consider that, in our current year analyses, a single multiplier reflected the entire range of services that could be combined. We also did not believe that a multiple procedure adjustment was consistent with the concept of the comprehensive service representing a single entire

service to a beneficiary. However we will continue to explore other options to account for multiple components, including multiple surgical procedures as well as multiple devices, as we continue to analyze comprehensive APCs in the future.

We considered but did not implement a less comprehensive packaging policy for comprehensive APCs. We had considered a less comprehensive packaging policy before our proposed rule, but we did not believe that was advantageous as we discussed in the proposed rule. We reconsidered those options after receiving comments, but noted that the few comments suggesting more limited packaging were balanced by the comments agreeing with our comprehensive concept. We did not receive any public comments on this topic concerning issues that we had not already considered, so therefore we did not modify the packaging rules other than the exclusion of brachytherapy seeds as noted.

- Alternatives Considered for Payment of Hospital Outpatient Visits

As described in section VII. of this final rule with comment period, we are finalizing our proposal to replace the current five levels of visit codes for each clinic visit with a new alphanumeric Level II HCPCS code representing a single level of payment for clinic visits. We also are finalizing our proposal to assign the new alphanumeric Level II HCPCS to newly created APC 0634 with CY 2014 OPPS payment rates based on the total geometric mean costs of Level 1 through Level 5 clinic visit codes obtained from CY 2012 OPPS claims data. For CY 2014, we are not finalizing our proposal to replace the current five levels of visit codes for each Type A ED, and Type B ED visits with two new alphanumeric Level II HCPCS codes representing a single level of payment for Type A and Type B of ED visits, respectively.

In developing this policy, we considered two alternatives, the first of which was to finalize our proposal to replace the current five levels of visit codes for each Type A ED, and Type B ED visits with two new alphanumeric Level II HCPCS codes representing a single level of payment for Type A and Type B of ED visits, respectively, in addition to finalizing our proposal to replace the current five levels of visit codes for each clinic visit with a new alphanumeric Level II HCPCS code representing a single level of payment for clinic visits.

While we believe this alternative could offer advantages over the current CY 2013 OPPS visit payment policy, we

did not choose this alternative because as we describe in section VII. of this final rule with comment period, in light of the thoughtful and detailed alternatives put forth by commenters, as well as the comments on the potential issues associated with a single level of payment for ED visits that both require additional study on our part here at CMS, we believe it is best to delay any change in ED visit coding while we further consider the most appropriate payment structure for Type A and Type B ED visits.

We also considered replacing the current five levels of visit codes for each clinic, Type A ED, and Type B ED visit with six new alphanumeric Level II HCPCS codes representing two levels (lower level and higher level) of payment for each of the three types of visits. The lower-level alphanumeric codes for clinic, Type A ED, and Type B ED visits would replace the current Level 1 and Level 2 visit codes, respectively, and would be assigned to newly created or reconfigured APCs with CY 2014 OPPS payment rates based on the total mean costs of Level 1 and 2 visit codes obtained from CY 2012 OPPS claims data for each visit type. The higher-level alphanumeric codes for clinic, Type A ED, and Type B ED visits would replace the current Level 3 through Level 5 visit codes, respectively, and would be assigned to newly created or reconfigured APCs with CY 2014 OPPS payment rates based on the total mean costs of Level 3 through Level 5 visit codes obtained from CY 2012 OPPS claims data for each visit type.

While we believe that this alternative could also offer advantages over the current CY 2013 OPPS visit payment policy, we did not choose this alternative because, as we describe in section VII. of this final rule with comment period, we believed that a single level of payment for each type of clinic visit was the best policy option as this proposal would be easily implemented by hospitals; reduces administrative burden relative to the existing 5-level visit payment structure; and maximizes hospitals' incentives to provide care in the most efficient manner as there would be no incentive to provide unnecessary care to achieve a higher level visit threshold. A two-level visit payment structure would not be as easily implemented by hospitals as a single-level visit payment structure, and the need for hospitals to develop and implement guidelines to differentiate the levels of service would continue to exist. Also, while the two-level visit payment structure may provide incentives for hospitals to be

efficient, the incentives may not be so great as under a single-level visit payment structure. For ED visits, we believe it is best to delay any change in ED visit coding while we consider further the most appropriate payment structure for Type A and Type B ED visits, for the reasons stated earlier in this section. Therefore, we are finalizing our proposal to create a new alphanumeric Level II HCPCS code to describe all levels of clinic visits rather than continue to recognize five levels each of clinic visits. We are not finalizing our proposal to create two new alphanumeric Level II HCPCS codes to describe all levels of Type A and Type B ED visits, respectively, rather than continue to recognize five levels each of Type A and Type B ED visits.

b. Estimated Effects of CY 2014 ASC Payment System Final Policies

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 2014 ASC relative payment weights by scaling the CY 2014 OPPS relative payment weights by the proposed ASC scaler of 0.9235. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 56 and 57 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 2014 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 2014 ASC conversion factor by adjusting the CY 2013 ASC conversion factor by 1.0009 to account for changes in the pre-floor and pre-reclassified hospital wage indices between CY 2013 and CY 2014 and by applying the CY 2014 MFP-adjusted CPI-U update factor of 1.2 percent (projected CPI-U update of 1.7 percent minus a projected productivity

adjustment of 0.5 percent). The CY 2014 ASC conversion factor is \$43,471.

(1) Limitations of Our Analysis

Presented here are the projected effects of the changes for CY 2014 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2012 and CY 2014 with precision. We believe that the net effect on Medicare expenditures resulting from the CY 2014 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 CY 2014 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 2014 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 2014 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2012 claims data. Table 56 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2013 payments to estimated CY 2014 payments, and Table 57 shows a comparison of estimated CY 2013 payments to estimated CY 2014 payments for procedures that we estimate will receive the most Medicare payment in CY 2013.

Table 56 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 56.

- 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 2013 ASC Payments were calculated using CY 2012 ASC utilization (the most recent full year of ASC utilization) and CY

2013 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2013 ASC payments.

- Column 3—Estimated CY 2014 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 2014 compared to CY 2013.

As seen in Table 56, we estimate that the update to ASC rates for CY 2014 will result in a 1 percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 5 percent increase in aggregate payment amounts for digestive system procedures, and a 3 percent decrease in aggregate payment amounts for nervous system procedures.

