DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416, 419, 476, 478, 480, and 495

[CMS-1589-FC]

RIN 0938-AR10

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Revision to Quality Improvement Organization Regulations

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2013 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 Inpatient Rehabilitation Facility (IRF) Quality Reporting Program. We are continuing the electronic reporting pilot for the Electronic Health Record (EHR) Incentive Program, and revising the various regulations governing Quality Improvement Organizations (QIOs),

including the secure transmittal of electronic medical information, beneficiary complaint resolution and notification processes, and technical changes. The technical changes to the QIO regulations reflect CMS' commitment to the general principles of the President's Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011).

DATES: Effective Date: This final rule with comment period is effective on January 1, 2013.

Comment Period: To be assured consideration, comments on the payment classifications 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 final rule with comment period must be received at one of the addresses provided in the ADDRESSES section no later than 5 p.m. EST on [Insert 60 days from date of display at the Office of the Federal Register].

Application Deadline--New Class of New Technology Intraocular Lenses: Requests for review of applications for a new class of new technology intraocular lenses must be received by 5 p.m. EST on March 1, 2013, at the following address: ASC/NTOL, Division of Outpatient Care, Mailstop C4-05-17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

ADDRESSES: In commenting, please refer to file code CMS-1589-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-1589-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-1589-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, S.W.,

Washington, DC 20201.

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

b. For delivery in Baltimore, MD—

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

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

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

FOR FURTHER INFORMATION, CONTACT:

Marjorie Baldo, (401) 786-4617, for issues related to new CPT and Level II HCPCS codes, exceptions to the 2 times rule, and new technology APCs.

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

Douglas Brown, (410) 786-0028, for issues related to Electronic Health Record (EHR) Incentive Program Electronic Reporting Pilot.

Carrie Bullock, (401) 786-0378, for issues related to blood products.

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

Caroline Gallaher, (410) 786-8705, for issues related to Inpatient Rehabilitation Facility (IRF) Quality Reporting Program.

Shaheen Halim (410) 786-0641, 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.

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

Thomas Kessler, (401) 786-1991, for issues related to QIO regulations.

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, cardiac resynchronization therapy composite APC, and cardiac electrophysiologic evaluation and ablation composite APC.

Jana Lindquist, (410) 786-4533, for issues related to partial hospitalization and community mental health center (CMHC) issues.

Ann Marshall, (410) 786-3059, for issues related to hospital outpatient supervision, outpatient status, proton beam therapy, and the Hospital Outpatient Payment (HOP) Panel.

John McInnes, (410) 786-0378, for issues related to new technology intraocular lenses (NTIOLs) and packaged items/services.

James Poyer, (410) 786-2261, 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, cost-to-charge ratios (CCRs), 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

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

Addenda Available Only Through the Internet on the CMS Web Site

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda will be 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. Readers who experience any problems accessing any of the Addenda that are posted on the CMS Web site identified above should contact Charles Braver at (410) 786-0378.

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
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
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

IPF	Inpatient Psychiatric Facility
IPPS	[Hospital] Inpatient Prospective Payment System
IQR	[Hospital] Inpatient Quality Reporting
IRF	Inpatient rehabilitation facility
IRF-PAI	Inpatient Rehabilitation Facility-Patient Assessment Instrument
IRF QRP	Inpatient Rehabilitation Facility Quality Reporting Program
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
OPPS	[Hospital] Outpatient Prospective Payment System
OPSF	Outpatient Provider-Specific File
OQR	[Hospital] Outpatient Quality Reporting
OT	Occupational therapy
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
RAC	Recovery Audit Contractor
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

Table of Contents

I. Summary and Background

A. Executive Summary of this Final Rule with Comment Period

1. Purpose

2. Summary of the Major Provisions

3. Summary of Costs and Benefits

B. Legislative and Regulatory Authority for the Hospital OPPS

C. Excluded OPPS Services and Hospitals

D. Prior Rulemaking

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

2. Establishment of the Panel

3. Panel Meetings and Organizational Structure

F. Public Comments Received in Response to the CY 2013 OPPS/ASC Proposed Rule

G. Public Comments Received on the CY 2012 OPPS/ASC Final Rule with Comment Period

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

b. Use of Single and Multiple Procedure Claims

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

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

a. Claims Preparation

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

(1) Splitting Claims

(2) Creation of "Pseudo" Single Procedure Claims

c. Completion of Claim Records and Geometric Mean Cost Calculations

(1) General Process

(2) Recommendations of the Advisory Panel on Hospital Outpatient Payment Regarding Data Development

d. Calculation of Single Procedure APC Criteria-Based Costs

(1) Device-Dependent APCs

(2) Blood and Blood Products

(3) Brachytherapy Sources

e. Calculation of Composite APC Criteria-Based Costs

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

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

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

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

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

(6) Cardiac Resynchronization Therapy Composite APC (APC 0108)

f. Geometric Mean-Based Relative Payment Weights

3. Changes to Packaged Services

a. Background

b. Clarification of Regulations at 42 CFR 419.2(b)

c. Packaging Recommendations of the HOP Panel ("The Panel") at its February 2012 Meeting

d. Packaging Recommendations of the HOP Panel ("The Panel") at its August 2012 Meeting

e. Other Packaging Proposals and Policies for CY 2013

f. Packaging of Drugs, Biologicals, and Radiopharmaceuticals

(1) Existing Packaging Policies

(2) Clarification of Packaging Policy for Anesthesia Drugs

g. Packaging of Payment for Diagnostic Radiopharmaceuticals, Contrast Agents, and Implantable Biologicals ("Policy-Packaged" Drugs and Devices)

h. Summary of Proposals

4. Calculation of OPPS Scaled Payment Weights

B. Conversion Factor Update

C. Wage Index Changes

D. Statewide Average Default CCRs

E. OPPS Payments to Certain Rural and Other Hospitals

1. Hold Harmless Transitional Payment Changes

2. Adjustment for Rural SCHs and EACHs under Section 1833(t)(13)(B) of the Act

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

1. Background

2. Payment Adjustment for Certain Cancer Hospitals for CY 2013

G. Hospital Outpatient Outlier Payments

1. Background

2. Proposed Outlier Calculation

3. Final Outlier Calculation

4. Outlier Reconciliation

H. Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment

I. Beneficiary Copayments

1. Background

2. OPPS Copayment Policy

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

III. OPPS Ambulatory Payment Classification (APC) Group Policies

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

1. Treatment of New CY 2012 Level II HCPCS and CPT Codes Effective April 1, 2012 and July 1, 2012 for Which We Solicited Public Comments in the CY 2013 OPPS/ASC Proposed Rule

2. Process for New Level II HCPCS Codes That Will Be Effective October 1, 2012 and New CPT and Level II HCPCS Codes That Will Be Effective January 1, 2013 for Which We Are Soliciting Public Comments in this CY 2013 OPPS/ASC Final Rule with Comment Period

B. OPPS Changes--Variations within APCs

1. Background

2. Application of the 2 Times Rule

3. Exceptions to the 2 Times Rule

C. New Technology APCs

1. Background

2. Movement of Procedures from New Technology APCs to Clinical APCs

3. Payment Adjustment Policy for Radioisotopes Derived from Non-Highly Enriched Uranium (HEU) Sources

a. Background

b. Payment Policy

D. OPPS APC-Specific Policies

1. Cardiovascular and Vascular Services

a. Cardiac Telemetry (APC 0213)

b. Mechanical Thrombectomy (APC 0653)

c. Non-Congenital Cardiac Catheterization (APC 0080)

d. Endovascular Revascularization of the Lower Extremity (APCs 0083, 0229, and 0319)

e. External Electrocardiographic Monitoring (APC 0097)

f. Echocardiography (APCs 0177, 0178, 0269, 0270, and 0697)

2. Gastrointestinal Services

a. Laparoscopic Adjustable Gastric Band (APC 0132)

b. Transoral Incisionless Fundoplication (APC 0422)

c. Gastrointestinal Transit and Pressure Measurement (APC 0361)

3. Integumentary System Services

a. Extracorporeal Shock Wave Wound Treatment (APC 0340)

b. Application of Skin Substitute (APCs 0133 and 0134)

c. Low Frequency, Non-Contact, Non-Thermal Ultrasound (APC 0015)

4. Nervous System Services

a. Scrambler Therapy (APC 0275)

b. Transcranial Magnetic Stimulation Therapy (TMS) (APC 0216)

c. Paravertebral Neurolytic Agent (APC 0207)

d. Programmable Implantable Pump (APC 0691)

e. Revision/Removal of Neurostimulator Electrodes (APC 0687)

5. Ocular Services: Placement of Amniotic Membrane (APC 0233)

6. Radiology Oncology

a. Proton Beam Therapy (APCs 0664 and 0667)

b. Device Construction for Intensity Modulated Radiation Therapy (IMRT) (APC 0305)

c. Other Radiation Oncology Services (APCs 0310 and 0412)

d. Stereotactic Radiosurgery (SRS) Treatment Delivery Services (APCs 0065, 0066, 0067 and 0127)

e. Intraoperative Radiation Therapy (IORT) (APC 0412)

(1) Background

(2) CY 2013 Proposals and Final Policies for CPT Codes 77424, 77425, and 77469

7. Imaging

a. Non-Ophthalmic Fluorescent Vascular Angiography (APC 0397)

b. Level II Nervous System Imaging (APC 0402)

c. Computed Tomography of Abdomen/Pelvis (APCs 0331 and 0334)

8. Respiratory Services

a. Bronchoscopy (APC 0415)

b. Upper Airway Endoscopy (APC 0075)

9. Other Services

a. Payment for Molecular Pathology Services

b. Bone Marrow (APC 0112)

IV. OPPS Payment for Devices

A. Pass-Through Payments for Devices

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

a. Background

b. CY 2013 Policy

2. Provisions for Reducing Transitional Pass-Through Payments to Offset Costs Packaged into APC Groups

a. Background

b. CY 2013 Policy

3. Clarification of Existing Device Category Criterion

a. Background

b. Clarification of CY 2013 Policy

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

1. Background

2. APCs and Devices Subject to the Adjustment Policy

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

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

1. Background

2. Drugs and Biologicals with Expiring Pass-Through Status in CY 2012

3. Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2013

4. Provisions for Reducing Transitional Pass-Through Payments for Diagnostic Radiopharmaceuticals and Contrast Agents to Offset Costs Packaged into APC Groups

a. Background

b. Payment Offset Policy for Diagnostic Radiopharmaceuticals

c. Payment Offset Policy for Contrast Agents

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

1. Background

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

a. Background

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

c. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological but Different Dosages

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

b. CY 2013 Payment Policy

4. Payment Policy for Therapeutic Radiopharmaceuticals

5. Payment for Blood Clotting Factors

6. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes, but without OPPS Hospital Claims Data

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

B. Estimate of Pass-Through Spending

VII. OPPS Payment for Hospital Outpatient Visits

A. Background

B. Policies for Hospital Outpatient Visits

C. Transitional Care Management

VIII. Payment for Partial Hospitalization Services

A. Background

B. PHP APC Update for CY 2013

C. Coding Changes

D. Separate Threshold for Outlier Payments to CMHCs

IX. Procedures That Would Be Paid Only as Inpatient Procedures

A. Background

B. Changes to the Inpatient List

X. Policies for the Supervision of Outpatient Services in Hospitals and CAHs

A. Conditions of Payment for Physical Therapy, Speech-Language Pathology, and Occupational Therapy Services in Hospitals and CAHs

B. Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in CAHs and Certain Small Rural Hospitals

XI. Outpatient Status: Solicitation of Public Comments in the CY 2013 OPPS/ASC Proposed Rule

A. Background

B. Summary of Public Comments Received

1. Part A to Part B Rebilling

2. Clarifying Current Admission Instructions or Establishing Specified Clinical Criteria

3. Hospital Utilization Review

4. Prior Authorization

5. Time-Based Criteria for Inpatient Admission

6. Payment Alignment

7. Public Comments on Other Topics

a. Rules for the External Review of Inpatient Claims

b. Improving Beneficiary Protections

c. Revising the Qualifying Criteria for Skilled Nursing Facility (SNF) Coverage

C. Summary

XII. CY 2013 OPPS Payment Status and Comment Indicators

A. CY 2013 OPPS Payment Status Indicator Definitions

B. CY 2013 Comment Indicator Definitions

XIII. OPPS Policy and Payment Recommendations

A. MedPAC Recommendations

B. GAO Recommendations

C. OIG Recommendations

XIV. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

B. Treatment of New Codes

1. Process for Recognizing New Category I and Category III CPT Codes and Level II HCPCS Codes

2. Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April and July 2012 for Which We Solicited Public Comments in the CY 2013 OPPS/ASC Proposed Rule

3. Process for New Level II HCPCS codes and Category I and Category III CPT Codes for Which We Are Soliciting Public Comments in this CY 2013 OPPS/ASC Final Rule with Comment Period

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

b. Covered Surgical Procedures Designated as Office-Based

(1) Background

(2) Changes for CY 2013 to Covered Surgical Procedures Designated as Office-Based

c. ASC Covered Surgical Procedures Designated as Device-Intensive

(1) Background

(2) Changes to List of Covered Surgical Procedures Designated as Device-Intensive for CY 2013

d. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

e. ASC Treatment of Surgical Procedures Removed from the OPPS Inpatient List for CY 2013

2. Covered Ancillary Services

D. ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. Payment for Covered Surgical Procedures

a. Background

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2013

c. Waiver of Coinsurance and Deductible for Certain Preventive Services

d. Payment for the Cardiac Resynchronization Therapy Composite

e. Payment for Low Dose Rate (LDR) Prostate Brachytherapy Composite

2. Payment for Covered Ancillary Services

a. Background

b. Payment for Covered Ancillary Services for CY 2013

E. New Technology Intraocular Lenses (NTIOLs)

1. NTIOL Cycle and Evaluation Criteria

2. NTIOL Application Process for Payment Adjustment

3. Requests to Establish New NTIOL Classes for CY 2013 and Deadline for Public Comments

4. Payment Adjustment

5. Revisions to the Major NTIOL Criteria Described in 42 CFR 416.195

6. Request for Public Comment on the "Other Comparable Clinical Advantages" Improved Outcome

7. Announcement of CY 2013 Deadline for Submitting Requests for CMS Review of Appropriateness of ASC Payment for Insertion of an NTIOL Following Cataract Surgery

F. ASC Payment and Comment Indicators

1. Background

2. ASC Payment and Comment Indicators

G. ASC Policy and Payment Recommendations

H. Calculation of the ASC Conversion Factor and the ASC Payment Rates

1. Background

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2013 and Future Years

b. Updating the ASC Conversion Factor

3. Display of CY 2013 ASC Payment Rates

XV. Hospital Outpatient Quality Reporting Program Updates

A. Background

1. Overview

2. Statutory History of the Hospital Outpatient Quality Reporting (Hospital OQR) Program

3. Measure Updates and Data Publication

a. Process for Updating Quality Measures

b. Publication of Hospital OQR Program Data

B. Process for Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

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

2. Removal of One Chart-Abstracted Measure for the CY 2013 and Subsequent Years Payment Determinations

3. Suspension of One Chart-Abstracted Measure for the CY 2014 and Subsequent Years Payment Determinations

4. Deferred Data Collection of OP-24: Cardiac Rehabilitation Measure: Patient Referral from an Outpatient Setting for the CY 2014 Payment Determination

D. Quality Measures for CY 2015 Payment Determination

E. Possible Quality Measures Under Consideration for Future Inclusion in the Hospital OQR Program

F. Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2013 Payment Update

1. Background

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2013

G. Requirements for Reporting of Hospital OQR Data for the CY 2014 Payment Determination and Subsequent Years

1. Administrative Requirements for the CY 2014 Payment Determination and Subsequent Years

2. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program for the CY 2014 Payment Determination and Subsequent Years

a. Background

b. General Requirements

c. Chart-Abstracted Measure Requirements for CY 2014 and Subsequent Payment Determination Years

d. Claims-Based Measure Data Requirements for the CY 2014 and CY 2015 Payment Determinations

e. Structural Measure Data Requirements for the CY 2014 Payment Determination and Subsequent Years

f. Data Submission Requirements for OP-22: ED-Patient Left Without Being Seen for the CY 2015 Payment Determination

g. Population and Sampling Data Requirements for the CY 2014 Payment Determination and Subsequent Years

3. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2014 Payment Determination and Subsequent Years

a. Random Selection of Hospitals for Data Validation of Chart-Abstracted Measures for the CY 2014 Payment Determination and Subsequent Years

b. Targeting and Targeting Criteria for Data Validation Selection for CY 2014 Payment Determination and for Subsequent Years

c. Methodology for Encounter Selection for the CY 2014 Payment Determination and Subsequent Years

d. Validation Score Calculation for the CY 2014 Payment Determination and Subsequent Years

H. Hospital OQR Reconsideration and Appeals Procedures for the CY 2014 Payment Determination and Subsequent Years

I. Extraordinary Circumstances Extension or Waiver for the CY 2013 Payment Determination and Subsequent Years

J. Electronic Health Records (EHRs)

K. 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs

XVI. Requirements for the Ambulatory Surgical Centers Quality Reporting (ASCQR) Program

A. Background

1. Overview

2. Statutory History of the ASC Quality Reporting (ASCQR) Program

3. History of the ASCQR Program

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

2. ASCQR Program Quality Measures

3. ASC Measure Topics for Future Consideration

4. Clarification Regarding the Process for Updating ASCQR Program Quality Measures

C. Requirements for Reporting of ASC Quality Data

1. Form, Manner, and Timing for Claims-Based Measures for the CY 2014 Payment Determination and Subsequent Payment Determination Years

a. Background

b. Form, Manner, and Timing for Claims-Based Measures for the CY 2015 Payment Determination and Subsequent Payment Determination Years

2. Data Completeness and Minimum Threshold for Claims-Based Measures Using QDCs

a. Background

b. Data Completeness Requirements for the CY 2015 Payment Determination and Subsequent Payment Determination Years

3. Other Comments on the ASCQR Program

D. Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements

1. Statutory Background

2. Reduction to the ASC Payment Rates for ASCs That Fail to Meet the ASCQR Program Requirements for the CY 2014 Payment Determination and Subsequent Payment Determination Years

XVII. Inpatient Rehabilitation Facility (IRF) Quality Reporting Program Updates

A. Overview

B. Updates to IRF QRP Measures Which Are Made as a Result of Review by the National Quality Forum (NQF) Process

C. Process for Retention of IRF Quality Measures Adopted in Previous Fiscal Year Rulemaking Cycles

D. Measures for the FY 2014 Payment Determination

1. Clarification Regarding Existing IRF Quality Measures That Have Undergone Changes During the NQF Measure Maintenance Processes

2. Updates to the "Percent of Residents Who Have Pressure Ulcers That Are New or Worsened" Measure

XVIII. Revisions to the Quality Improvement Organization (QIO) Regulations (42 CFR Parts 476, 478, and 480)

A. Summary of Changes

B. Quality of Care Reviews

1. Beneficiary Complaint Reviews

2. Completion of General Quality of Care Reviews

C. Use of Confidential Information That Explicitly or Implicitly Identifies Patients

D. Secure Transmissions of Electronic Versions of Medical Information

E. Active Staff Privileges

F. Technical Corrections

XIX. Files Available to the Public Via the Internet

XX. Collection of Information Requirements

A. Legislative Requirements for Solicitation of Comments

B. Requirements in Regulation Text

1. 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs (§ 495.8)

C. Associated Information Collections Not Specified in Regulatory Text

1. Hospital OQR Program

2. Hospital OQR Program Measures for the CY 2012, CY 2013, CY 2014 and CY 2015 Payment Determinations

a. Previously Adopted Hospital OQR Program Measures for the CY 2012, CY 2013, and CY 2014 Payment Determinations

b. Hospital OQR Program Measures for the CY 2014 Payment Determination

c. Hospital OQR Program Measures for CY 2015

3. Hospital OQR Program Validation Requirements for CY 2014

4. Hospital OQR Program Reconsideration and Appeals Procedures

5. ASCQR Program Requirements

a. Claims-Based Outcome Measures for the CY 2014 Payment Determination

b. Claims-Based Process, Structural, and Volume Measures for the CY 2015 and CY 2016 Payment Determinations

c. Program Administrative Requirements and QualityNet Accounts; Extraordinary Circumstance and Extension Requests; Reconsideration Requests

6. IRF QRP

a. Pressure Ulcer Measure

b. CAUTI Measure

XXI. Waiver of Proposed Rulemaking and Response to Comments

A. Waiver of Proposed Rulemaking

B. Response to Comments

XXII. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

2. Statement of Need

3. Overall Impacts for OPPS and ASC Payment Provisions

4. Detailed Economic Analyses

a. Estimated Effects of OPPS Changes in this Final Rule with Comment Period

(1) Limitations of Our Analysis

(2) Estimated Effects of OPPS Changes on Hospitals

(3) Estimated Effects of OPPS Changes on CMHCs

(4) Estimated Effect of OPPS Changes on Beneficiaries

(5) Estimated Effects of OPPS Changes on Other Providers

(6) Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

(7) Alternative OPPS Policies Considered

b. Estimated Effects of ASC Payment System Final Policies

(1) Limitations of Our Analysis

(2) Estimated Effects of ASC Payment System Final Policies on ASCs

(3) Estimated Effects of ASC Payment System Final Policies on Beneficiaries

(4) Alternative ASC Payment Policies Considered

c. Effects of the Revisions to the QIO Regulations

d. Accounting Statements and Tables

e. Effects of Requirements for the Hospital OQR Program

f. Effects of the EHR Electronic Reporting Pilot

g. Effects of Proposals for the ASCQR Program

h. Effects of Updates to the IRF QRP

B. Regulatory Flexibility Act (RFA) Analysis

C. Unfunded Mandates Reform Act Analysis

D. Conclusion

XXIII. Federalism Analysis

Regulation Text

I. Summary and Background

A. Executive Summary of this Final Rule with Comment Period

1. Purpose

In this final rule with comment period, we are updating the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments and Ambulatory Surgical Centers (ASCs) beginning January 1, 2013. 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.

In addition to establishing payment rates for CY 2013, we are updating and implementing new requirements under the Hospital Outpatient Quality Reporting (OQR) Program, the Ambulatory Surgical Center Quality Reporting (ASCQR) Program, and the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program. We are continuing

the electronic reporting pilot for the Electronic Health Record (EHR) Incentive Program and making revisions to the regulations governing the Quality Improvement Organizations (QIOs), including the secure transmittal of electronic medical information, beneficiary complaint resolution and notification processes, and technical corrections. The technical changes to the QIO regulations that we are making to improve the regulations reflect CMS' commitment to the principles of the President's Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011).

2. Summary of the Major Provisions

- *OPPS Update:* For CY 2013, we are increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.8 percent. This increase is based on the final hospital inpatient market basket percentage increase of 2.6 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the multifactor productivity (MFP) adjustment of 0.7 percentage points, and minus a 0.1 percentage point adjustment required by the Affordable Care Act. Under this final rule with comment period, we estimate that total payments for CY 2013, including beneficiary cost-sharing, to the more than 4,000 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers (CMHCs)), will be approximately $48.1 billion, an increase of approximately $4.6 billion compared to CY 2012 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.

- *Geometric Mean-Based Relative Payment Weights:* CMS has discretion under the statute to set OPPS payments based upon either the estimated mean or median costs of services within an Ambulatory Payment Classification (APC) group, the unit of payment. To improve our cost estimation process, for CY 2013 we are using the geometric mean costs of services within an APC to determine the relative payment weights of services, rather than the median costs that we have used since the inception of the OPPS. Our analysis shows that the change to means will have a limited payment impact on most providers, with a small number experiencing payment gain or loss based on their service-mix.

- *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 2013, 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 0.91 will be used to determine the CY 2013 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 0.91 for each cancer hospital.

- *Payment Adjustment Policy for Radio-Isotopes Derived from Non-Highly Enriched Uranium Sources:* We are exercising our statutory authority to make payment adjustments necessary to ensure equitable payments in order to provide an adjustment for CY 2013 to cover the marginal cost of hospital conversion to the use of non-HEU sources of radio-isotopes used in medical imaging. The adjustment will cover the marginal cost of radio-isotopes produced from non-HEU sources over the costs of radio-isotopes produced by HEU sources.

- *Payment of Drugs, Biologicals, and Radiopharmaceuticals:* For CY 2013, 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.

- *Supervision of Hospital Outpatient Therapeutic Services:* We are clarifying the application of the supervision regulations to physical therapy, speech-language pathology, and occupational therapy services that are furnished in OPPS hospitals and critical access hospitals (CAHs). In addition, in this final rule we note that we will extend the enforcement instruction one final year through CY 2013. This additional year, which we expect will be the final year of the extension, will provide additional opportunities for stakeholders to bring their issues to the Hospital Outpatient Payment Panel.

● *Outpatient Status:* We are concerned about recent increases in the length of time that Medicare beneficiaries spend as outpatients receiving observation services. In addition, hospitals continue to express concern about Medicare Part A to Part B rebilling policies when a hospital inpatient claim is denied because the inpatient admission was not medically necessary. In the CY 2013 OPPS/ASC proposed rule (77 FR 45155 through 45157), we provided an update on the Part A to Part B Rebilling Demonstration that is in effect for CY 2012 through CY 2014, which was designed to assist us in evaluating these issues. We also solicited public comments on potential clarifications or changes to our policies regarding patient status that may be appropriate, which we discuss in this final rule with comment period.

● *Ambulatory Surgical Center Payment Update:* For CY 2013, we are increasing payment rates under the ASC payment system by 0.6 percent. This increase is based on a projected CPI-U update of 1.4 percent minus a multifactor productivity adjustment required by the Affordable Care Act that is projected to be 0.8 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 2013 will be approximately $4.074 billion, an increase of approximately $310 million compared to estimated CY 2012 payments.

● *New Technology Intraocular Lenses:* We are revising the regulations governing payments for new technology intraocular lenses (NTIOLs) to require that the IOL's labeling, which must be approved by the FDA, contain a claim of a specific clinical benefit based on a new lens characteristic in comparison to currently available

IOLs. We also are revising the regulations to require that any specific clinical benefit referred to in § 416.195(a)(2) must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved outcome.

- *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we address the public comments received as a result of our solicitation in the proposed rule on our approach for future measure selection and development as well as certain measures for future potential inclusion in the ASCQR Program measure set. We are finalizing our approach to future measure selection and development for the ASCQR Program. For the CY 2015 payment determination and subsequent years' payment determinations, we are adopting requirements for claims-based measures regarding the dates for submission and payment of claims and data completeness. We also are finalizing our policy regarding how the payment rates will be reduced in CY 2014 and in subsequent calendar years for ASCs that fail to meet program requirements, and we are clarifying our policy on updating measures.

- *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are not establishing any new measures for CY 2013. We also are not specifying any new targeting criteria to select hospitals for validation of medical records. We are confirming the removal or suspension of data collection for specific measures. We are specifying that the criteria we will consider when determining whether to remove measures for the Hospital Inpatient Quality Reporting (IQR) Program will also apply to the Hospital OQR Program. We are providing that measures adopted in future rulemaking are automatically adopted for all subsequent year payment determinations

unless we remove, suspend, or replace them. We are making changes to administrative forms used in the program. We are extending the deadline for submitting a notice of participation form and to enter structural measures data.

- *Electronic Health Record (EHR) Incentive Program:* For the EHR Incentive Program, we are extending the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs through 2013, exactly as finalized for 2012. We recently issued a final rule (77 FR 53968) for Stage 2 of the Medicare and Medicaid EHR Incentive Programs.

- *Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP)*: We are: (1) adopting updates on one (out of two) previously adopted measure for the IRF QRP that will affect annual prospective payment amounts for FY 2014; (2) adopting a nonrisk-adjusted version of an NQF-endorsed pressure ulcer measure for the IRF QRP, and we will not publicly report any pressure ulcer measure data until we begin risk adjustment of these data; (3) adopting a policy that will provide that any measure that has been adopted for use in the IRF QRP will remain in effect until the measure is actively removed, suspended, or replaced; and (4) adopting policies regarding when notice-and-comment rulemaking will be used to update existing IRF QRP measures.

- *Revisions to the Quality Improvement Organization (QIO) Regulations:* We are revising the QIO program regulations to: (1) give QIOs the authority to send and receive secure transmissions of electronic versions of medical information; (2) provide more detailed and improved procedures for QIOs when completing Medicare beneficiary complaint reviews and general quality of care reviews, including procedures related to a

new alternative dispute resolution process called “immediate advocacy”; (3) increase the information beneficiaries receive in response to QIO review activities; (4) convey to Medicare beneficiaries the right to authorize the release of confidential information by QIOs; and (5) make other technical changes that are designed to improve the regulations. The technical changes to the QIO regulations that we are making to improve the regulations reflect CMS’ commitment to the principles of the President’s Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011).

3. Summary of Costs and Benefits

In sections XXII. and XXIII. 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 include the following:

a. Impacts of the OPPS Update

(1) Impacts of All OPPS Changes

Table 57 in section XXII. of this final rule with comment period displays the distributional impact all the OPPS changes on various groups of hospitals and CMHCs for CY 2013 compared to all estimated OPPS payments in CY 2012. We estimate that the policies in this final rule will result in a 1.9 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 $4.571 billion in OPPS expenditures, including beneficiary cost-sharing,

for CY 2013 compared to CY 2012 OPPS expenditures. We estimate that total OPPS payments, including beneficiary cost-sharing, will be $48.1 billion for CY 2013.

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 for CY 2011 and basing payment fully on the type of provider furnishing the service, we estimate a 4.4 percent decrease in CY 2013 payments to CMHCs relative to their CY 2012 payments.

(2) Impacts of Basing APC Relative Payment Weights on Geometric Mean Costs

We estimate that our final policy to base the APC relative payment weights on the geometric mean costs rather than the median costs of services within an APC will not significantly impact most providers. Payments to very low volume urban hospitals and to hospitals for which disproportionate share hospital (DSH) data are not available will increase by an estimated 2.5 and 4.3 percent, respectively. The hospitals for which DSH data are not available are largely non-IPPS psychiatric hospitals. In contrast, payments to CMHCs will decrease by an estimated 3.9 percent due to basing the relative payment weights on the geometric mean costs of services rather than the median costs of services.

(3) Impacts of the Updated Wage Indices

We estimate no significant impacts related to updating the wage indices and applying the frontier State wage index. Adjustments to the wage indices other than the frontier State wage adjustment will not significantly affect most hospitals. The updated wage indices will most affect urban hospitals in the Pacific and East South Central regions and rural hospitals in the Mountain and Pacific regions.

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

There are no significant impacts of our CY 2013 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.

(5) Impacts of the OPD Fee Schedule Increase Factor

We estimate that, for most hospitals, the application of the OPD fee schedule increase factor of 1.8 percent to the conversion factor for CY 2013 will mitigate the small negative impacts of the budget neutrality adjustments. Certain low volume hospitals and hospitals for which DSH data are not available will experience larger increases ranging from 4.5 percent to 8.2 percent. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that rural and urban hospitals will experience similar increases of approximately 1.8 percent for urban hospitals and 2.1 percent for rural hospitals. Classifying hospitals by teaching status or type of ownership suggests that these hospitals will receive similar increases.

b. Impacts of the ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2013 payment rates compared to estimated CY 2012 payment rates ranges

between -3 percent for respiratory system procedures, integumentary system procedures, and cardiovascular system procedures and 3 percent for nervous system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our CY 2013 policies to significantly affect the number of hospitals that do not receive a full annual payment update.

d. Impacts of the EHR Incentive Program Proposal

There are no changes from the 2012 OPPS/ASC final rule to the costs or impact for the 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs.

e. Impacts of the ASCQR Program

We do not expect our CY 2013 final policies to significantly affect the number of ASCs that do not receive a full annual payment update beginning in CY 2014.

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; and most recently the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112-96), enacted on February 22, 2012.

Under the OPPS, 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 OPPS includes payment for most hospital outpatient services, except those

identified in section I.C. of this final rule with comment period. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services designated by the Secretary that are furnished to inpatients who are entitled to Part A and have exhausted their Part A benefits, or who are not so entitled.

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

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

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary

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

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercised the authority granted under the statute to also exclude from the OPPS 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 composite rate; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals and entities that are excluded from payment under the OPPS. 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 OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

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

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel), 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 OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act and section 222 of the Public Health Service (PHS) Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the PHS Act which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel, or the Panel). The

Panel is not restricted to using data compiled by CMS, and in conducting its review it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the HOP Panel, at that time named the APC Panel. This expert panel, which may be composed of up to 19 appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise), reviews clinical data and advises CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). Since its initial chartering, the Secretary has renewed the Panel's charter five times: on November 1, 2002; on November 1, 2004; on November 21, 2006; on November 2, 2008 and November 12, 2010. The current charter specifies, among other requirements, that: the Panel continues to be technical in nature; is governed by the provisions of the FACA; may convene up to three meetings per year; has a Designated Federal Official (DFO); and is chaired by a Federal Official designated by the Secretary. The current charter was amended on November 15, 2011 and the Panel was renamed to reflect expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and therefore to add CAHs to its membership.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda

topics, and meeting reports, can be viewed on the CMS Web site at: http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage.

3. Panel Meetings and Organizational Structure

The Panel has held multiple meetings, with the last meeting taking place on August 27-28, 2012. 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 (previously known as the Packaging Subcommittee).

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

appropriate APC placement of HCPCS codes regarding services for which separate payment is made.

Each of these subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended that the subcommittees continue at the August 2012 Panel meeting. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the February 2012 and August 2012 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 OPPS/ASC proposed and final rules, the CMS Web site mentioned earlier in this section, and the FACA database at: http://fido.gov/facadatabase/public.asp.

F. Public Comments Received in Response to the CY 2013 OPPS/ASC Proposed Rule

We received approximately 668 timely pieces of correspondence on the CY 2013 PPS/ASC proposed rule that appeared in the **Federal Register** on July 30, 2012 (77 FR 45061). 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 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 2012 OPPS/ASC Final Rule with Comment Period

We received approximately 61 timely pieces of correspondence on the CY 2012 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 30, 2011 (76 FR 74122), some of which contained comments on the interim APC assignments and/or status indicators of HCPCS codes identified with comment indicator "NI" in Addendum B 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 OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

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

In the CY 2013 OPPS/ASC proposed rule (77 FR 45071), for the CY 2013 OPPS, we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2013, and before January 1, 2014 (CY 2013), using the same basic

methodology that we described in the CY 2012 OPPS/ASC final rule with comment period. That is, we proposed to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights. Therefore, for the purpose of recalibrating the proposed APC relative payment weights for CY 2013, we used approximately 141 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, 2011, and before January 1, 2012. For this final rule with comment period, for the purpose of recalibrating the final APC relative payment weights for CY 2013, we used approximately 153 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, 2011, and before January 1, 2012. For exact counts of claims used, we refer readers to the claims accounting narrative under supporting documentation for the 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 153 million final action claims for services provided in hospital outpatient settings used to calculate the final CY 2013 OPPS payment rates for this final rule with comment period, approximately 121 million claims were the type of bill potentially appropriate for use in setting rates for OPPS services (but did not necessarily contain services payable under the OPPS). Of the approximately 121 million

claims, approximately 5 million claims were not for services paid under the OPPS or were excluded as not appropriate for use (for example, erroneous cost-to-charge ratios (CCRs) or no HCPCS codes reported on the claim). From the remaining approximately 116 million claims, we created approximately 120 million single records, of which approximately 81 million were "pseudo" single or "single session" claims (created from approximately 39 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 120 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. Ultimately, we were able to use for CY 2013 ratesetting some portion of approximately 95 percent of the CY 2011 claims containing services payable under the OPPS.

The final APC relative weights and payments for CY 2013 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 2011 that were processed through June 30, 2012. While we have historically based the payments on median hospital costs for services in the APC groups, we proposed in the CY 2013 OPPS/ASC proposed rule (77 FR 45071) to establish the cost-based relative payment weights of the CY 2013 OPPS using geometric mean costs, as discussed in section II.A.2.f. of this final rule with comment period. Therefore, on the CMS Web site, along with Addenda A and B, we provided a file that presented payment information for the proposed CY 2013 OPPS payments based on geometric mean costs compared to those based on median costs. Under this methodology, we select claims for services paid under the OPPS and match these claims to the most recent cost report filed by the individual hospitals represented in our claims data. We continue to believe that it is appropriate to use the most current full calendar year claims data and the most recently submitted cost reports to calculate the relative costs underpinning the APC relative payment weights and the CY 2013 payment rates.

b. Use of Single and Multiple Procedure Claims

For CY 2013, in general, we proposed to continue to use single procedure claims to set the costs on which the APC relative payment weights are based. We generally use single procedure claims to set the estimated costs for APCs because we believe that the OPPS relative weights on which payment rates are based should be derived from the costs of furnishing one unit of one procedure and because, in many circumstances, we are

unable to ensure that packaged costs can be appropriately allocated across multiple procedures performed on the same date of service.

It is generally desirable to use the data from as many claims as possible to recalibrate the APC relative payment weights, including those claims for multiple procedures. As we have for several years, we proposed to continue to use date of service stratification and a list of codes to be bypassed to convert multiple procedure claims to "pseudo" single procedure claims. Through bypassing specified codes that we believe do not have significant packaged costs, we are able to use more data from multiple procedure claims. In many cases, this enables us to create multiple "pseudo" single procedure claims from claims that were submitted as multiple procedure claims spanning multiple dates of service, or claims that contained numerous separately paid procedures reported on the same date on one claim. We refer to these newly created single procedure claims as "pseudo" single procedure claims. The history of our use of a bypass list to generate "pseudo" single procedure claims is well documented, most recently in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74132 through 74134). 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 2012. Increased packaging and creation of composite APCs also increased the number of bills that we were able to use for ratesetting by enabling us to use claims that contained multiple major procedures that previously would not have been usable. Further, for CY 2009, we expanded the composite APC model to one additional clinical area, multiple imaging services (73 FR 68559 through 68569), which also increased the

number of bills we were able to use in developing the OPPS relative weights on which payments are based. We have continued the composite APCs for multiple imaging services through CY 2012. We did not receive any public comments on this policy, and therefore, we are finalizing our proposal to continue this policy for CY 2013. We refer readers to section II.A.2.e. of this final rule with comment period for a discussion of the use of claims in modeling the costs for composite APCs.

We proposed to continue to apply these processes to enable us to use as much claims data as possible for ratesetting for the CY 2013 OPPS. This methodology enabled us to create, for this final rule with comment period, approximately 81 million "pseudo" single procedure claims, including multiple imaging composite "single session" bills (we refer readers to section II.A.2.e.(5) of this final rule with comment period for further discussion), to add to the approximately 39 million "natural" single procedure claims. For this final rule with comment period, "pseudo" single procedure and "single session" procedure bills represented approximately 67 percent of all single procedure bills used for ratesetting purposes.

For CY 2013, we proposed to bypass 480 HCPCS codes that were identified in Addendum N to the CY 2013 OPPS/ASC proposed rule (which was 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 2013, data available for the February 27, 2012 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) from CY 2011 claims processed through September 30, 2011, and CY 2010 claims data processed through June 30, 2011, used to model the payment rates for CY 2012) to determine whether it would be appropriate to add additional codes to the previous year's bypass list. For CY 2013, we proposed to continue to bypass all of the HCPCS codes on the CY 2012 OPPS bypass list, with the exception of HCPCS codes that we proposed to delete for CY 2013, which are listed in Table 1 of the proposed rule. 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. In addition, we proposed to add to the bypass list for CY 2013 HCPCS codes not on the CY 2012 bypass list that, using either the CY 2012 final rule data (CY 2010 claims) or the February 27, 2012 Panel data (first 9 months of CY 2011 claims), met the empirical criteria for the bypass list that are summarized below. Finally, to remain consistent with the CY 2013 final policy to develop OPPS relative payment weights based on geometric mean costs, we proposed that the median cost of packaging criterion instead be based on the geometric mean cost of packaging. The entire list proposed for CY 2013 (including the codes that remain on the bypass list from prior years) was open to public comment in the CY 2013 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, in the CY 2013 OPPS/ASC proposed rule (77 FR 45072), we proposed to establish the CY 2013 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. The development of the CY 2013 OPPS relative payment weights

based on geometric mean costs is discussed in greater detail in section II.A.2.f. of this final rule with comment period.

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 2012 OPPS/ASC final rule with comment period (76 FR 74133), we proposed for CY 2013 to continue to update the packaged cost threshold by the market basket increase. By applying the final CY 2012 market basket increase of 1.9 percent to the prior non-rounded dollar threshold of $52.76 (76 FR 74133), we determined that the threshold remains for CY 2013 at $55 ($53.76 rounded to $55, the nearest $5 increment). Therefore, we proposed to set the geometric mean packaged cost threshold on the CY 2011 claims at $55 for a code to be considered for addition to the CY 2013 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 2013 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) and the CPT codes for additional hours of drug administration to the bypass list (73 FR 68513 and 71 FR 68117 through 68118).

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).

Addendum N to this final rule with comment period includes the list of bypass codes for CY 2013. The list of bypass codes contains codes that were reported on claims for services in CY 2011 and, therefore, includes codes that were in effect in 2011 and used for billing but were deleted for CY 2012. We retained these deleted bypass codes on the CY 2013 bypass list because these codes existed in CY 2011 and were covered OPD services in that period, and CY 2011 claims data are used to calculate CY 2013 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 proposed 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 2013 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 2013 bypass list for CY 2013 (77 FR 45073).

Comment: One commenter supported the proposal to include CPT codes 76881 (Ultrasound, extremity, nonvascular, real-time with image documentation; complete) and 76882 (Ultrasound, extremity, nonvascular, real-time with image documentation; limited, anatomic specific) on the CY 2013 OPPS bypass list.

Response: We appreciate the commenter's support.

Comment: Several commenters expressed appreciation for our efforts to include multiple procedure claims in the ratesetting process through processes such as the bypass list and date of service stratification, which are used to create "pseudo" single claims. However, the commenters remained concerned about the limited number of claims used to model brachytherapy APCs 0312 (Radioelement Applications), 0651 (Complex Interstitial Radiation Source Application), and 8001 (LDR Prostate Brachytherapy Composite) and encouraged CMS to continue exploring potential methodologies through which more claims data could be used in OPPS ratesetting.

Response: We appreciate the commenters' support of our efforts to include more appropriate claims data for ratesetting purposes. As discussed above, one of the challenges in modeling the APC costs on which the OPPS/ASC relative payment weights are based is appropriately allocating the packaged cost associated with a service, when multiple separately payable procedures appear on the claim. However, recognizing the challenges associated with obtaining additional information, we will continue to explore potential methodologies through which we would be able to derive accurate cost data from the multiple major procedure claims made available to us.