Generally, for the surgical specialty groups that account for less ASC utilization and spending, we estimate that the payment effects of the CY 2014 update are variable. For instance, we estimate that, in the aggregate, payment for musculoskeletal system procedures

will not change, whereas payment for genitourinary system procedures, integumentary system procedures and respiratory system procedures will increase by 3 to 14 percent under the CY 2014 rates.

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 2014 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 6 percent for CY 2014.

Also displayed in Table 56 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 11 percent for CY 2014.

TABLE 56.—ESTIMATED IMPACT OF THE FINAL CY 2014 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2014 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2013 ASC Payments (in Millions) (2)	Estimated CY 2014 Percent Change (3)
Total	\$3,675	1%
Eye and ocular adnexa	\$1,501	1%
Digestive system	\$744	5%
Nervous system	\$566	-3%
Musculoskeletal system	\$454	0%
Genitourinary system	\$160	3%
Integumentary system	\$133	4%
Respiratory system	\$46	14%
Cardiovascular system	\$32	1%
Ancillary items and services	\$21	-11%
Auditory system	\$12	3%
Hematologic & lymphatic systems	\$6	9%

Table 57 below shows the estimated impact of the updates to the revised

ASC payment system on aggregate ASC payments for selected surgical

procedures during CY 2014. The table displays 30 of the procedures receiving

the greatest estimated CY 2013 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2013 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.

- Column 3—Estimated CY 2013 ASC Payments were calculated using CY 2012 ASC utilization (the most recent full year of ASC utilization) and the CY 2013 ASC payment rates. The estimated CY 2013 payments are expressed in millions of dollars.

- Column 4—Estimated CY 2014 Percent Change reflects the percent differences between the estimated ASC payment for CY 2013 and the estimated payment for CY 2014 based on the update.

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TABLE 57.--ESTIMATED IMPACT OF THE FINAL CY 2014 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code* (1)	Short Descriptor (2)	Estimated CY 2013 ASC Payments (in millions) (3)	Estimated CY 2014 Percent Change (4)
66984	Cataract surg w/iol, 1 stage	\$1,102	0%
43239	Upper GI endoscopy, biopsy	\$163	6%
45380	Colonoscopy and biopsy	\$154	5%
45385	Lesion removal colonoscopy	\$97	5%
66982	Cataract surgery, complex	\$88	0%
45378	Diagnostic colonoscopy	\$80	5%
64483	Inj foramen epidural l/s	\$78	16%
62311	Inject spine l/s (cd)	\$71	16%
66821	After cataract laser surgery	\$59	3%
G0105	Colorectal scrn; hi risk ind	\$41	4%
64493	Inj paravert f jnt l/s 1 lev	\$40	16%
15823	Revision of upper eyelid	\$40	-11%
63650	Implant neuroelectrodes	\$39	4%
G0121	Colon ca scrn not hi risk ind	\$36	4%
64590	Insrt/redo pn/gastr stimul	\$33	5%
64721	Carpal tunnel surgery	\$31	1%
63685	Insrt/redo spine n generator	\$31	5%
64636**	Destroy l/s facet jnt addl	\$31	-100%
29826**	Shoulder/arthroscopy/surgery	\$30	-100%
29881	Knee arthroscopy/surgery	\$30	0%
29827	Arthroscop rotator cuff repr	\$28	8%
29880	Knee arthroscopy/surgery	\$25	0%
64484**	Inj foramen epidural add-on	\$24	-100%
43235	Uppr gi endoscopy diagnosis	\$23	6%
64635	Destroy lumb/sac facet jnt	\$23	77%
45384	Lesion remove colonoscopy	\$22	5%
52000	Cystoscopy	\$21	4%
62310	Inject spine c/t	\$20	16%
29823	Shoulder arthroscopy/surgery	\$19	8%
67042	Vit for macular hole	\$19	3%

*Note that HCPCS codes we are deleting for CY 2014 are not displayed in this table.

** The 100 percent decrease in estimated payment reflects our CY 2014 policy to package the payment for CPT codes 64636, 29826, and 64484.

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(3) Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2014 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 2014. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 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, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment. 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 for that service in the physician's office compared to the ASC. However, for those additional procedures that we are designating as office-based in CY 2014, the beneficiary coinsurance amount will be no greater than the beneficiary coinsurance in the physician's office because the coinsurance in both settings is 20 percent (except for certain preventive services where the coinsurance is waived in both settings).

(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 2014.

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 58 (below) illustrates the classification of expenditures for the CY 2014 estimated hospital OPPS incurred benefit impacts associated with the CY 2014 OPD fee schedule increase, based on the 2013 Trustee's Report. The second accounting statement, Table 59 (below) illustrates the classification of expenditures associated with the 1.2 percent CY 2014 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 2013 Trustee's Report. The third accounting statement, Table 60 (below), illustrates the classification of expenditures associated with the revision to the definition of hospital-based EP in payment year 2013 for EPs reassigning benefits to Method II CAHs. Lastly, the tables classify most estimated impacts as transfers.

TABLE 58.--ACCOUNTING STATEMENT: CY 2014 ESTIMATED HOSPITAL OPPTS TRANSFERS FROM CY 2013 TO CY 2014 ASSOCIATED WITH THE CY 2014 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	\$600 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPTS
Total	\$600 million

TABLE 59.--ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2013 TO CY 2014 AS A RESULT OF THE FINAL CY 2014 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	\$36 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	\$36 million

TABLE 60.--ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2013 TO CY 2014 AS A RESULT OF THE REVISIONS TO THE DEFINITION OF PROVIDER-BASED EP UNDER THE EHR INCENTIVE PROGRAM

Category	Transfers
Annualized Monetized Transfers	\$17,985,000 to \$35,970,000
From Whom to Whom	Federal Government to Medicare Providers
Total	\$17,985,000 to \$35,970,000

d. Effects of Requirements for the Hospital OQR Program

In section XIII. of this final rule with comment period, we are adopting policies affecting the Hospital OQR Program.

Out of 3,352 hospitals that met eligibility requirements, we determined that 94 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor for CY 2013. Most of these hospitals (90 of the 94) chose not to participate in the Hospital OQR Program. We estimate that 88 hospitals may not receive the full OPD fee schedule increase factor in CY 2014 and that 90 hospitals may not receive the full OPD fee schedule increase factor in CY 2015. We are unable at this time

to estimate the number of hospitals that may not receive the full OPD fee schedule increase factor in CY 2016.