After consideration of the public comments we received, we are adopting as final the proposed "pseudo" single claims process and the final CY 2013 bypass list of 480 HCPCS codes, as displayed in Addendum N of this final rule with comment period (available via the Internet on the CMS Web site). Table 1 below contains the list of codes that we are removing from the CY 2013 bypass list because these codes were either deleted from the HCPCS before CY 2011 (and therefore were not covered OPD services in CY 2011) or were not separately payable codes under the CY 2013 OPPS because these codes are not used for ratesetting (and therefore would not need to be bypassed). None of these deleted codes are "overlap bypass" codes.

TABLE 1.—HCPCS CODES REMOVED FROM THE CY 2013 BYPASS LIST

HCPCS Code	HCPCS Short Descriptor
76880	Us exam, extremity
86903	Blood typing, antigen screen
92135	Ophth dx imaging post seg
93231	Ecg monitor/record, 24 hrs
93232	ECG monitor/report, 24 hrs
93236	ECG monitor/report, 24 hrs

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

In the CY 2013 OPPS/ASC proposed rule (77 FR 45073), for CY 2013, 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 2013 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 2011 claims data from the most recent available hospital cost reports, in most cases, cost reports beginning in CY 2010. For the CY 2013 OPPS proposed rates, we used the set of claims processed during CY 2011. 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 2011 (the year of the claims data we used to calculate the proposed CY 2013 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2011 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 2011 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, in most cases, cost reports with cost reporting periods beginning in CY 2010. 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 2013 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 2013.

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 Research Triangle Institute, International (RTI). The RTI final report can be found on RTI's Web site at: http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf. For a complete discussion of the RTI recommendations, public comments, and our responses, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527).

We addressed the RTI finding that there was aggregation bias in both the IPPS and the OPPS cost estimation of expensive and inexpensive medical supplies in the FY 2009 IPPS final rule (73 FR 48458 through 45467). Specifically, we created one cost center for "Medical Supplies Charged to Patients" and one cost center for "Implantable Devices Charged to Patients," essentially splitting the then current cost center for "Medical Supplies Charged to Patients" into one cost center for low-cost medical supplies and another cost center for high-cost implantable devices in order to mitigate

some of the effects of charge compression. In determining the items that should be reported in these respective cost centers, we adopted commenters' recommendations that hospitals should use revenue codes established by the AHA's NUBC to determine the items that should be reported in the "Medical Supplies Charged to Patients" and the "Implantable Devices Charged to Patients" cost centers. For a complete discussion of the rationale for the creation of the new cost center for "Implantable Devices Charged to Patients," public comments, and our responses, 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. As discussed in the CY 2013 OPPS/ASC proposed rule (77 FR 45074), in order to develop a robust analysis regarding the use of cost data from the "Implantable Devices Charged to Patients" cost center, we believe that it is necessary to have a critical mass of cost reports filed with data in this cost center. In preparation for the CY 2013 proposed rule, we assessed the availability of data in the "Implantable Devices Charged to Patients" cost center using cost reports in the December 31, 2011 quarter ending update of HCRIS, which was the latest upload of the cost report data that we could use for the CY 2013 proposed rule. We determined that 2,063 hospitals, out of approximately 3,800 hospitals, utilized the "Implantable Devices Charged to Patients" cost center. Because we believe that this is a sufficient amount of data from which to generate a meaningful analysis, we proposed 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 for CY 2013.

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 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 are effective for cost report periods beginning on or after May 1, 2010, on the revised cost report Form CMS-2552-10. However, because cost reports that were filed on the revised cost report Form CMS-2552-10 are not currently accessible in the HCRIS, we were unable to calculate distinct CCRs for CT scans, MRIs, and cardiac catheterization using the new standard cost centers for these services. We believe that we

will have cost report data available for an analysis of creating distinct CCRs for CT scans, MRIs, and cardiac catheterization for the CY 2014 OPPS rulemaking.

Comment: Many commenters supported CMS' proposal 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 for CY 2013. The commenters also encouraged CMS to continue to engage in educational efforts related to the use of the new cost center so that hospitals understand how to accurately report data in the new cost center. In addition, the commenters suggested that the Medicare administrative contractors (MACs) develop an audit program that would identify hospitals that have not reported data for the new cost center.

Response: We appreciate the commenters' support of our proposal to use data from the "Implantable Devices Charged to Patients" cost center to create a distinct CCR. We agree with commenters that it is important that hospitals understand how to accurately report data in the "Implantable Devices Charged to Patients" cost center, and we have worked to add more clarity to the cost report instructions under the new Medicare cost report form CMS-2552-10. The new cost report form also facilitates greater audit scrutiny from the MACs. Line 121 of Worksheet S-2, Part I, of cost report form CMS-2552-10 asks "Did this facility incur and report costs for implantable devices charged to a patient? Enter in column 1 'Y' for yes and 'N' for no."

Comment: Two commenters recommended that CMS wait until CY 2014 OPPS rulemaking to determine if the "Implantable Devices Charged to Patients" cost center should be used to create a distinct CCR. The commenters did not believe that data from

2,063 hospitals provide a meaningful representation of all of the hospitals subject to the OPPS from which to base the proposal to use the new cost center for CY 2013.

Response: We disagree with the commenters and believe that data from the 2,063 hospitals that utilized the "Implantable Devices Charged to Patients" cost center, out of approximately 3,800 hospitals, are sufficient and appropriate for creating a distinct CCR to use in the calculation of the CY 2013 OPPS relative payment weights.

Comment: Commenters expressed disappointment that, because the revised cost report Form CMS-2552-10 was not accessible in the HCRIS at the time of the proposed rule, CMS was not able to create distinct CCRs for CT scans, MRIs, and cardiac catheterization services for use in the calculation of the CY 2013 OPPS relative payment weights. The commenters urged CMS to analyze the data in the new CT scan, MRI, and cardiac catheterization cost centers when the data are available and utilize the new cost centers in the development of the OPPS relative payment weights as soon as possible.

Response: We expect that we will have sufficient and appropriate cost report data available for an analysis of creating distinct CCRs for CT scans, MRIs, and cardiac catheterization for the CY 2014 rulemaking. If so, as was done for the "Implantable Devices Charged to Patients" cost center for the CY 2013 OPPS/ASC proposed rule, we expect to provide an impact analysis in the CY 2014 OPPS/ASC proposed rule that will enable the public to assess the full impact of the use of the new CCRs specific to CT scans, MRIs, and cardiac catheterization on payments for all services.

Comment: One commenter recommended that CMS require the use of the new nonstandard cost center for cardiac rehabilitation instead of making its use optional.

Response: We created the new nonstandard cost center for cardiac rehabilitation because we believed that this would facilitate more accurate cost reporting for these services. The nonstandard cost centers are additional common cost centers available to hospitals for reporting when preparing their Medicare hospital cost report. To the extent hospitals provide services captured by nonstandard cost centers, they should report the relevant nonstandard cost centers as well. However, we do not specify a revenue code-to-cost center crosswalk that hospitals must adopt to prepare the cost report and, therefore, we do not believe that we should require hospitals to use the nonstandard cost center for cardiac rehabilitation.

After consideration of the public comments we received, we are finalizing our proposal 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 for CY 2013.

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 OPPS payment rates for CY 2013. The Hospital OPPS page on the CMS Web site on which this final rule with comment period is posted (http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html) provides an accounting of claims used in the development of the final payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, below in this section we discuss the file of claims that comprises the data set that is available for

purchase under a CMS data use agreement. The CMS Web site, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html, includes information about purchasing the "OPPS Limited Data Set," which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD-9-CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2011 claims that were used to calculate the final payment rates for the CY 2013 OPPS.

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

We used the methodology described in sections II.A.2.a. through II.A.2.e. of this final rule with comment period to calculate the costs we used to establish the relative weights used in calculating the OPPS payment rates for CY 2013 shown in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site). For the proposed rule, we provided a comparison file so that the public could provide meaningful comment on our proposal to base the CY 2013 OPPS relative

payment weights on geometric mean costs. 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 OPPS payment rates from year to year. The commenters suggested a "stability policy" and suggested that the costs from claims be adjusted to limit changes from year to year and asked that CMS limit any decreases in payment compared to the prior year to no more than a 5-percent decline.

Response: As previously discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74139), 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, hospital costs and charges changes each year resulting in changes to the CCRs, reassignments of HCPCS codes, changes to OPPS payment policy (for example, changes to packaging), and implementation of composite APCs. We cannot stabilize hospital-driven fundamental inputs to the calculation of OPPS 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 OPPS, we believe that implementing the policy suggested by the commenters would make payments less reflective of the true service costs, which would be contrary to a purpose of our proposed CY 2013 policy of establishing relative payment weights based on geometric mean 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 2011 hospital outpatient claims processed through June 30, 2012, to calculate the geometric mean costs of APCs that underpin the relative payment weights for CY 2013. To begin the calculation of the relative payment weights for CY 2013, we pulled all claims for outpatient services furnished in CY 2011 from the national claims history file. This is not the population of claims paid under the OPPS, but all outpatient claims (including, for example, critical access hospital (CAH) claims and hospital claims for clinical laboratory services 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 121 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.

In the past several years, we have developed payment policy for nonpass-through separately paid drugs and biologicals based on a redistribution methodology that accounts for pharmacy overhead by allocating cost from packaged drugs to separately paid drugs.

This 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, as we proposed, we are paying 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. Therefore, under this policy, we do not redistribute the packaged cost. We refer readers to section V.B.3. of this final rule with comment period for a complete discussion of our policy to pay for separately paid drugs and biologicals in CY 2013.

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 2012 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 2013, as we proposed, we are continuing the policy we implemented for CY 2012 to exclude line-item data for pass-through drugs and biologicals (status indicator "G" for CY 2011) and nonpass-through drugs and biologicals (status indicator "K" for CY 2011) 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 2012 OPPS/ASC final rule with comment period (76 FR 74141) 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.

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

(1) Splitting Claims

For the CY 2013 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.) For CY 2013, as we proposed, we are continuing our current policy of defining major procedures as any HCPCS code having a status indicator of "S," "T," "V," or "X"; 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 2013, as we proposed, 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 2013 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.e. of this final rule with comment period.

Specifically, as we proposed, 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 or clinical laboratory tests, 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).

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 2013 "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.e.(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 2013 OPPS payments 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 examine the multiple procedure minor claims to determine whether we could create "pseudo" single procedure claims. Specifically, where the claim contained multiple codes with status indicator "Q1" ("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 2012 relative payment weight, 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 2012 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 2012 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 2012 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 2012 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 2012 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 2012 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 2012 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 2012 relative payment weights. If a status indicator "Q1" HCPCS code had a higher CY 2011 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 XII.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.

Comment: Commenters supported the proposed process for creating "pseudo" single procedure claims.

Response: We appreciate the commenters' support and will continue to look for ways to refine the process to secure more claims data for use in calculating costs.

After consideration of the public comments we received, we are finalizing our proposals to continue to apply the methodology described above for the purpose of creating "pseudo" single procedure claims for the CY 2013 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 2 below that appeared on the claim without a HCPCS code into the cost of the single major procedure remaining on the claim.

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 are adopting for CY 2013 to the revenue codes that the I/OCE will package for CY 2013 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 2013, as we did for CY 2012, we reviewed the changes to revenue codes that were effective during CY 2011 for purposes of determining the charges reported with

revenue codes but without HCPCS codes that we are packaging for CY 2013. We believe that the charges reported under the revenue codes listed in Table 2 below continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes. Therefore, for CY 2013, we proposed to continue to package the costs that we derive from the charges reported without HCPCS code under the revenue codes displayed in Table 2 below for purposes of calculating the geometric mean costs on which the final CY 2013 OPPS/ASC payment rates are based.

We did not receive any public comments on our proposed list of packaged revenue codes. Therefore, for the reasons set forth in the proposed rule (77 FR 45079 through 45081), we are finalizing the proposed packaged revenue codes for CY 2013, without modification, which are identified in Table 2 below. We note that these revenue codes include only revenue codes that were in effect in CY 2011, the year of the claims data on which the final CY 2013 OPPS payment rates are based.

TABLE 2.—CY 2013 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

Revenue Code	Description
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
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

Revenue Code	Description
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	Inpatient Renal Dialysis; 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

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 OPPS) for which the fiscal intermediary or 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 2013 OPPS.

For the remaining claims, we then standardized 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 OPPS, we 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 OPPS, and claims for services not paid under the OPPS, approximately 116 million claims were left. Using these approximately 116 million claims, we created approximately 120 million single and "pseudo" single procedure claims, of which we used slightly more than 120 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 2013 geometric mean cost development and ratesetting.

As discussed above, the OPPS has historically developed the relative weights on which APC payments are based using APC median costs. For the CY 2013 OPPS, we proposed to calculate the APC relative payment weights using geometric mean costs; 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 2013 OPPS/ASC policy to calculate relative payment weights based on geometric means, we refer readers to section II.A.2.f. of this final rule with comment period.

We proposed to use these claims to calculate the CY 2013 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, as part of the CY 2013 policy to develop the OPPS relative payment weights based on geometric mean costs, we also are applying the 2 times rule based on geometric mean costs. For a detailed discussion of the CY 2013 policy to develop the APC relative payment weights based on geometric mean costs, we refer readers to section II.A.2.f. of this final rule with comment period.

We note that, for purposes of identifying significant HCPCS 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 120 million single procedure or single session claims we use for establishing geometric mean costs. Similarly, a HCPCS code for which there are fewer than 99 single bills and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC

geometric mean. We note that this method of identifying significant HCPCS codes within an APC for purposes of the 2 times rule was used in prior years under the median-based cost methodology. Under our CY 2013 policy 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. Section III. of this final rule with comment period includes a discussion of many of the HCPCS code assignment changes that resulted from examination of the geometric mean costs and for other reasons. 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: Some commenters asked that CMS provide an adjustment for medical education costs under the OPPS. These commenters stated that CMS indicated that it would study the costs and payment differential among different classes of providers in the April 7, 2000 OPPS final rule but has not done so. The commenters requested that CMS conduct its own analysis and that, if that analysis showed a difference in their

payment to cost ratios (similar to the comparison study performed to calibrate the cancer hospital payment adjustment) due to the unique missions of teaching hospitals, CMS should add a teaching payment adjustment under the OPPS.

Response: Unlike payment under the IPPS, the law does not specifically provide for payment for direct or indirect graduate medical education costs to be made under the OPPS. Section 1833(t)(2)(E) of the Act states that the Secretary shall establish, in a budget neutral manner "* * * other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals." We have not found such an adjustment to be necessary to ensure equitable payments to teaching hospitals and, therefore, have not developed such an adjustment. As the commenters recognized, the cancer hospital payment adjustment discussed in section II.F. of this final rule with comment period was established based on section 1833(t)(18) of the Act. Similarly, those hospitals were permanently held harmless and continued to receive TOPs under section 1833(t)(7)(d)(ii) of the Act. Furthermore, in this final rule with comment period, we have developed OPPS relative payment weights that we believe provide appropriate and adequate payment for the complex medical services, such as new technology services and device-dependent procedures, which we understand are furnished largely by teaching hospitals. The impacts of the final CY 2013 policies, by class of hospital, are displayed in Table 57 in section XXII. of this final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposed CY 2013 methodology for calculating the costs upon which the CY 2013 OPPS payment rates are based.

As we discuss in sections II.A.2.d. and II.A.2.e. and in section 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.e. 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 Advisory Panel on Hospital Outpatient Payment Regarding Data Development

At the August 27–28, 2012 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel), we provided the Data Subcommittee with a list of all APCs fluctuating by greater than 10 percent when comparing the CY 2013 OPPS/ASC proposed rule costs based on CY 2011 claims processed through June 30, 2012, to those based on CY 2012 OPPS/ASC final rule data (CY 2010 claims processed through June 30, 2011). The Data Subcommittee reviewed the fluctuations in the APC costs and their respective weights.

At the August 27-28, 2012 Panel meeting, the Panel made a number of recommendations related to the data process. The Panel's 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 Traci Rabine serve as the acting chair of the Data Subcommittee for the August 2012 HOP Panel meeting.

CMS Response: We are accepting this recommendation.

Recommendation: The Panel recommends that CMS continue to provide a list of APCs fluctuating by more than 10 percent in costs.

CMS Response: We are accepting this recommendation.

d. Calculation of Single Procedure APC Criteria-Based Costs

(1) Device-Dependent APCs

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. 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 2013 OPPS/ASC proposed rule (77 FR 45081 through 45082), we proposed for CY 2013 to use the standard methodology for calculating costs for device-dependent APCs that was finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74148 through 74151). This methodology utilizes claims data that generally represent the full cost of the required device and the most recent cost report data. Specifically, we proposed to calculate the costs for device-dependent APCs for CY 2013 using only the subset of single procedure claims from CY 2011 claims data 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

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

contain the "FC" modifier signifying that the hospital received partial credit for the device. The procedure-to-device edits require that when a particular procedural HCPCS code is billed, the claim must also contain an appropriate device code, while the device-to-procedure edits require that a claim that contains one of a specified set of device codes also contain an appropriate procedure code. We stated in the proposed rule that we continue to believe the standard methodology for calculating costs for device-dependent APCs gives us the most appropriate costs for device-dependent APCs in which the hospital incurs the full cost of the device. In Table 4A of the proposed rule, we listed the APCs for which we proposed to use our standard device-dependent APC ratesetting methodology for CY 2012.

Subsequent to the publication of the CY 2013 OPPS/ASC proposed rule, the AMA's CPT Editorial Panel created several new CPT codes describing services related to device-dependent APCs, to be effective beginning January 1, 2013. Our standard process for dealing with new CPT codes effective on January 1 for the upcoming calendar year is to assign each code to the APC that we believe contains services that are comparable with respect to clinical characteristics and resources required to furnish the service. The new CPT code is given a comment indicator of "NI" in Addendum B to the final rule with comment period to identify it as a new interim APC assignment for the new year and the APC assignment for the new codes is then open to public comment for 60 days following the publication of the final rule with comment period. As with all new CPT codes, we encourage interested stakeholders to review those codes identified with the "NI" in

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

Addendum B and assigned to device-dependent APCs and submit public comments on those assignments.

Our interim assignment of some of the new CPT codes for CY 2013 to device-dependent APCs prompted us to change the titles of two APCs to reflect more accurately the clinical configurations of those APCs for CY 2013. Specifically, we assigned, on an interim basis, the following codes to device-dependent APC 0107, currently titled "Insertion of Cardioverter-Defibrillator": CPT code 0319T (Insertion or replacement of subcutaneous implantable defibrillator system with subcutaneous electrode), 0321T (Insertion of subcutaneous implantable defibrillator pulse generator only with existing subcutaneous electrode), and 0323T (Removal of subcutaneous implantable defibrillator pulse generator with replacement of subcutaneous implantable defibrillator pulse generator only). We note that the title of APC 0108 is currently "Insertion/Replacement/Repair of AICD Leads, Generator and Pacing Electrode." In order to streamline and simplify the titles of APCs 0107 and 0108, which both contain procedures for the implantation of cardioverter-defibrillator pulse generators, leads, and electrodes, we are revising their titles to reflect the insertion of cardioverter-defibrillators without specifying the component pieces involved. Specifically, we are revising the title of APC 0107 to read "Level I Implantation of Cardioverter-Defibrillator" and the title of APC 0108 to read "Level II Implantation of Cardioverter-Defibrillator."

The creation of new CPT codes involving intracoronary stent placement procedures for CY 2013 also requires us to create nine new HCPCS C-codes and to delete two existing HCPCS G-codes in order to maintain the correct implementation of

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

existing OPPS policy for CY 2013. Specifically, since CY 2003, under the OPPS, we assign coronary stent placement procedures to separate APCs based on the use of nondrug-eluting or drug-eluting stents (APC 0104 (Transcatheter Placement of Intracoronary Stents) or APC 0656 (Transcatheter Placement of Intracoronary Drug-Eluting Stents), respectively). In order to effectuate this policy, we created HCPCS G-codes G0290 (Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel) and G0291 (Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; each additional vessel) for drug-eluting intracoronary stent placement procedures that parallel existing CPT codes 92980 (Transcatheter placement of an intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel) and 92981 (Transcatheter placement of an intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; each additional vessel), which are used to describe nondrug-eluting intracoronary stent placement procedures. CPT codes 92980 and 92981 are assigned to APC 0104, while HCPCS codes G0290 and G0291 are assigned to APC 0656. We refer readers to the CY 2003 OPPS final rule with comment period (67 FR 66732 through 66734) for more information regarding the initial implementation of this policy.

Effective January 1, 2013, the AMA's CPT Editorial Panel is deleting CPT codes 92980 and 92981 and replacing them with the following new CPT codes:

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

- CPT code 92928 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch), 92929 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure));

- CPT code 92933 (Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch);

- CPT code 92934 (Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure));

- CPT code 92937 (Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel);

- CPT code 92938 (Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (List separately in addition to code for primary procedure));

- CPT code 92941 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel);

- CPT code 92943 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel); and

- CPT code 92944 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (List separately in addition to code for primary procedure)).

In order to maintain the existing policy of differentiating payment for intracoronary stent placement procedures involving nondrug-eluting and drug-eluting stents, we are deleting HCPCS codes G0290 and G0291 and replacing them with the following new HCPCS C-codes to parallel the new CPT codes:

- HCPCS code C9600 (Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch);

- HCPCS code C9601 (Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure));

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

- HCPCS code C9602 (Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch);

- HCPCS code C9603 (Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure));

- HCPCS code C9604 (Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel);

- HCPCS code C9605 (Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (List separately in addition to code for primary procedure));

- HCPCS code C9606 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel);

- HCPCS code C9607 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft,

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel); and

● HCPCS code C9608 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (List separately in addition to code for primary procedure)).

The interim APC assignment for CPT codes 92928, 92933, 92929, 92934, 92937, 92938, 92941, 92943, and 92944 is APC 0104, and the interim APC assignment for HCPCS codes C9600, C9601, C9602, C9603, C9604, C9605, C9606, C9607, and C9608 is APC 0656 for CY 2013.

Comment: One commenter requested that CPT code 0304T (Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only) be placed in APC 0107 (Level I Implantation of Cardioverter-Defibrillators (ICDs)), rather than APC 0090 (Insertion/Replacement of Pacemaker Pulse Generator), because CPT code 0304T describes the insertion or removal and replacement of a device, which is similar to other CPT codes assigned to APC 0107, such as CPT code 33262 (Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; single lead system). The commenter also stated that CPT code 33224 (Insertion of pacing electrode, cardiac venous system, for left ventricular

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

pacing, with attachment to previously placed pacemaker or pacing cardioverter-defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator) is better aligned with APC 0107 than with its current APC assignment of APC 0655 (Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode).

Response: We disagree with the commenter's assertion that CPT codes 0304T and 33224 should be placed in APC 0107. APC 0107 includes procedures involving the insertion of a cardioverter-defibrillator, and CPT codes 0304T and 33224 do not describe such procedures.

Comment: One commenter suggested that CMS consider the assignment of different APCs for upgrades to a pacemaker or cardioverter-defibrillator based on the number of leads inserted, which can result in cost differences among procedures.

Response: The commenter did not provide specific CPT codes for pacemaker or cardioverter-defibrillator insertion procedures for us to consider. Generally speaking, however, we believe that our standard ratesetting methodology for device-dependent APCs would appropriately capture hospitals' varying costs based on the number of leads inserted during these procedures because we use data from hospital claims and cost reports that would reflect any such differences in costs.

Comment: Commenters expressed appreciation for the proposed increase in payment for the cochlear implant procedure, described by CPT code 69930 (Cochlear device implantation, with or without mastoidectomy) which is assigned to APC 0259 (Level VII ENT Procedures). However, the commenters also expressed concern that the

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

increase does not reflect the actual cost of the procedure and device. The commenters indicated potential coding errors by major hospital facilities where claims for less expensive osseointegrated auditory device implant procedures (such as those assigned to APC 0425 (Level II Arthroplasty or Implantation with Prosthesis)) were included in the dataset used for calculation of cochlear implants, and requested that CMS review the APC 0259 source data and remove the claims that were inadvertently included as part of the original dataset to ensure the appropriate payment.

Response: We employ procedure-to-device and device-to-procedure edits to ensure that the appropriate procedures and devices are correctly billed together and those same edits are again used in modeling the OPPS payment rates for the respective device-dependent APCs. Only claims containing the appropriate procedure and device code pairings are used to model the estimated APC cost for device-dependent APCs. We also note that the cochlear implant procedure and the osseointegrated auditory device implant procedures are in different APCs; therefore, only single claims containing one of these procedures would be used to model the estimated APC cost for their respective APCs. Further, claims with multiple major procedures generally are not entered into the dataset used for calculating estimated APC costs. Therefore, we do not believe that the inclusion of claims containing both cochlear implant procedures and osseointegrated auditory device implant procedures would result in inaccurate procedure or APC cost estimations.

Comment: Some commenters pointed out an apparent discrepancy between the listed proposed payment rate for APC 0425 in Addendum B to the CY 2013 OPPS/ASC

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

proposed rule when compared to the listed proposed payment rate for APC 0425 in the data file entitled "CY 2013 OPPS Comparison Between Proposed Geometric Mean and Median-Based Payments." Commenters requested that CMS review its proposed payment rates and determine which proposed payment rate reflects the correct geometric mean cost for APC 0425 for use in CY 2013 OPPS ratesetting.

Some commenters also requested that CMS reconfigure APC 0425 to ensure the procedures in the APC are similar from both a cost and clinical cohesion perspective and thereby facilitate Medicare hospital outpatient payment rates that are more in line with hospitals' actual costs for orthopedic arthroplasty procedures. Specifically, the commenters argued that the osseointegrated auditory device implant procedures assigned to APC 0425, such as the procedure described by CPT code 69714 (Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy), are not related to the orthopaedic joint replacement procedures also assigned to APC 0425. The commenters also stated the proposed composition of APC 0425 violated the 2 times rule because CPT code 69717 (Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy) has a proposed mean cost of $5,382 and CPT code 25446 (Arthroplasty with prosthetic replacement; distal radius and partial or entire carpus (total wrist)) has a proposed mean cost of $15,020.

Response: We recognize the discrepancy between the proposed payment rate for APC 0425 in Addendum B to the CY 2013 OPPS/ASC proposed rule and the proposed

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

payment rate for APC 0425 listed in the "CY 2013 OPPS Comparison Between Proposed Geometric Mean and Median-Based Payments" data file. The cost statistics used in the generation of the "CY 2013 OPPS Comparison Between Proposed Geometric Mean and Median-Based Payments" data file did not reflect the final configuration of the proposed CY 2013 OPPS relative payment weights; thus, the proposed payment rate reflected in that data file was inaccurate.

We believe that the current configuration of APC 0425 is appropriate as all procedures within the APC share clinical and resource similarity. Specifically, we disagree with the commenters who asserted that the osseointegrated auditory device implant procedures assigned to APC 0425 are not related to the orthopaedic joint replacement procedures also assigned to APC 0425. As we have stated in the past (73 FR 68539), all procedures assigned to APC 0425, including the osseointegrated auditory device implant procedures, involve the implantation of a prosthetic device into bone. We also note the assignments of CPT codes 69717 and 25446 to APC 0425 do not violate the 2 times rule as the commenters claimed. As discussed in section III.B.2. of the proposed rule and this final rule with comment period, we consider only those HCPCS codes that are significant, based on the number of claims, in making this determination. 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 cost to be significant. CPT codes

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

69717 and 25446 do not meet this criteria and their inclusion in the same APC, therefore, does not violate the 2 times rule because they are not considered significant.

Comment: One commenter stated that CMS should study further the claims for any device-dependent APC for which the calculated proposed payment reduction would be greater than 10 percent and take action to correct issues that may artificially reduce these payments.

Response: We routinely examine all APCs with a greater than 10 percent fluctuation in costs as part of our annual rulemaking process.

Comment: Commenters supported CMS' determination that urology procedures in APCs 0385 (Level I Prosthetic Urological Procedures), 0386 (Level II Prosthetic Urological Procedures), and 0674 (Prostate Cryoablation) should be categorized as device-dependent APCs. The commenters also requested the mandatory reporting of all HCPCS device C-codes on hospital claims for services involving devices and asserted that CMS should require complete and correct coding for packaged services. The commenters urged CMS to continue to promote device coding edits, while encouraging hospitals to remain vigilant in reporting the costs of performing device related services, and educating hospitals on the importance of accurate coding for devices, supplies, and other technologies.

Response: We appreciate the commenters' support and will continue to promote device coding edits, as well as encourage hospitals to report all costs in performing device related services. As we have stated in the past (73 FR68535 through 68536 and 74 FR 60367), we agree that accurate reporting of device, supply, and technology charges

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

will help to ensure that these items are appropriately accounted for in future years' OPPS payment rates. As we stated in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68575), we strongly encourage hospitals to report a charge for each packaged service they furnish, either by billing the packaged HCPCS code and a charge for that service if separate reporting is consistent with CPT and CMS instructions, by increasing the charge for the separately paid associated service to include the charge for the packaged service, or by reporting the charge for the packaged service with an appropriate revenue code but without a HCPCS code. Any of these means of charging for the packaged service will result in the cost of the packaged service being incorporated into the cost we estimate for the separately paid service. If a HCPCS code is not reported when a packaged service is provided, we acknowledge that it can be challenging to specifically track the utilization patterns and resource cost of the packaged service itself. However, we have no reason to believe that hospitals have not considered the cost of the packaged service in reporting charges for the independent, separately paid service.

After consideration of the public comments we received, we are finalizing our proposed policy to use the standard methodology for calculating costs for device-dependent APCs for CY 2013 that was finalized in the CY 2012 OPPS/ASC final rule with comment period.

Table 3 below lists the APCs for which we used our standard device-dependent APC ratesetting methodology for CY 2013. We refer readers to Addendum A to this final rule with comment period (which is available via the Internet on the CMS Web site) for the payment rates for these device-dependent APCs for CY 2013.

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

TABLE 3.—CY 2013 DEVICE-DEPENDENT APCs

CY 2013 APC	CY 2013 Status Indicator	CY 2013 APC Title
0039	S	Level I Implantation of Neurostimulator Generator
0040	S	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes
0061	S	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes
0082	T	Coronary or Non-Coronary Atherectomy
0083	T	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization of the Lower Extremity
0084	S	Level I Electrophysiologic Procedures
0085	T	Level II Electrophysiologic Procedures
0086	T	Level III Electrophysiologic Procedures
0089	T	Insertion/Replacement of Permanent Pacemaker and Electrodes
0090	T	Insertion/Replacement of Pacemaker Pulse Generator
0104	T	Transcatheter Placement of Intracoronary Stents
0106	T	Insertion/Replacement of Pacemaker Leads and/or Electrodes
0107	T	Level I Implantation of Cardioverter-Defibrillator
0108	T	Level II Implantation of Cardioverter-Defibrillator
0115	T	Cannula/Access Device Procedures
0202	T	Level VII Female Reproductive Procedures
0227	T	Implantation of Drug Infusion Device
0229	T	Level II Endovascular Revascularization of the Lower Extremity
0259	T	Level VII ENT Procedures
0293	T	Level V Anterior Segment Eye Procedures
0315	S	Level II Implantation of Neurostimulator Generator
0318	S	Implantation of Cranial Neurostimulator Pulse Generator and Electrode
0319	T	Level III Endovascular Revascularization of the Lower Extremity
0384	T	GI Procedures with Stents

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

CY 2013 APC	CY 2013 Status Indicator	CY 2013 APC Title
0385	S	Level I Prosthetic Urological Procedures
0386	S	Level II Prosthetic Urological Procedures
0425	T	Level II Arthroplasty or Implantation with Prosthesis
0427	T	Level II Tube or Catheter Changes or Repositioning
0622	T	Level II Vascular Access Procedures
0623	T	Level III Vascular Access Procedures
0648	T	Level IV Breast Surgery
0652	T	Insertion of Intraperitoneal and Pleural Catheters
0653	T	Vascular Reconstruction/Fistula Repair with Device
0654	T	Insertion/Replacement of a Permanent Dual Chamber Pacemaker
0655	T	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode
0656	T	Transcatheter Placement of Intracoronary Drug-Eluting Stents
0674	T	Prostate Cryoablation
0680	S	Insertion of Patient Activated Event Recorders

(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 2013 OPPS/ASC proposed rule (77 FR 45082 through 45083), we proposed to continue for CY 2013 to establish payment rates for blood and blood

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

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 calculated the costs upon which the proposed CY 2013 payment rates for blood and blood products were 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 noted that we used geometric mean unit costs for each blood and blood product to calculate the proposed payment rates, consistent with the methodology we

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

proposed for other items and services, discussed in section II.A.2.f. of the proposed rule and this final rule with comment period.

We stated in the proposed rule that 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 stated in the proposed rule that we believe that it yields more accurate estimated costs for these products.

Comment: Some commenters expressed concern that the proposed APC payment rates for some blood products are less than the acquisition costs of those products, citing a published study of a national survey of blood acquisition and overhead costs. According to the commenters, the safety and availability of blood may be jeopardized without adequate payment. The commenters asked that CMS formally consider and evaluate potential alternative methodologies for setting APC payment rates for blood products, preferably by seeking input from affected stakeholders. The commenters also stated that the use of the geometric mean methodology to calculate blood costs would result in lower payment rates compared to the use of median costs to calculate the payment rates for blood and blood products and urged CMS to use the median cost instead.

Response: As we have stated in the past (75 FR 71838 through 71839 and 76 FR 74152), we continue to believe that using blood-specific CCRs applied to hospital

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

claims data results in payment that appropriately reflect hospitals' relative costs of providing blood and blood products as reported to us by hospitals. We will consider any information presented to us from affected stakeholders regarding alternative ratesetting methodologies. We address the use of geometric mean costs to calculate blood payment rates in section II.A.2.c. of this final rule with comment period.

Comment: One commenter expressed concern regarding coding and payment for pre-storage pooled, leukocyte reduced platelets. According to the commenter, hospitals currently bill for pre-storage pooled, leukocyte reduced platelets using HCPCS code P9031 (Platelets, leukocytes reduced, each unit) based on the number of platelet concentrates (PCs) that are combined to create one unit of the blood product. The commenter stated that because the number of PC units used to make a therapeutic dose of pre-storage pooled, leukocyte reduced platelets is variable, blood centers must notify hospitals of the number of PCs in each therapeutic dose for the hospital's billing purposes, even though it does not affect the cost of the product to the hospital.

According to the commenter, a new technology exists that can make a unit of pre-storage pooled, leukocyte reduced platelets out of fewer PCs. However, the commenter expressed concern that the current coding and payment based on the use of HCPCS code P9031 unfairly and inappropriately disadvantages the use of this technology. The commenter indicated that where a greater number of PCs are needed to make a unit of pre-storage pooled, leukocyte reduced platelets, the hospital may end up being paid at a rate that significantly exceeds the cost of the product. However, according to the commenter, where the blood center can make the pre-storage pooled, leukocyte reduced

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

platelets using fewer PCs, the hospital may end up receiving payment that is not sufficient to cover the cost of the product.

The commenter stated that a separate code will be necessary to differentiate pre-storage pooled, leukocyte reduced platelets from other platelet products, and that an application for a unique HCPCS code is currently pending. The commenter urged CMS, for OPPS purposes, to take action to ensure appropriate payment for pre-storage pooled, leukocyte reduced platelets, regardless of whether a new HCPCS code is created.

Response: The outcome of the commenter's application for a unique HCPCS code for pre-storage pooled, leukocyte reduced platelets is beyond the scope of OPPS rulemaking. We note that it is an expected and appropriate outcome of a prospective payment system that hospitals would receive payments that are less than their costs in some cases and exceed their costs in other cases, as the commenter described is occurring in the case of pre-storage pooled, leukocyte reduced platelets. Therefore, we do not believe that it is necessary for us to take action to ensure appropriate payment for pre-storage pooled, leukocyte reduced platelets at this time. However, we are interested in hearing from other stakeholders regarding the current incentives and disincentives that exist in the marketplace for pre-storage pooled, leukocyte reduced platelets and invite public comment on payment for the blood product described by HCPCS code P9031 in this final rule with comment period.

After consideration of the public comments we received, 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

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs, for CY 2013. We continue to believe that this methodology in CY 2013 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 refer readers to Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site) for the final CY 2013 payment rates for blood and blood products (which are identified with status indicator "R"). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

(3) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act, as added by section 621(b)(2)(C) of Pub. L. 108-173 (MMA), mandated the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) ("brachytherapy sources") separately from other services or groups of services. The additional groups must reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished and must include separate groups for palladium-103 and iodine-125 sources. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS proposed and final rules. As we have stated previously (72 FR 66780, 73 FR 41502, 74 FR 60533 through 60534,

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

75 FR 71978, and 76 FR 74160), we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons. The general OPPS payment methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to cost. We believe that the OPPS prospective payment methodology, as opposed to payment based on hospitals' charges adjusted to cost, has provided hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS.

Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45087), we proposed to use the costs from CY 2011 claims data for setting the proposed CY 2013 payment rates for brachytherapy sources, as we proposed for most other items and services that will be paid under the CY 2013 OPPS. We based the proposed rates for brachytherapy sources using geometric mean unit costs for each source, consistent with the methodology proposed for other items and services, discussed in section II.A.2.f. of the proposed rule. We proposed to continue the other payment policies for brachytherapy sources we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We proposed to pay for the stranded and non-stranded NOS codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or non-stranded prospective payment rate for such sources, respectively, on a per source

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

basis (as opposed, for example, to a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). We also proposed to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was superseded for a period of time by section 142 of Pub. L. 110-275). That policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals.

Consistent with our policy regarding APC payments made on a prospective basis, as we did for CY 2011 and CY 2012, we proposed to subject brachytherapy sources to outlier payments under section 1833(t)(5) of the Act, and also to subject brachytherapy source payment weights to scaling for purposes of budget neutrality. Hospitals can receive outlier payments for brachytherapy sources if the costs of furnishing brachytherapy sources meet the criteria for outlier payment specified at 42 CFR 419.43(d). In addition, implementation of prospective payment for brachytherapy sources provides opportunities for eligible hospitals to receive additional payments in CY 2013 under certain circumstances through the 7.1 percent rural adjustment, as described in section II.E. of the proposed rule and this final rule with comment period.

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

We referred readers to Addendum B to the proposed rule (which was available via the Internet on the CMS Web site) for the proposed CY 2013 payment rates for brachytherapy sources, identified with status indicator "U." We invited public comment on this proposed policy and also requested recommendations for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources. In the proposed rule, we provided an appropriate address for receipt of these recommendations; the address is repeated at the end of this section. We indicated that we will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

Comment: A number of commenters opposed our proposal to base the payment for brachytherapy sources on geometric mean costs, while other commenters supported the proposal. Commenters also addressed other payment issues related to brachytherapy:

First, some commenters claimed that there are longstanding problems with OPPS claims data for brachytherapy source payment. For example, commenters stated that high dose rate (HDR) sources can be used to treat multiple patients because they decay over a 90-day period. The commenters stated that, as a result, the per source cost depends on the number of patients treated as well as the number of treatments and the intensity of the treatments within the 90-day period, making adequate payment for all hospitals difficult. Commenters asserted, as further examples of problems with our claims data, that our claims data continue to show a huge variation in unit costs on claims across hospitals; that more than half of the brachytherapy APCs have proposed payment rates based on 50

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

or fewer hospitals; and that our claims data contain rank order anomalies between high-activity palladium-103 (HCPCS code C2635) and low-activity palladium-103 sources (HCPCS codes 2640 and C2641), claiming that high-activity palladium-103 always costs more than low-activity palladium-103.

Second, commenters stated that brachytherapy source payments proposed for CY 2013 are unstable and fluctuate significantly from CY 2012 levels. They expressed concern about unpredictable changes in payment rates for brachytherapy sources from year to year, stating that proposed rates for some sources would change significantly, ranging from a decrease of 14.2 percent for HCPCS code C2643 (Brachytherapy source, non-stranded, cesium-131, per source) to an increase of 216 percent for HCPCS code C1716 (Brachytherapy source, non-stranded, gold-198, per source).

Response: In response to the commenters' concerns regarding the proposal to base payment for brachytherapy sources on geometric mean cost, we refer readers to section II.A.2.f. of this final rule with comment period, where we address the use of the geometric means methodology for determining OPPS payments for brachytherapy sources for CY 2013.

We disagree with the commenters who stated that the CY 2013 proposed payment rates for brachytherapy sources based on geometric mean cost would change payment levels significantly from the CY 2012 payment rates. While the commenters are correct that the proposed CY 2013 payment rate changes range from -14.2 to 216 percent, when we compare the CY 2013 proposed payment rates to the CY 2012 final payment rates, we find that 10 of the 16 brachytherapy source codes will receive increases or decreases of

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

less than 10 percent, indicating stability for the majority of the brachytherapy sources. Moreover, when we compare the CY 2013 proposed payment rates to the CY 2012 final payment rates, we find that 10 of the 16 brachytherapy source codes will receive increased payment amounts per source, while 6 of the 16 codes will receive decreased payments per source.

With regard to the commenters who articulated concerns about perceived longstanding problems such as variability of brachytherapy source payment rates (which they have repeatedly opined in prior years), we are pleased that, unlike in past years, the commenters did not express objection to prospective payment for brachytherapy sources. As we stated previously (72 FR 66782, 74 FR 60534, 75 FR 71979, and 76 FR 74161), 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. As we also explained previously (72 FR 66782, 74 FR 60535, and 75 FR 71979), a prospective payment system such as the OPPS 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, but with the exception of outlier cases, it is adequate to ensure access to appropriate care. In the case of brachytherapy sources for which the law requires separate payment groups, without packaging, the costs of these individual items could be expected to show greater variation than some other APCs under the OPPS because higher variability in costs for some component items and services is not balanced with lower

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

variability in costs for other component items and services and because relative weights are typically estimated using a smaller set of claims.

As we have stated previously (75 FR 71979 and 76 FR 74161), under the budget neutral provision for the OPPS, it is the relativity of costs of services, not their absolute costs, that is important, and we believe that brachytherapy sources are appropriately paid according to the standard OPPS payment approach. Furthermore, some sources may have costs and payment rates based on 50 or fewer hospitals because it is not uncommon for OPPS prospective payment rates to be based on claims from a relatively small number of hospitals that furnished the service in the year of claims data available for the OPPS update year. Fifty hospitals may report hundreds of brachytherapy source claims for many cases and comprise the universe of hospitals using particular low-volume sources, for which we are required to pay separately by statute. Further, our methodology for estimating costs for brachytherapy sources utilizes all line-item charges for those sources, which allows us to use all hospital reported charge and estimated cost information to set payment rates for these items. Therefore, no brachytherapy source claims are lost. We believe that prospective payment rates based on claims from those hospitals furnishing a particular source appropriately reflect the cost of that source for hospitals.