In section XVI.E.3.a. of the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60647 through 60650), for the CY 2011 payment update, as part of the validation process, we required hospitals to submit paper copies of requested medical records to a designated contractor within the required timeframe. Failure to submit requested documentation could result in a 2.0 percentage point reduction to a hospital's CY 2011 OPD fee schedule increase factor, but the failure to attain a validation score threshold would not.

In section XVI.D.3.b of the CY 2011 OPPTS/ASC final rule with comment

period, we finalized our proposal to validate data submitted by 800 hospitals of the approximately 3,200 participating hospitals for purposes of the CY 2012 Hospital OQR Program payment determination. We stated our belief that this approach was suitable for the CY 2012 Hospital OQR Program because it would: Produce a more reliable estimate of whether a hospital's submitted data have been abstracted accurately; provide more statistically reliable estimates of the quality of care delivered in each selected hospital as well as at the national level; and reduce overall hospital burden because most hospitals would not be selected to undergo validation each year. We adopted a threshold of 75 percent as the threshold

for the validation score because we believed this level was reasonable for hospitals to achieve while still ensuring accuracy of the data. In addition, this level is consistent with what we adopted in the Hospital IQR Program (75 FR 50225 through 50229). As a result, we believed that the effect of our validation process for CY 2012 would be minimal in terms of the number of hospitals that would not meet all program requirements.

In the CY 2012 OPPI/ASC final rule with comment period, we finalized our proposal to validate data submitted by up to 500 of the approximately 3,200 participating hospitals for purposes of the CY 2013 Hospital OQR Program payment determination. Under our policy for CY 2011, CY 2012, and CY 2013, we stated that we would conduct a measure level validation by assessing whether the measure data submitted by the hospital matches the independently reabstracted measure data.

In the CY 2013 OPPI/ASC final rule with comment period, for the CY 2014 payment determination and subsequent years, we made some modifications to administrative requirements in extending a deadline to submit a Notice of Participation as well as to extraordinary circumstance waiver or extension and reconsideration processes to broaden the scope of personnel who can sign these requests. However, we did not make any modifications to our validation requirements. We expect these policies to have minimal impact on the program.

In this CY 2014 OPPI/ASC final rule with comment period, for CY 2016 payment determination and subsequent years, we are adding four quality measures with data collection to begin in CY 2014. For three of these measures, data will be submitted via an online tool located on a CMS Web site and one will be submitted via CDC's NHSN. We are removing two measures from the Hospital OQR Program.

As stated above, we are unable to estimate the number of hospitals that may not receive the full OPD fee schedule increase factor in CY 2016. We also are unable to estimate the number of hospitals that would fail the validation documentation submission requirement for the CY 2016 payment update.

The validation requirements for CY 2014 will result in medical record documentation for approximately 6,000 cases per quarter for CY 2014, being submitted to a designated CMS contractor. We will pay for the cost of sending this 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. We have found that an outpatient medical chart is generally up to 10 pages. Thus, as a result of validation requirements effective for CY 2014, we estimate that we will have expenditures of approximately \$13,200 per quarter for CY 2014. Because we will pay for the data collection effort, we believe that a requirement for medical record documentation for 6,000 total cases per quarter for up to 500 hospitals for CY 2014 represents a minimal burden to Hospital OQR Program participating hospitals.

e. Effects of CY 2014 Policies for the ASCQR Program

In section XV. of this final rule with comment period, for the ASCQR Program, we are adopting three additional quality measures for the CY 2016 payment determination and subsequent years. Data collection for these proposed measures will begin in CY 2014. We will collect aggregate data (numerators, denominators, and exclusions) on all ASC patients for these four proposed chart-abstracted measures via an online Web-based tool located on a CMS Web page. We also are adopting for the CY 2016 payment determination and subsequent years requirements for a QualityNet account and security administrator, facility participation, a minimum threshold and minimum volume for claims-based measures, and data collection and submission for new measures and for certain previously finalized measures.

We are unable at this time to estimate the number of ASCs that may not receive the full ASC annual payment update in CYs 2014, 2015, and 2016. However, we do expect our new policies to significantly affect the number of ASCs that do not receive a full annual payment update in CY 2016, although we are not able to estimate the level of this impact at this time.

f. Effects of Changes to the CfCs for OPOs Relating to the Outcome Measures Requirement for Recertification

In section XVI. of this final rule with comment period, we discussed our proposed and final policies to modify the current outcome measures requirement that OPOs meet all three outcome measures set forth in § 486.318 to a requirement that they meet two out of the three outcome measures. Our revised policy will result in those OPOs that fail only one outcome measures avoiding automatic decertification based upon the current outcome measures requirement.

While we are confident that our revised policy will have a significantly positive effect on the OPOs that avoided automatic decertification, it is very difficult to quantify the impact of this policy change. As discussed under section XXI.C. of this final rule with comment period relating to the ICR requirements, we anticipate that most OPOs that are decertified will engage in the appeals process as set forth in § 486.314. However, we have no reliable way of estimating how many OPOs will likely obtain reversals of their decertifications during reconsideration or how many would continue on to a hearing before a CMS hearing officer. Therefore, although we believe there would be a considerably large positive effect as a result of our policy change to the outcome measures requirement, we are unable to provide a specific estimate of that cost savings.

g. Effects of Revisions of the QIO Regulations

In section XVII. of this final rule with comment period rule, we are updating the regulations at 42 CFR 475 and 476 based on the recently enacted Trade Adjustment Assistance Extension Act of 2011 (TAAEA) (Pub. L. 112-40, Section 261) whereby Congress authorized numerous changes to the original legislation and included additional flexibility for the Secretary in the administration of the QIO program. Currently, 42 CFR Part 475 includes definitions and standards governing eligibility and the award of contracts to QIOs. In this final rule with comment period, we set forth policies for the partial deletion and revision of the regulations under 42 CFR Parts 475 and 476, which relate to the QIO program, including the following: (1) Replace nomenclature that has been amended by the TAAEA; (2) revise the existing definition for the term "physician" in Parts 475 and 476; (3) add new definitions as necessary to support the new substantive provisions in Subpart C; and (4) revise, add, and replace some of the substantive provisions in Subpart C to fully exercise the Secretary's authority for the program and update the contracting requirements to align with contemporary quality improvement.

We estimate the effects of the QIO Program changes to be consistent with the Congressional Budget Office's 2011 Cost Estimate of the Trade Bill (H.R. 2832) which included a reduction in spending of \$330 million over the 2012–2021 period. According to the CBO Estimate, the Act and subsequently the regulatory changes "would modify the provisions under which CMS contracts

with independent entities called ["Quality Improvement Organizations (QIOs)"] in Medicare. QIOs, generally staffed by health care professionals, review medical care, help beneficiaries with complaints about the quality of care, and implement care improvements. H.R. 2832 would make several changes to the composition and operation of QIOs, and would harmonize QIO contracts with requirements of the Federal Acquisition Regulation. Among those changes are a modification to expand the geographic scope of QIO contracts and a lengthening of the contract period. CBO estimates that those provisions would reduce spending by \$330 million over the 2012–2021 period."

h. Effects of Revised Policies Regarding Medicare-Fee-for-Service EHR Incentive Program

(1) Incentive Payments for Eligible Professionals (EPs) Reassigning Benefits to Method II CAHs

As discussed in section XVIII.A. of this final rule with comment period, we are revising the regulations to provide, during payment year 2013 alone, a special method for determining the hospital-based status of EPs who reassign their benefits to Method II CAHs. It is difficult to determine with precision the cost impact of this policy change. We lack specific information on key factors affecting this impact, including the number of EPs who reassign their benefits to Method II CAHs, the proportion of those EPs who will be determined to be nonhospital-based for 2013 under our revised policy, the proportion of those EPs who will qualify for Medicaid incentive payments and choose to accept those payments because they are higher, and the proportion of the remaining EPs who will successfully demonstrate meaningful use in order to qualify for Medicare incentive payments. Therefore, it is necessary to rely on estimates for each of these factors. As much as possible, we employ the methods of cost estimation that we used to determine the estimated costs of the Medicare incentives for EPs in our Stage 1 final rule (75 FR 44549) and Stage 2 final rule (77 FR 54139) for the Medicare Electronic Health Record Incentive Program, as well as the estimates that we have previously employed for specific factors.

Of the approximately 1,200 CAHs, about three-quarters, or 900, elect under section 1834(g)(2) of the Act to receive a cost-based payment for the facility costs of providing outpatient services, plus 115 percent of the fee schedule

amount for professional services included within outpatient CAH services. As we have indicated, we lack specific information on the numbers of EPs who reassign their benefits to these Method II CAHs. While CAHs are relatively small inpatient facilities, we understand that many of them have fairly substantial outpatient clinics. At the same time, we have also been informed that they rely largely on nonphysician practitioners (nurses and nurse practitioners) to staff these outpatient clinics. Therefore, we will assume that the typical outpatient department in a Method II CAH has a relatively small number of physicians, between 5 and 10, on staff and billing for professional services that are reassigned to the CAH. We also use this estimate of 5 to 10 physicians per Method II CAH to establish an upper and lower range to our impact estimate. The number of EPs reassigning benefits for outpatient services to Method II CAHs is therefore between 4,500 and 9,000.

In our Stage 2 final rule (77 FR 54139) for the Medicare Electronic Health Record Incentive Program, we determined that about 14 percent of EPs with Medicare claims were hospital-based, and thus ineligible to receive Medicare EHR incentive payments. For purposes of this impact statement, we assume that 10 percent of EPs reassigning benefits to Method II CAHs are hospital-based. Because CAHs have relatively small inpatient hospital facilities, we believe that the physicians practicing in these facilities will bill for somewhat fewer inpatient services than EPs generally. Using this assumption, the estimate of nonhospital-based EPs reassigning benefits to Method II CAHs is therefore between 4,050 and 8,100. Of these nonhospital-based EPs reassigning benefits to Method II CAHs, some proportion will qualify for Medicaid incentive payments and will choose to receive payments under that program because the payments are higher. For these purposes we employ the same estimate (20 percent) that we have employed for developing cost estimate in our Stage 2 final rule (77 FR 54140). Thus, we estimate that between 3,240 and 6,480 non-hospital-based EPs reassigning benefits to Method II CAHs do not choose to receive Medicaid incentive payments.

As we have discussed in prior rules (77 FR 54140), our estimates for the number of EPs that will successfully demonstrate meaningful use of CEHRT are uncertain. The percentage of Medicare EPs who will satisfy the criteria for demonstrating meaningful use of CEHRT and will qualify for

incentive payments is a key, but highly uncertain factor in developing cost estimates for the EHR incentive program in general and for the present purposes in particular. Consistent with the estimates that we have employed for EPs generally in developing cost estimates in the Stage II final rule, we assume that 37 percent of the nonhospital-based EPs reassigning benefits to Method II CAHs will satisfy the criteria for demonstrating meaningful use of CEHRT and will qualify for incentive payments in payment years 2013. Thus, we estimate that between 1,199 and 2,398 EPs reassigning benefits to Method II CAHs will actually qualify to receive Medicare EHR incentive payments in 2013. As we have previously discussed, section 1848(o)(1)(B) of the Act provides that the incentive payment for an EP for a given payment year shall not exceed the following amounts:

- For the EP's first payment year, for such professional, \$15,000 (or \$18,000, if the EP's first payment year is 2011 or 2012);
- For the EP's second payment year, \$12,000;
- For the EP's third payment year, \$8,000;
- For the EP's fourth payment year, \$4,000;
- For the EP's fifth payment year, \$2,000; and
- For any succeeding year, \$0.

We lack any information on how many of the EPs reassigning benefits to Method II CAHs will qualify for incentive payments for the first time in 2013. However, if we assume, for purposes of setting upper limits on our estimates, that all of the 1,199 to 2,398 EPs we have estimated will qualify for the first time and receive the maximum incentive payment, our revised policy will cost between \$17,985,000 and \$35,970,000 in payments that we have not previously been making in 2013. Despite the uncertainties of the assumptions that we have employed in developing these estimates, we can state with reasonable confidence that our revised policy will result in considerably less than \$50,000,000 in payments over and above the payments we would make in the absence of this policy for 2013.