In the case of high and low activity iodine-125 sources, our 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 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 (75 FR 71979 and 76 FR 74162),

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

we do not have any information about the expected cost differential between high and low activity sources of various isotopes other than what is available in our claims and hospital cost report data. For high activity palladium-103, only 8 hospitals reported this service in CY 2010, compared to 139 and 203 hospitals for low-activity palladium-103 sources described by HCPCS codes C2640 and C2641, respectively. As we stated regarding this issue in the CYs 2010, 2011, and 2012 OPPS/ASC final rules with comment period (74 FR 60535, 75 FR 71979, and 76 FR 74162, respectively), it is clear that fewer hospitals furnished high-activity palladium-103 sources than 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 sources. These varied cost distributions clearly contribute to the observed relationship in costs between the different types of sources. However, we see no reason why our standard ratesetting methodology for brachytherapy sources that relies on all claims from all hospitals furnishing brachytherapy sources will not yield valid costs for those hospitals furnishing the different brachytherapy sources upon which CY 2013 prospective payments rates are based.

As we indicated in the CYs 2011 and 2012 OPPS/ASC final rules with comment period (75 FR 71980 and 76 FR 74162, respectively), we agree that high dose rate (HDR) brachytherapy sources such as HDR irirdium-192 have a fixed active life and must be replaced every 90 days; 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, in establishing their charges for HDR

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

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, as we have stated previously (72 FR 66783, 74 FR 60535, 75 FR 71980, and 76 FR 74162). For most of these OPPS services, our practice is to establish prospective payment rates based on the costs from hospitals' claims data to provide incentives for efficient and cost effective delivery of these services.

Comment: One commenter requested that CMS establish appropriate payment for HCPCS code A9527 (Iodine, I-125, sodium iodide solution, therapeutic, per millicurie (mCi)), claiming that the source has not been available for patients from June 2010 to July 2012, when it became available for purchase by providers. The commenter stated that the claims from two hospitals that reported HCPCS code A9527 are erroneous. The commenter requested that CMS use external data based upon actual hospital invoices to assign payment for HCPCS code A9527, which, according to the commenter, cost hospitals in CY 2012 $28.00 per millicurie (mCi), which is above the proposed payment rate of $20.86.

Response: We have been paying for I-125 brachytherapy solution since 2003, both as HCPCS code A9527 and its predecessor code in the OPPS, C2632 (Brachytherapy solution, iodine-125, per mCi). Our claims data over the period of 2004 through 2011 show a consistent range of costs of $16.83 to $29.42 per mCi, with several thousand units of claims in most of those years. The claims data for HCPCS code A9527 reflect claims for 8 providers, rather than 2 as indicated by the commenter. Therefore, we believe that we are obtaining adequate and consistent data on HCPCS code A9527. We

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

will maintain our use of claims data for HCPCS code A9527 in our OPPS ratesetting for CY 2013.

Comment: One commenter requested that CMS add a new C-code and APC for a high-activity cesium-131 brachytherapy source, which is designed to generate isotropic emission of therapeutic radiation and to be used primarily for the treatment of head and neck and eye cancer.

Response: We appreciate the commenter informing us of a new high-activity cesium-131 source. However, our evaluation process of new sources for addition to our set of codes is beyond the scope of this rulemaking. As we state elsewhere in this final rule with comment period, and in previous rules, such as the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163), we ask parties to submit recommendations to us for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources. We suggest to the commenter to send its recommendation for this new brachytherapy source, along with the detailed rationale to support the new source, to the address provided at the end of this section. We will continue to add new brachytherapy source codes and descriptors to our systems on a quarterly basis.

Comment: One commenter supported CMS' proposal to continue the policy of paying for new sources for which we have no claims data, with prospective payment rates based on the consideration of external data as well as other relevant information. The commenter expressed appreciation for CMS' efforts to establish appropriate payment

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

rates for brachytherapy sources in a timely manner, and recommended that CMS finalize this proposal.

Response: We appreciate the support and recognition of our efforts to provide appropriate and timely payment. We are finalizing our proposal to pay for new sources using external data and other relevant information.

After consideration of the public comments we received, we are finalizing our proposal to pay for brachytherapy sources at prospective payment rates based on their source-specific geometric mean costs for CY 2013. We refer readers to Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html) for the final CY 2013 payment rates for brachytherapy sources, identified with status indicator "U." We also are finalizing our proposals to continue our policies regarding payment for NOS codes for stranded and non-stranded sources and new brachytherapy sources for which we have no claims data. Specifically, we are finalizing our proposals to continue payment for stranded and non-stranded NOS codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or non-stranded prospective payment for such sources, respectively, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786); and our proposal to assign HCPCS codes for new brachytherapy sources to their own APCs, with payment rates based on consideration of external data and other relevant information, in the absence of claims data. Once claims data are available, our standard ratemaking process will be applied to the calculation of the cost for the new brachytherapy source.

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

Consistent with our policy regarding APC payments made on a prospective basis, we are finalizing our proposal to subject the cost of brachytherapy sources to the outlier provision of section 1833(t)(5) of the Act, and also to subject brachytherapy source payment relative weights to scaling for purposes of budget neutrality.

As stated in the proposed rule (77 FR 45087), we continue to invite hospitals and other parties to submit recommendations to us for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources. Such recommendations should be directed to the Division of Outpatient Care, Mail Stop C4-05-17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

e. 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 and 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 2013 OPPS/ASC proposed rule (77 FR 45087 through 45094), we proposed for CY 2013 to continue our composite policies for extended assessment and

management services, LDR prostate brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, multiple imaging services, and cardiac resynchronization therapy services, as discussed in sections II.A.2.e.(1), II.A.2.e.(2), II.A.2.e.(3), II.A.2.e.(4), II.A.2.e.(5), and II.A.2.e.(6), respectively, of the proposed rule.

Comment: One commenter encouraged CMS to create payments that drive hospitals to develop low cost deliveries of care instead of rewarding them for excess deliveries of care, such as beneficiaries receiving up to three CT scans in a single emergency department visit.

Response: We agree with the commenter that it is important to create payment methodologies that encourage efficiency. As we have stated in the past, we believe that composite APCs enable hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. With respect to CT scans in particular, as we discuss in section II.A.2.e.(5) of this final rule with comment period, we provide a single payment each time a hospital bills more than one CT on the same date of service.

The final composite policies for extended assessment and management services, LDR prostate brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, multiple imaging services, and cardiac resynchronization therapy services are discussed in the following sections (II.A.2.e.(1), II.A.2.e.(2), II.A.2.e.(3), II.A.2.e.(4), II.A.2.e.(5), and II.A.2.e.(6), respectively) of this final rule with comment period.

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

In the CY 2013 OPPS/ASC proposed rule (77 FR 45088), we proposed to continue to include composite APC 8002 (Level I Extended Assessment and Management Composite) and composite APC 8003 (Level II Extended Assessment and Management Composite) in the OPPS for CY 2013. Beginning in CY 2008, we created these two composite APCs to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur (an extended visit). In most circumstances, observation services are supportive and ancillary to the other services provided to a patient. In the circumstances when observation care is provided in conjunction with a high level visit 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, we proposed to continue the extended assessment and management composite APC payment methodology and criteria for APCs 8002 and 8003 that we finalized for CYs 2009 through 2012. We continue to believe that the composite APCs 8002 and 8003 and related policies provide the most appropriate means of paying for these services. We also proposed to calculate the costs for APCs 8002 and 8003 using the same methodology that we used to calculate the costs for composite APCs 8002 and 8003 for the CY 2008 OPPS (72 FR 66649). That is, we proposed to use all single and "pseudo" single procedure claims from CY 2011 that met the criteria for payment of each

composite APC and apply the standard packaging and trimming rules to the claims before calculating the CY 2013 costs. The proposed CY 2013 cost resulting from this methodology for composite APC 8002 was approximately $446, which was calculated from 17,072 single and "pseudo" single claims that met the required criteria. The proposed CY 2013 cost for composite APC 8003 was approximately $813, which was calculated from 255,231 single and "pseudo" single claims that met the required criteria.

We did not receive any public comments on this proposal. We are finalizing our proposed policy, without modification, to calculate the costs for APCs 8002 and 8003 using the same methodology that we used to calculate the costs for composite APCs 8002 and 8003 for the CY 2008 OPPS (72 FR 66649). The final CY 2013 cost resulting from this methodology for composite APC 8002 is approximately $453, which was calculated from 19,028 single and "pseudo" single claims that met the required criteria. The final CY 2013 cost for composite APC 8003 is approximately $821, which was calculated from 284,861 single and "pseudo" single claims that met the required criteria.

At its August 2012 meeting, the Advisory Panel on Hospital Outpatient Payment (the Panel) recommended that CMS continue to report clinic/emergency department visit and observation claims data and, if CMS identifies changes in patterns of utilization or cost, that CMS bring those issues to the Visits and Observation Subcommittee. Additionally, the Panel recommended that CMS examine the costs and frequency for Level I and Level II Extended Assessment and Management Composite APCs associated with greater than 24 hours of observation, if available, and report the findings to the Visits and Observation Subcommittee. The Panel recommended that Scott Manaker,

M.D., Ph.D., be named the chair of the Visits and Observation Subcommittee. The Panel recommended that the work of the Visits and Observation Subcommittee continue. We are accepting these recommendations and will provide the requested data to the Panel at a future meeting.

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

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through the needles/catheters. At least two CPT codes are used to report the composite treatment service because there are separate codes that describe placement of the needles/catheters and the application of the brachytherapy sources: CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and CPT code 77778 (Interstitial radiation source application; complex), which are generally present together on claims for the same date of service in the same operative session. In order to base payment on claims for the most common clinical scenario, and to further our goal of providing payment under the OPPS for a larger bundle of component services provided in a single hospital encounter, beginning in CY 2008, we began providing a single payment for LDR prostate brachytherapy when the composite service, reported as CPT codes 55875 and 77778, is furnished in a single hospital encounter. We based the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the cost derived from claims for the same date of service that contain both CPT codes 55875 and 77778 and that do not contain other separately paid codes that are not on the bypass list. We refer

readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66652 through 66655) for a full history of OPPS payment for LDR prostate brachytherapy and a detailed description of how we developed the LDR prostate brachytherapy composite APC.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45088 through 45089), we proposed for CY 2013 to continue to pay for LDR prostate brachytherapy services using the composite APC methodology proposed and implemented for CY 2008 through CY 2012. That is, we proposed to use CY 2011 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 2012 practice, we proposed not to use the claims that met these criteria in the calculation of the costs for 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 costs for 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 stated that we continue to believe that data from claims reporting both services required for LDR prostate brachytherapy provide the most accurate cost upon which to base the composite APC payment rate.

Using a partial year of CY 2011 claims data available for the CY 2013 proposed rule, we were able to use 650 claims that contained both CPT codes 55875 and 77778 to

calculate the cost upon which the proposed CY 2013 payment for composite APC 8001 was based. The proposed cost for composite APC 8001 for CY 2013 was approximately $3,362.

Comment: A few commenters supported the proposed payment methodology and policy for APC 8001. The commenters also supported the continued use of the LDR prostate brachytherapy composite APC methodology and the proposed increase in payment for CY 2013.

Response: We appreciate the commenters' support.

We are finalizing, without modification, our proposed policy for composite APC 8001. Using a full year of CY 2011 claims data available for this CY 2013 final rule with comment period, we were able to use 677 claims that contained both CPT codes 55875 and 77778 to calculate the cost upon which the final CY 2013 payment for composite APC 8001 is based. The final cost for composite APC 8001 for CY 2013 is approximately $3,348.

(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 costs for these services, and advanced our stated goal of promoting hospital efficiency through larger payment bundles. In order to calculate the 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 OPPS/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 OPPS/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.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45089), we proposed for CY 2013 to continue to pay for cardiac electrophysiologic evaluation and ablation services using the composite APC methodology proposed and implemented for CY 2008 through CY 2012. We stated that we continue to believe that the cost for these services calculated from a high volume of correctly coded multiple procedure claims would result in an accurate and appropriate proposed payment for cardiac electrophysiologic

evaluation and ablation 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 costs for APCs 0085 and 0086, to which the CPT codes in both Groups A and B for composite APC 8000 are otherwise assigned. We proposed that the costs for APCs 0085 and 0086 would continue to be calculated using single procedure claims. For CY 2013, using a partial year of CY 2011 claims data available for the proposed rule we were able to use 11,358 claims containing a combination of Group A and Group B CPT codes to calculate a proposed cost of approximately $11,458 for composite APC 8000.

Subsequent to the publication of the CY 2013 OPPS/ASC proposed rule, the AMA's CPT Editorial Panel created five new CPT codes describing cardiac electrophysiologic evaluation and ablation services, to be 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.

Our standard process for dealing with new CPT codes effective on January 1 for the upcoming calendar year is to assign each code to the APC that we believe contains services that are comparable with respect to clinical characteristics and resources required to furnish the service. The new CPT code is given a comment indicator of ‘‘NI’’ in Addendum B to the final rule with comment period to identify it as a new interim APC assignment for the new year and the APC assignment for the new CPT codes is then open to public comment for 60 days following the publication of the final rule with comment period.

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 are assigning 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 are assigning them interim status indicator “Q3” (Codes that may be paid through a composite APC) in Addendum B to this final rule with comment period. To facilitate implementing this policy, we are assigning CPT codes 93653, 93654, and 93656 to a new Group C, which will be paid at the composite APC 8000 payment rate. (We note that we will use single and “pseudo”

single claims for CPT codes 93653, 93654, and 93656 when they become available for calculating the 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 believe that packaging CPT codes 93655 and 93657 with the primary procedures is appropriate, and we are assigning them interim status indicator "N." Because the CPT Editorial Panel deleted CPT codes 93651 and 93652, effective January 1, 2013, we are deleting them from the Group B code list, leaving only CPT 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 at this time.

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 is open to public comment for a period of 60 days following the publication of this final rule with comment period.

We did not receive any public comments on our proposal to continue to pay for cardiac electrophysiologic evaluation and ablation services using the composite APC methodology. We are finalizing our proposed policy for CY 2013 to continue to pay for cardiac electrophysiologic evaluation and ablation services using the composite APC methodology proposed and implemented for CY 2008 through CY 2012. We note that we are modifying our proposal for CY 2013 to reflect the CPT coding changes as discussed above. For CY 2013, using a full year of CY 2011 claims data available for

this final rule with comment period, we were able to use 12,235 claims containing a combination of Group A and Group B CPT codes to calculate a final cost of approximately $11,466 for composite APC 8000.

Table 4 below lists the groups of procedures upon which we will base composite APC 8000 for CY 2013.

TABLE 4.—GROUPS OF CARDIAC ELECTROPHYSIOLOGIC EVALUATION AND ABLATION PROCEDURES UPON WHICH COMPOSITE APC 8000 IS BASED

Codes Used in Combinations: At Least One in Group A and One in Group B, or At Least One in Group C	CY 2013 CPT Code	Single Code CY 2013 APC	CY 2013 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 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	93656	8000	Q3

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

(a) Mental Health Services Composite Policy

In the CY 2013 OPPS/ASC proposed rule (77 FR 45090), we proposed for CY 2013 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 provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health treatments for CY 2013. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 to 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

Specifically, we 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 partial hospitalization payment for a hospital, those specified mental health services would be assigned to APC 0034 (Mental Health Services Composite). We proposed to continue to set the payment rate for APC 0034 at the same rate as we pay for APC 0176 (Level II Partial Hospitalization (4 or more services) for Hospital-Based PHPs), which is the maximum partial hospitalization per diem payment for a hospital, and 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 make a single payment at the same rate as the APC 0176 per diem rate for partial hospitalization for all of the specified mental health services furnished by the hospital on that single date of service.

We did not receive any public comments on this proposal. Therefore, we are finalizing our CY 2013 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 2013.

(b) Coding Changes

Subsequent to the publication of the CY 2013 OPPS/ASC proposed rule, the AMA's CPT Editorial Panel deleted 16 psychotherapy and psychiatric diagnostic evaluation CPT codes to which the mental health services composite APC methodology applies, and replaced them with 12 new CPT codes, to be effective January 1, 2013. The new and deleted CPT codes are included in Table 5 below. Our standard process for addressing new CPT codes effective on January 1 for the upcoming calendar year is to assign each code to the APC that we believe contains services that are comparable with respect to clinical characteristics and resources required to furnish the service. The new CPT code is given a comment indicator of "NI" in Addendum B to the final rule with comment period to identify it as a new interim APC assignment for the new year and the APC assignment for the new codes is then open to public comment for 60 days following the publication of the final rule with comment period.

Because the new mental health CPT codes in Table 5 replace CPT codes that are subject to the mental health composite APC, and because all of the HCPCS codes in the respective APCs to which these codes are assigned for CY 2013 are subject to the mental

health composite APC, the new separately payable mental health CPT codes also will be assigned to composite APC 0034 with an interim status indicator of "Q3" (Codes that may be paid through a composite APC) in Addendum B to this final rule with comment period. The single code APC assignment, the composite APC assignment, and the interim status indicator assignment for each of these new CPT codes are included in Table 5 below. As discussed above for new CPT codes that were not available at the time of the proposed rule, our treatment of these new mental health CPT codes is open to public comment for a period of 60 days following the publication of this final rule with comment period. The current single code APC assignments for all of the HCPCS codes to which the mental health composite APC policy applies, along with their composite APC assignment and their APC assignments when the composite methodology does not apply, can be found in Addendum M to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 5.--NEW AND DELETED PSYCHOTHERAPY AND PSYCHIATRIC DIAGNOSTIC EVALUATION CPT CODES FOR CY 2013

Deleted CY 2012 Psychotherapy and Psychiatric Diagnostic Evaluation CPT Codes					
HCPCS Code	**CY 2012 Short Descriptor**	**CY 2012 CI**	**CY 2012 SI**	**CY 2012 Single Code APC Assignment**	**CY 2012 Composite APC Assignment**
90801	Psy dx interview		Q3	0323	0034
90802	Intac psy dx interview		Q3	0323	0034
90804	Psytx office 20-30 min		Q3	0322	0034
90805	Psytx off 20-30 min w/e&m		Q3	0322	0034
90806	Psytx off 45-50 min		Q3	0323	0034
90807	Psytx off 45-50 min w/e&m		Q3	0323	0034
90808	Psytx office 75-80 min		Q3	0323	0034
90809	Psytx off 75-80 w/e&m		Q3	0323	0034
90810	Intac psytx off 20-30 min		Q3	0322	0034
90811	Intac psytx 20-30 w/e&m		Q3	0322	0034
90812	Intac psytx off 45-50 min		Q3	0323	0034
90813	Intac psytx 45-50 min w/e&m		Q3	0323	0034
90814	Intac psytx off 75-80 min		Q3	0323	0034
90815	Intac psytx 75-80 w/e&m		Q3	0323	0034
90857	Intac group psytx		Q3	0325	0034
90862	Medication management		Q3	0605	0034
New CY 2013 Psychotherapy And Psychiatric Diagnostic Evaluation CPT Codes					
HCPCS Code	**CY 2013 Short Descriptor**	**CY 2013 CI**	**CY 2013 SI**	**CY 2013 Single Code APC Assignment**	**CY 2013 Composite APC Assignment**
90785	Psytx complex interactive	NI	N	N	n/a
90791	Psych diagnostic evaluation	NI	Q3	0323	0034
90792	Psych diag eval w/med srvcs	NI	Q3	0323	0034
90832	Psytx pt&/family 30 minutes	NI	Q3	0322	0034
90833	Psytx pt&/fam w/e&m 30 min	NI	N	n/a	n/a

90834	Psytx pt&/family 45 minutes	NI	Q3	0323	0034
90836	Psytx pt&/fam w/e&m 45 min	NI	N	n/a	n/a
90837	Psytx pt&/family 60 minutes	NI	Q3	0323	0034
90838	Psytx pt&/fam w/e&m 60 min	NI	N	n/a	n/a
90839	Psytx crisis initial 60 min	NI	Q3	0323	0034
90840	Psytx crisis ea addl 30 min	NI	N	n/a	n/a
90863	Pharmacologic mgmt w/psytx	NI	N	n/a	n/a

(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 8 of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74171 through 74175).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included in the policy do not involve contrast, both

CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

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

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

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

In the CY 2013 OPPS/ASC proposed rule (77 FR 45090), we proposed to continue for CY 2013 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 stated that 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 2013 payment rates for the five multiple imaging composite APCs (APC 8004, APC 8005, APC 8006, APC 8007, and APC 8008) were based on costs calculated from a year of CY 2011 claims available for the CY 2013 OPPS/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 costs, we used the same methodology that we used to calculate the final CY 2012 costs for these composite APCs, as described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74169). The imaging HCPCS codes that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC costs, pursuant to our established methodology (76 FR 74169), appeared in Table 11 of the proposed rule.

We were able to identify approximately 1.0 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 2013 costs for the multiple imaging composite APCs.

Comment: One commenter supported the proposed payment rate for APC 8004, while acknowledging the increased proposed payment rate for the ultrasound composite and for other standard (non-composite) ultrasound procedures.

Response: We appreciate the commenter's support.

Comment: Several commenters supported CMS' decision not to propose any new multiple imaging composite APCs, and requested that CMS analyze the potential impact on utilization and access for any newly proposed multiple imaging composite APCs, and to provide notice and seek comment for any new proposals.

Response: We appreciate the feedback regarding the multiple imaging composite APCs. As is our usual practice, we will analyze our claims data and provide public notice and seek comment for any new proposals through our annual rulemaking process.

After consideration of the public comments we received, we are finalizing our proposed policy, without modification, to calculate multiple imaging composite APC costs for CY 2013 pursuant to our established methodology. For this final rule with comment period, we were able to identify approximately 1.0 million "single session" claims out of an estimated 1.6 million potential composite cases from our ratesetting claims data, more than half of all eligible claims, to calculate the final CY 2013 costs for the multiple imaging composite APCs.

Table 6 below lists the HCPCS codes that will be subject to the multiple imaging composite policy and their respective families and approximate composite APC costs for CY 2013. Table 7 below lists the OPPS imaging family services that overlap with HCPCS codes on the CY 2013 bypass list. We note that we mistakenly did not include CPT code 70547 (Magnetic resonance angiography, neck; without contrast material(s)) on this list in the proposed rule. We are adding it to this list for the final rule with comment period because it is part of the MRI and MRA with and without contrast imaging family and is also on the CY 2013 bypass list.

TABLE 6.—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs

Family 1 – Ultrasound	
CY 2013 APC 8004 (Ultrasound Composite)	**CY 2013 Approximate APC Cost = $202**
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 2013 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2013 Approximate APC Cost = $412**
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 2013 APC 8006 (CT and CTA with Contrast Composite)	**CY 2013 Approximate APC Cost = $702**
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 2013 APC 8007 (MRI and MRA without Contrast Composite)*	**CY 2013 Approximate APC Cost = $727**
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 2013 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2013 Approximate APC Cost = $1,069**
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.	

TABLE 7.-OPPS IMAGING FAMILY SERVICES OVERLAPPING WITH HCPCS CODES ON THE CY 2013 BYPASS LIST

Family 1 – Ultrasound	
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
76856	Us exam, pelvic, complete
76870	Us exam, scrotum
76857	Us exam, pelvic, limited
Family 2 - CT and CTA with and without Contrast	
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
Family 3 - MRI and MRA with and without Contrast	
70336	Magnetic image, jaw joint
70544	Mr angiography head w/o dye

70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
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
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

(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 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 (including upgrade to dual chamber system) (List separately in addition to code for primary procedure)) and CPT code 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 service described by CPT code 33225, the service described by CPT code 33249 is also assigned to APC 0108. When not performed on the same day as the service described by CPT code 33249, the service described by CPT code 33225 is assigned to APC 0655.

In order to ensure that hospitals correctly code for CRT services in the future, 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).

In the CY 2013 OPPS/ASC proposed rule (77 FR45094), we proposed to continue for CY 2013 to recognize CRT-D as a single, composite service as described above and finalized in the CY 2012 OPPS/ASC final rule with comment period. 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 and, therefore, to address the inherent ratesetting challenges associated with CPT code 33225. 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. In calculating the costs upon which the proposed payment rate for APC 0108 was based for CY 2013, for the proposed rule, 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 9,790 single claims from the CY 2013 proposed rule claims data to calculate a proposed cost of approximately $31,491 for APC 0108. Because CPT codes 33225 and 33249 may be treated as a composite service for payment purposes, we

proposed to continue to assign them status indicator "Q3" (Codes that may be paid through a composite APC) in Addendum B to the proposed rule. 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).

As we noted in the proposed rule (77 FR 45094), we revised the claims processing edits in place for CPT code 33225 due to revised guidance from the AMA in the CPT code book 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 code book 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.

Comment: One commenter requested that CMS delay the status indicator change from "T" to "Q3" for CPT code 33225, stating that CMS does not have sufficient cost data to allow a composite payment for this procedure. The commenter also asked that CPT code 33225 be assigned to APC 0655 while CMS carries out further analysis.

Response: We disagree with the commenter that we do not have sufficient cost data to allow a composite payment for the procedure described by CPT code 33225. For this final rule with comment period, we were able to use 3,413 single claims containing the CRT-D composite service, defined as the combination of CPT codes 33225 and 33249 with the same date of service, to calculate the cost of APC 0108. We note that we did not propose to change the status indicator for CPT code 33225 from "T" to "Q3" for CY 2013 as the commenter indicated; rather, we proposed to continue to apply the "Q3" status indicator to CPT code 33225 in accordance with the status indicator and policy for this code finalized in the CY 2012 OPPS/ASC final rule with comment period. We also note that, when not performed on the same day as the service described by CPT code 33249, the service described by CPT code 33225 is assigned to APC 0655 and not paid as a composite service.

After consideration of the public comment we received, we are finalizing our proposed policy, without modification, to continue to recognize CRT-D as a single, composite service as described above and finalized in the CY 2012 OPPS/ASC final rule with comment period. In calculating the costs upon which the final payment rate for

APC 0108 is based for CY 2013, 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 11,251 single claims from the CY 2013 final rule claims data to calculate a final cost of approximately $31,561 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.

f. Geometric Mean-Based Relative Payment Weights

As we discussed in the CY 2013 OPPS/ASC proposed rule (77 FR 45094 through 45098), when the Medicare program was first implemented, payment for hospital services (inpatient and outpatient) was based on hospital-specific reasonable costs attributable to furnishing services to Medicare beneficiaries. Although payment for most Medicare hospital inpatient services became subject to a PPS under section 1886(d) of the Act in 1983, Medicare hospital outpatient services continued to be paid based on hospital-specific costs. This methodology for payment provided little incentive for hospitals to furnish such outpatient services efficiently and in a cost effective manner. At the same time, advances in medical technology and changes in practice patterns were bringing about a shift in the site of medical care from the inpatient setting to the outpatient setting.

In the Omnibus Budget Reconciliation Act of 1986 (OBRA 1986) (Pub. L. 99-509), the Congress paved the way for development of a PPS for hospital outpatient services. Section 9343(g) of OBRA 1986 mandated that fiscal intermediaries require hospitals to report claims for services under the Healthcare Common Procedure Coding System (HCPCS). Section 9343(c) of OBRA 1986 extended the prohibition against unbundling of hospital services under section 1862(a)(14) of the Act to include outpatient services as well as inpatient services. The codes under the HCPCS enabled us to determine which specific procedures and services were billed, while the extension of the prohibition against unbundling ensured that all nonphysician services provided to hospital

outpatients were reported on hospital bills and captured in the hospital outpatient data that were used to develop an outpatient PPS.

The brisk increase in hospital outpatient services further led to an interest in creating payment incentives to promote more efficient delivery of hospital outpatient services through a Medicare outpatient PPS. Section 9343(f) of OBRA 1986 and section 4151(b)(2) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Pub. L. 101-508) required that we develop a proposal to replace the hospital outpatient payment system with a PPS and submit a report to the Congress on the proposed system. The statutory framework for the OPPS was established by the Balanced Budget Act (BBA) of 1997 (Pub. L. 105-33) with section 4523 amending section 1833 of the Act by adding subsection (t), which provides for a PPS for hospital outpatient department services and the BBRA of 1999 (Pub. L. 106-113), with section 201 further amending section 1833(t) of the Act. The implementing regulations for these statutory authorities were codified at 42 CFR Part 419, effective for services furnished on or after August 1, 2000.

Section 1833 of the Act sets forth the methodological requirements for developing the PPS for hospital outpatient services (the OPPS). At the onset of the OPPS, there was significant concern over observed increases in the volume of outpatient services and corresponding rapidly growing beneficiary coinsurance. Accordingly, much of the focus was on finding ways to address those issues. Section 1833(t)(2)(C) of the Act initially provided that relative payment weights for covered outpatient department services be established based on median costs under section 4523(a) of the BBA of 1997. Later, section 201(f) of the BBRA of 1999 amended section 1833(t)(2)(C) of the Act to allow

the Secretary the discretion to base the establishment of relative payment weights on either median or mean hospital costs. Since the OPPS was initially implemented, we have established relative payment weights based on the median hospital costs for both statistical reasons and timely implementation concerns. The proposed rule for the OPPS was published prior to the passage of the BBRA of 1999, which amended the Act to permit the use of mean costs. At that time, we noted that making payment for hospital outpatient services based on the median cost of each APC was a way of discouraging upcoding that occurs when individual services that are similar have disparate median costs, as well as associating services for which there are low claims volume into the appropriate classifications based on clinical patterns and their resource consumption (63 FR 47562).

As discussed in the CY 2000 OPPS final rule with comment period (65 FR 18482 through 18483), initial implementation of the payment system for hospital outpatient services was delayed due to multiple extensions of the proposed rule comment period, Year 2000 (Y2K) system concerns, and other systems challenges in developing the OPPS. Even though the BBRA of 1999 passed during that period of time, and provided the Secretary with the discretion to establish relative payment weights under the OPPS based on mean hospital costs, we determined that reconstructing the database to evaluate the impact of using mean costs would have postponed implementation of the OPPS further. There were important challenges at the time, including being responsive to stakeholder comments regarding the initial OPPS and addressing implementation issues so that the payment and claims processing systems would work correctly. To do so in a

timely manner was critical; therefore, median costs were selected as an appropriate metric on which to base payment relativity, both based on the statistical reasons noted above and practical implementation concerns.

In addition to the reasons discussed above, developing relative payment weights based on median costs was a way of attenuating the impact of cost outlier cases. In an environment where facility coding practices were still in their infancy, median costs served to minimize the impact of any coding errors. Using median costs to establish service cost relativity served the same function as any measure of central tendency (including means), ensuring that the relative payment weights used in the OPPS would, in general, account for the variety of costs associated with providing a service.

Since the beginning of the OPPS and throughout its development, we have striven to find ways to improve our methods for estimating the costs associated with providing services. The dialogue with the public regarding these issues, the meaningful information and recommendations that the Panel (previously the APC Panel) has provided, and the policies we have established to better derive the costs on which OPPS payment is calculated have contributed to improving cost estimation. However, challenges remain in our continuing effort to better estimate the costs associated with providing services. These challenges include our limited ability to obtain more meaningful information from the claims and cost report data available and ensuring that the approach used to calculate the payments for services accurately captures the relative costs associated with providing the services. Over the years, we have implemented many changes to the OPPS cost modeling process to help address these challenges.

To obtain more information from the claims data we have available, we first began bypassing codes from the standard process to develop "pseudo" single claims in CY 2003 (67 FR 66746). In CY 2006, this concept later evolved into the bypass list (and its corresponding criteria for addition) which allows us to extract more cost information from claims that would otherwise be unusable for modeling service cost (70 FR 68525). In CY 2008, we examined clinical areas where packaging of services was appropriate, which allows us to use more claims in modeling the payments for primary procedures and encourage providers to make cost efficient choices where possible (72 FR 66610 through 66649). In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66590), we noted that this packaging approach increased the number of "natural" single bills, while simultaneously reducing the universe of codes requiring single bills for ratesetting. Beginning in CY 2008, we also established composite APCs for services that are typically provided together in the same encounter, allowing us to use even more previously unusable claims (due to containing multiple separately payable major codes) for modeling service cost, as well as develop APCs that reflect the combined encounter (72 FR 66650 through 66658). We have implemented many steps to obtain more information from the claims and cost report data available to us, and continue to examine ways in which we can derive more meaningful information on service costs for use in ratesetting.

In our experience in working with the OPPS, we also have implemented many processes to ensure that the cost information we derive from cost reports and claims data is accurate. In the beginning of the OPPS, we implemented a cost trim of three standard

deviations outside the geometric mean cost, similar to the cost data trim in the IPPS, because it would ensure that the most aberrant data were removed from ratesetting (65 FR 18484). We also have implemented similar trims to the hospital departmental CCR and claims based unit data related to the services (71 FR 67985 through 67987).

During the CY 2008 rulemaking cycle, we contracted with Research Triangle Institute, International (RTI) to examine possible improvements to the OPPS cost estimation process after RTI had investigated similar issues in the IPPS setting (72 FR 66659 through 66602). There was significant concern that charge compression, which results from the hospital practice of attaching a higher mark-up to charges for low cost supplies and a lower mark-up to charges for higher cost supplies, was influencing the cost estimates on which the OPPS relative payment weights are based. Based on RTI's recommendations in its July 2008 report, available on the Web site at: http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf, in CY 2009, we finalized modifications to the Medicare cost report form to create an "Implantable Medical Devices Charged to Patients" cost center to address public commenters' concerns related to charge compression in the "Medical Supplies Charged to Patients" cost center (73 FR 48458 through 48467). These modifications helped to address potential issues related to hospital mark-up practices and how they are reflected in the CCRs on the Medicare hospital cost reporting form.

In CY 2010, we incorporated a line item trim into our data process that removed lines that were eligible for OPPS payment in the claim year but received no payment,

presumably because of a line item rejection or denial due to claims processing edits (74 FR 60359). This line item trim was developed with the goal of using additional lines to model prospective payment.

In addition to these process changes that were designed to include more accurate cost data in ratesetting, we have developed a number of nonstandard modeling processes to support service or APC specific changes. For example, in the device-dependent APCs, we have incorporated edits into the cost estimation process to ensure that the full cost of the device is incorporated into the primary procedure.

While we have already implemented numerous changes to the data process in order to obtain accurate resource cost estimates associated with providing a procedure, we continue to examine possible areas of improvement. In the past, commenters have expressed concern over the degree to which payment rates reflect the costs associated with providing a service, believing that, in some cases, high cost items or services that might be packaged are not accordingly reflected in the payment weights (72 FR 66629 through 66630 and 66767). As mentioned above, in the CY 2008 OPPS/ASC final rule with comment period, we developed a packaging policy that identified a number of clinical areas where services would be commonly performed in a manner that was typically ancillary and supportive to other primary procedures. Packaging for appropriate clinical areas provides an incentive for efficient and cost-effective delivery of services. In that final rule with comment period, we recognized that there were strengths and weaknesses associated with using median costs as the metric for developing the OPPS relative payment weights (72 FR 66615). Medians are generally more stable than means

because they are less sensitive to extreme observations, but they also do not reflect subtle changes in cost distributions. As a result, the use of medians rather than means under the OPPS usually results in relative payment weight estimates being less sensitive to packaging decisions, as well as changes in the cost model due to factors such as the additional claims processed between the proposed rule and the final rule.

The OPPS, like other prospective payment systems, relies on the concept of averaging, where the payment may be more or less than the estimated costs of providing a service or package of services for a particular patient (73 FR 68570). Establishing the cost-based relative payment weights based on a measure of central tendency, such as means or medians, ensures that the payments for the package of services should generally account for the variety of costs associated with providing those services. Prospective payments are ultimately adjusted for budget neutrality and updated by an OPD update factor, which affects the calculated payments, but the accuracy of the cost-based weights is critical in ensuring that the relative payment weights are adjusted appropriately.

We recognize that median costs have historically served and may continue to serve as an appropriate measure on which to establish relative payment weights. However, as discussed above, the metric's resistance to outlier observations is balanced by its limited ability to be reflective of changes to the dataset used to model cost or changes beyond the center of the dataset. While there was significant concern in the initial years of the OPPS regarding outlier cost values and the possible introduction of potentially aberrant values in the cost modeling, hospital experience in coding under the system, the data modeling improvements we have made to obtain more accurate cost

information while removing erroneous data, and other changes in our experience with the system have all lessened the potential impact of error values (rather than actual, accurate cost outliers). As noted above, over the history of the OPPS, we have made multiple refinements to the data process to better capture service costs, respond to commenter concerns regarding the degree to which OPPS relative payment weights accurately reflect service cost and APC payment volatility from year to year, and better capture the variety of resource cost associated with providing a service as provided under section 1833(t)(2)(C) of the Act. In the CY 2013 OPPS/ASC proposed rule (77 FR 45098), we proposed for CY 2013 to shift the basis for the CY 2013 APC relative payment weights that underpin the OPPS from median costs to geometric mean-based costs.

Geometric means better encompass the variation in costs that occur when providing a service because, in addition to the individual cost values that are reflected by medians, geometric means reflect the magnitude of the cost measurements, and are thus more sensitive to changes in the data. We believe developing the OPPS relative payment weights based on geometric mean costs would better capture the range of costs associated with providing services, including those cases involving high-cost packaged services, and those cases where very efficient hospitals have provided services at much lower costs. The use of geometric mean-based costs also would allow us to detect changes in the cost of services earlier, because changes in cost often diffuse into the industry over time as opposed to impacting all hospitals equally at the same time. Medians and geometric means both capture the impact of uniform changes, that is, those changes that influence

all providers, but only geometric means capture cost changes that are introduced slowly into the system on a case-by-case or hospital-by-hospital basis.

We stated that an additional benefit of this proposed policy relates to the 2 times rule, described in section III.B. of the proposed rule, which is our primary tool for identifying clinically similar services that have begun to deviate in terms of their financial resource requirements. We stated that basing HCPCS projections on geometric mean costs would increase the sensitivity of this tool as we configure the APC mappings because it would allow us to detect differences when higher costs occur in a subset of services even if the number of services does not change. This information would allow us to better ensure that the practice patterns associated with all the component codes appropriately belong in the same APC.

In addition to better incorporating those cost values that surround the median and, therefore, describing a broader range of clinical practice patterns, we stated in the proposed rule that basing the relative payment weights on geometric mean costs may also promote better stability in the payment system. In the short term, geometric mean-based relative payment weights would make the relative payment weights more reflective of the service costs. Making this change also may promote more payment stability in the long term by including a broader range of observations in the relative payment weights, making them less susceptible to gaps in estimated cost near the median observation and also making changes in the relative payment weight a better function of changes in estimated service costs.

We noted that this proposed change would bring the OPPS in line with the IPPS, which utilizes hospital costs derived from claims and cost report data to calculate prospective payments, and specifically, mean costs rather than median costs to form the basis of the relative payment weights associated with each of the payment classification groups. We stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74181) our intent to explore methods to ensure our payment systems do not provide inappropriate payment incentives to provide services in one setting of care as opposed to another setting of care based on financial considerations rather than clinical needs. By adopting a means cost-based approach to calculating relative payment weights under the OPPS, we stated that we expect to achieve greater consistency between the methodologies used to calculate payment rates under the IPPS and the OPPS, which would put us in a better position from an analytic perspective to make cross-system comparisons and examine issues of payment parity.

For the reasons described above, in the CY 2013 OPPS/ASC proposed rule (77 FR 45098), we proposed to establish the CY 2013 OPPS relative payment weights based on geometric mean costs. While this would involve a change to the metric used to develop the relative payment weights, the use of claims would not be affected. We proposed to continue to subset claims using the data processes for modeling the standard APCs and the criteria-based APCs described in section II.A.2. of the proposed rule, where appropriate. The reasoning behind implementing modeling edits or changes in the criteria-based APCs would not be affected because the process of developing the relative

payment weights based on a measure of central tendency is the last step of the modeling process, and occurs only once the set of claims used in ratesetting has been established.

One important step that occurs after the development of relative payment weights is the assignment of individual HCPCS codes (services) to APCs. In our analysis of the impacts of a process conversion to geometric means, we determined that the change to means would not significantly influence the application of the 2 times rule. Very few services would need to be shifted to new APCs because of 2 times rule violations because the use of geometric means would resolve some violations that would exist under the use of medians, even as it creates other violations due to new cost projections. The net impact of the proposed change results in seven more violations of the 2 times rule created by the entire rebasing process than would exist if median-based values were used.

During the development of this proposed policy, we also determined that the cumulative effect of data shifts over the 12 years of OPPS introduced a number of inconsistencies in the APC groupings based on clinical and resource homogeneity. We believe that a shift to payments derived from geometric means would improve our ability to identify resource distinctions between previously homogenous services, and we intend to use this information over the next year to reexamine our APC structure and assignments to consider further ways of increasing the stability of payments for individual services over time.

We noted that this proposed policy to establish all OPPS relative payment weights using geometric mean costs would apply to all APCs that would have previously been paid based on median costs. In addition, we proposed to calculate the relative payment

weights for line item based payments such as brachytherapy sources, which were discussed in section II.A.2.d.(6) of the proposed rule, as well as blood and blood products, which were discussed in section II.A.2.d.(2) of the proposed rule, based on their proposed geometric mean costs for the CY 2013 OPPS.

We indicated that the CY 2013 proposed policy to base relative payment weights on geometric mean costs would specifically include the CMHC and hospital-based partial hospitalization program APCs, which were previously based on median per diem costs. Their estimated payments would continue to be included in the budget neutral weight scaling process, and their treatment is similar to other nonstandard APCs discussed in section II.A. of the proposed rule. The process for developing a set of claims that is appropriate for modeling these APCs would continue to be the same as in recent years, with the only proposed difference being that a geometric mean per diem cost would be calculated rather than a median per diem cost. The proposed CY 2013 partial hospitalization payment policies were described in section VIII. of the proposed rule.

In the proposed rule, we stated that we believe it is important to make the transition from medians to means across all APCs in order to capture the complete range of costs associated with all services, and to ensure that the relative payment weights of the various APCs are properly aligned. If some OPPS payments calculated using relative payment weights are based on means while others are based on medians, the ratio of the two payments will not accurately reflect the ratio of the relative costs reported by the hospitals. This is of particular significance in the process of establishing the budget neutral weight scaler, discussed in section II.A.4. of the proposed rule.