(2) Cost Reporting Periods for Interim and Final EHR Incentive Payments to Eligible Hospitals

As we discussed in section XVIII.B. of this final rule with comment period, we are revising the regulations to provide that, in cases where there is no 12-month cost reporting period that begins on or after the beginning of a payment

year, we will use the most recent 12-month cost reporting period available at the time of final settlement in order to determine final EHR incentive payments for the hospital. We are making this policy change solely to address situations in which hospitals have been receiving interim EHR payments but the contractors have not been able to make a determination of final payments because there is no hospital cost report that meets the existing requirements of the regulations. Therefore, we do not expect this to have any financial impact. This policy change will merely allow us to make final settlements in cases that the current regulations do not cover.

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 \$35.5 million or less in any single year. Most ASCs and most CMHCs are considered small businesses with total revenues of \$10 million or less in any single year. We estimate that this final rule with comment period may have a significant impact on approximately 2,040 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 604 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 OPPIs and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPIs will experience a modest increase or a minimal decrease in payment for services furnished under the OPPIs in CY 2013. Table 55 demonstrates the estimated distributional impact of the OPPIs budget neutrality requirements that will result in a 1.8 percent increase in payments for all services paid under the OPPIs in CY 2014, 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 OPPIs will experience more significant gains and others will experience modest losses in OPPIs payments in CY 2014.

The updates to the ASC payment system for CY 2014 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 56 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted CPI-U update factor of 1.2 percent for CY 2014.

XXIIV. 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 OPPIs 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 55 of this final rule with comment period, we estimate that OPPIs payments to governmental hospitals (including State and local governmental hospitals) will increase by 1.1 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.

XXV. Waiver of 60-Day Delay of Effective Date

In the absence of an appropriation for FY 2014 or a Continuing Resolution, the Federal Government shut down on October 1, 2013. During this shutdown, which lasted from October 1, 2013 through October 16, 2013, only excepted operations continued, which largely excluded work on the final rule with comment period and the final rules contained in this document. Accordingly, most of the work on these rules was not completed in accordance with our usual schedule for final payment rules, which aims for an issuance date of November 1, followed by an effective date of January 1, to ensure that the policies are effective at the start of the calendar year to which they apply.

We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued. The 60-day delay in effective date can be waived, however, if the agency finds, for good cause, that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. We believe it would be contrary to the public interest to delay the effective date of the OPPIs and ASC payment systems portions,

including the Hospital OQR Program and the ASCQR Program parts of the final rule with comment period contained in this document. In accordance with sections 1833(t) and 1833(i) of the Act, the OPPS and the ASC payment systems are calendar year payment systems, and we typically issue the OPPS/ASC payment systems final rule with comment period by November 1 of each year to both comply with the requirement to annually review and update these payment systems and ensure that the payment policies for these systems are effective on January 1, the first day of the calendar year to which the policies are intended to apply. The Hospital OQR Program and the ASCQR Program are intended to align with the OPPS and the ASC payment system, respectively.

We also believe it would be contrary to the public interest to delay the effective date of the Hospital VBP Program performance and baseline period policies being finalized in this document. These policies are being finalized in this document solely because we inadvertently neglected to propose and finalize them in the FY 2014 IPPS/LTCH PPS proposed and final rules. These policies are intended to align with the previously finalized performance and baseline periods for other measures included in the FY 2016 Hospital VBP Program, with January 1, 2014 being the start date of reporting. In addition, a delay in effective date would be contrary to the public interest in ensuring that payments under the IPPS to hospitals in FY 2016 properly and completely reflect their performance on quality measures in 2014.

We also believe that it would be contrary to the public interest to delay the effective date of the revisions to the provider reimbursement determinations and appeals reopening rule under 42 CFR 405.1885 in this document because, as stated herein, we have determined that applying these revisions to currently pending cost reports, appeals, and reopenings is in the public interest in finality of payment amounts and necessary to comply with the requirements of sections 1878 and 1886 of the Act.

If the effective date of this final rule with comment period and final rules mentioned above in this document is delayed by 60 days, the OPPS and ASC payment system policies (including the Hospital OQR and the ASCQR Program policies), the Hospital VBP Program performance and baseline period policies, and the revisions to the provider reimbursement determinations and appeals regulations at 42 CFR 405.1885, adopted in this final rule with

comment period and final rules, will not be effective as of the beginning of the payment year. We note that our waiver of the delayed effective date only applies to the OPPS and ASC payment system policies (including the Hospital OQR and the ASCQR Program policies), the Hospital VBP Program performance and baseline period policies, and the revisions to the provider reimbursement determinations and appeals regulations at 42 CFR 405.1885, that are adopted in this final rule with comment period and in the applicable final rules. The delayed effective date for all other policies in the final rules in this document is not waived, and these policies will be effective on January 27, 2014.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 475

Grant programs-health, Health care, Health professions, Quality Improvement Organization (QIO).

42 CFR Part 476

Health care, Health professional, Health record, Quality Improvement Organization (QIO), Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs-health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 495

Computer technology, Electronic health records, Electronic transactions, Health, Health care. Health information technology, Health insurance, Health records, Hospitals, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

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 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405, Subpart R continues to read as follows:

Authority: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

■ 2. Section 405.1804 is amended by revising paragraph (a) to read as follows:

§ 405.1804 Matters not subject to administrative and judicial review under prospective payment system.

* * * * *

(a) The determination of the requirement, or the proportional amount, of the budget neutrality adjustment in the prospective payment rates required under section 1886(e)(1) of the Social Security Act.

* * * * *

■ 3. Section 405.1885 is amended by revising paragraph (a)(1) and adding paragraph (b)(2)(iv) to read as follows:

§ 405.1885 Reopening an intermediary determination or reviewing entity decision.

(a) * * *

(1) A Secretary determination, an intermediary determination, or a decision by a reviewing entity (as described in § 405.1801(a)) may be reopened, with respect to specific findings on matters at issue in a determination or decision, by CMS (with respect to Secretary determinations), by the intermediary (with respect to intermediary determinations), or by the reviewing entity that made the decision (as described in paragraph (c) of this section).

(i) A specific finding on a matter at issue may be legal or factual in nature or a mixed matter of both law and fact.

(ii) A specific finding on a matter at issue may include a factual matter that arose in or was determined for the same cost reporting period as the period at issue in an appeal filed, or a reopening requested by a provider or initiated by an intermediary, under this subpart.

(iii) A specific finding on a matter at issue may include a predicate fact, which is a finding of fact based on a factual matter that first arose in or was first determined for a cost reporting period that predates the period at issue (in an appeal filed, or a reopening

requested by a provider or initiated by an intermediary, under this subpart), and once determined, was used to determine an aspect of the provider's reimbursement for one or more later cost reporting periods.

(iv) Except as provided for by this section, § 405.1887, and § 405.1889, a specific finding on a matter at issue may not be reopened and, if reopened, revised.

* * * * *

(b) * * *

(2) * * *

(iv) The 3-year period described in paragraphs (b)(2)(i) through (b)(2)(iii) of this section applies to, and is calculated separately for, each specific finding on a matter at issue (as described in paragraphs (a)(1)(i) through (a)(1)(iv) of this section, but not to such findings when made as part of a determination of reasonable cost under section 1861(v)(1)(A) of the Act.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 4. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 5. Section 410.27 is amended by—

■ a. Revising paragraph (a) introductory text.

■ b. Removing the word “and” at the end of paragraph (a)(1)(iii).

■ c. Removing the period at the end of paragraph (a)(1)(iv)(E) and adding in its place “; and”.

■ d. Adding paragraph (a)(1)(v).

The revisions and addition read as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service, which are defined as all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals which are not usually self-administered, if—

(1) * * *

(v) In accordance with applicable State law.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 6. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102, 1862, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395y, and 1395hh).

■ 7. Section 412.167 is amended by redesignating paragraph (c) as paragraph (d) and adding a new paragraph (c) to read as follows:

§ 412.167 Appeals under the Hospital Value-Based Purchasing (VBP) Program.

* * * * *

(c) If a hospital is dissatisfied with CMS' decision on an appeal request submitted under paragraph (b) of this section, the hospital may request an independent CMS review of that decision.

* * * * *

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) introductory text, (b)(3), and (b)(11) and adding paragraphs (b)(13) through (18) to read as follows:

§ 419.2 Basis of payment.

* * * * *

(b) *Determination of hospital outpatient prospective payment rates: Packaged costs.* The prospective payment system establishes a national payment rate, standardized for geographic wage differences, that includes operating and capital-related costs that are integral, ancillary, supportive, dependent, or adjunctive to performing a procedure or furnishing a service on an outpatient basis. In general, these packaged costs may include, but are not limited to, the following items and services, the payment for which are packaged or conditionally packaged into the payment for the related procedures or services.

* * * * *

(3) Observation services;

* * * * *

(11) Implantable and insertable medical items and devices, including, but not limited to, prosthetic devices (other than dental) which replace all or part of an internal body organ

(including colostomy bags and supplies directly related to colostomy care), including replacement of these devices;

* * * * *

(13) Image guidance, processing, supervision, and interpretation services;

(14) Intraoperative items and services;

(15) Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents;

(16) Drugs and biological 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 biological);

(17) Certain clinical diagnostic laboratory tests; and

(18) Certain services described by add-on codes.

* * * * *

■ 10. Section 419.22 is amended by revising the introductory text and paragraphs (j) and (1) to read as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

The following services are not paid for under the hospital outpatient prospective payment system (except when packaged as a part of a bundled payment):

* * * * *

(j) Except as provided in § 419.2(b)(11), prosthetic devices, prosthetic supplies, and orthotic devices.

* * * * *

(l) Except as provided in § 419.2(b)(17), clinical diagnostic laboratory tests.

* * * * *

■ 11. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(5) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(5) For calendar year 2014, a multifactor productivity adjustment (as determined by CMS) and 0.3 percentage point.

* * * * *

■ 12. Section 419.46 is added to Subpart D to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

(a) *Participation in the Hospital OQR Program.* To participate in the Hospital OQR Program, a hospital as defined in section 1886(d)(1)(B) of the Act and is paid under the OPSS must—

(1) Register on the QualityNet Web site before beginning to report data;

(2) Identify and register a QualityNet security administrator as part of the registration process under paragraph (a)(1) of this section; and

(3) Complete and submit an online participation form available at the QualityNet.org Web site if this form has not been previously completed, if a hospital has previously withdrawn, or if the hospital acquires a new CMS Certification Number (CCN). For Hospital OQR Program purposes, hospitals that share the same CCN are required to complete a single online participation form. Once a hospital has submitted a participation form, it is considered to be an active Hospital OQR Program participant until such time as it submits a withdrawal form to CMS or no longer has an effective Medicare provider agreement. Deadlines for the participation form are described in paragraphs (a)(3)(i) and (ii) of this section, and are based on the date identified as a hospital's Medicare acceptance date.

(i) If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must complete and submit to CMS a completed Hospital OQR Notice of Participation Form by July 31 of the calendar year prior to the affected annual payment update.

(ii) If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must submit a completed participation form no later than 180 days from the date identified as its Medicare acceptance date.

(b) *Withdrawal from the Hospital OQR Program.* A participating hospital may withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet Web site. The hospital may withdraw any time from January 1 to November 1 of the year prior to the affected annual payment updates. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under § 419.43(h), and is required to submit a new

participation form in order to participate in any future year of the Hospital OQR Program.

(c) *Submission of Hospital OQR Program data.* (1) *General rule.* 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 in a form and manner, and at a time, specified by CMS.

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on the QualityNet Web site.

(3) *Initial submission deadlines for a hospital that did not participate in the previous year's Hospital OQR Program.*

(i) If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update, in addition to submitting a completed Hospital OQR Notice of Participation Form under paragraph (a)(3)(i) of this section.

(ii) If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must submit data for encounters beginning with the first full quarter following submission of the completed Hospital OQR Notice of Participation Form under paragraph (a)(3)(ii) of this section.

(iii) Hospitals with a Medicare acceptance date before or after January 1 of the year prior to an affected annual payment update must follow data submission deadlines as specified in paragraph (c)(2) of this section.

(d) *Exception.* CMS may grant an extension or waiver 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 waiver as follows:

(1) Upon request by the hospital. Specific requirements for submission of a request for an extension or waiver are available on the QualityNet Web site.

(2) At the discretion of CMS. CMS may grant waivers or extensions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

(e) *Validation of Hospital OQR Program data.* CMS may validate one or more measures selected under section 1833(17)(C) of the Act by reviewing

documentation of patient encounters submitted by selected participating hospitals.