We noted that the few exceptions to the applications of the geometric mean-based relative payment weights would be the same exceptions that exist when median-based weights are applied, including codes paid under different payment systems or not paid under the OPPS, items and services not paid by Medicare, items or services paid at reasonable cost or charges reduced to cost, among others. For more information about the various proposed payment status indicators for CY 2013, we referred readers to Addendum D1 to the proposed rule (which was available via the Internet on the CMS Web site).

We proposed for CY 2013 that payment for nonpass-through separately payable drugs and biologicals will continue to be developed through its own separate process. Payments for drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, but the budget neutral weight scaler is not applied to their payments because they are developed through a separate methodology, outside the relative payment weight based process. We noted that, for CY 2013, we proposed to pay for nonpass-through 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. Also, as is our standard methodology, for CY 2013, we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2011 for budget neutrality estimates, packaging determinations, and the impact analyses. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we proposed to use their mean unit cost derived from the CY 2011 hospital claims data to determine their per day cost. The nonpass-through

separately payable drug and biological payment policy for CY 2013 is described in greater detail in section V.B. of the proposed rule and this final rule with comment period.

Comment: Many commenters expressed cautious support for the proposal to calculate the relative payment weights based on geometric mean costs. The commenters believed that the inclusion of additional cost data in developing the APC relative payment weights would represent an improvement to the ratesetting process, while the generally limited provider impacts and enhanced sensitivity to cost changes in calibrating the 2 times rule would be appropriate. While the commenters supported improvements in the accuracy of the OPPS relative payment weights and the goals of the proposed policy, they requested that CMS proceed with caution and transparency in this process to avoid unintended consequences on beneficiaries and hospitals. The commenters also suggested that CMS monitor changes in frequency and cost distributions for services for several years to ensure that no access to care issues develop as a result of the geometric means-based payment policy. Several commenters requested a transitional approach to relative payment weights based on geometric mean costs to mitigate any potentially negative payment effects.

Response: We appreciate the commenters' support. As discussed in the CY 2013 OPPS/ASC proposed rule, we believe that using geometric mean costs to calculate the APC relative payment weights will make them more reflective of the range of service costs, introduce greater sensitivity to the 2 times rule, as well as potentially allow for cross-system payment comparisons (77 FR 45094). We believe that the numerous

changes we have made to the data process to obtain additional information from the available cost report and claims data and ensure the accuracy of the cost estimation, in addition to hospital experience with the OPPS, have prepared us to make this incremental change. We agree that the change to base the relative payment weights on geometric mean costs is appropriate.

We recognize the concerns that commenters have regarding a transitional process towards geometric mean-based APC payment and the possibility that payment fluctuations based on both the naturally occurring variation from year to year and those variations associated with basing the relative payment weights on geometric mean costs may occur. However, we do not believe that an approach to geometric mean-based OPPS relative payment weights beyond the changes we have proposed for the CY 2013 OPPS is necessary or appropriate. Prior to proposing this change, we evaluated the last 4 years of OPPS claims data to model the fluctuations that would have resulted from geometric or arithmetic means in comparison to our traditional medians. We determined that there was no significant difference in the degree of fluctuation with geometric means or with medians, and we also believe that the one-time differences created by the switch are typically small; therefore, we do not believe that a transition period is necessary. In the CY 2013 OPPS/ASC proposed rule, we noted that we made limited changes in APC assignments except where necessary as a result of the proposal to base the relative payment weights on geometric mean costs and stated our intention to further examine appropriate OPPS reconfigurations in the future to resolve potential clinical or resource homogeneity inconsistencies in the future to promote stability (77 FR 45097). Geometric

mean costs more fully encompass the range of costs, including packaged costs, associated with providing a service and, therefore, may result in payments that are more reflective of actual cost. Transitioning into a geometric mean-based system would not be practical, as one of the overarching goals of using geometric mean costs is better relativity across the OPPS. Applying a phased-in approach would potentially distort the relativity of the OPPS payment weights. As we discuss in section II.A.2 of this final rule with comment period, there are various reasons that contribute to cost fluctuation from year to year. We believe that artificially introducing stability into the payment system could potentially distort the relativity of the payment system, especially when doing so could potentially dampen both decreases and increases.

We agree that continued monitoring of changes in cost distributions and the frequency of services is important in understanding the impact of basing the APC relative payment weights on geometric mean costs. However, we note that the frequency of services may change from year to year based on a variety of factors, issues unrelated to OPPS payment, and situations where APC overpayment may have potentially led to inappropriate incentives to provide care. Despite the consideration of the many reasons that may cause service frequency and cost structures to change over time, we will continue to monitor these data, as well as make that information available online through the cost statistics files associated with each rulemaking cycle.

Comment: A number of commenters disagreed with the proposal to base the CY 2013 OPPS/ASC relative payment weights on geometric mean costs. Many of these commenters preferred continued use of median costs in the ratesetting process. Several

commenters believed that the geometric mean costs were inappropriate for OPPS ratesetting for statistical reasons, including their heightened sensitivity to lower cost inliers and lowered sensitivity for high-cost outliers relative to arithmetic means. Other commenters were concerned about the range between minimum and maximum cost values for each APC, and believed them to be implausible. A few commenters stated that while there have been advances in coding practice over the past decade, the same problems of upcoding and outliers will continue to exist, and that the original selection of median costs would continue to be appropriate. One commenter suggested that, beyond the initial years of the OPPS, there have been no cost reporting and coding practice improvements over the years.

Response: We noted in the CY 2013 OPPS/ASC proposed rule that median costs have historically served and may continue to serve as an appropriate measure on which to base the relative payment weights (77 FR 45096). However, we believe that a policy of developing the relative payment weights based on geometric mean costs would represent an improvement beyond our current use of the cost information available to us.

In our discussion in the CY 2013 OPPS/ASC proposed rule relating to basing the relative payment weights on geometric mean costs, we stated that there are a variety of reasons that one metric might be more appropriate than the other. However, the reasoning for selecting one metric relative to any others must be considered in the context of the issues at that time. In our discussion of our proposal to develop the relative payment weights based on geometric mean costs, we described the issues at the initial development of the OPPS and our original reasons for selecting median costs as the

preferred metric. We also described in the proposed rule the many data process changes that we made over the history of the OPPS, including various trimming methodologies, processes to generate more information from the claims and cost report data available to us, steps to address charge compression, modeling and payment edits, modeling configurations to make payment more reflective of the service or services provided, and others (77 FR 45095 through 45096). In addition, we discussed our belief that CMS and hospital experience with the OPPS as well as the coding methodologies for payment would have improved over the past decade. Finally, we discussed various aspects of the geometric means proposal that would affect other policy areas, such as ASC payment, application of the 2 times rule, and other payment methodologies under the OPPS. For these reasons, we established the CY 2013 OPPS/ASC proposal to base the relative payment weights using geometric mean costs (77 FR 45094 through 45098).

We recognize that there are different aspects of each statistical metric that may make any of them preferable to the others. Means-based methodologies, whether arithmetic means or geometric means, incorporate a broader range of estimated cost values into the relative payment weights, whereas medians are less sensitive to that range of costs as well as any changes in them. Depending on whether sensitivity towards changes in service costs is viewed as a relevant objective or not may guide whether selecting means or medians is a preferable alternative. As described above, several commenters have suggested that the lack of sensitivity towards cost changes is precisely why medians remain the preferable option. However, in the CY 2013 OPPS/ASC proposed rule, we noted comments in the past expressing concern regarding the degree to

which payment rates failed to reflect the costs associated with providing a service (77 FR 45096). In light of those concerns, we believe that geometric means and their ability to better reflect packaging patterns and ranges in cost represent an improvement in our cost estimation process.

With regards to the varying level of sensitivity towards cost outliers that geometric means represent, as described above, there are various benefits and drawbacks to each selected metric. Accordingly, the relative payment weights associated with any service may rise or fall, depending on the specific distribution of reported costs, and where the geometric mean appears not only relative to the median but also that of APC 606 (Level 3 Hospital Clinic Visits). While commenters have suggested that there is a systemic risk for "implausible" values, we believe that many of the outlier values present in the data represent actual cost outliers rather than errors, with different accounting assumptions creating different populations of values. At the low-cost and high-cost ends of the cost spectrum for each APC, there is thus the potential for both "spurious" (atypical and/or incorrect) data as well as accurate data to appear. Furthermore, while the minimum and maximum values identify the most extreme outlier values, they do not necessarily reflect the distribution of costs within the model; the minimum and maximum values may not accurately represent the range of costs describing the codes with greatest representation within an APC.

While commenters suggested that there has not been much of an improvement we believe the possibility exists that conditions and circumstances have stabilized to a certain degree over the past decade. Part of the argument for medians at the inception of the

OPPS was that the coding system was still new, as was our use of claims data to calculate prospective payments. Given the many improvements we have made to our internal process of modeling and using data, we would expect that coding and cost reporting practices have improved over that time period as both CMS and hospitals have had the opportunity to develop more experience with the system.

Comment: Some commenters believed that aligning the OPPS relative payment weights on geometric mean costs would hamper hospitals' ability to plan budgets for each year, given the degree to which payments might fluctuate. The commenters also believed that geometric mean costs would lead to greater instability of OPPS payment. Some commenters were concerned about the negative impacts of APC payments declining due to use of geometric mean costs, believing that those changes hindered hospitals' ability to provide high quality health care.

Response: We do not believe that the policy of calculating relative payment weights based on geometric mean costs will inevitably lead to greater payment instability. There are a variety of factors that may contribute to payment volatility from year to year, as we have previously described in section II.A.2. of this final rule with comment period. While there may be some interim fluctuation in the short term as we realign the OPPS to be based on geometric mean costs, we expect many of those issues to stabilize over time. When discussing payment stability, the natural inclination is to view stability as a fixed numerical value that stays the same over time. We evaluated this numerical definition of stability and determined that it was not significantly greater when geometric means were used. However, another view of payment stability is through the

relationship between costs and the degree to which they are reflected in payments. We believe that a policy of using geometric mean costs to develop the APC relative payment weights will make them more reflective of the costs associated with providing services. Further, using geometric mean costs helps ensure that the relative payment weights accurately reflect the distribution of costs associated with providing services, and mitigates the possibility that any fluctuation occurs due to gaps in the distribution of the model, rather than any material changes to the service costs.

We also disagree with the commenter's belief that use of geometric mean costs in calculating the relative payment weights will lead to hospitals being unable to provide access to high-quality health care. Geometric mean costs encompass a broader range of costs, and will result in payments that more fully reflect the range of costs both on the low and high ends, than median-based costs. We believe that this will ultimately be an improvement in the data process as well as OPPS payment policy. Although, as commenters have noted, there are many APC payment rates that decline as a result of the alignment of relative payments weights based on geometric mean costs, we note that a number of APC payment rates also increase as a result of this policy. We believe that, for most provider classes that furnish a mixed array of services to meet the various needs of their patients, the financial impacts from the changes in APC payment rates will be relatively limited. In consideration of all of those factors, we believe that the use of geometric mean costs will result in APC payments that are more reflective of the range of service costs.

Comment: One commenter believed that median costs and the fact that they do not reflect subtle changes in cost distributions was appropriate to use to determine the OPPS payment rates, given aberrant coding, billing, and charging practices by hospitals. The commenter also believed that OPPS outlier payments would address issues where high-cost services did not have those costs reflected in their APC payments. Several commenters suggested that lack of sensitivity towards packaging patterns when using median cost was why median costs would be a more appropriate metric. Other commenters believed that the hospital claims do not provide reliable data and that the Medicare cost report data at the departmental level are not accurate because there is no financial incentive to report accurate data. Commenters also stated that RTI identified flawed cost data and pointed out that charges on hospital claims do not match those on the cost reports. One commenter requested that CMS delay the proposal to use geometric mean costs in ratesetting until it can verify that the data are not flawed.

Response: We appreciate the need for accurate and reliable cost information for use in the OPPS ratesetting process. Many of the changes we have made to our data process over the past decade have arisen with consideration of the need for accurate and reliable cost information. To a certain extent, we can mitigate the issues raised by those concerns through data process changes like trimming methodologies, such as those for the line items as well as cost and unit outliers, and modeling changes, such as those for composite and device-dependent methodologies, to more accurately estimate cost. However, more broadly, we rely on OPPS providers to submit accurate cost and charge information to establish the relativity in the OPPS on which APC payments are based.

We value the comments that stakeholders provide with regards to potential data improvements as well as methods by which we can obtain more accurate data. In situations such as the proton beam APCs for the CY 2013 OPPS/ASC proposed rule and subsequent information about cost report revisions and inaccurate coding, we must balance our reliance on information from OPPS providers with the complementing goal of obtaining accurate cost information. As we described in the CY 2013 OPPS/ASC proposed rule, we have taken steps to address issues such as charge compression in areas such as the former "Medical Supplies Charged to Patients" cost center by establishing a new standard cost center for "Implantable Medical Devices Charged to Patients."

In the case of calculating relative payment weights based on geometric mean costs, we believe that such a change, while affecting the OPPS very broadly, would not involve much manipulation of the data. Although several commenters have suggested that the lack of sensitivity towards cost outliers is appropriate, we also have received comments and HOP Panel presentations in the past regarding the degree to which APC relative payments fail to reflect high-cost packaged services. Calculating relative payment weights based on geometric mean cost is one way of being responsive to those concerns regarding the degree to which correctly reported claims with unusually high costs are incorporated into the relative payment weights. While we agree that OPPS outliers do help mitigate the financial risk associated with performing certain services that require additional complexity or resources, we also believe that developing the relative payment weights based on geometric mean-based costs will help ensure that payments are more reflective of the range of service cost.

In the CY 2013 OPPS/ASC proposed rule, in our proposal to base the CY 2013 relative payments weights on geometric mean costs, we described the many changes we have made since the inception of the OPPS to improve upon our data process. These improvements have helped us obtain more information from the claims and cost report data we have available to us, in addition to ensuring the accuracy of the resource cost estimates we use to model the APC relative payment weights. While we continue to look for ways in which we can improve the OPPS and our modeling of the estimated costs used to develop the relative payment weights, we do not believe that the cost information and methods through which we establish the relative payment weights are inherently flawed. Aligning the relative payment weights based on geometric mean costs may be a significant change in how the relative payment weights are calculated; however, the change can be viewed as incremental based on the other data improvements throughout the history of the OPPS, as described earlier in this section.

We believe that incentives exist for accurate cost reporting beyond direct financial incentives. We believe that external perceptions of incorrect reporting are based primarily on the failure to consider limitations of the data collection methodology when making assumptions and conclusions. The Medicare cost report form allows hospitals to report in a manner that is consistent with their own financial accounting systems and, therefore, should be accurate for each individual hospital.

The regulations at 42 CFR 413.24(f)(4)(iv) specify the certification statement on the first page of the Medicare cost report (Hospital and Hospital Heath Care Complex Cost Report, Form CMS-2552-10) that must be signed by the hospital's administrator or

chief financial officer certifying that the data contained in the cost report are true and accurate. Also included on the certification page is a "penalty statement" which conveys to the hospital official signing the cost report that misrepresentation or falsification of any information contained in the cost report is punishable by criminal, civil, and administrative action, fine, and/or imprisonment under Federal law. Further, the "penalty statement" also states that if services identified in the cost report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, then criminal, civil, and administrative action, fine, and/or imprisonment may result. We believe that the possibility of mandatory cost report adjustments by fiscal intermediaries or MACs where erroneous amounts are found to exist and the possibility of Federal prosecution where potentially false claims and/or fraudulent conduct are found to exist act as reasonable incentives to complete the cost report accurately. Further, the cost report data and their use in the OPPS cost estimation and payment rate development process, combined with potential penalties for inaccurate reporting, provide financial incentive for reporting costs accurately.

We recognize that hospitals are complex entities, each having their own accounting systems and reporting methodology. As such, the cost and charge data that they provide through the Medicare cost report forms are structured in a way that reflects their own internal accounting systems. Although we would obtain the most accurate information by using a highly structured reporting format across hospitals, in using these data for OPPS ratesetting, we must balance between our use of these data for the cost estimation process and the burden associated with forcing hospitals to convert to a

government-mandated standardized financial management system. The current mechanism allows us to collect information that is accurate in the aggregate and that further, at a granular level, reflects the relative allocation of costs to departments and services by the industry as a whole without creating additional burden.

We note that while the RTI investigation into charge compression and the calculation of the relative payment weights yielded areas where the cost estimation process could be improved, there was no suggestion that the process or data itself were fundamentally flawed. We also note that we have tried to be responsive to the concerns raised in the RTI report regarding charge compression and the accuracy of the relative payment weights, for example, through the creation of the new "Implantable Medical Devices Charged to Patients" standard cost center or through the packaged cost redistribution to account for pharmacy overhead in the past several years. Regarding the concern about the matching process between the data used to calculate the CCRs on the Medicare cost report and the claims-based charges, we note that we use the most updated accurate information made available to us and match them to the degree possible to accurately calculate estimated costs. In the revenue code-to-cost center modeling crosswalk that we use to estimate cost, the hierarchy of cost center CCRs is based on our best assumption of where those revenue code charges would be placed even though it may not necessarily reflect every hospitals' individual cost report structure.

As discussed earlier in this section, we have made many improvements to the OPPS data process over the course of the past decade. Many of those changes were intended to either derive more information from the claims and cost report data we have

available to us, while others were intended to estimate cost in a way that more accurately represented the provision of the service and associated resources. We believe that basing the relative payment weights on geometric mean costs will improve the degree to which our APC payments reflect the range of resource costs associated with providing services, and represents an incremental data improvement. Therefore, we do not believe it is appropriate to postpone the use of geometric mean costs in establishing the CY 2013 OPPS/ASC relative payment weights.

Comment: Several commenters requested clarification regarding why CMS selected geometric mean costs as the metric for our proposed policy for calculating the CY 2013 OPPS/ASC relative payment weights rather than arithmetic mean costs. Other commenters noted that using arithmetic means would bring the OPPS even further in line with the IPPS ratesetting methodology.

Response: While developing the proposal to establish the CY 2013 OPPS/ASC relative payment weights using geometric mean costs, we also reviewed the volatility associated and impact of an OPPS based on arithmetic mean costs. We also considered many of the same issues that commenters described with respect to the use of arithmetic means, including whether their ability to more sensitively consider the variety of cost patterns, provide a better reflection of total costs, and to synchronize the OPPS system with the IPPS methodology, would be a preferable option among the three metrics.

We noted that because only natural and "pseudo" single major claims would be used to model the relativity of the OPPS, arithmetic means would not truly reflect total cost in the system. Although arithmetic mean costs would be more sensitive towards

outlier values than both geometric mean costs and median costs, there would also be greater volatility associated with the use of them due to their sensitivity towards outlier values. Similarly, the short-term transition from medians to arithmetic means would also include a greater range of both positive and negative provider payment impacts and would result in the need for more reconfiguration of the APCs to resolve 2 times rule violations than geometric mean costs. While we have discussed our intention to perform a thorough review of the OPPS in the future that may involve more significant reconfiguration, that review would be performed with the goal of developing more accurate and stable payment rates, to the extent that they reflect the range of service costs. Although we stated the possibility of using these geometric mean based payments for exploring cross-system payment comparisons, we recognize that there may be aspects of each payment system data methodology that may be unique. While using arithmetic mean costs would potentially capture the full range of costs better than both geometric means and medians, that benefit has limited value in a relative system such as the OPPS, where all total costs are reduced to relative rates. Conversely, it also would potentially allow an inappropriate impact due to aberrant values because there would be no mitigation of the influence of outlier costs, which could be accurate or aberrant values. Therefore, we viewed the use of geometric mean costs as a balanced approach between both the strengths and weaknesses of using medians and arithmetic means.

Comment: Several commenters expressed concern with regard to the decline in APC payment to CMHCs due to use of the geometric mean cost for calculating the OPPS

relative payment weights, and recommended that CMS continue to monitor the impact of its payment policies on CMHCs.

Response: Over the past several years, we have made changes to the calculation of PHP relative payment weights to more accurately align their PHP APC payments to their specific costs. These changes to PHP relative payment weights have included establishing a separate cost estimation process based on provider type as well as a two-tiered APC payment system under which we pay one amount for days with 3 services and a higher amount for days with 4 or more services for both CMHC and hospital-based PHPs. As discussed in the CY 2013 OPPS/ASC proposed rule, we believe that the use of geometric mean costs rather than median costs in the ratesetting process is one such improvement because it allows the payment metric to consider a broader range of service costs (77 FR 45097). We will continue to monitor the impact of our payment policies on OPPS providers, including CMHCs.

Comment: One commenter was concerned with the minimum and maximum values associated with APCs 0690 (Level I Electronic Analysis of Devices) and 0105 (Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices). In the case of APC 0690, the commenter suggested that the APC payment rate be set to the median cost and not allowed to drop below the payment that CMS would have calculated using medians. For CPT 0307T (Removal of intracardiac ischemia monitoring device), the commenter also believed that its placement in APC 0105 was appropriate. However, the commenter requested that CMS perform an analysis to determine whether some of the procedures might be more appropriately placed in a different APC.

Response: In the case of both of these APCs, the presence of high-cost, low-volume services in the claims used to model each APC creates outliers that foster the perception that the services spread more evenly across the range between the minimum and maximum values than actually is the case. Those minimum and maximum values represent individual points at the most extreme ends of the model, and include service cost estimations that do not contribute significantly enough to the APC weight to be considered in the application of the 2 times rule. In that sense, those values can be misleading because the minimum and maximum should be considered as the most extreme outlier cases; we evaluate the range through the application of the 2 times rule, which only considers services that have sufficient volume to demonstrate stability and reliability and which significantly contribute to the relative payment weight of the APC. Both medians and means are measures of central tendency and have strengths and weaknesses when considering the degree to which they accurately represent the dataset. Similarly, the minimum and maximum values are informative in identifying the most extreme outliers of a dataset but do not necessarily reflect the bulk of the distribution.

For CPT codes 0305T and 0306T which are assigned to APC 0690, we note that the geometric mean cost ($34.78) was slightly higher than the median cost ($33.71) for the APC in the data used for the CY 2013 OPPS/ASC proposed rule. In addition, after calculation of budget neutrality and other adjustments, the national unadjusted payment rate for a geometric mean cost-based APC payment was proposed to be higher than a median cost-based one for CY 2013. Finally, for prospective APC payment rates which are calculated through the standard process, we would not pay using the cost as a rate but

we would use the estimated costs to establish the relative payment weights on which OPPS payments are based. Therefore, we are not setting the payment rate for APC 0690 at the median cost.

We appreciate the commenters' support regarding the placement of CPT code 0307T in APC 0105. We do not agree that having a wide distribution of costs in an APC necessarily implies that a problem in the construction of the APC exists, particularly in cases where we believe the clinical placement and resource use is appropriate. As described above, the minimum and maximum values identified within each CPT or APC are the most extreme outliers, and may not necessarily reflect where the majority of the cost estimates are within each code. For application of the 2 times rule discussed in section III.B. of this final rule with comment period, we only consider codes that are "significant" in their contribution towards the cost estimates in the APC as being useful in the identification of how similar the services within an APC are to each other, from a cost perspective. However, this does not eliminate the need to consider clinical factors when constructing the APC assignments. We do not believe that differences in the distribution of costs for a service automatically creates the need for further study, especially because the purpose of geometric mean costs is to more fully include those cost observations. Similarly, the APC configurations are intended to group together services with clinical and resource homogeneity. However, in the CY 2013 OPPS/ASC proposed rule, we stated our intention of using the information we have available to us to reexamine the APC structure and assignments to consider further ways of increasing the stability of payments over time, and will consider these issues as we do so in the future.

Comment: Commenters expressed concern with regard to the impact of the use of geometric mean-based costs for other specific APCs as well as certain clinical areas. APCs that commenters requested specific detail about included APCs 0690 (Level I Electronic Analysis of Devices); 0105 (Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices); 0331 (Combined Abdomen and Pelvis CT without Contrast); 0334 (Combined Abdomen and Pelvis CT with Contrast); 0383 (Cardiac Computed Tomographic Imaging); 0336 (Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast); 0337 (Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast); 0308 (Positron Emission Tomography (PET) imaging); 0402 (Level II Nervous System Imaging); 0408 (Level III Tumor/Infection Imaging); 0169 (Lithotripsy); 0385 (Level I Prosthetic Urological Procedures); 0386 (Level II Prosthetic Urological Procedures); and 0674 (Prostate Cryoablation). Other clinical areas that commenters expressed concern about included otolaryngological and orthopaedic procedures. One commenter requested that CMS ensure that there was no disproportionate impact to any given medical specialty.

Response: In the case of these APCs, generally the issue is that the geometric mean costs reflect lower cost values than otherwise indicated by the median value. We have identified numerous other data issues or policies beyond the use of geometric mean costs that may attribute to potential declines in the relative payment weight.

For APCs 0331 and 0334, this is the first year where actual data are available for ratesetting based on the new CY 2011 computed tomography of abdomen/pelvis codes: CPT codes 74176 (Computed tomography, abdomen and pelvis; without contrast

material); 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)); and 74178 (Computed tomography, abdomen and pelvis, without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions). For more discussion on the Computed Tomography of Abdomen/Pelvis APCs, we refer readers to section II.A.7.c. of this final rule with comment period.

Another influencing factor may be the use of the new standard cost center for "Implantable Devices Charged to Patient". For device-dependent APCs 0385, 0386, and 0674, there may be effects based on use of the new standard cost center CCR being mapped to revenues codes where appropriate. For a discussion of the cost report CCRs used to estimate service cost, we refer readers to section II.A.1.c. of this final rule with comment period.

For APC 0169, the estimated costs of the APC may have changed based on corrections to the revenue code-to-cost center crosswalk described in the second correction notice to the CY 2012 OPPS/ASC final rule with comment period (77 FR 24409). Further, because CPT code 50590 (Lithotripsy, extracorporeal shock wave) is the only code used to model the APC, any variation with the estimated costs for the CPT code will directly affect the APC relative payment weight.

For all the APCs referenced by commenters, the relative payment weights based on using geometric mean costs now include a greater range of resource costs associated with furnishing the services. Declines in their APC relative payment weights can partially be attributable to these changes in the degree to which the relative payment are reflective of costs. As we have noted, there also may be additional influencing factors

that have led to those changes, including use of actual rather than simulated claims data, the use of the new "Implantable Medical Devices Charged to Patients" standard cost center, the corrections we made to our revenue code-to-cost center modeling crosswalk in our data process, and others. We also note that, because of budget neutrality, for each APC that commenters identified as having decreased payments, there are other APCs that have increased payments. As a general matter, we believe that, in their totality, the newly based APC payment rates better reflect the underlying costs in both cases.

We have typically analyzed the impacts of any proposals at the CPT code, APC, and provider levels of granularity, as most hospitals furnish a variety of services to Medicare beneficiaries. We do not believe that observed declines or increases in the payments for codes are typically associated with any individual specialty because, as we have noted, there are both increases and decreases in relative payment weight associated with this proposal. Additionally, changes generally are due to the degree to which medians were insensitive to the range of service costs.

Comment: One commenter expressed concern regarding the impact of geometric means-based payment on blood products because many of the blood product APCs would experience declines in payment. The commenter recommended that blood products continue to be separately paid based on simulated median costs or that a CY 2013 payment floor be set at the CY 2012 APC payment rates.

Response: While we appreciate the concerns expressed by the commenter, we do not believe that it is appropriate to establish the relative payment weights using different cost metrics for various APC categories. Doing so would potentially distort the cost

relativity and APC payments of services paid through the OPPS. We note that, to ensure that the cost estimation process for blood products is as accurate as possible, we have continued to use simulated CCRs where appropriate, as discussed under section II.A.d.2. of this final rule with comment period. Similarly, we do not believe that setting a payment floor for a specific set of services is appropriate. The estimated resource costs associated with providing a service change from year to year and establishing arbitrary payment floors would decrease the degree to which APC payments reflect the range of costs associated with providing a service.

Comment: Commenters also expressed concern regarding the use of geometric mean costs as the basis for APC relative payment weights for brachytherapy sources and recommended that they not be used in establishing the relative payment weights. The commenters believed that geometric mean costs would be inappropriate for use in ratesetting, in particular for the case of brachytherapy sources.

One commenter stated that the geometric mean is inappropriate for use in determining payment levels under the OPPS because it will overemphasize the weight of low and potentially spurious values in the data. The commenter had other statistical concerns regarding the extent to which there were high-cost and low-cost outliers that they believed were not plausible values as well as variation in estimated costs for brachytherapy relative to other OPPS services. The commenter attributed that variation as being due to hospital reporting practices, and contrasted that variation in the OPPS to the IPPS, where the commenter believed the main concern was high-cost outliers and high-cost values. Under the commenter's belief that geometric means would pay

inadequately for brachytherapy, the commenter also believed it would create a disincentive to use brachytherapy in the treatment of cancer and create access to care issues. The commenter stated that CMS would be acting contrary to the intent of the cost-based payment extensions for brachytherapy payment from CY 2004 through CY 2009. Further, the commenter stated that CMS did not provide sufficient warning to other policymakers in CYs 2010 and 2011 regarding the likelihood that it might potentially change the cost metric used to establish relative payment weights. The commenter believed that geometric mean costs should not be used to develop the relative payment weights of brachytherapy sources.

Response: As with all other OPPS services that would be affected by the proposed policy, we do not believe that the use of geometric mean costs in establishing the APC relative payment weights for brachytherapy sources is inappropriate. While the use of geometric mean costs will include the weight of low values in the data, we note that it also better incorporates cost observations from the higher values in the data. This can be seen in the increases in the relative payment weight for certain brachytherapy sources based on using geometric mean costs. As discussed earlier in this section, the values now being included could potentially include spurious values on both ends of the dataset, as well as legitimate and accurate data. We believe that encompassing a broader range of service costs in establishing the relative payment weights is a technical improvement and may increase the degree to which payments reflect the range of costs associated with providing a service.

Both the IPPS and OPPS contain reporting variations due to the different charging practices among hospitals. While we agree that some of the variations in cost outlier values may be due to the fact that brachytherapy sources rely on charges and costs associated with a CCR, that does not imply that they are necessarily inappropriate, as all OPPS payments rely on charges and CCRs. As we have noted earlier in this section, as long as providers are using generally acceptable accounting practices (GAAP), and the cost report structure reflects their charging practices, we believe that this results in accurate calculations. While the commenter has suggested that the variation in the costs of brachytherapy sources is inappropriate, this can be attributed to both accounting and real cost differences among the various providers that furnish the service in addition to low frequency of line items which may be used to model cost. Although medians may be less sensitive to cost outliers, or even the range of costs, we believe that is both a strength and a weakness of that metric, but is not a reflection of greater or lesser accuracy. While commenters have provided examples with a sample size of three values to illustrate their point regarding sensitivity to low cost values, we note that cases with this order of extreme observations used to model the relative payment weights would be exceptionally rare. For example, the commenter posited a reported charge of $0.01 which is not only extremely unlikely but also is not supported by institutional claims processing. In situations where there are few claims available to model the service costs, the basic issue is the claims volume and their use in establishing the relative payment weights, and not necessarily the fact that medians or geometric means are used. We can address small claim volumes in some cases through assigning similar services based on resource costs

or clinical similarity to the same APCs. However, this method of addressing variability based on low claims volume is unavailable as a tool for line item cost-based APCs.

We do not believe that changes in payment based on the use of geometric mean costs will create a disincentive towards using brachytherapy as a viable option in the treatment of cancer. As we noted earlier in this section, there is variation even among the brachytherapy APCs, which suggests that some of those APC payment rates may now better reflect the range of costs associated with them. There also is extreme variation in the costs reported by individual hospitals for each service within the APC. In considering whether a median cost-based system or a geometric mean-based system is more appropriate at this juncture, the inclination is to view declines in payments as aberrant, without consideration of increases in payment. However, it is equally possible that medians and their lack of sensitivity towards outliers may have led to more payments based on overstated costs than would have been appropriate when considering the broader range of service costs. As discussed in an earlier response, we will continue to monitor the impact of this proposal to base the relative payment weights on geometric mean costs.

With respect to the comments regarding the process through which we establish payment policy for each prospective payment year, we note that the OPPS rulemaking process occurs annually, and is intended to give providers notice as well as the opportunity to inform rulemaking and express their stances regarding various policy proposals. While being able to prepare for each rulemaking cycle so that each prospective payment policy proposal is known years in advance may be preferred by

commenters, it is not operationally feasible. As we have discussed in this section, as well as in the CY 2013 OPPS/ASC proposed rule, the situations that were pressing during the inception of the initial OPPS, and the changes we have made since then, have allowed us to consider different issues as well as areas for improvement. We believe that basing the relative payment weights on geometric mean costs is one such improvement. Although Congress did extend the prior cost-based methodology for brachytherapy sources from CYs 2004 through 2009, we note that no such additional extension has been enacted. Further, the discretion to use a median-based or mean-based system in establishing the OPPS relative payment weights predates those extensions, as authorized by section 201(f) of the BBRA of 1999.

While we recognize the concerns regarding the payments for brachytherapy sources based on geometric mean costs, we continue to believe that this change will result in more accuracy in the cost estimation. We do not believe that paying for some services based on median costs while using geometric mean costs for other services is appropriate, equitable, or consistent with statute. Further, using different cost metrics for different services could distort the relativity of services within the system and increase the inaccuracy and instability of service payment.

Comment: Several commenters noted that they had difficulty modeling the budget neutrality and impact calculations, and suggested that CMS provide a more thorough explanation before proceeding with the proposal to establish OPPS relative payment weights based on geometric mean costs. The commenters stated that lack of a study, in particular one that studies the effect of using geometric mean costs as the basis

for the relative payment weights over time, made it difficult for them to make an informed decision. The commenters also stated that an explanation regarding the impacts was necessary before proceeding, with several commenters noting that the effect of basing the relative payment weights on geometric mean costs was not evenly distributed by provider types. One commenter disagreed that there would generally be limited financial impact to hospitals, due to the fluctuations in certain APCs. Some commenters claimed that the proposal to base the relative payment weights on geometric mean costs disproportionately affected teaching hospitals. Other commenters asked CMS to provide a list of APCs whose costs fluctuated above a certain threshold each year, so that those APCs could be identified through rulemaking for public comment and to allow for presentations before the HOP Panel. A few commenters expressed concern in using geometric mean costs for small sample sizes, as was the case with those associated with proton beam therapy.

Response: For the past several years, each OPPS/ASC rule has included a discussion summarizing both our data process, as well as the calculations associated with budget neutrality and hospital impacts. However, we also make available online a claims accounting document that summarizes in great detail the claims manipulation that goes into modeling the costs used to develop the relative payment weights, as well as the calculations and data processes used to model budget neutrality and the hospital impacts each cycle. The budget neutrality and hospital impacts portions of this document were developed beginning with the CY 2007 OPPS proposed rule, and have been available for every OPPS rulemaking cycle thereafter.

While we appreciate the concerns that commenters have with regard to studying the effects over time, we believe that any increased fluctuations due to geometric mean-based payments are generally not significant enough to create cause for concern. This data process change applied to the cost metric used to develop the relative payment weights more fully captures the range of costs associated with providing a service. However, service costs and APC payments fluctuate over time for a variety of reasons, as we have previously discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74139). As we have discussed earlier in this section, we will continue to monitor the impact of using geometric mean costs to establish the APC relative payment weights and any changes in service frequency or beneficiary access. Our investigation into the impact of using geometric mean costs to establish the relative payment weights also suggest that there should be limited volatility in the payment rates after this initial change. We note that some services do have payment decreases associated with using geometric mean-based relative weights. However, many services also experience payment increases as a result of the geometric mean-based calculation, presumably because the relative payment weights more accurately reflect higher costs associated with provisions of those services. Finally, we note that the one-time effect of converting from medians to means this year is not to be confused with the much less significant effect of year-to-year variation associated with means.

We agree with the commenters' concern regarding the issue of APCs with small sample sizes. However, our concern has less to do with the use of geometric mean costs being used to model the relative payment weights where they are appropriate, but more

with the degree to which a substantive cost baseline can be established. In general, APCs with relatively low service costs or those where there is low claims volume tend to be more vulnerable to cost and payment volatility. We continue to examine methods and APC configurations, such as larger bundles, to mitigate any concerns related to those issues. As the commenter discussed regarding the case of proton beam therapy, there are situations where the costs of the service reflect only provision from a small number of providers and, therefore, may not establish a broad baseline as is the case for most APCs. However, in the case of the proton beam APCs, a sufficiently large volume of claims had been provided and the geometric means helped carry out our intention of capturing the full range of costs. As discussed in the APC-specific policy section of this final rule with comment period, section II.D., the issues relayed by the commenter primarily were due to presumed idiosyncrasies and errors in the submission of the cost reports, which, in turn, affected the estimation of costs, and was further impacted by the coding practices at an individual provider. We note that the potential of these issues to affect the relative payment weights would occur both under a median-based system, provided there was enough significant volume, as well as under geometric mean costs.

In both the CY 2013 OPPS/ASC proposed rule and in this CY 2013 OPPS/ASC final rule with comment period, we have included a column in the impact tables that separately shows the effects of the use of geometric mean costs on the APC relative payment weights. At a very basic level, provider categories that experienced more significant negative or positive payment impacts did so because of the mix of services furnished by those providers based on our claims data. We note that the OPPS provider

payment impacts identified in section XXIII. of this CY 2013 OPPS/ASC final rule are relatively limited. Some commenters have stated that the policy of developing relative payment weights using geometric mean costs disproportionately affects teaching hospitals; other commenters have noted that the impacts are not identical based on the provider categories. That differential in the impacts is to be expected based on this policy, just as any estimated payment impact based on the mix of services that a hospital provides will vary from year to year. Because this policy affects the calculation of the relative payment weights and does not affect the relative payment weights uniformly, it is natural for the changes in those weights to have corresponding variation reflected in the provider impacts based on the mix of services furnished by providers. In the provider impact table in this CY 2013 OPPS/ASC final rule with comment period, we note that, even among major and minor teaching hospitals, there are different estimated impacts based on this policy. We further note that, while the payment category may reflect an increase or decrease in total estimated payment, even among the hospitals in that category, there may be differential impacts that may not necessarily be in the same direction. As discussed earlier in this section, we will continue to monitor any changes that may be associated with the policy of calculating the relative payment weights using geometric mean costs.

We make available with each proposed rule and final rule cost statistics files that include information about costs by CPT code and APC, as well as modeling and total frequency information for each code. Addenda A and B which show the payment rates associated with each rule, also are made available on the CMS Web site. Therefore, the

information to continue monitoring changes in APC payment, code frequency, and cost are made available to the public.

Comment: One commenter supported the goal of making cross-system payment comparison of payment parity. Two commenters cautioned against using OPPS payments based on geometric mean costs as a basis for examining payment parity across the prospective payment systems. They noted that other factors may be involved that would cause those comparisons to potentially be inappropriate, including the acuity of the patients, case- mix, ratesetting methodologies, and resource use in different care settings, as well as different payment adjustments in each system.

Response: While we believe that each of the payment systems has an internally consistent methodology, we recognize the value of including useful information in making potential payment comparisons. We note that we already implement cross-system payment and utilization comparisons in cases such as the MPFS DRA imaging cap, the ASC cap on separately payable radiology services, the cap on ASC office-based covered surgical procedures, and the comparison of service provision across settings for purposes of the inpatient list. The goal in making any potential payment comparisons is to analyze the differences and similarities in as appropriate a manner as possible.

As we discussed in the CY 2012 OPPS/ASC final rule with comment period, in the context of the proposed Cardiac Resynchronization Therapy composite APC, there are various goals associated with making cross-system payment comparisons, including ensuring that we do not create an inappropriate payment incentive to provide services in

one setting of care as opposed to another, using more accurate information where it is available, and constructing the payment groups to be more clinically and resource similar to each other where appropriate, among others (76 FR 74179 through 74182). We specifically noted that there could be many payment approaches that could be chosen for comparison purposes for any given item or service (76 FR 74181).

After consideration of the public comments we received, we are finalizing our proposal to develop the APC relative payment weights using geometric mean costs in the manner described above.

As we also discussed in the CY 2013 OPPS/ASC proposed rule (77 FR 45097), under the revised ASC payment system that was effective January 1, 2008, we established a standard ASC ratesetting methodology that bases payment for most ASC covered surgical procedures and some covered ancillary services on the OPPS relative payment weights (72 FR 42491 through 42493). Therefore, because we proposed to calculate CY 2013 OPPS relative payment weights using geometric mean costs, we also proposed that CY 2013 ASC payment rates under the standard ASC ratesetting methodology would be calculated using the OPPS relative payment weights that are based on geometric mean costs. We noted that basing the relative payment weights on geometric mean costs rather than median costs affects the proposed CY 2013 payment rates. We stated that differences in the proposed payment rates, as with any changes from year to year, affect other parts of the OPPS, including the copayments described in section II.I. of the proposed rule as well as the fixed-dollar outlier threshold described in section II.G. of the proposed rule.

We did not receive any public comments on the adoption of OPPS relative payment weights based on geometric means in the ASC system. For a more detailed discussion of the ASC ratesetting methodology, we refer readers to section XIV. of this final rule with comment period.

Under the CY 2013 proposed policy to base the relative payment weights on geometric mean costs, we also proposed to revise the related regulations that currently reflect a median cost-based OPPS to instead reflect a geometric mean cost-based OPPS. Specifically, we proposed to revise 42 CFR 419.31, which describes the 2 times rule discussed in section III.B. of the proposed rule and this final rule with comment period and the development of relative payment weights based on the cost metrics discussed in section II.A.4 of the proposed rule and this final rule with comment period.

Comment: One commenter stated that CMS did not address why it did not apply the 2 times rule based on geometric means while continuing to use medians for calculating the relative weights because the commenter believed that it would improve the detection of changes in service cost while basing relative payment weights on the less volatile median.

Response: In the CY 2013 OPPS/ASC proposed rule, we discussed the impact of evaluating the 2 times rule based on geometric mean costs rather than median costs, noting that while doing so did not significantly affect the application of the rule, it created several additional 2 times rule violations in the rebasing process (77 FR 45097). Similar to the IPPS and since the inception of the OPPS, we have used a statistical outlier trim of three standard deviations beyond the geometric mean cost, even though we have

historically used median costs as the metric on which to base the relative payment weights. The application of the 2 times rule is inherently tied to the configuration of the APCs and, therefore, how individual codes are paid. To apply the 2 times rule based on geometric mean cost and reconfigure the APCs based on that metric, while calculating relative payment weights based on medians, would be an inconsistency in the data process in the same way that using geometric mean costs for some services and median costs for others would be. Further, section 1833(t)(2) of the Act states that the application of the 2 times rule should be based on the metric selected in section 1833(t)(2)(C) of the Act.