(1) Upon written request by CMS or its contractor, a hospital must submit to CMS supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 45 days of the date identified on the written request, in the form and manner specified in the written request.

(2) A hospital meets the validation requirement with respect to a fiscal year if it achieves at least a 75-percent reliability score, as determined by CMS.

(f) *Reconsiderations and appeals of Hospital OQR Program decisions.* (1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program for a particular fiscal year. Except as provided in paragraph (d) of this section, a hospital must submit a reconsideration request to CMS via the QualityNet Web site, no later than the first business day of the month of February of the affected payment year.

(2) A reconsideration request must contain the following information:

(i) The hospital's CMS Certification Number (CCN);

(ii) The name of the hospital;

(iii) The CMS-identified reason for not meeting the requirements of the affected payment year's Hospital OQR Program as provided in any CMS notification to the hospital;

(iv) The hospital's basis for requesting reconsideration. The hospital must identify its specific reason(s) for believing it should not be subject to the reduced annual payment update;

(v) The hospital-designated personnel contact information, including name, email address, telephone number, and mailing address (must include physical mailing address, not just a post office box);

(vi) The hospital-designated personnel's signature;

(vii) A copy of all materials that the hospital submitted to comply with the requirements of the affected Hospital OQR Program payment determination year; and

(viii) If the hospital is requesting reconsideration on the basis that CMS determined it did not meet the affected payment determination year's validation requirement set forth in paragraph (e)(1) of this section, the hospital must provide a written justification for each appealed data element classified during the validation process as a mismatch.

Only data elements that affect a hospital's validation score are eligible to be reconsidered.

(3) 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 under part 405, subpart R, of this chapter.

■ 13. Section 419.66 is amended by revising paragraph (b)(3) 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, whether or not it remains with the patient when the patient is released from the hospital.

* * * * *

PART 475—QUALITY IMPROVEMENT ORGANIZATIONS

■ 14. The authority citation for part 475 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 15. Section 475.1 is amended by—

■ a. Redesignating paragraphs (a) through (d) in the definition of “Five percent or more owner” as paragraphs (1) through (4).

■ b. Adding, in alphabetical order, the definitions of “Case reviews”, “Practitioner”, “QIO area”, and “Quality improvement initiative”.

■ c. Revising the definition of “Physician.”

The additions and revision read as follows:

§ 475.1 Definitions.

* * * * *

Case reviews means the different types of reviews that QIOs are authorized to perform. Such reviews include, but are not limited to—

- (1) Beneficiary complaint reviews;
- (2) General quality of care reviews;
- (3) Emergency Medical Treatment and Labor Act (EMTALA) reviews;
- (4) Medical necessity reviews, including appeals and DRG validation reviews; and
- (5) Admission and discharge reviews.

* * * * *

Physician means:

- (1) A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatry, a doctor of optometry, or a chiropractor as described in section 1861(r) of the Act;

- (2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice as a doctor as described in paragraph (1) of this definition; and

- (3) An individual licensed to practice as a doctor as described in paragraph (1) of this definition in any Territory or Commonwealth of the United States of America.

Practitioner has the same meaning as provided in § 476.1 of this chapter.

QIO area means the defined geographic area, such as the State(s), region(s), or community(ies), in which the CMS contract directs the QIO to perform.

Quality improvement initiative has the same meaning as provided in § 476.1 of this chapter.

■ 16. Subpart C is revised to read as follows:

Subpart C—Quality Improvement Organizations

Sec.

475.100 Scope and applicability.

475.101 Eligibility requirements for QIO contracts.

475.102 Requirements for performing case reviews.

475.103 Requirements for performing quality improvement initiatives.

475.104 [Reserved]

475.105 Prohibition against contracting with health care facilities, affiliates, and payor organizations.

475.106 [Reserved]

475.107 QIO contract awards.

Subpart C—Quality Improvement Organizations

§ 475.100 Scope and applicability.

This subpart implements sections 1152 and 1153(b) and (c) of the Social Security Act as amended by section 261 of the Trade Adjustment Assistance Extension Act of 2011. This subpart defines the types of organizations that are eligible to become Quality Improvement Organizations (QIOs) and describes certain steps CMS will take in selecting QIOs.

§ 475.101 Eligibility requirements for QIO contracts.

In order to be eligible for a QIO contract, an organization must meet the following requirements:

(a) Have a governing body that includes at least one individual who is a representative of health care providers and at least one individual who is a representative of consumers.

(b) Demonstrate the ability to perform the functions of a QIO, including—

- (1) The ability to meet the eligibility requirements and perform activities as set forth in the QIO Request for Proposal; and

(2) The ability to—

- (i) Perform case reviews as described in § 475.102; and/or

- (ii) Perform quality improvement initiatives as set forth in § 475.103.

(c) Demonstrate the ability to actively engage beneficiaries, families, and consumers, as applicable, in case reviews as set forth in § 475.102, and/or quality improvement initiatives as set forth in § 475.103.

(d) Demonstrate the ability to perform the functions of a QIO with objectivity and impartiality and in a fair and neutral manner.

§ 475.102 Requirements for performing case reviews.

(a) In determining whether or not an organization has demonstrated the ability to perform case review, CMS will take into consideration factors such as:

(1) The organization's proposed processes, capabilities, quantitative, and/or qualitative performance objectives and methodology to perform case reviews;

(2) The organization's proposed involvement of and access to physicians and practitioners in the QIO area with the appropriate expertise and specialization in the areas of health care related to case reviews;

(3) The organization's ability to take into consideration urban versus rural, local, and regional characteristics in the health care setting where the care under review was provided;

(4) The organization's ability to take into consideration evidence-based national clinical guidelines and professionally recognized standards of care; and

(5) The organization's access to qualified information technology (IT) expertise.

(b) In making determinations under this section, CMS may consider characteristics such as the organization's geographic location and size. CMS may also consider prior experience in health care quality improvement that CMS considers relevant to performing case reviews; such prior experience may include prior similar case review experience.

(c) A State government that administers a Medicaid program will be considered incapable of performing case review in an effective manner, unless the State demonstrates to the satisfaction of CMS that the State agency performing the case review will act with complete objectivity and independence from the Medicaid program.

§ 475.103 Requirements for performing quality improvement initiatives.