After consideration of the public comments we received, we are finalizing our proposal to apply the 2 times rule based on geometric mean costs and the corresponding changes in 42 CFR 419.31.

In section XXII. of this final rule with comment period, which discusses the regulatory impact analysis, we are providing an additional column in the impact tables for the OPPS that identifies the estimated impact due to APC recalibration of a geometric means-based OPPS as well as a column that estimates the impact of recalibration based on CY 2011 claims and historical cost report data. As depicted in the impact tables, many provider categories will experience limited impacts under the final policy to base the OPPS relative payment weights on geometric means. We note that the impact tables only estimate the OPPS payment impact based on the most current available claims and cost report data, and that providers' actual payments may vary, depending on the mix of services provided in the actual claims year. Also, the budget neutral payment

adjustments ensure that, under a geometric mean-based system or a median cost-based system, aggregate OPPS payments will remain the same.

Section XXII. of this final rule with comment period contains an OPPS provider impact table that estimates the effect of policy changes and budget neutrality adjustments on provider payment under the CY 2013 OPPS. Column 3 of the impact table shows the estimated impact by provider category of calculating the CY 2013 OPPS payments based on geometric mean costs rather than median costs. While the policy to shift the basis for relative payment weights to geometric mean costs may involve some changes to the relative weights on which OPPS payments are based, providers will generally experience limited impacts to payment as a result of the CY 2013 final policy. Those provider categories that are estimated to experience increased payments as a result of the policy to base the CY 2013 relative payment weights on geometric mean costs generally included non-IPPS hospitals that provided psychiatric, hospital-based PHPs, and other services whose relative payment weights increased based on geometric mean costs. As noted above, we recognize that there may be fluctuations in the relative payment weights based on this CY 2013 final policy, but we believe that this policy represents an improvement that more accurately estimates the costs associated with providing services.

In our experience developing the OPPS, we have implemented many changes to obtain more cost information from the claims and cost report data available to us, in an effort to arrive at more accurate estimates of service cost. Many of those changes are described above and in prior OPPS final rules. Despite the challenges created by the complexity of the data and the diversity of facility accounting systems, we continue to examine possible

process and data changes that may further improve precision, validity, and utility. Commenters have historically expressed concerns about the degree to which OPPS relative payment weights are reflective of the service costs associated with providing them, APC payment rate volatility from year to year, and other cost modeling related issues. We recognize that some of those issues will remain because they are related to naturally occurring changes in the economic environment, clinical practice, and the nature of payment systems, among other reasons. However, we believe that basing the OPPS relative payment weights on geometric means better captures the range of costs associated with providing services, improves payment accuracy while limiting year-to-year volatility, and allows reconfigurations in the APC environment using a metric that provides greater computational depth. For these reasons, and those discussed above, we are basing the CY 2013 OPPS/ASC final relative payment weights on geometric mean costs.

3. Changes to Packaged Services

a. Background

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. However, with the exception of outlier cases, overall payment is adequate to ensure access to appropriate care. The OPPS packages payment for multiple interrelated services into a single payment to create incentives for providers to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby

encouraging long-term cost containment. For example, where there are a variety of supplies that could be used to furnish a service, some 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 could result if separate payment is provided for the items. Packaging also encourages hospitals to 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. 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 services and lower cost cases requiring fewer ancillary services. For these reasons, packaging payment for items and services that are typically ancillary and supportive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000.

We use the term "dependent service" to refer to the HCPCS codes that represent services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality. We use the term "independent service" to refer to the HCPCS codes that represent the primary therapeutic or diagnostic modality into which we package payment for the dependent service. In future years, as we consider the development of larger

payment groups that more broadly reflect services provided in an encounter or episode of care, it is possible that we might propose to bundle payment for a service that we now refer to as "independent."

We assign status indicator "N" to those HCPCS codes of dependent services that we believe are always integral to the performance of the primary modality; therefore, we always package their costs into the costs of the separately paid primary services with which they are billed. Services assigned to status indicator "N" are unconditionally packaged.

We assign status indicator "Q1" (STVX-Packaged Codes), "Q2" (T-Packaged Codes), or "Q3" (Codes that may be paid through a composite APC) to each conditionally packaged HCPCS code. An STVX-packaged code describes a HCPCS code whose payment is packaged with one or more separately paid primary services with the status indicator of "S," "T," "V," or "X" furnished in the hospital outpatient encounter. A T-packaged code describes a code whose payment is only packaged with one or more separately paid surgical procedures with the status indicator of "T" are provided during the hospital outpatient encounter. STVX-packaged codes and T-packaged codes are paid separately in those uncommon cases when they do not meet their respective criteria for packaged payment. STVX-packaged codes and T-packaged codes are conditionally packaged. We refer readers to section XII.A.1. of this final rule with comment period and Addendum D1, which is available via the Internet on the CMS Web site with other Addenda, for a complete listing of status indicators and the meaning of each status indicator.

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. We encourage hospitals to report all HCPCS codes that describe packaged services provided, unless the CPT Editorial Panel or CMS provides other 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. Packaging under the OPPS also includes composite APCs, which are described in section II.A.2.e. of this final rule with comment period.

We recognize that decisions about packaging and bundling payment involve a balance between ensuring that payment is adequate to enable the hospital to provide quality care and establishing incentives for efficiency through larger units of payment. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45098 through 45101), we invited public comments regarding our packaging proposal for the CY 2013 OPPS.

b. Clarification of the Regulations at 42 CFR 419.2(b)

In the CY 2013 OPPS/ASC proposed rule (77 FR 45099), we proposed to clarify the regulatory language at 42 CFR 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. We stated that this proposed clarification is consistent with our interpretation and application of 42 CFR 419.2(b) since the inception of the OPPS. We invited public comments on this clarification.

Comment: One commenter objected to the proposed clarification of the regulatory language at 42 CFR 419.2(b). The commenter expressed concern that the proposed changes to the regulatory language are ambiguous and may result in confusion for hospitals and contractors. The commenter believed that Medicare audit contractors will try to assert that all services furnished during a particular encounter, such as E/M visits, drug administration, X-rays, or other ancillary tests, are all related to the main procedure or service received. The commenter further stated that this may lead to payment denials or monies taken during audits and/or post-payment reviews based on the proposed clarification. Therefore, the commenter recommended that CMS abandon this

proposal because the current regulatory language is clear and instructs all entities about CMS' packaging principles.

Another commenter did not object to the proposed wording change from "included costs" to "packaged costs" because, the commenter stated, CMS did not propose to add or alter any of the examples of packaged items and services, and the language used already notes that the list provided is not an inclusive one. However, the commenter was concerned that the proposed addition of the phrase "the payments for which are packaged into the payment for the related procedures or services" introduces a new concept that may lead to a broad interpretation of the regulatory text. The commenter expressed concern that when audits of OPPS accounts occur, the proposed regulatory text may be used to broaden the packaging concept beyond accurate CPT coding by using a subjective interpretation of the term "related". Therefore, the commenter requested that CMS not add the phrase "the payments for which are packaged into the payment for the related procedures or services".

Response: We disagree with the commenters' assertion that the proposed clarification of the regulatory text at 42 CFR 419.2 (b) is ambiguous or confusing. We note our proposal simply clarifies our longstanding policy of packaging, which is a fundamental concept of the OPPS. Specifying that included costs are packaged under the OPPS and that the payment for these packaged costs is packaged into the payment of the related procedures or services is consistent with our longstanding policies related to packaging. In addition, we disagree with the commenter's statement that the proposed addition to 42 CFR 419.2 (b) of the phrase "the payment for which are packaged into the

payment for the related procedures or services" introduces a new concept into the current regulation text.

As we have repeatedly stated, since the inception of the OPPS, packaging payment for items and services that are typically ancillary and supportive to a primary service has been a fundamental part of the OPPS. The concept of packaging entails that the costs for packaged services that are billed with a status indicator of "N" are packaged into the costs of the separately paid primary service with which they are billed. This then means that no separate APC payment is made for the packaged service alone but payment is instead included in the payment for the service or procedure with which the packaged service has been billed.

We believe that our clarification of the regulations at 42 CFR 419.2(b) is consistent with the concept of packaging under the OPPS and does not deviate in any way from our current and longstanding policies regarding packaging under the OPPS.

After consideration of the public comments we received, we are finalizing our proposed policy, without modification, to clarify 42 CFR 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.

c. Packaging Recommendations of the HOP Panel ("The Panel") at its February 2012 Meeting

During its February 2012 meeting, the Panel made five recommendations related to packaging and to the function of the subcommittee. One additional recommendation

that originated from the APC Groups and Status Indicator (SI) Assignment Subcommittee about observation services is discussed in section II.A.2.e. of this final rule with comment period. The report of the February 2012 meeting of the Panel may be found on the CMS Web site at: http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

Below we present each of the Panel's five packaging recommendations and our responses to those recommendations.

Panel Recommendation: CMS should delete HCPCS code G0259 (Injection procedure for sacroiliac joint; arthrography) and HCPCS code G0260 (Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography), and instead use CPT code 27096 (Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography, when performed) with a status indicator of "T," and assign CPT code 27096 to APC 0207 (Level III Nerve Injections).

Response: In the CY 2013 OPPS/ASC proposed rule, we did not accept the Panel's recommendation to delete HCPCS code G0259 and G0260 and instead use CPT code 27096 with a status indicator of "T' and assign CPT code 27096 to APC 0207. For CY 2012, we assigned CPT code 27096 to status indicator "B," meaning that this code is not payable under the OPPS. In order to receive payment for procedures performed on the sacroiliac joint with or without arthrography or with image guidance under the OPPS, hospitals must use either HCPCS code G0259, which is assigned to status indicator "N"

for CY 2012, or HCPCS code G0260, which is assigned to status indicator "T" for CY 2012, as appropriate. CMS created HCPCS codes G0259 and G0260 to separate and distinguish the image guidance procedure from the therapeutic injection procedure for the sacroiliac joint. As stated above, guidance procedures are packaged under the OPPS because we believe that they are typically ancillary and supportive to a primary diagnostic or therapeutic modality and are an integral part of the primary service they support.

We believe that the existence of HCPCS codes G0259 and G0260 is necessary to assign appropriate packaged payment for the image guidance procedure, according to our established packaging policy, and separate payment for the therapeutic injection procedure. Therefore, we did not accept the Panel's recommendation and followed the previously established policy to continue to assign HCPCS code G0259 to status indicator "N," HCPCS code G0260 to status indicator "T," and CPT code 27096 to status indicator "B" for CY 2013.

Comment: Several commenters disagreed with CMS' proposal to not accept the Panel's recommendation on HCPCS codes G0259 and G0260 and to continue to assign a status indicator of "B" for CPT code 27096. One commenter expressed concern that the continued use of HCPCS codes G0259 and G0260 instead of the CPT code 27096 is administratively burdensome to hospitals because it does not allow standardized code reporting among all payers.

Another commenter stated that there is no CPT code that would describe the radiological portion of the procedure to be reported in addition to HCPCS code G0259

because the AMA deleted CPT code 73054. As of January 1, 2012, the commenter stated that CPT code 27096 is always a complete procedure that includes the injection of a diagnostic or therapeutic agent and the associated imaging. The commenter recommended that CMS recognize CPT code 27096 and assign the appropriate APC code to this CPT code based on the CY 2011 claims data for HCPCS code G0259 with CPT code 73542 and HCPCS code G0260 or modify the descriptor of HCPCS code G0259 to include the radiological portion of the procedure and assign the appropriate status indicator and APC for the complete procedure.

One commenter stated that CPT codes 77003 (Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid)) and 77012 (Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation) that are billed with HCPCS code G0260 have a NCCI edit with an indicator of "1." Therefore, the commenter stated that CPT codes 77003 and 77012 cannot be reported with modifier "59" because the imaging guidance is not separate and distinct and it is instead part of the procedure. The commenter stated that providers cannot accurately report the cost of the imaging guidance (either fluoroscopy or CT) due to the CCI edits and the fact that the HCPCS code G0260 descriptor does not indicate if either fluoroscopy or CT imaging is bundled into the procedure code. Therefore, the commenter asked that CMS establish a new HCPCS code to describe the sacroiliac injection procedure performed with imaging (fluoroscopy or

CT) or allow the reporting of CPT code 27096 and revise the status indicator from "B" to "T."

Response: We continue to believe that assigning HCPCS codes G0259 to status indicator "N" is necessary in order to designate appropriate packaged payment for the image guidance procedure, according to our established packaging policy, and separate payment for the therapeutic injection procedure. However, we will reevaluate the descriptors for HCPCS code G0259 and G0260 for CY 2014 in light of the commenter's concerns on the AMA's modification of the descriptor for CPT code 27096 in CY 2012 to include the arthrography services described by CPT code 73542.

After consideration of the public comments we received, for CY 2013, we are continuing to assign a status indicator of "N" to HCPCS code G0259, a status indicator of "T" to HCPCS code G0260, which is assigned to APC 0207 with a final CY 2013 geometric mean cost of approximately $582, and a status indicator of "B" to CPT code 27096.

Panel Recommendation: CMS provide data to the APC Groups and SI Subcommittee on the following arthrography services, so that the Subcommittee can consider whether the SI for these services should be changed from "N" to "S":

- HCPCS code 21116 (Injection procedure for temporomandibular joint arthrography);
- HCPCS code 23350 (Injection procedure for shoulder arthrography or enhanced CT/MRI shoulder arthrography);
- HCPCS code 24220 (Injection procedure for elbow arthrography);

- HCPCS code 25246 (Injection procedure for wrist arthrography);
- HCPCS code 27093 (Injection procedure for hip arthrography; without anesthesia);
- HCPCS code 27095 (Injection procedure for hip arthrography; with anesthesia);
- HCPSC code 27096 (Injection procedure for sacroiliac joint, anesthetic/steroid with image guidance (fluoroscopy or CT) including arthrography when performed);
- HCPCS code 27370 (Injection procedure for knee arthrography); and
- HCPCS code 27648 (Injection procedure for ankle arthrography).

CMS Response: In the CY 2013 OPPS/ASC proposed rule, we accepted the Panel's recommendation that CMS provide data to the APC Groups and SI Assignment Subcommittee on CPT codes 21116, 23350, 24220, 25246, 27093, 27095, 27096, 27370, and 27648 at a future Panel meeting.

We did not receive any public comments on this recommendation.

Panel Recommendation: CMS change the status indicator for HCPCS code 19290 (Preoperative placement of needle localization wire, breast) from "N" to "Q1" and continue to monitor the frequency of the code when used in isolation.

CMS Response: In the CY 2013 OPPS/ASC proposed rule, we agreed with the Panel that a status indicator of "Q1" is appropriate for CPT code 19290. This status indicator will allow for separate payment when this procedure is performed alone or packaged payment when this procedure is performed with an associated surgical procedure. Therefore, as we proposed, we are accepting the Panel's recommendation and

assigning CPT code 19290 to APC 0340 (Minor Ancillary Procedures) and status indicator "Q1" for the CY 2013 OPPS. APC 0340 has a final geometric mean cost of approximately $51 (as compared to approximately $50 calculated for the proposed rule) for CY 2013.

Comment: Several commenters supported CMS' proposal to reassign HCPCS code 19290 from "N" to "Q1". However, one commenter recommended that CMS review the APC assignments for HCPCS codes 19290 and 19295 (Image guided placement, metallic localization clip, percutaneous, during breast biopsy/aspiration (list separately in addition to code for primary procedure) during the CY 2014 rulemaking cycle and propose a more appropriate and higher paying APC for these services.

Response: We appreciate the commenters' support. For CY 2013, we are accepting the Panel's recommendation and finalizing our proposal to assign a status indicator of "Q1" to HCPCS code 19290, which is assigned to APC 0340 with a CY 2013 final payment rate of approximately $51. As has been our practice since the implementation of the OPPS in 2000, we review, on an annual basis, the APC assignments for the procedures and services paid under the OPPS. We will continue to review, on an annual basis, the APC assignments for CPT codes 19290 and 19295.

Panel Recommendation: Judith Kelly, R.H.I.T., R.H.I.A., C.C.S., remain the chair of the APC Groups and SI Subcommittee.

CMS Response: In the CY 2013 OPPS/ASC proposed rule, we indicated that we accepted the Panel's recommendation that Judith Kelly, R.H.I.T., R.H.I.A., C.C.S., continue to chair the APC Groups and SI Assignment Subcommittee.

We did not receive any public comments on this recommendation. We appreciate the services of Ms. Kelly as chair of the Subcommittee for CY 2012.

Panel Recommendation: The work of the APC Groups and SI Assignment Subcommittee continue.

CMS Response: In the CY 2013 OPPS/ASC proposed rule, we indicated that we accepted the Panel's recommendation that the work of the APC Groups and SI Assignment Subcommittee continue.

We did not receive any public comments on this recommendation.

d. Packaging Recommendations of the HOP Panel ("The Panel") at its August 2012 Meeting

During its August 2012 meeting, the Panel accepted the report of the Subcommittee for APC Groups and Status Indicator (SI) Assignments, heard several public presentations related to packaged services and APC grouping and status indicator assignments, and made two recommendations related to the function of the subcommittee. The subcommittee also made recommendations with regard to APC assignment of specific services that are discussed in section III.D. of this final rule with comment period. The report for the August 2012 meeting of the Panel may be found on the CMS Web site at: http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

Below we present the two recommendations related to the function of the subcommittee. Recommendations that evolved from the discussions of the

Subcommittee on APC Groups and SI Assignments that are specific to the APC assignment of HCPCS codes and the removal of HCPCS codes from the inpatient list are discussed in section III. and IX., respectively, of this final rule with comment period.

Panel Recommendation: The Panel recommends that Jacqueline Phillips be named chair of the APC Groups and SI Assignments Subcommittee.

CMS Response: We accept the Panel's recommendation that Jacqueline Phillips be named chair of the APC Groups and SI Assignments Subcommittee. We thank Ms. Judith Kelly for her service as chair of the APC Groups and SI Assignments Subcommittee, and we welcome Ms. Phillips as chair of the APC Groups and SI Assignments Subcommittee.

Panel Recommendation: The Panel recommends that the work of the APC Groups and SI Assignments Subcommittee continue.

CMS Response: We are accepting the APC Panel's recommendation that the work of the APC Groups and SI Assignments Subcommittee continue.

e. Other Packaging Proposals and Policies for CY 2013

The HCPCS codes that we proposed to be packaged either unconditionally (for which we continue to assign status indicator "N"), or conditionally (for which we continue to assign status indicator "Q1", "Q2", or "Q3"), were displayed in Addendum B of the CY 2013 OPPS/ASC proposed rule. The supporting documents for the CY 2013 OPPS/ASC proposed rule, including but not limited to Addendum B, are available at the CMS Webs site at: http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html. To view the status indicators by HCPCS

code in Addendum B, select "CMS 1589" and then select the folder labeled "2013 OPPS Proposed Rule Addenda" or "2013 OPPS Final Rule with Comment Period Addenda" from the list of supporting files. Open the zipped file and select Addendum B, which is available as both an Excel file and a text file.

Comment: Commenters stated that CMS' packaging policies would likely lead to less efficient use of resources, limited access to innovative treatment options, and greater instability in payment because the policies are based on several flawed assumptions. The commenters believed that, to the extent that hospitals control the array of services they provide, CMS' packaging policies assume that the same incentives apply to services furnished in HOPDs as to inpatient services. One commenter stated that, under the IPPS, hospitals have an incentive to provide care in an efficient manner to ensure the lowest cost for the patient's diagnosis. In contrast, in HOPDs, because Medicare payment is based on procedures rather than diagnoses, the commenter believed that hospitals have an incentive to provide the lowest cost item or service included in an APC. The commenter further believed that if that service does not fully address the patient's needs, the hospital would receive better payment by bringing the patient back for a second visit or admitting the patient for inpatient care than by providing a more costly option within the same APC.

Moreover, the commenters believed that when an APC's payment rate is significantly less than the cost of a technology, hospitals have a strong disincentive to use that technology, even if it could reduce the costs of care at a later date. The commenters believed that CMS' use of expanded packaging has the risk of encouraging hospitals to

forego performing needed services and using new technologies that may be more resource intensive during one visit, but could save the patient future outpatient department visits or inpatient care.

Response: As we stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74186), packaging payment for items and services that are ancillary to and dependent on the major procedure for which a payment rate is established is a fundamental concept of the OPPS, based in regulation in the definition of costs that are included in the national payment rate for a service (42 CFR 419.2(b)) and in place since the inception of the OPPS (65 FR 18447). We continue to believe that packaging creates incentives for hospitals and their practitioner partners to work together to establish appropriate protocols that eliminate unnecessary services where they exist and institutionalize approaches to providing necessary services more efficiently. With respect to new services or new applications of existing technology, we believe that packaging payment for ancillary and dependent services creates appropriate incentives for hospitals to consider whether a new service or a new technology offers a benefit that is sufficient to justify the cost of the new service or new technology. Whether this review results in reductions in services that are only marginally beneficial or influences hospitals' choices to not utilize certain technologies, we believe that these changes could improve, rather than harm, the quality of care for Medicare beneficiaries because every service furnished in a hospital carries some level of risk to the patient and the beneficiary would be spared the risk associated with the additional service or different technology. Moreover, we believe that hospitals strive to provide the best care they can to the patients they service

so that when new technologies are proven to improve the quality of care, their utilization will increase appropriately, whether the payment for them is packaged or not. While we believe hospitals are committed to provide optimal care to their patients, we are aware that there are financial pressures on hospitals that might motivate some hospitals to split services among different hospital encounters in such a way as to maximize payments. While we do not expect that hospitals would routinely change the way they furnish services or the way they bill for services in order to maximize payment, we recognize that it would be possible and we consider that possibility as we annually review hospital claims data. We will continue to examine claims data for patterns of fragmented care, and if we find a pattern in which a hospital appears to be dividing care across multiple days, we will refer it for investigation to the QIO or to the Program Safeguard Contractor, as appropriate to the circumstances we find.

Comment: One commenter stated that continued reporting by CMS on utilization of all packaged services and access to care will be essential to ensure that Medicare's payment policies do not restrict beneficiaries' access to necessary care. The commenter asked that CMS make annual reports to the HOP Panel on reporting of services subject to CMS' expanded packaging services.

Response: Each year, we make 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 proposed and final rules. In addition, as we discuss in detail in section II.A.2. of this final

rule with comment period, 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, stakeholders 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 public 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 cost for every independent service. However, stakeholders 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 current and prior proposed and final rules.

Furthermore, we are not required, nor do we intend, to make annual reports to the Panel regarding services that are subject to CMS' packaging policies. We note that the Panel did not recommend at either the February 2012 meeting or the August 2012 meeting that CMS present annual reports on services subject to CMS' packaging services.

Comment: Commenters stated that CMS assumes that its packaging policies will allow it to continue to collect the data it needs to set appropriate, stable payment rates in

the future. The commenters stated that CMS' past experience with packaging payment for ancillary items indicates that hospitals do not submit codes for services that do not directly affect calculations of future payment rates for that Medicare Severity-Diagnosis Related Group (MS-DRG). The commenters further stated that, under the IPPS, hospitals report only the data required to assign a case to the highest paying appropriate MS-DRG, even though other data might affect payment in the long term. The commenters stated that they saw no reason to believe that the current approach would have a different outcome unless CMS gives clear instruction to continue coding for all items and services provided and provides some incentive to do so. The commenters asked that CMS require complete and correct coding for packaged services.

Response: We do not believe that there has been or will be a significant change in what hospitals report and charge for the outpatient service they furnish to Medicare beneficiaries and other patients as a result of our current packaging methodology. Medicare cost reporting standards specify that hospitals must impose the same charges for Medicare patients as for other patients. We are often told by hospitals that many private payers pay based on a percentage of charges and that, in accordance with Medicare cost reporting rules and generally accepted accounting principles, hospital chargemasters do not differentiate between the charges to Medicare patients and other patients. Therefore, we have no reason to believe that hospitals will stop reporting HCPCS codes and charges for packaged services they provide to Medicare beneficiaries. As we stated in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68575), we strongly encourage hospitals to report a charge for each packaged service they

furnish, either by billing the packaged HCPCS code and a charge for that service if separate reporting is consistent with CPT and CMS instructions, by increasing the charge for the separately paid associated service to include the charge for the packaged service, or by reporting the charge for the packaged service with an appropriate revenue code but without a HCPCS code. Any of these means of charging for the packaged service will result in the cost of the packaged service being incorporated into the cost we estimate for the separately paid service. If a HCPCS code is not reported when a packaged service is provided, we acknowledge that it can be challenging to specifically track the utilization patterns and resource cost of the packaged service itself. However, we have no reason to believe that hospitals have not considered the cost of the packaged service in reporting charges for the independent, separately paid service. We expect that hospitals, as other prudent businesses, have a quality review process that ensures that they accurately and completely report the services they furnish, with appropriate charges for that service to Medicare and all other payers. We encourage hospitals to report on their claim for payment all HCPCS codes that describe packaged service that were furnished, unless the CPT Editorial Panel or CMS provides other guidance. To the extent that hospitals include separate charges for packaged services on their claims, the estimated costs of those packaged services are then added to the costs of separately paid procedures on the same claims and used in establishing payment rates for the separately paid services. It is impossible to know with certainty whether hospitals are failing to report HCPCS codes and charges for service for which the payment is packaged into payment for the independent service with which the packaged service is furnished. Moreover, if a

hospital fails to report the HCPCS codes and charges for packaged services, the reason may be that the hospital has chosen to package the charge for the ancillary and dependent service into the charge for the service with which it is furnished. Although we prefer that hospitals report HCPCS codes and charges for all service they furnish, if the hospital's charge for the independent services also reflects the charge for all ancillary and supportive service it typically provides, the absence of HCPCS codes and separate charges would not result in inappropriately low cost for the independent service, although CMS would not know which specific ancillary and supportive services were being furnished. If a hospital is no longer providing a service, there may be many reasons that a hospital chooses not to provide a particular service or chooses to cease providing a particular service, including, but not limited to, because the hospital has determined that it is no longer cost effective for the hospital to furnish the service and that there may be other hospitals in the community that can furnish the service more efficiently.

Comment: One commenter asked that CMS reinstate separate payment for radiation oncology guidance procedures because these services are vital to the safe provision of radiation therapy and unconditionally packaging payment for them may discourage hospitals from providing them.

Response: As we stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188), we recognize that radiation oncology guidance services, like most packaged services, are important to providing safe and high quality care to patients. However, we continue to believe that hospitals will invest in services that represent genuinely increased value to patient care. We will continue to pay separately for

innovative technologies if a device meets the conditions for separate payment as a pass-through device or if a new procedure meets the criteria for payment as a new technology APC.

Comment: One commenter expressed concern over a statement made in the proposed rule that indicated that CMS might propose to bundle payment for [services] that [it] now refers to as "independent [services"]. The commenter stated that CMS did not provide any statutory authority that would allow it to move away from a fundamental OPPS policy, that only "dependent services" are potentially considered as part of a bundled reimbursement methodology. The commenter further stated that packaging payment for multiple services that are not interrelated presents no efficiency or resource management incentives, because, by definition, these services are not related, meaning there are no efficiencies to be gained and no overlap in resources expended.

Response: In the CY 2013 OPPS/ASC proposed rule (77 FR 45089), we noted that we use the term "independent service" to refer to the HCPCS codes that represent the primary therapeutic or diagnostic modality into which we package payment for the dependent service. We also noted that, in future years, as we consider the development of larger payment groups that more broadly reflect services provided in an encounter or episode of care, it is possible that we might propose to bundle payment for a service that we now refer to as "independent." We disagree with the commenter that we do not have the statutory authority to consider larger payment bundles that more broadly reflect services provided in an encounter or episode of care. Our statutory authority is defined in

section 1833(t)(2)(B) of the Act, which allows the OPPS to establish groups of covered HOPD services, namely APC groups, and use them as the basic unit of payment.

Furthermore, for CY 2008, we expanded packaging to services that were once considered independent services and items, such as nonpass-through contrast agents and observation services. We now consider these services to be ancillary and supportive to a primary diagnostic or therapeutic modality and have assigned these services an unconditionally packaged status indicator of "N." It follows then that items or services that are currently considered to be "independent" services within this final rule with comment period may be packaged where appropriate in future years, after taking into consideration the clinical nature of the item or service and then determining whether or not that item or service is considered ancillary and supportive to a primary diagnostic or therapeutic modality.

We note that we did not make any new proposals to develop additional payment bundles for CY 2013, but that we will likely do so in future rulemaking. For CY 2013, we proposed to continue to package the payment for items and services in seven categories with the primary diagnostic or therapeutic modality to which we believe that these items and services are typically ancillary and supportive. Because the commenter does not question the appropriateness of these seven categories of packaged payment given in the proposed rule nor does the commenter question the appropriateness of a specific APC assignment for a packaged HCPCS or CPT code, we cannot fully address the commenter's concerns about bundling multiple services that are not interrelated and that may or may not present efficiency or resource management incentives. We continue

to believe that the seven categories of packaged services and items are appropriate to encourage hospital efficiency, flexibility, and ultimately cost containment.

Comment: One commenter requested that CMS change the status indicator for HCPCS code L8604 (Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml, includes shipping and necessary supplies) from "N" to "A." The commenter argued that this would allow HCPCS code L8604 to be paid under a different fee schedule and would allow for access to the product SOLESTA® in the HOPD. The commenter also asked that CMS cover and pay for SOLESTA® in the same manner as other hyaluronic acid products and assign SOLESTA® a separate and unique HCPCS code.

Response: HCPCS code L8604 describes several products that are implantable prosthetic devices. According to 42 CFR 419.2(b)(11), implantable prosthetic devices are packaged under the OPPS. Therefore, status indicator "N" is the correct status indicator for HCPCS code L8604. We also note that any coverage, reclassification, or HCPCS code change requests for SOLESTA® are outside the scope of this final rule with comment period. Such issues are addressed by processes outside the OPPS/ASC rule by either CMS' HCPCS Workgroup or CMS' Coverage and Analysis Group.

Comment: One commenter requested that CMS assign HCPCS code J7665 (Mannitol, administered through an inhaler, 5 mg) to a status indicator of "K" for CY 2013. The commenter stated that the product that is described by HCPCS code J7665 is a drug indicated for the assessment of bronchial hyperresponsiveness in individuals at least six years of age without clinically apparent asthma and that, consistent with its FDA

labeling, the product that is described by HCPCS code J7665 can only be used in an institutional setting or a physician's office. The commenter argued that HCPCS code J7665 was incorrectly assigned a status indicator of "N" because this product is approved as a drug through the NDA process and should be paid under the OPPS as a separately paid drug as opposed to a supply under the OPPS.

Response: We agree with the commenter that HCPCS code J7665 can be administered in the HOPD. However, we do not believe that the product described by HCPCS code J7665 is a separately payable drug as we have described here within this final rule with comment period, and is instead a supply with costs included in the payment under the OPPS as described in 42 CFR 419.2(b). Mannitol (HCPCS code J7665), when administered through an inhaler, is always used as a supply in bronchial challenge testing. Therefore, for CY 2013, we are assigning a status indicator of "N" to HCPCS code J7665.

After consideration of the public comments we received, for CY 2013, we are finalizing our proposed policy to continue to package payment for the services for which we proposed unconditional or conditional packaged payment in the proposed rule for the reasons set forth above.

f. Packaging of Drugs, Biologicals, and Radiopharmaceuticals

(1) Existing Packaging Policies

In the OPPS, we currently package five categories of drugs, biologicals, and radiopharmaceuticals (unless temporary pass-through status applies): (1) those with per day costs at or below the packaging threshold; (2) diagnostic radiopharmaceuticals;

(3) contrast agents; (4) anesthesia drugs; and (5) drugs treated as surgical supplies. Anesthesia drugs are discussed further in section II.A.3.c.(2) of this final rule with comment period. For detailed discussions of the established packaging policies for diagnostic radiopharmaceuticals and contrast agents, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765 through 66768). For further details on drugs treated as surgical supplies, we refer readers to the CY 2003 OPPS final rule (67 FR 66767) and Chapter 15, Section 50.2 of the Medicare Benefit Policy Manual.

(2) Clarification of Packaging Policy for Anesthesia Drugs

It has been longstanding OPPS policy to package "anesthesia" and "supplies and equipment for administering and monitoring anesthesia or sedation," as described in 42 CFR 419.2(b)(4) and (b)(5). As described above, items and services paid under the OPPS that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are considered dependent items and services are packaged into the payment of their accompanying independent primary service. In accordance with our current policy on packaging items and services, drugs that are used to produce anesthesia in all forms are ancillary and supportive to a primary diagnostic or therapeutic modality, and are included in our definition of "anesthesia" as described in § 419.2(b)(4) and (b)(5). However, we recognize that some anesthesia drugs may qualify for transitional pass-through status under section 1833(t)(6) of the Act. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR45100), we proposed to clarify that our general policy is to package drugs used to produce anesthesia, and that those anesthesia drugs with pass-through status will be packaged upon the expiration of pass-through

status. We invited public comment on our clarification of the existing packaging policies for anesthesia drugs under § 419.2(b)(4) and (b)(5).

Comment: Commenters objected to the proposed clarification of the OPPS policy on anesthesia and all future policies that expand the packaging of drugs, through the increase of the drug packaging threshold or otherwise. The commenters expressed their concern over the increase in packaging for drugs in general and urged CMS not to finalize this policy. The commenters also stated their concern that the CMS drug packaging polices used in the HOPD could encourage hospitals to under utilize critically important drugs and ultimately compromise beneficiary's access to care and undercut CMS' work to improve the quality of care. The commenters urged CMS not to finalize this proposal, to conduct a careful review to assess the effect of packaging on quality of care, and to forego any new packaging policies as a whole.

One commenter expressed support for the clarification of this policy. The commenter further encouraged CMS to continue to monitor packaged drugs and biologicals to ensure they are appropriately paid.

Response: For the CY 2013 OPPS/ASC proposed rule (77 FR 45100), we proposed to clarify the existing policies related to nonpass-through and pass-through anesthesia drugs. It has been our longstanding policy to package anesthesia drugs, which are drugs that are used to produce anesthesia in all forms and are ancillary and supportive to a primary diagnostic or therapeutic modality, that are not on pass-through status as included costs under the OPPS, as described in 42 CFR 419.2(b)(4) and (b)(5). However, we also clarified in the proposed rule that anesthesia drugs are eligible for transitional

pass-through status as a drug, as provided in section 1833(t)(6) of the Act. Therefore, we noted that we were not finalizing a new policy to package nonpass-through anesthesia drugs but were clarifying in our preamble language our currently existing policies.

In addition, as we stated above, we continue to believe that packaging payment for items and services that are ancillary to and dependent on the major procedure for which a payment rate is established is a fundamental concept of the OPPS. We address additional comments on packaging for drugs, biologicals, diagnostic radiopharmaceuticals, and contrast agents below in section II.A.3.f. and section V.A. of this final rule with comment period.

After consideration of the public comments we received, we are finalizing this proposed clarification for CY 2013. Anesthesia drugs that are used to produce anesthesia in all forms are ancillary and supportive to a primary diagnostic or therapeutic modality under 42 CFR 419.2(b)(4) and (b)(5). Therefore, nonpass-through anesthesia drugs are packaged under the OPPS. New anesthesia drugs that were not being paid for as an HOPD service as of December 31, 1996, and whose cost is "not insignificant" in relation to the OPPS payment for the procedures or services associated with the new anesthesia drug are eligible for transitional pass-through status as a drug or biological, as described in section 1833 (t)(6) of the Act. We discuss OPPS transitional pass-through payment for additional costs of drugs, biologicals, and radiopharmaceuticals in section V.A. of this final rule with comment period.

g. Packaging of Payment for Diagnostic Radiopharmaceuticals, Contrast Agents, and Implantable Biologicals ("Policy-Packaged" Drugs and Devices)

Prior to CY 2008, the methodology of calculating a product's estimated per day cost and comparing it to the annual OPPS drug packaging threshold was used to determine the packaging status of drugs, biologicals, and radiopharmaceuticals under the OPPS (except for the CYs 2005 through 2009 exemption for 5-HT3 antiemetics). However, as established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66766 through 66768), we began packaging payment for all diagnostic radiopharmaceuticals and contrast agents into the payment for the associated procedure, regardless of their per day costs. In addition, in CY 2009, we adopted a policy that packaged the payment for nonpass-through implantable biologicals into payment for the associated surgical procedure on the claim, regardless of their per day cost (73 FR 68633 through 68636). We refer to diagnostic radiopharmaceuticals and contrast agents collectively as "policy-packaged" drugs. We refer to implantable biologicals as "devices" because, in CY 2010, we finalized a policy to treat implantable biologicals as devices for OPPS payment purposes (74 FR 60471 through 60477).

As set forth at § 419.2(b), as a prospective payment system, the OPPS establishes a national payment rate, standardized for geographical wage differences, that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis, and in general, these costs include, but are not limited to, implantable prosthetics, implantable durable medical equipment, and medical and surgical supplies. Packaging costs into a single aggregate

payment for a service, encounter, 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 efficiency and also enables hospitals to manage their resources with maximum flexibility.

Prior to CY 2008, we noted that the proportion of drugs, biologicals, and radiopharmaceuticals that were separately paid under the OPPS had increased in recent years, a pattern that we also observed for procedural services under the OPPS. Our final CY 2008 policy that packaged payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, regardless of their per day costs, contributed significantly to expanding the size of the OPPS payment bundles and is consistent with the principles of a prospective payment system.

As discussed in more detail in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68645 through 68649), we presented several reasons supporting our initial policy to package payment of diagnostic radiopharmaceuticals and contrast agents into their associated procedures on a claim. Specifically, we stated that we believed packaging was appropriate because: (1) the statutorily required OPPS drug packaging threshold had expired; (2) diagnostic radiopharmaceuticals and contrast agents function effectively as supplies that enable the provision of an independent service, rather than serving themselves as a therapeutic modality; and (3) section 1833 (t)(14)(A)(iii) of the Act required that payment for specified covered outpatient drugs (SCODs) be set prospectively based on a measure of average hospital acquisition cost (76 FR 74307).

Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR45100), we stated that we believe it is appropriate to continue to treat diagnostic radiopharmaceuticals and contrast agents differently from specified covered outpatient drugs (SCODs) for CY 2013. Therefore, we proposed to continue packaging payment for all contrast agents and diagnostic radiopharmaceuticals, collectively referred to as "policy-packaged" drugs, regardless of their per day costs, for CY 2013. We also proposed to continue to package the payment for diagnostic radiopharmaceuticals into the payment for the associated nuclear medicine procedure and to package the payment for contrast agents into the payment for the associated echocardiography imaging procedure, regardless of whether the agent met the OPPS drug packaging threshold. We refer readers to the CY 2010 OPPS/ASC final rule with comment period for a detailed discussion of nuclear medicine and echocardiography services (74 FR 35269 through 35277).

Comment: Commenters objected to CMS' proposal to package payment of all nonpass-through diagnostic radiopharmaceuticals and contrast agents in CY 2013. A number of commenters stated that diagnostic radiopharmaceuticals and contrast agents with per day costs over the proposed OPPS drug packaging threshold are defined as SCODs and, therefore, should be assigned separate APC payments. In particular, the commenters questioned CMS' authority to classify groups of drugs, such as diagnostic radiopharmaceuticals and contrast agents, and implement packaging and payment policies that do not reflect their status as SCODs. Several commenters disagreed with CMS' labeling of radiopharmaceuticals as supplies and stated instead that they should be treated as other SCODs. The commenters recommended that diagnostic

radiopharmaceuticals should be subject to the same per day cost drug packaging threshold that applies to other drugs, in order to determine whether their payment would be packaged or made separately.

One commenter supported CMS' continued packaging policy for diagnostic radiopharmaceuticals and contrast agents that do not have pass-through status. The commenter noted that diagnostic radiopharmaceuticals are supplies that are necessary to the provision of the service in which they are used and, like other supplies, payment for them should be part of the payment for the service.

Response: As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66766), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68645), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60497), the CY 2011 OPPS/ASC final rule with comment period (75 FR 71949), and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74307), we continue to believe that diagnostic radiopharmaceuticals and contrast agents are different from other drugs and biologicals for several reasons. We note that the statutorily required OPPS drug packaging threshold, as described in section 1833(t)(16)(B) of the Act, has expired, and we continue to believe that diagnostic radiopharmaceuticals and contrast agents function effectively as supplies that enable the provision of an independent service and are always ancillary and supportive to an independent service, rather than themselves serving as the therapeutic modality. We packaged their payment in CYs 2008, 2009, 2010, 2011, and 2012 as ancillary and supportive services in order to provide incentives for greater efficiency and to provide hospitals with additional flexibility in managing

their resources. In order for payment to be packaged, it is not necessary that all products be interchangeable in every case, and we recognized that, in some cases, hospitals may utilize higher cost products and, in some cases, lower cost products, taking into consideration the clinical needs of the patient and the efficient use of hospital resources. While we recognize this variability from case to case, on average under a prospective payment system, we expect payment to cover the costs for the services furnished. In the past, we have classified different groups of drugs for specific payment purposes, as evidenced by our CY 2005 through CY 2009 policy regarding 5-HT3 anti-emetics and their exemption from the drug packaging threshold. We note that we treat diagnostic radiopharmaceuticals and contrast agents as "policy-packaged" drugs because our policy is to package payment for all of the products in this category.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68634), we also began packaging the payment for all nonpass-through implantable biologicals into payment for the associated surgical procedure because we consider these products to always be ancillary and supportive to an independent service, similar to implantable non-biological devices that are always packaged. Therefore, we currently package payment of nonpass-through implantable biologicals, also known as devices that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body. As we stated in the CY 2013 OPPS/ASC proposed (77 FR 45101), we continue to believe that payment should be packaged for nonpass-through implantable biologicals for CY 2013.

We are continuing our CY 2009 policy for CY 2013 as discussed below, which packages payment for all nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals into the payment for their associated procedures. We also continue to believe that the line-item estimated cost for nonpass-through diagnostic radiopharmaceuticals, contrast agents, or implantable biologicals in our claims data is a reasonable approximation of average acquisition and preparation and handling costs for nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals, respectively. As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68645), we believe that hospitals have adapted to the CY 2006 coding changes for nonpass-through diagnostic radiopharmaceuticals and responded to our instructions to include charges for diagnostic radiopharmaceutical handling in their charges for the diagnostic radiopharmaceutical products. Further, because the standard OPPS packaging methodology packages the total estimated cost of each nonpass-through diagnostic radiopharmaceutical, contrast agent, or nonimplantable biological on each claim (including the full range of costs observed on the claims) with the cost of associated procedures for ratesetting, this packaging approach is consistent with considering the average cost for nonpass-through diagnostic radiopharmaceuticals, contrast agents, or implantable biologicals, rather than the cost. In addition, as we noted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68646), these drugs, biologicals, or diagnostic radiopharmaceuticals for which we have not established a separate APC and, therefore, for which payment would be packaged rather than separately provided under the OPPS are not considered to be SCODs. Similarly, drugs

and biologicals with per day costs of less than the drug packaging threshold for CY 2013, which is discussed in section V.B. of this final rule with comment period, that are packaged and for which a separate APC has not been established also are not SCODs. This reading is consistent with our final packaging payment policy, as discussed in this section, whereby we package payment for nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals and provide payment for these products through payment for their associated procedures.

Comment: Several commenters disagreed with the proposal to distinguish between diagnostic and therapeutic radiopharmaceuticals for payment purposes under the OPPS. Some commenters noted that CMS' identification of HCPCS code A0544 (Iodine I-131 tositumomab, diagnostic, per study dose) as a diagnostic radiopharmaceutical is inappropriate because this radiopharmaceutical functions as a dosimetric radiopharmaceutical and not as a diagnostic radiopharmaceutical. A few commenters explained that this particular radiopharmaceutical product is used as part of a therapeutic regimen and, therefore, should be considered therapeutic for OPPS payment purposes. Furthermore, many commenters urged CMS to classify dosimetric doses used in radiopharmaceutical procedures as therapeutic in nature, and allow for separate payment for that dosimetric dose.

Response: As discussed above and in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66641), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68645), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60498), the CY 2011 OPPS/ASC final rule with comment period (75 FR 71949), and the

CY 2012 OPPS/ASC final rule with comment period (76 FR 74308), we classified each radiopharmaceutical into one of the two groups according to whether its long descriptor contained the term “diagnostic” or “therapeutic.” HCPCS code A9544 contains the term “diagnostic” in its long code descriptor. Therefore, according to our established methodology, we continued to classify it as diagnostic for the purposes of CY 2012 OPPS payment. While we understand that this item is provided in conjunction with additional supplies, imaging tests, and therapeutic radiopharmaceuticals for patients already diagnosed with cancer, we continue to believe that the purpose of administering the product described by HCPCS code A9544 is diagnostic in nature. As we first stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66641), we continue to believe that the product described by HCPSC code A9544 is a diagnostic radiopharmaceutical. While it is not used to necessarily diagnose a general disease state, we understand that it is used to determine whether future therapeutic services would be beneficial to the patient and to determine how to proceed with therapy. We note that this is not different than the use of a laboratory test to guide therapy; the fact that the diagnostic test, a service which provides information, is used to guide therapy does not make it a therapeutic service, on which its intent is to improve a patient’s clinical condition. While a group of associated services may be considered a therapeutic regimen by some commenters, HCPCS code A9544 is provided in conjunction with a series of nuclear medicine imaging scans. Many nuclear medicine studies using diagnostic radiopharmaceuticals are provided to patients who already have an established diagnosis. We continue to consider HCPCS code A9544 to be diagnostic because this item is

provided for the purpose of conducting a diagnostic imaging procedure and is used to identify the proposed dose of the therapeutic agent to be provided at a later time.

Comment: Commenters recommended using the ASP methodology and the proposed statutory default rate of ASP+6 percent to make payment for nonpass-through diagnostic radiopharmaceuticals and contrast agents. The commenters noted that it would be inconsistent for CMS to treat diagnostic radiopharmaceuticals and contrast agents as "drugs" for pass-through payment purposes and provide payment for diagnostic radiopharmaceuticals and contrast agents that have pass-through status based on the ASP methodology, and, then, after the diagnostic radiopharmaceutical's or contrast agent's pass-through payment status expires, package the costs included in historical hospital claims data, rather than use the ASP methodology to pay for the product and treat the drug as a supply. A few commenters suggested that diagnostic radiopharmaceuticals could be paid separately as therapeutic radiopharmaceuticals are paid, which would allow manufacturer to voluntarily submit ASP data, and then default to the mean unit cost when ASP data are unavailable. Some commenters recommended that CMS use ASP data as a benchmark for determining costs for diagnostic radiopharmaceuticals that are packaged.

One commenter stated that payment for diagnostic radiopharmaceuticals should not be paid at ASP+6 percent for the reasons commenters provided when CMS proposed to make payment at ASP+6 percent in prior years. Specifically, the commenter noted that the ASP statute excludes reporting of the ASP for diagnostic radiopharmaceuticals and, therefore, such reporting would need to be voluntary. However, in terms of voluntary reporting of diagnostic radiopharmaceuticals, the commenter further noted that CMS

could never be confident that it would receive reports from all manufacturers of any particular diagnostic radiopharmaceutical. Moreover, the commenter stated, high volume diagnostic radiopharmaceuticals are furnished using generators that hospitals use for up to 28 days to provide doses of diagnostic radiopharmaceuticals as needed and therefore the manufacturer, who would report the ASP under penalty of perjury, would never be able to certify the actual number of doses furnished with confidence. The commenter finally noted that packaging is consistent with the general principles of a prospective payment system, one goal of which is to encourage hospital cost containment.

Response: As we stated above, the statutorily required OPPS drug packaging threshold has expired, and we continue to believe that nonpass-through diagnostic radiopharmaceuticals and contrast agents are always ancillary and supportive to an independent service, rather than services themselves as the therapeutic modality. We disagree with commenters who suggest that nonpass-through diagnostic radiopharmaceuticals and contrast agents should be paid under the ASP methodology, that nonpass-through diagnostic radiopharmaceuticals and contrast agents should be paid as pass-through drugs and biologicals, or that nonpass-through diagnostic radiopharmaceuticals should be paid similarly to therapeutic radiopharmaceuticals. We continue to believe that nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals function effectively as supplies that enable the provision of an independent service. As we noted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68646) and restate above, drugs, biologicals, or radiopharmaceuticals for which we have not established a separate APC will receive

packaged payment under the OPPS, and are considered not to be SCODs. We continue to believe that the line-item estimated cost for nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals in our claims data is a reasonable approximation of average acquisition and preparation and handling costs for diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals, respectively.

Further, as we have stated above, we believe that packaging costs into a single aggregate payment for a service, encounter, or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. Our policy of packaging payment for nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals 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. Paying separately for nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals, when each of these items is ancillary or supportive to an independent service, is contrary to this principle of a prospective payment system.

Finally, we do not agree with the commenter's assertion that separate payment for diagnostic radiopharmaceuticals would result in more accurate payment for these products. When CMS discussed possible ASP-based payment for diagnostic radiopharmaceuticals in the CY 2006 OPPS final rule with comment period (70 FR 68653 through 68657), numerous commenters advised CMS that diagnostic radiopharmaceuticals are formulated, distributed, compounded, and administered in

unique distribution channels that preclude the determination of ASP relevant to a diagnostic radiopharmaceutical HCPCS codes. Further, commenters advised CMS that the manufacturer has no way to calculate the ASP of the end product patient dose and, consequently, could not supply CMS with accurate ASP data. In the intervening period between the CY 2006 final rule with comment period and the present, diagnostic radiopharmaceutical use has become more widespread and its formulation more complex. Moreover, we believe that the phenomena described by commenters (including radiopharmaceutical manufacturers) in the comment period preceding the CY 2006 OPPS final rule with comment period, including the many preparatory and compounding steps between manufacturer and the patient's bedside, remain an impediment to manufacturers' calculations of accurate ASP and thus accurate payment for these products. Therefore, we do not believe that diagnostic radiopharmaceuticals (or contrast agents or implantable biologicals) should be paid separately under the OPPS such that manufactures voluntarily can submit ASP data and then default to mean unit cost when ASP data are unavailable. We believe they are appropriately packaged into a single aggregate payment for the accompanying services.

Comment: Commenters recommended that CMS modify the way that it applies the "2 times" rule for nuclear medicine APCs by including the cost of the packaged diagnostic radiopharmaceutical drugs in its analysis and not just the cost of services. The commenters argued that this is mandated by the statute, which provides that 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 APC group is more than two times greater than the

lowest cost for an item or service within the same APC group. Therefore, the commenters believed that it is logical that as long as CMS views the packaged nuclear medicine service and the radiopharmaceutical as one unit for APC payment purposes, it should consider both components together in applying the 2 times rule and analysis to APC payment.

Response: While the language in section 1833(t)(2) of the Act regarding the 2 times rule describes consideration of both items and services for purposes of identifying exceptions to the rule, it does so within the context of services that belong to an APC group. Unconditionally packaged items and services, being associated with the particular item or service being modeled for separate payment, would not individually belong to any APC group. However, these unconditionally packaged costs would be incorporated into the system through the separately paid items or services with which they appear on the claim, and would thus be factored into the ultimate consideration of the 2 times rule. Therefore, consideration of items and services within each APC only applies to the separately paid HCPCS and CPT codes assigned to each APC and would thus not include any discrete calculation for packaged costs with regards to the two times rule.

Comment: One commenter recommended that CMS establish a threshold for radiopharmaceutical drugs that would trigger separate payment when the cost of the radiopharmaceutical is greater than the total APC payment or over another threshold value.

Response: Consistent with the CY 2013 OPPS/ASC proposed rule, for this final rule with comment period, we continue to believe that diagnostic radiopharmaceuticals

are ancillary and supportive to the nuclear medicine procedures in which they are used and that their costs should be packaged into the primary procedures with which they are associated. We do not believe it would be appropriate to set a cost threshold for packaging diagnostic radiopharmaceuticals because, regardless of their per day cost, they are always supportive of an independent procedure that is the basis for administration of the diagnostic radiopharmaceutical. We also do not believe that it is appropriate to consider alternate packaging criteria for nonpass-through diagnostic radiopharmaceuticals because we continue to believe that, regardless of their per-day cost, these items are always supportive of an independent procedure that is the basis for administration of the diagnostic radiopharmaceutical. Therefore, our policy of packaging costs for these products into an associated APC continues to be the approach best suited for use in this prospective payment system.

Further, we note that the OPPS, as a prospective payment system, already includes the costs associated with diagnostic radiopharmaceuticals into the APCs for which the product is ancillary and supportive. We believe that the cost associated with a given product at a given point in time is immaterial because the OPPS, as a prospective payment system with payments based on average costs associated with a covered procedure, already takes into account both higher and lower input costs associated with that procedure. We also note that the OPPS, like many of Medicare's prospective payment systems, has polices in place to provide hospitals with additional outlier payments for certain high-cost cases whose costs exceed certain thresholds. This system of outliers already provides hospitals (or, in the case of partial hospitalization services,

community mental health centers) with additional reimbursement to offset costs that are high relative to the prospective payment amount, regardless of whether the costs are associated with diagnostic radiopharmaceuticals or another relatively high cost element in the patient's course of care.

Comment: One commenter requested that CMS present additional, detailed information regarding how the agency ensures that the full cost of diagnostic radiopharmaceuticals are captured in the associated packaged APC procedural payments, including the validation methods used by the agency.

Response: The data that CMS used to calculate, propose, and finalize APC assignments and rates, including costs associated with diagnostic radiopharmaceuticals, for the CY 2013 OPPS, 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/HospitalOutpatinetPPS/index.html. This Web site includes information about purchasing the "OPPS Limited Data Set," which now includes the additional variable previously available only in the OPPS Identifiable Data set, including ICD-9-CMS diagnosis codes and revenue code payment amounts.

As we state above, we discuss in detail in section II.A.2. of this final rule with comment period the availability to the public of the use of 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.

We continue to believe that the cost of a diagnostic radiopharmaceutical is captured into the associated packaged APC procedural payment. We see no need at this time to provide further data analyses.

For CY 2013, we proposed to make an additional payment of $10 for diagnostic radiopharmaceuticals that utilize the Tc-99m radioisotope produced by non-HEU methods (77 FR 45121). We proposed to base this payment on the best available estimations of the marginal costs associated with non-HEU radioisotope production, pursuant to our authority described in section 1833(t)(2)(E) of the Act which allows us to establish "other adjustments as determined to be necessary to ensure equitable payments" under the OPPS. We described this policy in further detail in section III.C.3. of the proposed rule.

We received numerous comments on this proposal, including comments that suggested that separate payment for diagnostic radiopharmaceuticals is the most effective way to encourage hospital conversion from HEU to non-HEU sources that utilize Tc-99m. We have addressed these comments on the proposed payment for non-HEU sources that recommended separate payment for diagnostic radiopharmaceuticals above and in section III.C.3. of this final rule with comment period.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68634), we began packaging the payment for all nonpass-through implantable biologicals into payment for the associated surgical procedure because we consider these products to always be ancillary and supportive to independent services, similar to implantable nonbiological devices that are always packaged. We continued to follow this policy in

CY 2012 (76 FR 74306 through 74310). Specifically, we continue to package payment for nonpass-through implantable biologicals, also known as devices that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body. In the CY 2013 OPPS/ASC proposed rule (77 FR45101), for CY 2013, we proposed to continue to apply the policies finalized in CY 2012, to package payment for nonpass-through implantable biologicals ("devices") that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body.

Comment: One commenter requested that HCPCS code Q4130 (Strattice tm, per square centimeter) be assigned status indicator "K" for CY 2013 because, the commenter argued, HCPCS code Q4130 is a skin substitute graft for chronic wounds and a surgical biological implant for breast reconstruction and hernia repair procedures. The commenter stated that assigning HCPCS code Q4130 to a status indicator of "K" would signify its use as a biological skin substitute graft for which separate payment is available.

The commenter further noted that Transmittal 2418 of the Medicare Claims Processing Manual lists HCPCS code Q4130 in table 5 of the transmittal, along with other biologicals with "dual" use.

Response: HCPCS code Q4130 was assigned a status indicator of "N" in the CY 2013 OPPS/ASC proposed rule, signifying that the product that is represented by this code is an implantable biological device. We continue to believe that the product described by HCPCS code Q4130 is an implantable biological device, as evidenced by language within the 510(k) FDA clearance which lists the product described by HCPCS

code Q4130 as a surgical mesh intended for the reinforcement of soft tissue repaired by sutures or suture anchors during tendon repair surgery including reinforcement of rotator cuff, patella, Achilles, biceps, quadriceps, or other tendons. Further indications of use include the repair of body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome. As we stated above, the payment for nonpass-through implantable biologicals, or implanted devices, is packaged into the payment for the primary procedure. Therefore, we are continuing to assign a status indicator of "N" to HCPCS code Q4130 for CY 2013. Additionally, we are correcting the table within Transmittal 2418 which contains a list of skin substitutes only.

Comment: One commenter who responded to the CY 2012 OPPS/ASC final rule with comment period expressed concern that Medicare contractors had been inadvertently making separate payment for nonpass-through biological implants as they process OPPS claims for breast reconstruction and hernia repair procedures. The commenter stated that these procedure claims included claims for biological implants, including HCPCS codes Q4100 through Q4130. The commenter noted that HCPCS code Q4116 (Alloderm, per square centimeter) in particular was paid separately on several occasions. Therefore, the commenter recommended that CMS take several steps to prevent further billing errors with respect to the OPPS payment policy for implantable biologicals.

Response: For the April 2012 quarterly update, we installed logic changes in the I/OCE to allow for separate payment for separately payable skin substitute HCPCS codes that are coded with skin substitute procedure CPT codes only. We reminded hospitals that HCPCS codes describing skin substitutes should only be separately reported when

used with one of the CPT codes describing the application of a skin substitute (CPT codes 15271 through 15278). Therefore, we have previously addressed the commenters' concerns.

Under the OPPS, HCPCS codes that describe skin substitute products, with a separately payable status indicator of "K" or "G" that are billed with a skin substitute application procedure, will receive separate payment for both the skin substitute product and the procedure. Payment for skin substitute HCPCS codes that are billed with other procedures will be packaged into the payment for the corresponding procedure.

After consideration of the public comments we received, we are finalizing our proposals, without modification, to continue to package payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, and implantable biologicals that are surgically inserted or implanted into the body through a surgical incision or a natural orifice, regardless of their per day costs. Given the inherent function of diagnostic radiopharmaceuticals and contrast agents as ancillary and supportive to the performance of an independent procedure and the similar functions of implantable biologicals and nonbiological devices as integral to and supportive of the separately paid surgical procedures in which either may be used, we continue to view the packaging of payment for diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals as a logical expansion of packaging payment for drugs and biologicals. In addition, as we initially established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66768), we will continue to identify diagnostic radiopharmaceuticals specifically as those Level II HCPCS codes that include the term "diagnostic" alone with a

radiopharmaceutical in their long code descriptors, and therapeutic radiopharmaceuticals as those Level II HCPCS codes that include the term "therapeutic" along with a radiopharmaceuticals in their long code descriptors. We believe that the current descriptors accurately discriminate between those radiopharmaceuticals that are used to gather information and those which are intended to improve the patient's medical condition.

In addition, any new biological lacking pass-through status that is surgically inserted or implanted through a surgical incision or natural orifice will be packaged in CY 2013.

We refer reader to section III.D.1.f. of this final rule with comment period for a discussion of comments related to echocardiography services furnished with and without contrast. For more information on how we set CY 2013 payment rates for nuclear medicine procedures in which diagnostic radiopharmaceuticals are used an echocardiography services provided with and without contrast agents, we refer readers to the CY 2010 OPPS/ASC final rule with comment period for a detailed discussion of nuclear medicine and echocardiography services (74 FR 35269 through 35277).

h. Summary of Proposals

As we proposed, we are finalizing, for this final rule with comment period, the HCPCS codes that we unconditionally packaged (for which we continue to assign status indicator "N"), or conditionally packaged (for which we continue to assign status indicators "Q1," "Q2," or "Q3"), and those codes are displayed in Addendum B of this final rule with comment period (which is available via the Internet on the CMS Web site).

The supporting documents for this CY 2013 OPPS/ASC final rule with comment period, including, but not limited to, Addendum B, are available on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html. To view the status indicators by HCPCS code in Addendum B, select "CMS 1589-FC" and then select the folder labeled "2013 OPPS Final Rule Addenda" from the list of supporting files. Open the zipped file and select Addendum B, which is available as both an Excel file and a text file.

4. Calculation of OPPS Scaled Payment Weights

In the CY 2013 OPPS/ASC proposed rule (77 FR 45101), we proposed for CY 2013 to calculate the relative payment weights for each APC for CY 2013 shown in Addenda A and B to the proposed rule (which were 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. 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 CY 2013, we proposed to base the relative payment weights on which OPPS

payments will be made by using geometric mean costs, as described in section II.A.2.f. of the proposed rule. 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 continue to use the cost of the mid-level clinic visit APC (APC 0606) in calculating unscaled weights. Following our general methodology for establishing relative payment weights derived from APC costs, but using the proposed CY 2013 geometric mean cost for APC 0606, for CY 2013, we proposed to assign APC 0606 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 0606 to derive the proposed unscaled relative payment weight for each APC. We stated that 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 2013 is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To comply with this requirement concerning the APC changes, we proposed to compare the estimated aggregate weight using the CY 2012 scaled relative payment weights to the estimated aggregate weight using the CY 2013 unscaled relative payment weights. For CY 2012, we multiplied the CY 2012 scaled APC relative weight applicable to a service paid under the OPPS by the volume of that service from CY 2011 claims to calculate the total weight for each service.

We then added together the total weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2013, as we proposed, we performed the same process using the CY 2013 unscaled relative payment weights rather than scaled relative payment weights. We then calculated the weight scaler by dividing the CY 2012 estimated aggregate weight by the CY 2013 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. 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.

As we proposed, in this final rule with comment period, we include estimated payments to CMHCs in our comparison of estimated unscaled weights in CY 2013 to estimated total weights in CY 2012 using CY 2011 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we adjusted the unscaled relative payment weights for purposes of budget neutrality. The CY 2013 unscaled relative payment weights were adjusted by multiplying them by a weight scaler of 1.3596 to ensure that the CY 2013 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) was included in the budget neutrality calculations for the CY 2013 OPPS.

We did not receive any public comments on the proposed methodology for calculating scaled weights based on the geometric mean costs for the CY 2013 OPPS. Therefore, for the reasons set forth in the proposed rule (77 FR 45101), we are finalizing our proposed methodology without modification, including updating of the budget neutrality scaler for this final rule with comment period as we proposed. Under this methodology, the final unscaled relative payment weights were adjusted by a weight scaler of 1.3596 for this final rule with comment period. The final scaled 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 final recalibration adjustments discussed in sections II.A.1. and II.A.2. of this final rule with comment period.

We noted in the proposed rule that we were providing additional information, in association with the proposed rule, so that the public could provide meaningful comment on our proposed policy to base the CY 2013 OPPS relative payment weights on geometric mean costs. The scaled 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 2013 IPPS/LTCH PPS final rule (77 FR 53414), consistent with current law, based on IHS Global Insight, Inc.'s second quarter 2012 forecast of the FY 2013 market basket increase, the FY 2013 IPPS market basket update is 2.6 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(ii) of the Act, as added by section 3401(i) of Pub. L. 111-148 and as amended by section 10319(g) of that law and further amended by section 1105(e) of Pub. L. 111-152, provide adjustments to the OPD fee schedule increase factor for CY 2013.

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 2013 IPPS/LTCH PPS proposed rule (77 FR 27975 through 27976), we discussed the calculation of the proposed MFP adjustment for FY 2013, which was 0.8 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 2013 market basket update and the MFP adjustment, components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and (F) of the Act, in this CY 2013 OPPS/ASC final rule with comment period. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53414), we discussed the calculation of the final MFP adjustment for FY 2013, which is 0.7 percentage point.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that for each of year 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 2013, section 1833(t)(3)(G)(ii) of the Act provides a 0.1 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)(ii) of the Act, in the CY 2013 OPPS/ASC proposed rule (77 FR 45102), we proposed to apply a 0.1 percentage point reduction to the OPD fee schedule increase factor for CY 2013.

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 would result in an OPD fee schedule increase factor of 1.8 percent for the CY 2013 OPPS (2.6 percent, which is the final estimate of the hospital inpatient market basket percentage increase, less the final 0.7 percentage point MFP adjustment, less the 0.1 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 -0.2 (2.6 percent, which is the final estimate of the hospital inpatient market basket percentage increase, less the final 0.7 percentage point MFP adjustment, less the 0.1 percentage point additional adjustment, less 2.0 percentage points for the Hospital OQR Program reduction). For further discussion of the Hospital OQR Program, we refer readers to section XV.F. of this final rule with comment period.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45103), we proposed to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (4) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2013, 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)(ii) 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 0.1 percentage point for CY 2013.

Comment: Several commenters expressed support for the OPD fee schedule increase factor because they believed it would better align payment with hospital costs.

Response: We appreciate the commenters' support.

We did not receive any public comments on the proposed amendment to 42 CFR 419.32(b)(1)(iv)(B) to add a new paragraph (*4*) to reflect the requirements in section 1833(t)(3)(F) of the Act. For the reasons discussed above, we are adjusting the OPD fee schedule increase factor and adopting as final the amendment to 42 CFR 419.32(b)(1)(iv)(B), as proposed.

We did not receive any public comments on our proposed methodology for calculating the CY 2013 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 2013, we are increasing the CY 2012 conversion factor of $70.016 by 1.8 percent. In accordance with section 1833(t)(9)(B) of the Act, we are further adjusting the conversion factor for CY 2013 to ensure that any revisions made to the updates for a revised wage index and rural adjustment are made on a budget neutral basis (77 FR 45103). We are calculating an overall budget neutrality factor of 0.9998 for wage index changes by comparing total estimated payments from our simulation model using the final FY 2013 IPPS wage

indices to those payments using the current (FY 2012) IPPS wage indices, as adopted on a calendar year basis for the OPPS.

For CY 2013, 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 2013, 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 2013 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing the estimated total CY 2013 payments under section 1833(t) of the Act including the CY 2013 cancer hospital payment adjustment to the estimated CY 2013 total payments using the CY 2012 final cancer hospital payment adjustment under sections 1833(t)(18)(B) and 1833(t)(2)(E) of the Act. The difference in the CY 2013 estimated payments as a result of applying the CY 2013 cancer hospital payment adjustment relative to the CY 2012 final cancer hospital payment adjustment does not have a significant impact on the budget neutrality calculation. Therefore, we are applying a budget neutrality adjustment factor of 1.0000 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 2013 would equal approximately $74 million, which represents 0.15 percent of total projected CY 2013 OPPS spending.

Therefore, the conversion factor is also adjusted by the difference between the 0.22 percent estimate of pass-through spending for CY 2012 and the 0.15 percent estimate of CY 2013 pass-through spending, resulting in an adjustment for CY 2013 of -0.07 percent. Finally, estimated payments for outliers remain at 1.0 percent of total OPPS payments for CY 2013.

The OPD fee schedule increase factor of 1.8 percent for CY 2013 (that is, the estimate of the hospital inpatient market basket percentage increase of 2.6 percent less the 0.7 percentage point MFP adjustment and less the 0.1 percentage point required under section 1833(t)(3)(F) of the Act), the required wage index budget neutrality adjustment of approximately 0.9998, the cancer hospital payment adjustment of 1.0000, and the adjustment of –0.07 percent of projected OPPS spending for the difference in the pass-through spending result in a conversion factor for CY 2013 of $71.313.

As we stated in the proposed rule, 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 XV.F. of this final rule with comment period. To calculate the CY 2013 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the Hospital OQR Program for the full CY 2013 payment update, we are making all other adjustments discussed above, but

using a reduced OPD fee schedule update factor of -0.2 percent (that is, the OPD fee schedule increase factor of 1.8 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 2013 of $69.887 for those hospitals that fail to meet the Hospital OQR requirements (a difference of -$1.426 in the conversion factor relative to those hospitals that met the Hospital OQR requirements).

In summary, for CY 2013, we are using a final conversion factor of $71.313 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs. For further discussion regarding our final policy to base the CY 2013 OPPS relative payment weights on geometric mean costs, we refer readers to section II.A.2.f. of this final rule with comment period. We are finalizing our proposed amendment to § 419.32(b)(1)(iv)(B) by adding a new paragraph (*4*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2013 in order to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(ii) of the Act. We also are using a reduced conversion factor of $69.887 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 account for geographic wage differences in a portion of the OPPS

payment rate, which includes the copayment standardized amount and is attributable to labor and labor-related costs. This portion of the OPPS payment rate is called the OPPS labor-related share. This adjustment must be made in a budget neutral manner and 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, as we proposed, we are not revising this policy for the CY 2013 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 2013 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

As published in the original OPPS April 7, 2000 final rule with comment period (65 FR 18545), the OPPS has consistently 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 requires a "frontier State" wage index floor of 1.00 in certain cases. For the CY 2013 OPPS, as we proposed, we are implementing this provision in the same manner as we did for CY 2012. That is, frontier State hospitals will receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, rural 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 FY 2011 and FY 2012 IPPS/LTCH PPS final rules (75 FR 50160 through 50161 and 76 FR 51586, respectively) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53369 through 53370) for a detailed discussion 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

In addition to the changes required by the Affordable Care Act, we note that the final FY 2013 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 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 2013 IPPS/LTCH PPS final rule (77 FR 53365 through 53374) for a detailed discussion of all changes to the FY 2013 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.

Section 102 of the Medicare and Medicaid Extender Act extended, through FY 2011, section 508 reclassifications as well as certain special exceptions. The most recent extension of these special wage indices was included in section 302 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112-78), as amended by section 3001 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112-96). These legislative provisions extended certain section 508 reclassifications and special exception wage indices for a 6-month period during FY 2012, from October 1, 2011 through March 31, 2012. We implemented this extension in a notice (CMS-1442-N) published in the **Federal Register** on April 20, 2012 (77 FR 23722). As

we did for CY 2010, we revised wage index values for certain special exception hospitals from January 1, 2012 through June 30, 2012, under the OPPS, in order to give these hospitals the special exception wage indices under the OPPS for the same time period as under the IPPS. In addition, because the OPPS pays on a calendar year basis, the end date under the OPPS for certain nonsection 508 and nonspecial exception providers to receive special wage indices was June 30, 2012, instead of March 31, 2012, so that these providers also received a full 6 months of payment under the revised wage index comparable to the IPPS. However, section 508 reclassifications and special exceptions have not been reauthorized since their expiration under Pub. L. 112-96 and, therefore, are no longer applicable.

For purposes of the OPPS, as we proposed, we are continuing our policy in CY 2013 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)). We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage adjustment. Table 4J listed in the FY 2013 IPPS/LTCH PPS final rule (available via the Internet on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html) identifies counties eligible for the out-migration adjustment and hospitals that will receive the adjustment for FY 2013. We note that, beginning with FY 2012, under the IPPS, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban

status and, thus, is rural for all purposes under the IPPS, including being considered rural for the 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 2013 IPPS/LTCH PPS final rule (77 FR 53371) for a more detailed discussion on the Lugar redesignation waiver for the out-migration adjustment). As we have done in prior years, we are including Table 4J from the FY 2013 IPPS/LTCH PPS final rule 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 2013 OPPS. Addendum L is available via the Internet on the CMS Web site.

In response to concerns frequently expressed by providers and other relevant parties that the current wage index system does not effectively reflect the true variation in labor costs for a large cross-section of hospitals, two studies were undertaken by the Department. First, section 3137(b) of the Affordable Care Act required the Secretary to submit to Congress a report that includes a plan to comprehensively reform the Medicare wage index applied under section 1886(d) of the Act. In developing the plan, the Secretary was directed to take into consideration the goals for reforming the wage index that were set forth by the Medicare Payment Advisory Commission (MedPAC) in its June 2007 report entitled "Report to Congress: Promoting Greater Efficiency in Medicare" and to "consult with relevant affected parties." Second, the Secretary commissioned the Institute of Medicine (IOM) to "evaluate hospital and physician geographic payment adjustments, the validity of the adjustment factors, measures and methodologies used in those factors, and sources of data used in those factors." Reports

on both of these studies for geographic adjustment to hospital payments recently have been released. For summaries of the studies, their findings, and recommendations on reforming the wage index system, we refer readers to section IX.B. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53660 through 53664).

Comment: Several commenters expressed disappointment that CMS did not set forth a proposal in the CY 2013 OPPS/ASC proposed rule to begin reform of the wage index process and simply proposed to continue adopting the IPPS fiscal year wage indexes. Several commenters encouraged CMS to expedite wage index reform to create a more equitable system that adequately pays hospitals for care provided to Medicare beneficiaries. A few commenters supported the continuation of the current wage index system; one commenter suggested that, as more comprehensive reforms continue to be developed, they encompass the goals of minimizing volatility, discouraging manipulation of the system, and limiting adverse effects on high wage area markets.

Response: In the CY 2012 OPPS/ASC proposed rule, we solicited comment on possible alternative wage index systems under the OPPS (76 FR 42212 through 42213). However, in the CY 2012 OPPS/ASC final rule with comment period, we stated our belief that maintaining the current policy of adopting the fiscal year IPPS wage index and adopting it in the OPPS on a calendar year basis would continue to be appropriate, given our longstanding use of the fiscal year IPPS wage index in the OPPS on a calendar year basis (76 FR 74192) and the broader wage index reform currently under development and consideration (76 FR 74193). In the CY 2013 OPPS/ASC proposed rule, we proposed that continuing to use 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 (77 FR 45105). As discussed above, the FY 2013 IPPS/LTCH PPS final rule contains a discussion of a MedPAC report and an IOM study focused on potential models for wage index reform (77 FR 53660 through 53664).

After consideration of the public comments we received, we are finalizing our policy to adopt the FY 2013 IPPS wage index for the CY 2013 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 2013 IPPS wage indices for calculating OPPS payments in CY 2013. 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 2013 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 2013 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). 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 2013, 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 2013 OPPS relative payment weights. Table 12 published in the proposed rule (77 FR 45106) listed the proposed CY 2013 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.

Comment: One commenter expressed concern that Florida has the lowest CCR in the United States for both rural and urban areas. The commenter suggested that the statewide average default CCRs for Florida are "significantly skewed" due to cost report information submitted by hospitals in the Miami area and recommended that CMS evaluate the data used to calculate the CCRs in order to validate this assumption.

Response: As detailed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66680 through 66682), we use only valid CCRs to calculate the default ratios. That is, we remove the CCRs for all-inclusive hospitals and CAHs, we identify and remove any obvious error CCRs, and we trim any outliers. The Florida statewide average default CCRs have been very stable over the last several years. Contrary to the

commenter's belief that we use statewide average default CCRs to estimate the costs (from charges on claims) that are used to calculate the OPPS relative weights, Medicare contractors use statewide average default CCRs to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments for hospitals with no available cost report.

After consideration of the public comment we received on our CY 2013 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 2013 OPPS relative weights. We used this methodology to calculate the statewide average default CCRs listed in Table 8 below.

For this CY 2013 OPPS/ASC final rule with comment period, approximately 62 percent of the submitted cost reports utilized in the default ratio calculations represented data for cost reporting periods ending in CY 2010, and approximately 38 percent were for cost reporting periods ending in CY 2009. 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 2012 and CY 2013 are modest and the few significant changes are associated with areas that have a small number of hospitals.

Table 8 below lists the finalized statewide average default CCRs for OPPS services furnished on or after January 1, 2013.

TABLE 8.–CY 2013 STATEWIDE AVERAGE CCRs

State	Urban/Rural	CY 2013 Default CCR	Previous Default CCR (CY 2012 OPPS Final Rule)
ALASKA	RURAL	0.489	0.487
ALASKA	URBAN	0.307	0.305
ALABAMA	RURAL	0.209	0.210
ALABAMA	URBAN	0.193	0.194
ARKANSAS	RURAL	0.219	0.221
ARKANSAS	URBAN	0.234	0.245
ARIZONA	RURAL	0.238	0.237
ARIZONA	URBAN	0.190	0.190
CALIFORNIA	RURAL	0.192	0.193
CALIFORNIA	URBAN	0.202	0.201
COLORADO	RURAL	0.331	0.342
COLORADO	URBAN	0.226	0.226
CONNECTICUT	RURAL	0.364	0.365
CONNECTICUT	URBAN	0.287	0.288
DISTRICT OF COLUMBIA	URBAN	0.302	0.302
DELAWARE	RURAL	0.282	0.280
DELAWARE	URBAN	0.353	0.347
FLORIDA	RURAL	0.182	0.182
FLORIDA	URBAN	0.167	0.164
GEORGIA	RURAL	0.237	0.238
GEORGIA	URBAN	0.214	0.214
HAWAII	RURAL	0.323	0.321

State	Urban/Rural	CY 2013 Default CCR	Previous Default CCR (CY 2012 OPPS Final Rule)
HAWAII	URBAN	0.306	0.306
IOWA	RURAL	0.296	0.296
IOWA	URBAN	0.269	0.269
IDAHO	RURAL	0.417	0.417
IDAHO	URBAN	0.357	0.353
ILLINOIS	RURAL	0.240	0.238
ILLINOIS	URBAN	0.230	0.230
INDIANA	RURAL	0.285	0.292
INDIANA	URBAN	0.256	0.262
KANSAS	RURAL	0.290	0.279
KANSAS	URBAN	0.210	0.208
KENTUCKY	RURAL	0.217	0.217
KENTUCKY	URBAN	0.241	0.239
LOUISIANA	RURAL	0.242	0.247
LOUISIANA	URBAN	0.225	0.224
MARYLAND	RURAL	0.275	0.276
MARYLAND	URBAN	0.246	0.246
MASSACHUSETTS	RURAL	0.427	0.427
MASSACHUSETTS	URBAN	0.323	0.322
MAINE	RURAL	0.445	0.438
MAINE	URBAN	0.449	0.453
MICHIGAN	RURAL	0.303	0.305
MICHIGAN	URBAN	0.303	0.305
MINNESOTA	RURAL	0.469	0.482
MINNESOTA	URBAN	0.321	0.320
MISSOURI	RURAL	0.241	0.243
MISSOURI	URBAN	0.262	0.260
MISSISSIPPI	RURAL	0.226	0.224
MISSISSIPPI	URBAN	0.182	0.189
MONTANA	RURAL	0.431	0.434
MONTANA	URBAN	0.384	0.386
NORTH CAROLINA	RURAL	0.253	0.251
NORTH CAROLINA	URBAN	0.254	0.257
NORTH DAKOTA	RURAL	0.322	0.322

State	Urban/Rural	CY 2013 Default CCR	Previous Default CCR (CY 2012 OPPS Final Rule)
NORTH DAKOTA	URBAN	0.414	0.421
NEBRASKA	RURAL	0.318	0.318
NEBRASKA	URBAN	0.254	0.252
NEW HAMPSHIRE	RURAL	0.317	0.323
NEW HAMPSHIRE	URBAN	0.292	0.291
NEW JERSEY	URBAN	0.207	0.212
NEW MEXICO	RURAL	0.256	0.264
NEW MEXICO	URBAN	0.279	0.288
NEVADA	RURAL	0.234	0.233
NEVADA	URBAN	0.162	0.167
NEW YORK	RURAL	0.420	0.419
NEW YORK	URBAN	0.369	0.356
OHIO	RURAL	0.321	0.320
OHIO	URBAN	0.237	0.234
OKLAHOMA	RURAL	0.239	0.239
OKLAHOMA	URBAN	0.212	0.217
OREGON	RURAL	0.314	0.311
OREGON	URBAN	0.335	0.328
PENNSYLVANIA	RURAL	0.267	0.270
PENNSYLVANIA	URBAN	0.200	0.199
PUERTO RICO	URBAN	0.504	0.492
RHODE ISLAND	URBAN	0.264	0.270
SOUTH CAROLINA	RURAL	0.211	0.211
SOUTH CAROLINA	URBAN	0.214	0.214
SOUTH DAKOTA	RURAL	0.307	0.307
SOUTH DAKOTA	URBAN	0.218	0.252
TENNESSEE	RURAL	0.209	0.211
TENNESSEE	URBAN	0.195	0.199
TEXAS	RURAL	0.235	0.236
TEXAS	URBAN	0.206	0.196
UTAH	RURAL	0.374	0.379
UTAH	URBAN	0.359	0.359
VIRGINIA	RURAL	0.227	0.226
VIRGINIA	URBAN	0.237	0.239

State	Urban/Rural	CY 2013 Default CCR	Previous Default CCR (CY 2012 OPPS Final Rule)
VERMONT	RURAL	0.408	0.407
VERMONT	URBAN	0.384	0.384
WASHINGTON	RURAL	0.366	0.368
WASHINGTON	URBAN	0.301	0.298
WISCONSIN	RURAL	0.345	0.351
WISCONSIN	URBAN	0.307	0.311
WEST VIRGINIA	RURAL	0.277	0.280
WEST VIRGINIA	URBAN	0.338	0.337
WYOMING	RURAL	0.379	0.386
WYOMING	URBAN	0.301	0.302

E. OPPS Payments to Certain Rural and Other Hospitals

1. Hold Harmless Transitional Payment Changes

The OPPS was implemented in CY 2000 under the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33). The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113) made major changes in the hospital OPPS, including adding a new paragraph (7) to section 1833(t) of the Act, effective as if included in the enactment of the BBA. Section 1833(t)(7) of the Act sets forth that every provider was eligible to receive an additional payment adjustment (called either transitional corridor payments or transitional outpatient payments (TOPs)) if the payments it received for covered OPD services under the OPPS were less than the payments it would have received for the same services under the prior reasonable cost-based system (referred to as the pre-BBA amount), and that the TOPs were temporary payments for most providers and intended to ease their transition from the prior

reasonable cost-based payment system to the OPPS system. There are two types of hospitals excepted from the policy described above, cancer hospitals and children's hospitals. Specifically, such a hospital could receive TOPs to the extent its PPS amount was less than its pre-BBA amount in the applicable year. Section 1833(t)(7)(D)(i) of the Act originally provided for TOPs to all hospitals for covered OPD services furnished before January 1, 2004. However, section 411 of Pub. L. 108-173 (the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) amended section 1833(t)(7)(D)(i) of the Act to extend these payments through December 31, 2005, for rural hospitals with 100 or fewer beds. Section 411 also extended the TOPs to sole community hospitals (SCHs) located in rural areas for services furnished during the period that began with the provider's first cost reporting period beginning on or after January 1, 2004, and ending on December 31, 2005. Accordingly, the authority for making TOPs under section 1833(t)(7)(D)(i) of the Act, as amended by section 411 of Pub. L. 108-173, for rural hospitals having 100 or fewer beds and SCHs located in rural areas expired on December 31, 2005.

Section 5105 of Pub. L. 109-171 (the Deficit Reduction Act of 2005) extended the TOPs for covered OPD services furnished on or after January 1, 2006, and before January 1, 2009, for rural hospitals having 100 or fewer beds that are not SCHs. Section 5105 of Pub. L. 109-171 also reduced the TOPs to rural hospitals from 100 percent of the difference between the provider's OPPS payments and the pre-BBA amount. This provision provided that, in cases in which the OPPS payment was less than the provider's pre-BBA amount, the amount of payment would be increased by 95 percent of the

amount of the difference between the two amounts for CY 2006, by 90 percent of the amount of that difference for CY 2007, and by 85 percent of the amount of that difference for CY 2008.

For CY 2006, we implemented section 5105 of Pub. L. 109-171 through Transmittal 877, issued on February 24, 2006. In Transmittal 877, we did not specifically address whether TOPs applied to essential access community hospitals (EACHs), which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act. Accordingly, by law, EACHs are treated as SCHs. In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010), we stated that EACHs were not eligible for TOPs under Pub. L. 109-171. However, we stated they were eligible for the adjustment for rural SCHs authorized under section 411 of Pub. L. 108-173. In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68228), we updated § 419.70(d) of our regulations to reflect the requirements of Pub. L. 109-171.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41461), we stated that, effective for services provided on or after January 1, 2009, rural hospitals with 100 or fewer beds that are not SCHs would no longer be eligible for TOPs, in accordance with section 5105 of Pub. L. 109-171. However, subsequent to issuance of the CY 2009 OPPS/ASC proposed rule, section 147 of Pub. L. 110-275 (the Medicare Improvements for Patients and Providers Act of 2008) amended section 1833(t)(7)(D)(i) of the Act by extending the period of TOPs to rural hospitals with 100 beds or fewer for 1 year, for services provided before January 1, 2010. Section 147 of Pub. L. 110-275 also extended TOPs to SCHs (including EACHs) with 100 or fewer beds for covered OPD services provided on or

after January 1, 2009, and before January 1, 2010. In accordance with section 147 of Pub. L. 110-275, when the OPPS payment is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payment amounts for CY 2009.

For CY 2009, we revised our regulations at §§ 419.70(d)(2) and (d)(4) and added paragraph (d)(5) to incorporate the provisions of section 147 of Pub. L. 110-275. In addition, we made other technical changes to § 419.70(d)(2) to more precisely capture our existing policy and to correct an inaccurate cross-reference. We also made technical corrections to the cross-references in paragraphs (e), (g), and (i) of § 419.70.