(a) In determining whether or not an organization has demonstrated the

ability to perform quality improvement initiatives, CMS will take into consideration factors such as:

(1) The organization's proposed processes, capabilities, quantitative, and/or qualitative performance objectives, and methodology to perform quality improvement initiatives;

(2) The organization's proposed involvement of and access to physicians and practitioners in the QIO area with the appropriate expertise and specialization in the areas of health care concerning the quality improvement initiatives;

(3) The organization's access to professionals with appropriate knowledge of quality improvement methodologies and practices; and

(4) The organization's access to qualified information technology (IT) expertise.

(b) In making determinations under this section, CMS may consider characteristics such as the organization's geographic location and size. CMS may also consider prior experience in health care quality improvement that CMS considers relevant to performing quality improvement initiatives; such prior experience may include prior similar quality improvement initiative experience and whether it achieved successful results.

(c) A State government that administers a Medicaid program will be considered incapable of performing quality improvement initiative functions in an effective manner, unless the State demonstrates to the satisfaction of CMS that the State agency performing the quality improvement initiatives will act with complete objectivity and independence from the Medicaid program.

§ 475.104 [Reserved]

§ 475.105 Prohibition against contracting with health care facilities, affiliates, and payor organizations.

(a) *Basic rule.* Except as permitted under paragraph (a)(3) of this section, the following are not eligible for QIO contracts:

(1) A health care facility in the QIO area.

(2) A health care facility affiliate; that is, an organization in which more than 20 percent of the members of the governing body are also either a governing body member, officer, partner, five percent or more owner, or managing employee in a health care facility in the QIO area.

(3) A payor organization, unless the Secretary determines that—

(i) There is no other entity available for an area with which the Secretary can enter into a contract under this part; or

(ii) A payor organization is a more qualified entity to perform one or more of the functions of a QIO described in § 475.101(b), meets all other requirements and standards of this part, and demonstrates to the satisfaction of CMS that, in performing QIO activities, the payor organization will act with complete objectivity and independence from its payor program.

(b) [Reserved]

(c) *Subcontracting.* A QIO must not subcontract with a health care facility to perform any case review activities except for the review of the quality of care.

§ 475.106 [Reserved]

§ 475.107 QIO contract awards.

Subject to the provisions of § 475.105, CMS will—

(a) Ensure that all awardees meet the requirements of §§ 475.101 through 475.103, as applicable; and

(b) Award the contract to the selected organization for a specific QIO area for a period of 5 years.

PART 476—QUALITY IMPROVEMENT ORGANIZATION REVIEW

■ 17. The authority for part 476 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 18. The heading of part 476 is revised to read as set forth above.

■ 19. In § 476.1, paragraphs (a) through (d) in the definition of “Five percent or more owner” are redesignated as paragraphs (1) through (4) and the definition of “Physician” is revised to read as follows:

§ 476.1 Definitions.

* * * * *

Physician means:

(1) A doctor or medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatry, a doctor of optometry, or a chiropractor, as described in section 1861(r) of the Act;

(2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice as a doctor as described in paragraph (1) of this definition; and

(3) An individual licensed to practice as a doctor as described in paragraph (1) of this definition in any Territory or Commonwealth of the United States of America.

* * * * *

■ 20. The heading of Subpart C is revised to read as follows:

Subpart C—Review Responsibilities of Quality Improvement Organizations (QIOs)

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 21. The authority citation of part 486 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1302b-8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

■ 22. Section 486.316 is amended by revising paragraphs (a)(1) and (b) to read as follows:

§ 486.316 Re-certification and competition processes.

(a) * * *

(1) Meets two out of the three outcome measures requirements at § 486.318; and * * *

(b) *De-certification and competition.* If an OPO does not meet two out of the three outcome measures as described in paragraph (a)(1) of this section or the requirements described in paragraph (a)(2) of this section, the OPO is de-certified. If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs. The de-certified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

* * * * *

■ 23. Section 486.318 is amended by revising paragraph (a) introductory text and paragraph (b) introductory text to read as follows:

§ 486.318 Condition: Outcome measures.

(a) With the exception of OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, or possessions, an OPO must meet two out of the three following outcome measures:

* * * * *

(b) For OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, and possessions, an OPO must meet two out of the three following outcome measures:

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 24. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 25. Section 495.4 is amended by revising the definition of “Hospital-based EP” to read as follows:

§ 495.4 Definitions.

* * * * *

Hospital-based EP. Unless it meets the requirements of § 495.5, a hospital-based EP means an EP who furnishes 90 percent or more of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting in the year preceding the payment year, or in the case of a payment adjustment year, in either of the 2 years before the year preceding such payment adjustment year.

(1) For Medicare, this is calculated based on—

(i) The Federal fiscal year preceding the payment year; and

(ii) For the payment adjustments, based on—

(A) The Federal fiscal year 2 years before the payment adjustment year; or

(B) The Federal fiscal year 3 years before the payment adjustment year.

(2) For Medicaid, it is at the State’s discretion if the data are gathered on the Federal fiscal year or calendar year preceding the payment year.

(3) For the CY 2013 payment year only, an EP who furnishes services billed by a CAH receiving payment under Method II (as described in § 413.70(b)(3) of this chapter) is considered to be hospital-based if 90 percent or more of his or her covered professional services are furnished in sites of service identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting in each of the Federal fiscal years 2012 and 2013.

* * * * *

■ 26. Section 495.104 is amended by revising paragraph (c)(2) to read as follows:

§ 495.104 Incentive payments to eligible hospitals.

* * * * *

(c) * * *

(2) *Interim and final payments.* CMS uses data on hospital acute care inpatient discharges, Medicare Part A acute care inpatient bed-days, Medicare Part C acute care inpatient bed-days,

and total acute care inpatient bed-days from the latest submitted 12-month hospital cost report as the basis for making preliminary incentive payments. Final payments are determined at the time of settling the first 12-month hospital cost report for the hospital fiscal year that begins on or after the first day of the payment year, and settled on the basis of data from that cost reporting period. In cases where there is no 12-month hospital cost report period beginning on or after the first day of the payment year, final payments may be determined and settled on the basis of data from the most recently submitted 12-month hospital cost report.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Program No. 93.778 (Medical Assistance))

Dated: November 14, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 20, 2013.

Kathleen Sebelius,

Secretary.

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