For CY 2010, we made a technical correction to the heading of § 419.70(d)(5) to correctly identify the policy as described in the subsequent regulation text. The paragraph heading now indicates that the adjustment applies to small SCHs, rather than to rural SCHs.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60425), we stated that, effective for services provided on or after January 1, 2010, rural hospitals and SCHs (including EACHs) having 100 or fewer beds would no longer be eligible for TOPs, in accordance with section 147 of Pub. L. 110-275. However, subsequent to the issuance of the CY 2010 OPPS/ASC final rule with comment period, section 3121(a) of the Affordable Care Act (Pub. L. 111-148) amended section 1833(t)(7)(D)(i)(III) of the Act by extending the period of TOPs to rural hospitals that are not SCHs with 100 beds or fewer for 1 year, for services provided before January 1, 2011. Section 3121(a) of the Affordable Care Act amended section 1833(t)(7)(D)(i)(III) of the Act and extended the

period of TOPs to SCHs (including EACHs) for 1 year, for services provided before January 1, 2011, and section 3121(b) of the Affordable Care Act removed the 100-bed limitation applicable to such SCHs for covered OPD services furnished on or after January 1, 2010, and before January 1, 2011. In accordance with section 3121 of the Affordable Care Act, when the OPPS payment is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payment amounts for CY 2010. Accordingly, in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71882), we updated § 419.70(d) of the regulations to reflect the self-implementing TOPs extensions and amendments described in section 3121 of the Affordable Care Act.

Section 108 of the Medicare and Medicaid Extenders Act of 2010 (MMEA) (Pub. L. 111-309) extended for 1 year the hold harmless provision for a rural hospital with 100 or fewer beds that is not an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act). Therefore, for such a hospital, for services furnished before January 1, 2012, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment to the hospital is increased by 85 percent of the amount of the difference between the two payments. In addition, section 108 of the MMEA also extended for 1 year the hold harmless provision for an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act (including EACHs) and the removal of the 100-bed limit applicable to such SCHs for covered OPD services furnished on or after January 1, 2010, and before January 1, 2012. Therefore, for such hospitals, for services furnished before January 1, 2012, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment to the

hospital is increased by 85 percent of the amount of the difference between the two payments. Effective for services provided on or after January 1, 2012, a rural hospital with 100 or fewer beds that is not an SCH and an SCH (including EACHs) are no longer eligible for TOPs, in accordance with section 108 of the MMEA. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74199), we revised our regulations § 419.70(d) to conform the regulation text to the self-implementing provisions of section 108 of the MMEA described above.

Subsequent to the issuance of the CY 2012 OPPS/ASC final rule with comment period, section 308 of the Temporary Payroll Tax Cut Continuation Act of CY 2011 (Pub. L. 112-78), as amended by section 3002 of the Middle Class Tax Relief and Jobs Creation Act (Pub. L. 112-96), extended through December 31, 2012, the hold harmless provision for a rural hospital with 100 or fewer beds that is not an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act). Therefore, for such a hospital, for services furnished before January 1, 2013, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payments.

Section 308 of Pub. L. 112-78 also extended through February 29, 2012, the hold harmless provision for an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act), including an EACH, without the bed size limitation. Therefore, for such hospitals, for services furnished before March 1, 2012, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payments. However, section 3002 of Pub. L. 112-96

extended through December 31, 2012, the hold harmless provision for an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act), including an EACH, that has no more than 100 beds. Therefore, for such hospitals, for services furnished before January 1, 2013, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payments. Accordingly, as we proposed in the CY 2013 OPPS/ASC proposed rule (77 FR 45108), we are revising § 419.70(d) of the regulations to reflect the TOPs extensions and amendments described in section 308 of Pub. L. 112-78 and section 3002 of Pub. L. 112-96.

Effective for services provided on or after March 1, 2012, SCHs (including EACHs) with greater than 100 beds are no longer eligible for TOPs, in accordance with section 308 of Pub. L. 112-78. Effective for services provided on or after January 1, 2013, a rural hospital with 100 or fewer beds that is not an SCH and an SCH (including an EACH) are no longer eligible for TOPs, in accordance with section 3002 of Pub. L. 112-96.

2. 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 Pub. L. 108-173. Section 411 gave the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective

January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In 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 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised § 419.43(g) to clarify that EACHs are also 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 Pub. L. 105-33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2012. Further, in the CY 2009

OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45109), we proposed to continue for CY 2013 our policy of a budget neutral 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. We indicated in the proposed rule that we intend to reassess the 7.1 percent adjustment in the future by examining differences between urban hospitals' costs and rural hospitals' costs using updated claims data, cost reports, and provider information.

Comment: Several commenters expressed support for the proposed continuation of the 7.1 percent rural SCH adjustment. A few commenters also suggested that the rural SCH adjustment also apply to urban SCHs. One commenter suggested that the 7.1 percent payment adjustment also be applied to MDHs, given that their inpatient classification was set to expire in October 2012.

Response: We agree that it is appropriate to continue the 7.1 percent adjustment for rural SCHs (including EACHs) as we proposed for CY 2013. We note that the rural SCH adjustment was developed under the authority described in section 1833(t)(13) of the Act, which applies specifically to rural hospitals. Although commenters have suggested that the rural SCH adjustment also apply to urban SCHs, the study authorized

under section 1833(t)(13)(A) of the Act specifically focuses on APC costs incurred by rural hospitals, as they exceed those costs incurred by hospitals in urban areas. Moreover, the Secretary's authority to make an adjustment based on that study was with respect to a determination that costs incurred by rural hospitals exceed those costs incurred by urban hospitals and to reflect those higher costs. Therefore, the authority to make any such adjustment was limited to reflect the higher costs incurred by such applicable rural hospitals. Although the MDH classification is currently set to expire, we note that the definition of a MDH at 1886(d)(5)(G)(iv)(III) of the Act specifically excludes sole community hospitals, to which the rural adjustment applies. Further, as we discussed in the CY 2006 OPPS final rule, our analysis of urban SCHs as well as rural MDHs did not support the application of a rural adjustment (70 FR 68560 through 68561).

After consideration of the public comments we received, we are finalizing our CY 2013 proposal, without modification, to apply the 7.1 percent payment adjustment to rural SCHs, including EACHs, for all services and procedures paid under the OPPS in CY 2013, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. We continue to believe that the adjustment is appropriate for application in CY 2013.

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

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA), Medicare has paid cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act (cancer hospitals) under the OPPS 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. These 11 cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999, Congress created section 1833(t)(7) of the Act, "Transitional Adjustment to Limit Decline in Payment," to serve as a permanent payment floor by limiting cancer hospitals' potential losses under the OPPS. Through section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a "pre-BBA" amount. That is, cancer hospitals are permanently held harmless to their "pre-BBA" amount, and they receive TOPs to ensure that they do not receive a payment that is lower under the OPPS than the payment they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The "pre-BBA" payment 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. 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 amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed the costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. In addition, section 3138 of the Affordable Care 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 3138 of the Affordable Care Act provides that if the Secretary determines that cancer hospitals' costs 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 3138, we determined in 2012 that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on our findings that costs incurred by cancer hospitals were greater than the costs incurred by other OPPS 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 CY 2012, the target PCR for purposes of the cancer hospital payment adjustment is 0.91.

2. Payment Adjustment for Certain Cancer Hospitals for CY 2013

In the CY 2013 OPPS/ASC proposed rule (77 FR 45110), 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 proposed rule. To calculate the proposed CY 2013 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 2013 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 91 percent of reasonable cost (weighted average PCR of 0.91). Based on these data, we proposed a target PCR of 0.91 that would be used to determine the CY 2013 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 0.91 for each cancer hospital.

Comment: Some commenters suggested 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 indicate would result in a target PCR equal to 0.94 for CY 2013.

Response: 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), 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: 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, it is unlikely that the target PCR (the weighted average PCR for the other OPPS hospitals) would fluctuate significantly from year to year. The target PCR is 0.91 for purposes of the CY 2012 cancer hospital payment adjustment and remained at 0.91 when recalculated for the CY 2013 OPPS/ASC proposed rule and this final rule with comment period. In addition to the apparent stability of the target PCR, 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.

Comment: Commenters stated that CMS must make the cancer hospital payment adjustment effective for services furnished on or after January 1, 2011, in order to comply with section 3138 of the Affordable Care Act.

Response: As explained in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71886 through 71887), we did not finalize the proposed cancer hospital adjustment for CY 2011 for a variety of reasons, including, ultimately, a determination that further study and deliberation of the issues were necessary. The obligation to provide a cancer hospital payment adjustment is triggered only insofar as the Secretary determines under section 1833(t)(18)(A) of the Act that costs incurred by hospitals described in section 1886(d)(1)(B)(v) of the Act exceed those costs incurred by other hospitals furnishing services under that subsection. Several commenters on the CY 2011 OPPS/ASC proposed rule raised concerns about the agency's study of costliness conducted under section 1833(t)(18)(A) of the Act; for example, one commenter suggested that the CMS analysis was inadequate to conclude that costs are higher in cancer hospitals and that an adjustment was warranted. Given the uncertainty surrounding these issues, public comments arguing against implementing a cancer hospital payment adjustment for CY 2011, and our determination that further study and deliberation were necessary, we decided to not finalize a cancer hospital payment adjustment for CY 2011. We note that, because the cancer hospital payment adjustment is budget neutral, the lack of a cancer hospital payment adjustment for CY 2011 also meant that other payments were not reduced for CY 2011 to offset the increased payments from the adjustment.

Comment: One commenter noted that, although CMS indicated the estimated percent by which each cancer hospital's OPPS payments would be increased under the cancer hospital payment adjustment policy in the CY 2012 OPPS/ASC proposed and final rules, CMS did not include this information in the CY 2013 OPPS/ASC proposed rule. The commenter requested that CMS include this information in the CY 2013 OPPS/ASC final rule with comment period.

Response: We agree with the commenter that it would be informative to provide the estimated percentage increase in CY 2013 OPPS payments to each cancer hospital due to the cancer hospital payment adjustment policy. Therefore, we are including that information in the last column of Table 9 below.

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 2013 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 2013 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 2011 claims data that we used to model the impact of the final CY 2013 APC relative weights (4,026 hospitals) because it is appropriate to use the same set of hospitals that we

are using to calibrate the modeled CY 2013 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2010 to 2011. 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 182 hospitals because the 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 3,796 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 91 percent of reasonable cost (weighted average PCR of 0.91). Based on these data, we will use a target PCR of 0.91 to determine the CY 2013 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 0.91 for each cancer hospital.

Table 9 below indicates the estimated percentage increase in OPPS payments to each cancer hospital for CY 2013 due to the cancer hospital payment adjustment policy. The actual amount of the CY 2013 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's

CY 2013 payments and costs. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 9.—ESTIMATED CY 2013 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS (WITHOUT REGARD TO TOPS) TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2013
050146	City of Hope Helford Clinical Research Hospital	15.8%
050660	USC Kenneth Norris Jr. Cancer Hospital	32.8%
100079	University of Miami Hospital & Clinic	28.2%
100271	H. Lee Moffitt Cancer Center & Research Institute	21.2%
220162	Dana-Farber Cancer Institute	44.9%
330154	Memorial Hospital for Cancer and Allied Diseases	39.5%
330354	Roswell Park Cancer Institute	30.7%
360242	James Cancer Hospital & Solove Research Institute	33.7%
390196	Hospital of the Fox Chase Cancer Center	10.0%
450076	University of Texas M. D. Anderson Cancer Center	42.0%
500138	Seattle Cancer Care Alliance	44.7%

G. Hospital Outpatient Outlier Payments

1. Background

Currently, the OPPS provides outlier payments on a service-by-service basis. In CY 2011, 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 2011 OPPS payment, using available CY 2011 claims and the revised OPPS expenditure estimate for the 2012 Trustee's Report, is approximately 1.2 percent of the total aggregated OPPS payments. Therefore, for CY 2011, we estimate that we paid 0.2 percent above the CY 2011 outlier target of 1.0 percent of total aggregated OPPS payments.

As explained in the CY 2012 OPPS/ASC final rule with comment period (77 FR 74207 through 74209), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for CY 2012. The outlier thresholds were set so that estimated CY 2012 aggregate outlier payments would equal 1.0 percent of the total estimated aggregate payments under the OPPS. Using CY 2011 claims data and CY 2012 payment rates, we currently estimate that the

aggregate outlier payments for CY 2012 will be approximately 0.9 percent of the total CY 2012 OPPS payments. The difference between 1.0 percent and 0.9 percent is reflected in the regulatory impact analysis in section XXII. of this final rule with comment period. We note that we provide estimated CY 2013 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 2013 OPPS/ASC proposed rule (77 FR 45110), we proposed to continue for CY 2013 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 0.12 percent of outlier payments (or 0.0012 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.C. of the CY 2013 OPPS/ASC proposed rule, for CMHCs, we proposed to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) or APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs), exceeds 3.40 times the payment rate for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost

exceeds 3.40 times the APC 0173 payment rate. For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of this final rule with comment period.

To ensure that the estimated CY 2013 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 $2,400 fixed-dollar threshold.

We proposed to calculate the fixed-dollar threshold using largely the same methodology as we did in CYs 2011 and 2012 (75 FR 71887 through 71889 and 76 FR 74207 through 74209). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2012 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 2013 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2011 claims using the same inflation factor of 1.1406 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28142). We used an inflation factor of 1.0680 to estimate CY 2012 charges from the CY 2011 charges reported on CY 2011 claims. The methodology for determining this charge inflation factor is discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28142). As we stated in the CY 2005 OPPS final

rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors are appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we proposed in the CY 2013 OPPS/ASC proposed rule to apply the same CCR inflation adjustment factor that we applied for the FY 2013 IPPS outlier calculation to the CCRs used to simulate the CY 2013 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2013, we proposed to apply an adjustment factor of 0.9790 to the CCRs that were in the April 2012 OPSF to trend them forward from CY 2012 to CY 2013. The methodology for calculating this proposed adjustment was discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28142 through 28144). We note that, due to the issue described in the IPPS proposed rule correction notice published on June 11, 2012, the operating and capital CCR inflation factors were reversed (77 FR 34326). In estimating the proposed CY 2013 OPPS fixed-dollar outlier threshold, we applied the corrected CCR inflation factor.

Therefore, to model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2012 OPSF file after adjustment (using the proposed CCR inflation adjustment factor of 0.9790 to approximate CY 2013 CCRs) to charges on CY 2011 claims that were adjusted (using the charge inflation factor of 1.1406 to

approximate CY 2013 charges). We simulated aggregated CY 2013 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 2013 OPPS payments. We estimated that a proposed fixed-dollar threshold of $2,400, combined with the 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 $2,400 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 XV. of this final rule with comment period.

Comment*:* Several commenters expressed concern with respect to the relative increase in the proposed CY 2013 OPPS fixed-dollar outlier threshold of $2,400. The commenters believed that the increase in the fixed-dollar threshold would bring about a drastic reduction in outlier payments as well as the ability to furnish services to beneficiaries. Commenters also suggested CMS to reconsider the fixed-dollar threshold value, confirm that the data used to develop the threshold were accurate, and provide data to support the increase in the threshold. Commenters also suggested alternative fixed-dollar threshold setting methodologies such as a 3-year transition to the threshold or a calculation based on prior year estimated percent OPPS outlier spending.

Response*:* As indicated above, we introduced a fixed-dollar 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. We maintain the target outlier percentage of 1.0 percent of estimated aggregate total payment under the OPPS and have a fixed-dollar threshold so that OPPS outlier payments are made only

when the hospital would experience a significant loss for supplying a particular service. While commenters have expressed concern based on the assumption that OPPS outlier payments made under an increased fixed-dollar threshold would decrease, we note that the threshold may increase or decrease from year to year, to maintain the 1.0 percent outlier spending target. While we described issues related to the charge and CCR inflation factors in the CY 2013 OPPS/ASC proposed rule, there were no other errors in the methodology (77 FR 45111). The methodology for determining the OPPS fixed-dollar threshold is described in this section, the LDS files used to model the threshold that are available for public purchase, and a detailed claims accounting document that is available online, which all support the determination of the fixed-dollar threshold. We do not believe that a transitional methodology to determine the outlier threshold or a methodology that takes into account prior spending is appropriate because the relationship between a hospital's costs and the APC payment rates changes each year.

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 2013, we are applying the overall CCRs from the July 2012 OPSF with a CCR adjustment factor of 0.9880 to approximate CY 2013 CCRs to charges on the final CY 2011 claims that were adjusted to approximate CY 2013 charges (using the final 2-year charge inflation factor of 1.0894). These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed-dollar threshold for the FY 2013 IPPS/LTCH PPS final rule (77 FR 53695 through 53696). We simulated aggregated CY 2013 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 2013 OPPS payments. We estimate that a fixed-dollar threshold of $2,025, 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 2013, 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 $2,025 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 0.12 percent of outlier payments to CMHCs for PHP outlier payments.

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 CFR 68599), we adopted as final policy a process to reconcile hospital or CMHC outlier payments at cost report settlement for services furnished during cost reporting periods beginning in CY 2009. OPPS outlier reconciliation more fully ensures accurate outlier payments for those facilities that have CCRs that fluctuate significantly relative to the CCRs of other

facilities, and that receive a significant amount of outlier payments (73 FR 68598). As under the IPPS, we do not adjust the fixed-dollar threshold or the amount of total OPPS payments set aside for outlier payments for reconciliation activity because such action would be contrary to the prospective nature of the system. Our outlier threshold calculation assumes that overall ancillary CCRs accurately estimate hospital costs based on the information available to us at the time we set the prospective fixed-dollar outlier threshold. For these reasons, and as we have previously discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68596), and as we proposed for CY 2013, we are not incorporating any assumptions about the effects of reconciliation into our calculation of the OPPS fixed-dollar outlier threshold in this final rule with comment period.

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 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 2013 scaled weight for the APC by the CY 2013 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 XV. 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 did not receive any public comments on the proposed calculation of an adjusted Medicare payment. Therefore, we are finalizing the calculation of an adjusted Medicare payment, where appropriate, in the manner described as follows. Individual providers interested in calculating the payment amount that they will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site) should follow the formulas presented in the following steps. For purposes of

the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the "full" national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the "reduced" national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.980 times the "full" national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements in order to receive the full CY 2013 OPPS fee schedule increase factor of 1.8 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. We confirmed that this labor-related share for hospital 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).

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

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

X = .60 * (national unadjusted payment rate)

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. 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 2013 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. We note that the reclassifications of hospitals under section 508 of Pub. L. 108-173, as extended by sections 3137 and 10317 of the Affordable Care Act, expired on September 30, 2010. Section 102 of the Medicare and Medicaid Extenders Act of 2010 extended section 508 and certain additional special exception hospital reclassifications from October 1, 2010 through September 30, 2011. Section 302 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112-78) as amended by section 3001 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112-96) extended section 508 and certain additional special exception hospital reclassifications from October 1, 2011 through March 31, 2012. Therefore, these reclassifications will not apply to the CY 2013 OPPS. (For further discussion of the changes to the FY 2013 IPPS wage indices, as applied to the CY 2013 OPPS, we refer readers to section II.C. of this final rule with comment period). We proposed to continue to apply a wage index floor of 1.00 to frontier States, in accordance with section 10324 of the Affordable Care Act.

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 2013 IPPS and listed as Table 4J in the FY 2013 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 * (national unadjusted payment rate) * applicable wage index.

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

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

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

Y = .40 * (national unadjusted payment rate)

Adjusted Medicare Payment = $Y + X_a$

Step 6. If a provider is an SCH, 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 2013 full national unadjusted payment rate for APC 0019 is $336.38. The reduced national unadjusted payment rate for a hospital that fails to meet the Hospital OQR

Program requirements is $329.65. This reduced rate is calculated by multiplying the reporting ratio of 0.980 by the full unadjusted payment rate for APC 0019.

The FY 2013 wage index for a provider located in CBSA 35644 in New York is 1.2971. The labor-related portion of the full national unadjusted payment is $261.79 (.60 * $336.38 * 1.2971). The labor-related portion of the reduced national unadjusted payment is $256.55 (.60 * $329.65 * 1.2971). The nonlabor-related portion of the full national unadjusted payment is $134.55 (.40 * $336.38). The nonlabor-related portion of the reduced national unadjusted payment is $131.86 (.40 * $329.65). The sum of the labor-related and nonlabor-related portions of the full national adjusted payment is $396.34 ($261.79 + $134.55). The sum of the reduced national adjusted payment is $388.41 ($256.55 + $131.86).

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 to the amount of the inpatient deductible.

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

2. OPPS Copayment Policy

In the CY 2013 OPPS/ASC proposed rule (77 FR 45113), we proposed to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we proposed to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with

comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The national unadjusted copayment amounts for services payable under the OPPS that will be effective January 1, 2013, 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). As discussed in section XV. of this final rule with comment period, for CY 2013, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies equals the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that APC copayments may increase or decrease each year based on changes in the calculated APC payment rates due to updated cost report and claims data, and any changes to the OPPS cost modeling process. The CY 2013 proposed policy to base APC relative weights on geometric mean costs would also affect the APC payment rates and, through them, the corresponding beneficiary copayments. However, as described in the CY 2004 OPPS/ASC final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459). For a more detailed discussion of the final policy to base the APC relative payment weights on geometric mean costs, we refer readers to section II.A.2.f. of this final rule with comment period.

We did not receive any public comments regarding the proposed methodology for calculating copayments for CY 2013. Therefore, for the reasons set forth in the proposed

rule (77 FR 45113), we are finalizing our CY 2013 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, $67.28 is 20 percent of the full national unadjusted payment rate of $336.38. For APCs with only a minimum unadjusted copayment in Addenda A and B of 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 national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

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

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

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

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

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

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

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

The unadjusted copayments for services payable under the OPPS that will be effective January 1, 2013, 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 2013 OPD fee schedule increase factor discussed in section II.B. of this final rule with comment period.

Also, as noted above, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected to the amount of the inpatient deductible.

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 2013 OPPS/ASC proposed (77 FR 45114), in Table 10 below (Table 13 of the proposed rule), we summarize 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 2012 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 2012 OPPS quarterly update were included in Addendum B. Nevertheless, we requested public comments on the codes included in the July 2012 OPPS quarterly update and included these codes in the preamble of the proposed rule.

TABLE 10.—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April l, 2012	Level II HCPCS Codes	April 1, 2012	CY 2013 OPPS/ASC proposed rule	CY 2013 OPPS/ASC final rule with comment period
July 1, 2012	Level II HCPCS Codes	July 1, 2012	CY 2013 OPPS/ASC proposed rule	CY 2013 OPPS/ASC final rule with comment period
	Category I (certain vaccine	July 1, 2012	CY 2013 OPPS/ASC	CY 2013 OPPS/ASC final

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
	codes) and III CPT codes		proposed rule	rule with comment period
October 1, 2012	Level II HCPCS Codes	October 1, 2012	CY 2013 OPPS/ASC final rule with comment period	CY 2014 OPPS/ASC final rule with comment period
January 1, 2013	Level II HCPCS Codes	January 1, 2013	CY 2013 OPPS/ASC final rule with comment period	CY 2014 OPPS/ASC final rule with comment period
	Category I and III CPT Codes	January 1, 2013	CY 2013 OPPS/ASC final rule with comment period	CY 2014 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 2013 OPPS/ASC proposed rule or whether we are soliciting public comments in this CY 2013 OPPS/ASC final rule with comment period. We note that we sought public comments in the CY 2012 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2012. We also sought public comments in the CY 2012 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2011. These new codes, with an effective date of October 1, 2011, or January 1, 2012, 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 2012 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 2012 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 2013 OPPS/ASC final rule with comment period.

We received comments on several new codes that were assigned to comment indicator "NI" in Addendum B of the CY 2012 OPPS/ASC final rule with comment period. We respond to those comments in sections II.A., III.D., V.B., and IX of this final rule with comment period. Table 11 below lists the long descriptors for the CPT codes that were assigned to comment indicator "NI" for which we received public comments to the CY 2012 OPPS/ASC final rule with comment period and the specific sections where the comments are addressed.

TABLE 11.—COMMENTS TO THE CY 2012 OPPS/ASC FINAL RULE WITH COMMENT PERIOD ON NEW HCPCS CODES ASSIGNED TO COMMENT INDICATOR "NI"

CY 2012 CPT Code	CY 2012 Long Descriptor	Section In This CY 2013 OPPS/ASC Final Rule With Comment Period Where Comments Are Addressed
0278T	Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes)	III.D.4.a. (Scrambler Therapy)
0293T	Insertion of left atrial hemodynamic monitor; complete system, includes implanted communication module and pressure sensor lead in left atrium including transseptal access, radiological supervision and interpretation, and associated injection procedures, when performed	IX. (Inpatient Procedures)
0294T	Insertion of left atrial hemodynamic monitor;	

CY 2012 CPT Code	CY 2012 Long Descriptor	Section In This CY 2013 OPPS/ASC Final Rule With Comment Period Where Comments Are Addressed
	pressure sensor lead at time of insertion of pacing cardioverter-defibrillator pulse generator including radiological supervision and interpretation and associated injection procedures, when performed (list separately in addition to primary procedure)	
0296T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; recording (includes connection and initial recording)	III.D.1.e. (External Electrocardiographic Monitoring)
0297T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; scanning analysis with report	
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	III.D.3.a. (Extracorporeal Shock Wave Wound Treatment)
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)	
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)	
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)	
15276	Application of skin substitute graft to face, scalp,	

CY 2012 CPT Code	CY 2012 Long Descriptor	Section In This CY 2013 OPPS/ASC Final Rule With Comment Period Where Comments Are Addressed
	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)	III.D.3.b. (Application of Skin Substitute)
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)	
15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (eg, breast, trunk) (list separately in addition to code for primary procedure)	II.A.3. (Changes to Packaged Services)
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or ct); cervical or thoracic, single facet joint	III.D.4.c. (Paravertebral Neurolytic Agent)
62369	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill	III.D.4.d. (Programmable Implantable Pump)
62370	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring physician's skill)	
77424	Intraoperative radiation treatment delivery, x-ray, single treatment session	III.D.6.e. (Intraoperative Radiation

CY 2012 CPT Code	CY 2012 Long Descriptor	Section In This CY 2013 OPPS/ASC Final Rule With Comment Period Where Comments Are Addressed
77425	Intraoperative radiation treatment delivery, electrons, single treatment session	Therapy)
81200-81383	Tier I Molecular Pathology Procedures	III.D.9.a. (Molecular Pathology Procedures)
81400-81408	Tier 2 Molecular Pathology Procedures	
J9179	Injection, eribulin mesylate, 0.1 mg	V.A. (OPPS Transitional Pass-through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals)
Q4128	Flexhd or allopatch hd, per square centimeter	V.B. (OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status)

1. Treatment of New CY 2012 Level II HCPCS and CPT Codes Effective April 1, 2012 and July 1, 2012 for Which We Solicited Public Comments in the CY 2013 OPPS/ASC Proposed Rule

Through the April 2012 OPPS quarterly update CR (Transmittal 2418, Change Request 7748, dated March 2, 2012) and the July 2012 OPPS quarterly update CR (Transmittal 2483, Change Request 7847, dated June 8, 2012), we recognized several new HCPCS codes for separate payment under the OPPS. Effective April 1 and July 1 of CY 2012, we made effective 13 new Level II HCPCS codes and 7 Category III CPT

codes. Specifically, 5 new Level II HCPCS codes were effective for the April 2012 update and another 8 new Level II HCPCS codes were effective for the July 2012 update for a total of 13. Seven new Category III CPT codes were effective for the July 2012 update. Of the 13 new Level II HCPCS codes, we recognized for separate payment 11 of these codes, and of the 7 new Category III CPT codes, we recognized for separate payment all 7 new Category III CPT codes, for a total of 18 new Level II HCPCS and Category III CPT codes that are recognized for separate payment for CY 2013.

Through the April 2012 OPPS quarterly update CR, we allowed separate payment for each of the five new Level II HCPCS codes. Specifically, as displayed in Table 12 below, we provided separate payment for HCPCS codes C9288, C9289, C9290, C9291 and C9733.

TABLE 12.— NEW LEVEL II HCPCS CODES IMPLEMENTED IN APRIL 2012

CY 2012 HCPCS Code	CY 2012 Long Descriptor	April 2012 Status Indicator	April 2012 APC
C9288	Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial	G	9288
C9289	Injection, asparaginase Erwinia chrysanthemi, 1,000 international units (I.U.)	G	9289
C9290	Injection, bupivacaine liposome, 1 mg	G	9290
C9291*	Injection, aflibercept, 2 mg vial	G	9291
C9733	Non-ophthalmic fluorescent vascular angiography	Q2	0397

*Level II HCPCS code C9291 (Injection, aflibercept, 2 mg vial) was deleted June 30, 2012, and replaced with HCPCS code Q2046 (Injection, aflibercept, 1 mg) effective July 1, 2012.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45115), we solicited public comments on the proposed status indicators and APC assignments for Level II HCPCS

codes C9288, C9289, C9290, C9291, and C9733, which were listed in Table14 of the proposed rule (77 FR 45115) and now appear in Tables 12 and 13 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 C9288, C9289, C9290, and C9291. However, we received several public comments on HCPCS code C9733, which are addressed in section III.D.7.a. of this final rule with comment period.

For CY 2013, the HCPCS Workgroup replaced HCPCS codes C9288, C9289, and C9291 (which was replaced with HCPCS code Q2046, effective July 1, 2012) with permanent HCPCS J-codes. Table 13 below list 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 OPPS in order to streamline coding, we are showing the replacement HCPCS codes C9288, C9289, and C9291/Q2046, effective January 1, 2013, in Table 13.

In this final rule with comment period, we are assigning the Level II HCPCS codes listed in Table 13 below to the specific APCs and status indicators for CY 2013.

TABLE 13.—FINAL CY 2013 STATUS INDICATOR AND APC ASSIGNMENTS FOR THE LEVEL II HCPCS CODES THAT WERE NEWLY IMPLEMENTED IN APRIL 2012

CY 2012 HCPCS Code	CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 Status Indicator	Final CY 2013 APC
C9288	J0716	Injection, centruroides immune f(ab)2, up to 120 milligrams	G	1431

CY 2012 HCPCS Code	CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 Status Indicator	Final CY 2013 APC
C9289	J9019	Injection, asparaginase (Erwinaze), 1,000 IU	G	9289
C9290	C9290	Injection, bupivacaine liposome, 1 mg	G	9290
C9291 / Q2046	J0178	Injection, aflibercept, 1 mg	G	1420
C9733	C9733	Non-ophthalmic fluorescent vascular angiography	Q2	0397

For CY 2013, we note that we are not making any changes to the status indicators and APC assignments for HCPCS code C9290 and C9733. That is, HCPCS code C9290 will continue its pass-through status and will also continue to be assigned to APC 9290 for CY 2013. Similarly, HCPCS code C9733 will continue to be assigned to status indicator "Q2" and also will continue to be assigned to APC 0397 for CY 2013.

Furthermore, because HCPCS code J9019 describes the same drug and the same dosage currently designated by HCPCS code C9289, this drug will continue its pass-through status in CY 2013. Therefore, we are assigning HCPCS code J9019 to the same status indicator and APC as its predecessor HCPCS code, as shown in Table 13.

However, we note that the replacement code for HCPCS code C9291, which was replaced with HCPCS code Q2046 effective July 1, 2012, did not describe the same dosage descriptor, and consequently, the replacement HCPCS code was assigned a new APC number. Specifically, HCPCS code Q2046, which has a dosage descriptor of 1 mg, was assigned to APC 1420 effective July 1, 2012. Because the predecessor HCPCS code

C9291 was assigned to pass-through status, HCPCS code Q2046 also was assigned to pass-through status for CY 2013. Similarly, the replacement code for HCPCS code C9288 does not describe the same dosage descriptor, and, consequently, its replacement HCPCS code J0716 was assigned a new APC. Specifically, HCPCS code C9288 has a dosage descriptor of 1 vial; however, its replacement HCPCS code J0716 has a dosage descriptor of "up to 120 milligrams." Therefore, effective January 1, 2013, HCPCS codes J0716 is assigned to APC 1431, a different APC, to maintain data consistency for future rulemaking. Because the predecessor HCPCS code C9288 was assigned to pass-through status, HCPCS code J0716 will continue to be assigned status indicator "G" for CY 2013.

As discussed in the CY 2013 OPPS/ASC proposed rule (77 FR 45115 through 45116), through the July 2012 OPPS quarterly update CR, which included HCPCS codes that were made effective July 1, 2012, we allowed separate payment for 6 of the 8 new Level II HCPCS codes. Specifically, as displayed in Table 14 below (also Table 14 of the proposed rule), we provided separate OPPS payment for HCPCS codes C9368, C9369, Q2045, Q2046, Q2048, and Q2049.

TABLE 14.—NEW LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2012

CY 2012 HCPCS Code	CY 2012 Long Descriptor	July 2012 Status Indicator	July 2012 APC
C9368	Grafix core, per square centimeter	G	9368
C9369	Grafix prime, per square centimeter	G	9369
Q2034	Influenza virus vaccine, split virus, for intramuscular use (Agriflu)	L	N/A
Q2045*	Injection, human fibrinogen concentrate, 1 mg	K	1414
Q2046**	Injection, aflibercept, 1 mg	G	1420

CY 2012 HCPCS Code	CY 2012 Long Descriptor	July 2012 Status Indicator	July 2012 APC
Q2047	Injection, peginesatide, 0.1 mg (for ESRD on dialysis)	A	N/A
Q2048***	Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg	K	7046
Q2049	Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg	K	1421

*HCPCS code Q2045 replaced HCPCS code J1680 effective July 1, 2012. The status indicator for HCPCS code J1680 was changed to "E" (Not Payable by Medicare) effective July 1, 2012.
**HCPCS code Q2046 replaced HCPCS code C9291 effective July 1, 2012.
***HCPCS code Q2048 replaced HCPCS code J9001 effective July 1, 2012. The status indicator for HCPCS code J9001 was changed to "E" (Not Payable by Medicare) effective July 1, 2012.

We note that three of the Level II HCPCS Q-codes that were made effective July 1, 2012, were previously described by HCPCS J-codes or C-codes that were separately payable under the hospital OPPS. First, HCPCS code Q2045 replaced HCPCS code J1680 (Injection, human fibrinogen concentrate, 100 mg), beginning July 1, 2012. HCPCS code J1680 was assigned to status indicator "K" (Nonpass-through drugs and nonimplantable biologicals, including therapeutic radiopharmaceuticals; paid under OPPS; separate APC payment) on January 1, 2012. However, because HCPCS code J1680 was replaced by HCPCS code Q2045 effective July 1, 2012, we changed its status indicator to "E" (Not Payable by Medicare) effective July 1, 2012. Because HCPCS code Q2045 describes the same drug as HCPCS code J1680, we continued its separate payment status and assigned it to status indicator "K" effective July 1, 2012. However, because the dosage descriptor for HCPCS code Q2045 is not the same as HCPCS code J1680, we assigned HCPCS code Q2045 to a new APC to maintain data consistency for

future rulemaking. Specifically, HCPCS code Q2045 was assigned to APC 1414 effective July 1, 2012.

Second, HCPCS code Q2046 replaced HCPCS code C9291 effective July 1, 2012. HCPCS code C9291 was assigned pass-through status when it was effective April 1, 2012. Because HCPCS code Q2046 describes the same product as HCPCS code C9291, we continued its pass-through status and assigned HCPCS code Q2046 to status indicator "G" as well as assigned it to the same APC, specifically APC 9291, effective July 1, 2012. HCPCS code C9291 was deleted on June 30, 2012.

Third, the HCPCS Workgroup replaced HCPCS code J9001 (Injection, doxorubicin hydrochloride, all lipid formulations, 10 mg) with new HCPCS code Q2048, effective July 1, 2012. Consequently, the status indicator for HCPCS code J9001 was changed to "E" (Not Payable by Medicare) effective July 1, 2012. Because HCPCS code Q2048 describes the same drug as HCPCS code J9001, we continued its separate payment status and assigned HCPCS code Q2048 to status indicator "K" effective July 1, 2012. In addition, because, HCPCS code Q2049 is similar to HCPCS code Q2048, we assigned HCPCS code Q2049 to status indicator "K" effective July 1, 2012.

Of the 15 HCPCS codes that were effective July 1, 2012, we did not recognize for separate OPPS payment two HCPCS codes because they are both paid under a payment system other than OPPS. Specifically, HCPCS code Q2047 was assigned to status indicator "A" (Not paid under OPPS; paid by fiscal intermediaries/MACs under a fee schedule or payment system other than OPPS), and HCPCS code Q2034 was assigned to status indicator "L" (Not paid under OPPS; paid at reasonable cost).

In the CY 2013 OPPS/ASC proposed rule (77 FR 45116), we solicited public comments on the proposed status indicators and APC assignments for the HCPCS codes that were listed in Table 15 of the proposed rule and now appear in Table 14 and 15 of this final rule with comment period.

We did not receive any other public comments on the new Level II HCPCS codes that were implemented in July 2012. We are adopting as final, without modification, our proposal to assign the Level II HCPCS codes listed in Table 15 to the APCs and status indicators as proposed for CY 2013.

Table 15 below includes a complete list of the Level II HCPCS codes that were made effective July 1, 2012, with their final status indicators and APC assignments for CY 2013.

TABLE 15.—FINAL CY 2013 STATUS INDICATORS AND APC ASSIGNMENTS FOR THE LEVEL II HCPCS CODES THAT WERE NEWLY IMPLEMENTED IN JULY 2012

CY 2012 HCPCS Code	CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 Status Indicator	Final CY 2013 APC
C9368	Q4132	Grafix core, per square centimeter	G	9368
C9369	Q4133	Grafix prime, per square centimeter	G	9369
Q2034	Q2034	Influenza virus vaccine, split virus, for intramuscular use (Agriflu)	L	N/A
Q2045*	J7178	Injection, human fibrinogen concentrate, 1 mg	K	1414
Q2046**	J0178	Injection, aflibercept, 1 mg	G	1420
Q2047	J0890	Injection, peginesatide, 0.1 mg (for esrd on dialysis)	A	N/A
Q2048***	J9002	Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg	K	7046

CY 2012 HCPCS Code	CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 Status Indicator	Final CY 2013 APC
Q2049	Q2049	Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg	K	1421

We note that the HCPCS Workgroup replaced HCPCS codes C9368, C9369, Q2045, Q2046, Q2047, and Q2048 with HCPCS codes Q4132, Q4133, J7178, J0178, J0890, and J9002, respectively, effective January 1, 2013. Because HCPCS codes Q4132, Q4133, and J0178 describe the same products currently designated by HCPCS codes C9368, C9369, and Q2046, respectively, these products will continue their pass-through status in CY 2013. Therefore, we are assigning HCPCS codes Q4132, Q4133 and J0178 to the same status indicators and APCs as their predecessor HCPCS codes, which share the same dosage descriptors, as shown in Table 15. We note that because HCPCS codes Q2045 and Q2048 are assigned to status indicator "K" (Nonpass-Through Drugs; Paid under OPPS; Separate APC payment), their replacement HCPCS codes J7178 and J9002, which share the same code descriptors as their predecessor codes, also will continue their nonpass-through status and APC assignments in CY 2013.

Finally, HCPCS code Q2047 will be replaced with HCPCS code J0890 effective January 1, 2013. Because HCPCS code J0890 describes the same product currently designated by HCPCS code Q2047, this product will continue to be assigned to the same status indicator as its predecessor HCPCS code, as shown in Table 15.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45116), 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 2012 update, there were no new Category I CPT vaccine codes. Through the July 2012 OPPS quarterly update CR (Transmittal 2483, Change Request 7847, dated June 8, 2012), we allowed separate OPPS payment for all seven new Category III CPT codes effective July 1, 2012. Specifically, as displayed in Table 16 of the proposed rule and in Table 16 below, we allowed separate payment for Category III CPT codes 0302T, 0303T, 0304T, 0305T, 0306T, 0307T, and 0308T.

We received one public comment on one of the Category III CPT codes that were implemented in July 2012, specifically on CPT code 0304T, which is addressed in section II.A.2.d.(1) of this final rule with comment period. Table 16 below lists the Category III CPT codes that were implemented in July 2012, along with their final status indicators and APC assignments, for CY 2013. The final payment rates for these codes can be found in Addendum B to this CY 2013 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 16.—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2012

CY 2013 CPT Code	CY 2013 Long Descriptor	Final CY 2013 Status Indicator	Final CY 2013 APC
0302T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode)	T	0089
0303T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only	T	0106
0304T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only	T	0090
0305T	Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report	S	0690
0306T	Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report	S	0690
0307T	Removal of intracardiac ischemia monitoring device	T	0105
0308T	Insertion of ocular telescope prosthesis including removal of crystalline lens	T	0234

In the CY 2013 OPPS/ASC proposed rule (77 FR 45114 through 45117), we solicited public comments on the CY 2013 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, 2012, and July 1, 2012, through the respective OPPS quarterly update CRs. These codes were listed in Tables 14, 15, and 16 of the proposed rule. We proposed to finalize their status indicators and their APC assignments and payment rates, if applicable, in this CY 2013 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 15 and 16, respectively, of the proposed rule. We proposed to incorporate these codes into Addendum B to this CY 2013 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 2012 OPPS update CR and displayed in Table 14 were included in Addendum B to the proposed rule (which was available via the Internet on the CMS Web site), where their proposed CY 2013 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 2012 or July 2012 OPPS update CR are found 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 Will Be Effective October 1, 2012 and New CPT and Level II HCPCS Codes That Will Be Effective January 1, 2013 for Which We Are Soliciting Public Comments in this CY 2013 OPPS/ASC Final Rule with Comment Period

As has been our practice in the past, we incorporate those new Category I and III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the OPPS for the following calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January OPPS quarterly update CRs. In the past, we also have released new Level II HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period updating the OPPS for the following calendar year. For CY 2013, these codes are flagged with comment indicator "NI" in Addendum B to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. In addition, the CPT and Level II HCPCS codes that will be effective January 1, 2013, are flagged with comment indicator "NI" in Addendum B to the OPPS/ASC final rule with comment period. Specifically, the status indicator and the APC assignment and payment rate, if applicable, for all such codes flagged with comment indicator "NI" are open to public comment in the final rule with comment period, and we respond to these comments in the OPPS/ASC final rule with comment period for the next calendar year's OPPS/ASC update. In the CY 2013 OPPS/ASC proposed rule (77 FR 45117 through 45118), we

proposed to continue this process for CY 2013. Specifically, for CY 2013, we proposed to include in Addendum B to this CY 2013 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2013 (including the Category III CPT codes that were released by the AMA in July 2012) that would be incorporated in the January 2013 OPPS quarterly update CR and the new Level II HCPCS codes, effective October 1, 2012, or January 1, 2013, that would be released by CMS in its October 2012 and January 2013 OPPS quarterly update CRs. As proposed, in this final rule with comment period, the October 1, 2012 and January 1, 2013 codes are flagged with comment indicator "NI" in Addendum B to this CY 2013 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim OPPS payment status for CY 2013. 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 2014 OPPS/ASC final rule with comment period.

We did not receive any public comments on our proposal. Therefore, we are finalizing our proposal to flag new Level II HCPCS codes that become effective October 1, 2012, and new CPT and Level II HCPCS codes that become effective January 1, 2013 with comment indicator "NI" in Addendum B to this CY 2013 OPPS/ASC final rule with comment period to indicate that these codes have been assigned an interim OPPS payment status for CY 2013. 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 2014 OPPS/ASC final rule with comment period.

B. OPPS Changes--Variations within APCs

1. Background

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

(a) Use of an operating, treatment, or procedure room;

(b) Use of a recovery room;

(c) Observation services;

(d) Anesthesia;

(e) Medical/surgical supplies;

(f) Pharmaceuticals (other than those for which separate payment may be allowed under the provisions discussed in section V. of the proposed rule and this final rule with comment period);

(g) Incidental services such as venipuncture;

(h) Guidance services, image processing services, intraoperative services, imaging, supervision and interpretation services, diagnostic radiopharmaceuticals, and contrast media.

Further discussion of packaged services is included in section II.A.3. of this final rule with comment period.

In CY 2008, we implemented composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service (72 FR 66650 through 66652). Under CY 2012 OPPS policy, we provide composite APC payment for certain extended assessment and management services, low dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation, mental health services, multiple imaging services, and cardiac resynchronization therapy services. Further discussion of composite APCs is included in section II.A.2.e. of this final rule with comment period.

Under the OPPS, we generally pay for hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or

combination of services is assigned. Each APC weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 0606 (Level 3 Hospital Clinic Visits). The APC weights are scaled to APC 0606 because it is the middle level hospital clinic visit APC (the Level 3 hospital clinic visit CPT code out of five levels), and because middle level hospital clinic visits are among the most frequently furnished services in the hospital outpatient setting.

Section 1833(t)(9)(A) of the Act requires the Secretary to review, 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 HOP Panel recommendations for specific services for the CY 2013 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"). In the CY 2013 OPPS/ASC proposed rule

(77 FR 45118), for CY 2013, we proposed to use the cost of the item or service in implementing this provision, as discussed in section II.A.2.f. of this final rule with comment period. 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 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 cost to be significant (75 FR 71832). This longstanding definition of when a HCPCS code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing 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 2013 OPPS/ASC proposed rule (77 FR 45118), 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 2013.

In the CY 2013 OPPS/ASC proposed rule, we identified APCs with 2 times rule violations but 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 2013 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 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 2013 included in the proposed rule were related to changes in costs of services that were observed in the CY 2011 claims data newly available for CY 2013 ratesetting. We also proposed changes to the status indicators for some codes that were not specifically and separately discussed in the proposed rule. In these cases, we proposed to change the status indicators for some 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 2013. Addendum B of the CY 2013 OPPS/ASC proposed rule identified with a comment indicator "CH" those HCPCS codes for which we proposed a change to the APC assignment or status indicator as assigned in the April 2012 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 of this final rule with comment period (available via the Internet on the CMS Web site) identifies with the "CH" comment indicator the final CY 2013 changes compared to the codes' status as reflected in the October 2012 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 2013, 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).

Table 17 of the CY 2013 OPPS/ASC proposed rule listed 21 APCs that we proposed to exempt from the 2 times rule for CY 2013 based on the criteria cited above and based on claims data processed from January 1, 2011, through December 31, 2011.

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.

For the CY 2013 OPPS/ASC proposed rule, we based the listed exceptions to the 2 times rule on claims data for dates of service between January 1, 2011, and December 31, 2011, that were processed before January 1, 2011. For this final rule with comment period, we used claims data for dates of service between January 1, 2011, and December 31, 2011, that were processed on or before June 30, 2012 and updated CCRs, if available. Thus, after considering the public comments we received on the CY 2013 OPPS/ASC proposed rule and making changes to APC assignments based on those comments, we analyzed the CY 2011 claims data used for this final rule with comment period to identify the APCs with 2 times rule violations. Based on the final CY 2011 claims data, we found that there are 19 APCs with 2 times rule violations, a cumulative decrease of 2 APCs compared to the proposed rule. We applied the criteria as described earlier to identify the APCs that are exceptions to the 2 times rule for CY 2013, and

identified two additional APCs that meet the criteria for exception to the 2 times rule for this final rule with comment period:

- APC 0148 (Level I Anal/Rectal Procedures)
- APC 0254 (Level V ENT Procedures)

In addition, we also determined that four APCs no longer violated the 2 times rule:

- APC 0128 (Echocardiogram with Contrast)
- APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs)
- APC 0604 (Level 1 Hospital Clinic Visits)
- APC 0655 (Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing)

As discussed in section III.D.1.f. of this final rule with comment period, because of concerns raised regarding the 2 times rule violation for echocardiography services, and after further analysis of our claims data, we deleted APC 0128 and replaced it with two new APCs to correct the 2 times rule violation. Specifically, APC 0128 has been replaced with APC 0177 (Level I Echocardiogram with Contrast) and APC 0178 (Level II Echocardiogram with Contrast). We have not included in this count those APCs where a 2 times rule violation is not a relevant concept, such as APC 0375 (Ancillary Outpatient Services when Patient Expires), with an APC cost set based on multiple procedure claims; therefore, we have identified only final APCs, including those with criteria-based costs, such as device-dependent APCs, with 2 times rule violations.

Comment: Several commenters urged CMS to reassign HCPCS G0379 (Direct admission of patient for hospital observation care) from APC 0604 (Level 1 Hospital Clinic Visits) to APC 0608 (Level 5 Hospital Clinic Visits). In particular, the commenters requested that CMS assign HCPCS G0379 to the same APC as CPT code 99205 (Office or other outpatient visit for the evaluation and management of a new patient (Level 5)) when the Composite APC 8002 (Level I Extended Assessment & Management Composite) criteria are not met. The commenters indicated that the reassignment of HCPCS code G0379 to APC 0608 would be appropriate because it would resolve the 2 times rule violation in APC 0604 and also align the resources with a high-level hospital visit when the criteria for Composite APC 8002 are not met. The commenters suggested that continuing to assign HCPCS code G0379 to APC 0604 would result in continued underpayments to HOPDs when the services and claims processing requirements for APC 8002 are not met for a direct referral. The commenters further added that this same issue was discussed during the February 2012 HOP Panel meeting, and that after the discussion, the Panel recommended that CMS reassign HCPCS code G0379 from APC 0604 to an appropriate APC. The commenters urged CMS to accept the Panel's recommendation.

Response: Based on the recommendation of the HOP Panel at its February 2012 meeting, we reviewed our claims data for HCPCS code G0379. Our analyses revealed that the level of hospital resources used to provide HCPCS code G0379 is about the same as for CPT code 99205. In particular, our claims data show similar geometric mean costs for HCPCS code G0379 and CPT code 99205. Specifically, our claims data show a

geometric mean cost of approximately $181 for HCPCS code G0379 based on 2,368 single claims (out of 3,975 total claims), and a geometric mean cost of approximately $179 based on 95,017 single claims (out of 104,246 total claims) for CPT code 99205. Based on our review of the claims data associated with HCPCS code G0379 and CPT code 99025, we agree with the commenters that the reassignment of HCPCS code G0379 to APC 0608 is appropriate. Because APC assignments are made based on consideration of both hospital resources and clinical homogeneity, we believe this reassignment improves the clinical homogeneity of APC 0608 and appropriately aligns the resource costs of HCPCS code G0379 to those procedures assigned to APC 0608.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal with modification to reassign HCPCS code G0379 from APC 0604 to APC 0608, which has a final CY 2013 geometric mean cost of approximately $181.

Comment: One commenter indicated that APC 0623 violates the 2 times rule and requested that CMS review the costs associated with CPT code 36260 (Insertion of implantable intra-arterial infusion pump (eg, for chemotherapy of liver)) and reassign the CPT code to a more appropriate APC.

Response: Table 17 of the CY 2013 OPPS/ASC proposed rule listed 21 APCs that violated the 2 times rule for CY 2013. APC 0623 does not appear in Table 17 and assignment of CPT code 36260 to APC 0623 does not violate the 2 times rule. As stated above, in determining whether a 2 times rule violation exist in an APC, we consider only those HCPCS codes that are significant based on the number of claims. 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 cost to be significant (75 FR 71832). This longstanding definition of when a HCPCS code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing 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. For this CY 2013 OPPS/ASC final rule with comment period, there are only 3 single claims for CPT code 36260 (each of the 3 total claims). Because CPT code 36260 does not represent a significant HCPCS code based on the number of claims, it does not violate the 2 times rule.

After consideration of the public comments we received and our review of the CY 2011 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 exemption of 17 of the original APCs (that appeared in Table 17 of the CY 2013 OPPS/ASC proposed rule with comment period and also appears in Table 17 below) from the 2 times rule for CY 2013. We are removing four APCs that no longer violated the 2 times rule and decreasing the number of APC exceptions from 21 to 19 APCs, as described previously in this section. Our final list of 19 APCs exempted from the 2 times rule for CY 2013 is displayed in Table 17 below.

TABLE 17.—FINAL APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2013

Final CY 2013 APC	Final CY 2013 APC Title
0006	Level I Incision & Drainage
0012	Level I Debridement & Destruction
0045	Bone/Joint Manipulation Under Anesthesia
0057	Bunion Procedures
0060	Manipulation Therapy
0105	Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices
0148	Level I Anal/Rectal Procedures
0152	Level I Percutaneous Abdominal and Biliary Procedures
0230	Level I Eye Tests & Treatments
0254	Level V ENT Procedures
0272	Fluoroscopy
0325	Group Psychotherapy
0330	Dental Procedures
0340	Minor Ancillary Procedures
0369	Level III Pulmonary Tests
0403	Level I Nervous System Imaging
0409	Red Blood Cell Tests
0688	Revision/Removal of Neurostimulator Pulse Generator Receiver
0690	Level I Electronic Analysis of Devices

C. New Technology APCs

1. Background

In the November 30, 2001 final rule (66 FR 59903), we finalized changes to the time period a service was eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical

APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

We note that the cost bands for New Technology APCs range from $0 to $50 in increments of $10, from $50 to $100 in increments of $50, from $100 to $2,000 in increments of $100, and from $2,000 to $10,000 in increments of $500. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology – Level VII ($500 - $600)) is made at $550. Currently, there are 82 New Technology APCs, ranging from the lowest cost band assigned to APC 1491 (New Technology – Level IA ($0 - $10)) through the highest cost band assigned to APC 1574 (New Technology – Level XXXVII ($9,500 - $10,000). In CY 2004 (68 FR 63416), we last restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs, one set with a status indicator of "S" (Significant Procedure, Not Discounted When Multiple) and the other set with a status indicator of "T" (Significant Procedure, Multiple Reduction Applies). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

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

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

For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the techniques and their clinical utility. Quite often, parties request that Medicare make higher payment amounts under our New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that

require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies.

We note that, in a budget neutral environment, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice.

2. Movement of Procedures from New Technology APCs to Clinical APCs

As we explained in the November 30, 2001 final rule (66 FR 59902), we generally keep a procedure in the New Technology APC to which it is initially assigned until we have collected sufficient data to enable us to move the procedure to a clinically appropriate APC. However, in cases where we find that our original New Technology

APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that most appropriately reflects its cost.

Consistent with our current policy, in the CY 2013 OPPS/ASC proposed rule (77 FR 45120), for CY 2013, we proposed to retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to a clinically appropriate APC. The flexibility associated with this policy allows us to move a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for reassignment have not been collected. Table 18 of the proposed rule listed the HCPCS codes and associated status indicators that we proposed to reassign from a New Technology APC to a clinically appropriate APC or to a different New Technology APC for CY 2013.

In the CY 2013 OPPS/ASC proposed rule, we noted that currently, in CY 2012, there are three procedures described by HCPCS G-codes receiving payment through a New Technology APC(77 FR 45121). Specifically, HCPCS code G0417 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 21-40 specimens) is assigned to New Technology APC 1505 (New Technology - Level V ($300 - $400)); HCPCS code G0418 (Surgical pathology, gross and

microscopic examination for prostate needle saturation biopsy sampling, 41-60 specimens) is assigned to New Technology APC 1506 (New Technology - Level VI ($400 - $500)); and HCPCS code G0419 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens) is assigned to New Technology APC 1508 (New Technology - Level VIII ($600 - $700)). These HCPCS codes have been assigned to New Technology APCs since CY 2009.

Analysis of the hospital outpatient data for claims submitted in CYs 2009, 2010, and 2011 indicate that prostate needle saturation biopsy procedures are rarely performed on Medicare beneficiaries. For OPPS claims submitted from CY 2009 through CY 2011, our final rule claims data show very minimal claims for HCPCS code G0417, G0418, and G0419, as shown in Table 18.

TABLE 18.—CY 2009 THROUGH CY 2011 OPPS CLAIMS FOR HCPCS CODES G0417, G0418, AND G0419 (PROSTATE NEEDLE SATURATION BIOPSY)

HCPCS Code	Long Descriptor	CY 2009 Claims	CY 2010 Claims	CY 2011 Claims
G0417	Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 21-40 specimens	6	1	0
G0418	Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41-60 specimens	0	0	0
G0419	Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens	0	0	1

Given the continued lack of cost data for these HCPCS codes, we proposed to reassign these procedures to an APC that is appropriate from a clinical standpoint (77 FR

45121). Specifically, we proposed to reassign HCPCS G-codes G0417, G0418, and G0419 to clinical APC 0661 (Level V Pathology), with a proposed APC payment rate of approximately $160 for CY 2013. We stated that we believe that all three procedures, as described by HCPCS codes G0417, G0418, and G0419, are comparable clinically to other pathology services currently assigned to APC 0661 and likely require similar resources. Table 18 of the proposed rule listed the HCPCS G-codes and associated status indicators that we proposed to reassign from New Technology APCs 1505, 1506, and 1508 to APC 0661 for CY 2013.

We did not receive any public comments on the APC reassignments for HCPCS codes G0417, G0418, and G0419. Therefore, for the reasons set forth above, we are finalizing our proposal, without modification, to assign these codes to APC 0661. We note that APC 0661 is the same APC to which the other HCPCS G-code for prostate needle saturation biopsy procedure, G0416 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 1-20 specimens), is assigned. In addition, for the CY 2013 update, we are revising the long descriptor for HCPCS code G0416 to read "Surgical pathology gross and microscopic examination for prostate needle saturation biopsy sampling 10-20 specimens" effective January 1, 2013. The final CY 2013 geometric mean cost for APC 0661 is approximately $162.

Table 19 below lists the HCPCS codes and associated status indicators that we are reassigning from a New Technology APC to a different New Technology APC for CY 2013. The final CY 2013 payment rates for HCPCS codes G0417, G0418, and

G0419 can be found in Addendum B of this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 19.—REASSIGNMENT OF PROCEDURES FROM NEW TECHNOLOGY APCs FOR CY 2013

CY 2013 HCPCS Code	CY 2013 Short Descriptor	CY 2012 SI	CY 2012 APC	Final CY 2013 SI	Final CY 2013 APC
G0417	Sat biopsy prostate 21-40	S	1505	X	0661
G0418	Sat biopsy prostate 41-60	S	1506		
G0419	Sat biopsy prostate: >60	S	1508		

3. Payment Adjustment Policy for Radioisotopes Derived from Non-Highly Enriched Uranium Sources

a. Background

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.

Full Cost Recovery, which is routinely considered in CMS payment under Medicare, is the accounting practice used by producers and suppliers to describe the recovery of all contributing costs. Unlike legacy sources that often benefit from government subsidized multifunction facilities, the cost of these alternative methods will be increased over the cost of medical radioisotopes produced using HEU because hospitals' payments to producers and suppliers will have to cover capital expense (such as, for example, the cost of building new reactors, particle accelerators, or other very long-term investments), as well as all other new industry-specific ancillary costs (such as, for example, the cost of long-term storage of radioactive waste). Hospitals that use medical radioisotopes that are produced from non-HEU sources can expect producers and suppliers to pass on to them the full impact of these costs.

In the short term, some hospitals will be able to depend on low cost legacy producers using aging subsidized reactors while other hospitals will be forced to absorb the full cost of non-HEU alternative sources. Over several years, we believe that these cost differentials will promote increased regional shortages and create larger cost differentials and greater cost variations among hospitals. As a result, we believe this change in supply source will create a significant payment inequity among hospitals resulting from factors that are outside of normal market forces.

b. Payment Policy

In the CY 2013 OPPS/ASC proposed rule (77 FR 45121 through 45123), we proposed to exercise our authority to establish "other adjustments as determined to be necessary to ensure equitable payments" under the OPPS in accordance with section 1833(t)(2)(E) of the Act. We stated that we do not believe that we can ensure equitable payments to hospitals over the next 4 to 5 years in the absence of an adjustment to account for the significant payment inequities created by factors that will likely arise due to the change in supply source for the radioisotope used commonly in modern medical imaging procedures. We proposed to provide an adjustment for the marginal cost for radioisotopes produced from non-HEU sources over the costs for radioisotopes produced by HEU sources. We stated that we believe such an adjustment would ensure equitable payments in light of the Administration's HEU agenda, market influences, cost differentials, and cost variations that will create significant payment inequities among hospitals.

For CY 2013, we proposed to make an additional payment of $10, which is an amount based on the best available estimations of the incremental costs associated with non-HEU Tc-99m production as calculated using the Full Cost Recovery accounting methodology. We proposed to establish a new HCPCS code, QXXXX (Tc-99m from non-HEU source, full cost recovery add-on, per dose), to describe the Tc-99m radioisotope produced by non-HEU methods and used in a diagnostic procedure. Under the proposal, hospitals would be able to report this HCPCS Q-code 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 as coming from non-HEU sources and have been priced using a Full Cost Recovery accounting methodology. The HCPCS Q-code would be used to pay hospitals for the additional (incremental) cost of using Tc-99m from a non-HEU source.

Under the proposal, hospitals would not be required to make a separate certification of the non-HEU source on the claim; the inclusion of the new HCPCS code QXXXX on the claim would indicate that the hospital has met the conditions of the service definition as it does for any billed service. However, in the event of an audit, we stated that hospitals would be expected to be able to produce documentation that the individual dose delivered to the patient was completely produced from a non-HEU source. We proposed three ways in which hospitals could accomplish this.

First, the hospital could produce documentation such as invoices or patient dose labels or tracking sheets that indicated that the patient's dose was completely produced from non-HEU sources and priced based on Full Cost Recovery. In this first case, the supplier would be expected to be able to trace a specific dose of Tc-99m to a completely non-HEU batch. Current pharmacy recordkeeping is generally able to trace all components of radiopharmaceuticals back to their source production batches. A hospital would not be compliant with the HCPCS Q-code definition if the documentation indicated the supplier produced a mixed batch and labeled a fraction of the doses equal to the non-HEU fraction in the batch.

Second, a hospital could produce documentation that the entire batch of Tc-99m doses derives from non-HEU sources for a specified period of time, for example, the time

that a single non-HEU based generator is in use. This approach would obviate the need for specific dose tracking from a claims audit perspective, although that information is typically required for other purposes. An attestation from the generator supplier would be sufficient evidence for the hospital, as would invoices that show that all doses of Tc-99m during a specified period came from inherently non-HEU alternative sources.

Third, if the industry was to implement labeling of generators and/or doses with labels attesting to 100 percent non-HEU sources priced based on Full Cost Recovery, documentation of labeled isotope usage using either the specific dose approach or the 100 percent hospital usage approach could provide evidence of hospital compliance. The hospital would be required to retain appropriate documentation within the hospital (including pharmacy) records but would not need to keep any specific documentation within the individual medical record. Also, we would consider a dose to be priced based on Full Cost Recovery when the supplier could attest that the supply chain adheres to usual industry practices to account for Full Cost Recovery, specifically including the capital cost of sustainable production and the environmental cost of waste management.

To reduce the administrative overhead for hospitals, we proposed not to require hospitals to separately track additional costs for Tc-99m doses from non-HEU sources, but to include the cost of the radioisotope in the cost of the diagnostic radiopharmaceutical as usual, reporting only a token $1 charge for the HCPCS code QXXXX line. Under the proposal, we would continue to calculate the total costs of radionuclide scans using claims data, and would periodically recalculate the estimated incremental cost of Tc-99m from non-HEU sources based on Full Cost Recovery, using

models relying on the best available industry reports and projections, and would adjust the payment for HCPCS code QXXXX accordingly, reducing the payment for the scans by the amount of cost paid through HCPCS code QXXXX payment. We stated that we believe this proposal allows us to continuously compensate for unanticipated changes in Tc-99m cost attributable to new non-HEU supply sources while avoiding a double payment for the increased cost.

Comment: The vast majority of commenters conceptually agreed with CMS' proposed payment policy. However, the commenters differed in opinion on how CMS should implement a proposal to encourage hospitals to switch from Tc-99m derived from HEU sources to Tc-99m derived from non-HEU sources.

Many commenters disagreed specifically with CMS' proposal to make an additional payment of $10 per dose for Tc-99m radioisotopes produced by non-HEU methods, used in a diagnostic procedure. These commenters agreed that an additional payment is necessary in order to ensure that hospitals are fully paid for the additional costs incurred for the use of non-HEU Tc-99m radioisotopes, but the commenters argued that the additional $10 payment is insufficient and inadequate to incentivize hospitals to change their current practices and transition purchases of Tc-99m to non-HEU sources. The commenters suggested that CMS instead adjust or increase the payment amount to more adequately cover any additional costs to providers.

One commenter asked that CMS conduct a study of the actual costs at a time when non-HEU Tc-99m is actually available to hospitals, and propose an adjustment that

will better reflect both the marginal additional costs of the non-HEU sources and the administrative and compliance burden on hospitals.

Another commenter recommended that CMS establish HCPCS code QXXXX (Tc-99m from non-HEU sources, full cost recovery add-on, per dose) and make an interim payment of $10 per unit for CY 2013 and CY 2014. The commenter further suggested that, beginning in CY 2015, CMS calculate the cost of the service described by the recommended code based on the standard CMS payment methodology because the calculations will be based on charges for services furnished in CY 2013, and for CY 2015 and years following, CMS will have estimated costs on which to base the additional payment for the HCPCS Q-code. In addition, the commenter recommended that CMS carefully track the phase-out of the HEU sources and eliminate HCPCS code QXXXX once HEU is phased out of the market in the United States.

Overall, most of the commenters encouraged CMS to continue to work with pertinent stakeholders and providers in the industry on this issue.

Response: We agree with the commenters that $10 is not a large incentive payment to promote a conversion to non-HEU sources of Tc-99m. However, we are concerned that many commenters have mischaracterized this payment. We did not create an additional payment to promote the Administration's initiative to eliminate domestic reliance on legacy production processes producing Tc-99m from HEU, as that is outside the scope of the OPPS. Rather, the industry has conveyed to us that this conversion to non-HEU sources will occur in response to U.S. strategic policy, but that cost considerations have created barriers to that movement. One of the cost considerations is

the fact 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, in fact, a probability not only that costs will increase but that those costs will not be passed on uniformly as the industry converts. Therefore, we used our authority to ensure payment equity among hospitals by proposing to create this additional payment to address the incremental cost of obtaining Tc-99m from the new sources of supply. Although commenters have opined that a larger payment would be a better incentive to support non-HEU conversion, the purpose for the additional payment is limited to mitigating any adverse impact of existing payment policy and is based on the authority set forth at section 1833(t)(2)(E) of the Act.

Most of the comments raising concerns about the inadequacy of the additional payment suggested that we did not account for the administrative costs involved in implementing this additional payment at the hospital level, at the radiopharmacy level, and at the level of the generator manufacturer. However, we note that previous discussions with the industry indicated that the actual costs of conversion, distinct from the administrative costs of billing, are confined to the producer (reactor) and the processor and are passed down through the supply chain from there. In our own analysis, we concurred with that finding and calculated a payment that would readily cover the additional cost of this change in supply as it is passed down the supply chain. We do not believe that it promotes efficiency to add administrative markup to this increased cost of a supply, especially given that we believe that the administrative cost of adding a new service into the billing system should be small at the hospital and the pharmacy levels.

Moreover, due to the small absolute difference in cost between non-HEU and HEU sourced Tc-99m, we do not believe that significant inequities would exist in hospital costs until a significant amount of more expensive non-HEU Mo-99 enters the system, at which point any administrative cost would be spread over a large number of claims.

Finally, we agree with commenters who stated that this additional payment should be updated as better data become available. We stated in the proposed rule that we intend to look at the amount of the add-on payment and potentially update it as better economic information becomes available. Although we did not limit ourselves to the methodology beyond a commitment to use the best available data, we also did not propose using our usual OPPS methodologies to update the payment. We had specifically advised hospitals that separate reporting of the cost of Tc-99m from non-HEU sources was not required for several reasons. First, a particular generator manufacturer could elect to provide HEU and non-HEU generators at the same averaged cost, a method that would enable the client hospitals to defray any overall cost increase as non-HEU generators became randomly available. Because there could still be an incremental cost differential incurred by doing business with that manufacturer as compared with a purely non-HEU manufacturer, our normal OPPS methods would show no incremental cost and thus could not be used to mitigate a payment inequity. Second, we noted that separate reporting of the costs of the two sources or the calculation and reporting of a cost differential would significantly increase the administrative burden on hospitals, a burden of which we have been particularly mindful.

Comment: Several commenters asked that CMS provide separate payment for all diagnostic radiopharmaceuticals, regardless of their per day cost, as this policy would support conversion to non-HEU sources. A few commenters recommended that CMS unpackage all radiopharmaceuticals that meet the annual packaging threshold. They also suggested that CMS unpackage all radiopharmaceuticals that use Tc-99m, regardless of their per day cost. One commenter suggested that the proposed add-on payment of $10 be made in addition to separate payment for the diagnostic radiopharmaceutical.

The commenters emphasized their concern over increased costs of conversion to 100 percent non-HEU for radioisotopes. One commenter argued that separate payment would provide a direct, measurable incentive to the entire radiopharmaceutical market supply chain to support the efforts to convert from HEU to non-HEU sources. Additionally, the commenter stated that separate payment would allow CMS to obtain accurate hospital cost data on the cost of both HEU and non-HEU radiopharmaceuticals.

Response: We have already discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765 through 66768) the reasons why the agency has determined that it is appropriate to package payment for a diagnostic radiopharmaceutical into the payment for the nuclear medicine scan, and we have finalized this policy again in section II.A.3.f. of this final rule with comment period. However, specifically from the standpoint of this add-on payment to ensure equitable payments to hospitals, a separate payment for the diagnostic radiopharmaceutical would not unpackage the cost of the radioisotope from the much larger cost of the drug component, nor would it differentiate between HEU and non-HEU sources. Therefore, unpackaging the cost of the diagnostic

radiopharmaceutical would not create a differential payment to ensure payment equity amongst hospitals.

Comment: Several commenters were concerned with CMS' proposal that Tc-99m doses be derived 100 percent from non-HEU sources in order to receive the additional $10 payment. A few commenters stated that it would be impossible to accurately predict the percentage of Tc-99m doses that will be comprised 100 percent from non-HEU sources. Other commenters expressed concern over the significant costs that will be incurred for segregating 100 percent non-HEU sources, especially in the radiopharmacy.

Response: We agree with the commenters that it will be impossible to accurately predict the percentage of Tc-99m doses that will be comprised of 100 percent of non-HEU sourced material, but that is because it will be impossible to predict the percentage of non-HEU Tc-99m available to manufacturers at any point in time. This presumption is one of the reasons that led us to the conclusion that payment for doses where 100 percent comes from non-HEU sources was the only reasonable option. We do not need to predict the amount of non-HEU Mo-99 available to the industry to establish a blend; instead, the HCPCS Q-code can be used whenever and wherever enough non-HEU Tc-99m is available to be kept separate down to the level of the generator or patient dose. Multiple codes to reflect different blends are not needed, and we do not need to create smaller payments for blends that reflect smaller amounts of non-HEU material. Because payment must be driven by cost, a 20-percent blend would be limited to 20 percent of the $10 cost or $2, and hospitals are already concerned that the $10 additional payment is a

small payment when they consider it against the effort involved in making tracking and billing changes.

However, we do not believe that any costs created by changes in radiopharmacy procedures will be significant in the charges passed on to hospitals. We do understand that there may be some instances in which a radiopharmacy will have both a non-HEU and an HEU generator, and the pharmacy will need to determine whether it wants to keep those sources separate or blend them and eschew labeling of a non-HEU source. We also understand that this may be a larger issue at the generator manufacturer level, especially very early in the conversion when non-HEU Mo-99 is scarce. On the other hand, when non-HEU Mo-99 is scarce, the incremental cost of higher priced non-HEU Mo-99 is small and the blending of small amounts of non-HEU Mo-99 will not create payment inequities among hospitals. We expect that as conversion progresses and more non-HEU Mo-99 enters the supply chain, manufacturing processes may evolve. Ultimately, there is no requirement to use this HCPCS Q-code or label non-HEU based Mo-99; the payment exists as a tool if it is necessary to reduce payment inequities that might occur as a consequence of industry conversion to non-HEU based Mo-99.

One of the concerns about reporting doses derived from 100 percent non-HEU sources had to do with compliance concerns if, in the process of switching between an HEU and a non-HEU run, the manufacturer or pharmacy did not add in an extra step of flushing lines to ensure that cross-contamination did not occur. Our understanding is that using different sources for consecutive manufacturing runs would not create source contamination of more than 1 or 2 percent based on usual manufacturing processes. We

note that it is not our intent to introduce unnecessary inefficiencies solely to support payment, and in this case we can confirm that production steps, such as cleaning lines, should be driven by FDA manufacturing requirements, not by payment artificialities. We believe that manufacturing steps that do not risk reducing the non-HEU sourced Mo-99 or Tc-99m to less than 95 percent of the generator, elution or dose (that is, do not risk reducing the content of the dose supplied to the patient to less than 95 percent non-HEU sourced Tc-99m) are consistent with a product that is completely derived from a non-HEU source. Therefore, we are modifying our proposal to state that any dose of Tc-99m that can be traced to a Mo-99 supply containing no more than 5 percent HEU sourced Mo-99 shall be considered to be completely derived from non-HEU sources for the purposes of this final rule with comment period, this additional payment, and any compliance practices that support it. It is our understanding that the normal manufacturing records will still support processes that created the non-HEU supply.

Comment: One commenter expressed concern regarding the administrative and financial burden that hospitals may incur upon adoption of this proposed policy. The commenter stated that these burdens may exceed the marginal additional cost of moving to non-HEU sources. The commenter believed that the proposed policy would result in additional administration and documentation burdens which include the following additional expenses: expenses for developing and maintaining policies to track, certify, and document HEU versus non-HEU sources in order to use the newly required HCPCS Q-code; new compliance program checks and monitoring to ensure the appropriate codes are used and documentation is maintained should an audit be conducted; additional

personnel time and resources to create and maintain line items on the hospital charge master for non-HEU versus HEU codes and charges; and additional resources to develop nuclear medicine department information technology infrastructure, as well as billing policies for documentation and use of the new HCPCS Q-code.

Another commenter also believed that this proposal would create a significant burden on hospitals by requiring them to obtain, document, and track information from the supplier and thereby create an unnecessary level of complexity for hospitals that could result in code errors and omissions on claims. The commenter urged CMS not to finalize this proposal.

Response: We do not believe that this additional payment will result in a significant administrative burden to hospitals. We note that most hospitals have computerized inventory and billing systems that are able to track low-cost items such as needles and aspirins. We have reiterated in our response to public comments in this final rule with comment period that we expect hospitals requesting this additional payment to be able to track a dose that has been labeled or claimed as "non-HEU sourced" and do not expect hospitals to audit the validity of such claims made by their suppliers. We also note that the cost of adding a new code to the hospital chargemaster is not large, and that a hospital is not being subject to a significant payment inequity if the cost of adding a new code to the chargemaster actually exceeds the added cost of non-HEU sourced Tc99m to the hospital. Hospitals that are not experiencing high volumes of significantly increased costs are not obligated to use this additional payment as its use is entirely optional.

Comment: One commenter asked that CMS confirm in this final rule with comment period that hospitals will not be required to audit or otherwise independently verify manufacturer or radiopharmacy documentation that a dose/injection meets the standard of non-HEU priced at Full Cost Recovery.

A few commenters expressed concern regarding the compliance and liability burden that adopting this policy may place on hospitals. These commenters stated that hospitals may be uncomfortable attesting that the supplies they receive are from non-HEU sources when there is no reliable guarantee that the products are from non-HEU sources. Further, the commenters stated that they believe that the term "attesting" in the ASP model is significantly different from what they believe is the original intent of this proposal. Therefore, the commenters suggested that CMS clarify the adequate documentation necessary to confirm that the provider obtained a dose that is 100 percent from non-HEU sources.

Response: We are aware that providers must exert considerable effort to conscientiously perform their compliance responsibilities over such a vast health care system, and we specifically attempted to offer examples of acceptable compliance steps to alleviate that burden in this instance. We acknowledge that the end product used by hospitals is effectively homogenous, and there is no practical way for a hospital to prove chemically that a supply purported to be derived from a non-HEU source truly meets those requirements. On the other hand, the radiopharmaceutical industry is a heavily regulated industry closely monitored by the Food and Drug Administration, and it is our understanding that if a supplier indicates that a source is non-HEU, manufacturing

records will be able to confirm that. We are confident that claims by suppliers as to the source of the Tc-99m used can be satisfactorily audited through usual manufacturing processes without creating additional requirements for hospitals. We do not expect hospitals to assay doses of drugs to ensure that they received what the invoice claimed, and we do not expect any chemical or physical verification here. It was our intent in the proposed rule to indicate that providers are expected to exercise due diligence, and to ensure that their claims are supported by internal records of some type, but that facilities could accept any tracking mechanism by a supplier (invoice, label, contract, among others) regarding a non-HEU source as satisfactory proof for the purposes of the facility.

We also note that any use of the word "attestation" in the proposed rule was meant only to indicate a formal statement by one party to assure another party of the source and composition. We further note that these were examples in the proposed rule rather than requirements.

Comment: Several commenters asked that CMS publish the methodology and data used to establish the additional payment amount of $10 for Tc-99m derived from non-HEU sources.

Response: There are two data sources on which we relied. First, the Organization for Economic Cooperation and Development - Nuclear Energy Agency (OECD-NEA) has published several economic analyses of the world market for Tc-99m, which are pertinent for the United States because, at present, our entire supply comes from foreign sources. Although some members of the industry have opined that these data are not accurate because the data include little information from U.S. suppliers, the fact remains

that there is currently no supply available domestically. Thus, while the data we used may not reflect all of the unique market forces present in the domestic market, this data source provides the best estimation of the costs of non-HEU sources compared to HEU sources because the manufacturing steps are primarily performed overseas and therefore reflect the global market. Nonetheless, as an additional data source, we invited industry entities to submit additional information regarding their manufacturing and supply costs, production levels, and prices. However, given that the industry is small with limited numbers of competitors at each level of the supply chain, most American companies were reluctant to provide information and were insistent on confidentiality (as protected by FOIA Exemption 4) to safeguard the sensitive (business competitive) information that they did share. Therefore, we accepted supplemental information from the industry and pledged to maintain its confidentiality, and consequently are unable to provide details of the additional information. We can disclose our methodology and refer readers to the OECD-NEA models that form the basis of our model, noting that the supplemental information submitted to date has not significantly altered the conclusions drawn by the OECD-NEA.

To estimate costs, we tracked costs through the entire supply chain, using a building block approach to add the cost of each step onto the steps that occurred before it. Because the OECD-NEA provided ranges rather than point estimations, we used an averaging approach to factor in the possible low cost, the possible high cost, and the most likely "expected" cost. This is a common estimation technique used in business when significant uncertainty exists. By avoiding optimistic assumptions, we were able to

model a payment that reflects not only the likely costs but ones that would also be adequate to cover unexpected costs in one or more of the manufacturing steps.

In response to the request to provide as much detail about our methodology as possible, we are detailing that methodology here. We used a supply chain model to accumulate costs through the Tc-99m supply chain based on--

(Unit Cost of Supply / Production Efficiency) + Unit Production Cost + ((Fixed Production Costs + Overhead) / Units Produced) = Unit Production Cost = Downstream Unit Cost of Supply.

In tracking units (efficiency), we allowed for product loss during production and for product loss as a function of time (decay). We applied this model across a supply chain that consisted of--

Irradiator/Producer > Processor > Generator Manufacturer > Nuclear Pharmacy > Hospital > Patient.

Using a Program Evaluation and Review Technique (PERT) 3-point estimation applied to costs, we based the upper and lower bounds on the OECD-NEA economic models for Full Cost Recovery (2011) and non-HEU Conversion (2012), given that U.S. supply is based on the global market. We then varied the expected value to model a range of outcomes. Finally we calculated the incremental cost of process changes by subtracting current costs. Almost all of the incremental costs of switching to non-HEU sources occur in the irradiation and the processing steps, with very little impact on generator assembly, generator elution, or the preparation of the patient dose. We noted that any artificial costs of tracking during conversion would not be reflected in the final

post-conversion costs of supply. Due to the wide variation in cost projections, we rounded up to the nearest $5 as most of the estimators could not be regarded as sufficiently precise to justify a more precise value until actual cost data become available. This methodology resulted in a projection that fully accounts for the cost of conversion in almost all probable scenarios and that also accounts for or significantly offsets the costs of Full Cost Recovery under most combinations of assumptions. Therefore, the $10 value can be expected to offset any payment inequities under most likely combinations of cost changes within the Tc-99m supply chain.

Comment: One commenter stated that suppliers of Mo-99 are currently working toward full conversion to non-HEU sources by 2015. However, the commenter stated that it is estimated that only 10 percent of the Tc-99m doses used in the United States could be produced from 100 percent non-HEU sources in 2013. The commenter further believed that the proposed policy will cause a substantial increase in material costs, require duplicative effort in the preparation of radiopharmaceutical doses, add additional administrative costs, increase the costs for non-HEU products, and create a disincentive for hospitals that cannot purchase non-HEU products as they would be unwilling to pay higher prices for their nuclear pharmaceutical products when they are not receiving any additional benefits.

The commenter instead suggested that these impacts can be reduced by establishing a threshold amount of Mo-99 that must be used by a generator manufacturer for CY 2013, based on information provided by the OECD-NEA and other pertinent stakeholders. The commenter stated that this amount could then be adjusted upward in

later years. The commenter further explained that, in order for a technetium generator to be considered "compliant" with the requirements for the additional payment, the manufacturer of that generator would need to certify to providers that it used at least the established threshold amount of non-HEU sourced Mo-99 in the production of its generators for CY 2013 and for subsequent quarters. In turn, the hospitals that purchased the Tc-99m doses prepared by complaint manufactures would receive separate payment during that specific period. The commenter stated that this approach would require a downward adjustment to the proposed $10 additional payment to reflect the lower amount of non-HEU Mo-99.

Response: We acknowledge the desirability of a simplified payment for non-HEU sourced material in the generators, and agree that the proposed blended payment would be much easier to implement. However, we note that we do not have the authority to create that type of payment. Within the OPPS, we depend on reported costs, as calculated from claims and cost report information, to set prospective payments. Our authority to deviate from this system in this instance is based on the authority of the Secretary to adjust payments if necessary to ensure payment equity among hospitals. A payment adjustment based on industry-wide thresholds would not create a payment differential among those hospitals with predominantly higher cost non-HEU sources and those hospitals with predominantly lower cost HEU sources. However, although we lack the authority to create a special payment to cover rising costs at the industry or manufacturer level, we note that the normal OPPS payment mechanism does exactly that: as costs rise, those costs will be passed on globally to hospitals and reflected in their

charges adjusted to costs and, therefore, ultimately reflected in the prospective payments calculated by our usual methodology. This add-on payment merely ensures equitable payments to hospitals through the transition where non-HEU sources are not uniformly distributed, while our established OPPS mechanisms will ensure that the total costs of new sources are incorporated into final payments year by year. We also have previously stated that we believe that costly changes in manufacturing solely to facilitate a transitional payment are not likely to occur, and that instead the payment can be expected to trigger small administrative changes. We expect that expensive changes in industry processes will not be driven by an interim payment but will occur only when those changes will continue to be necessary or desirable after the transition is complete.

Comment: A few commenters suggested that CMS, at a minimum, allow a payment adjustment for lower percentages (less than 100 percent) of non-HEU sources and institute a multiyear phase-in period. One commenter suggested that CMS establish a "threshold quotient" of non-HEU content in Tc-99m radiopharmaceuticals during CY 2013 and allow partial payment of the $10 additional payment amount. The commenter explained that this would require CMS to accept a given percentage amount of non-HEU source content and pay a corresponding percentage of the proposed $10 additional payment amount. The commenter gave the example of a payment of $1.50 for Tc-99m sources that contain 15 percent non-HEU, as $1.50 is 15 percent of the $10 proposed additional payment amount. The commenter also suggested that CMS could further promote the conversion to 100 percent non-HEU sources by adopting industry-wide

targets for conversion, which would include conversion to 25 percent in CY 2013, 50 percent in CY 2014, 75 percent in CY 2015, and 100 percent in CY 2016.

Another commenter suggested that a 10-percent industry threshold program be considered for CY 2013 in lieu of the 100 percent non-HEU sources proposed requirement. The commenter stated that a payment of no less than $10 could be given for non-HEU documented doses and that this would be more reflective of the short-term non-HEU Mo-99 supply.

Response: As noted above, our authority to establish this additional payment is based on the necessity to ensure equitable payments to hospitals, an authority that does not allow us to develop payments to promote the conversion of the industry to non-HEU sources. Therefore, our ability to create industry-wide payments is limited. We considered using one or more thresholds ranging from 10 percent to 80 percent to pay for blended sources that were not derived entirely from non-HEU sourced Mo-99, but determined that to be impractical for several reasons. First, the use of multiple codes to describe different mixtures of HEU and non-HEU sourced Mo-99 is immeasurably more complex than a simple single all or nothing coding choice, and many commenters were concerned about the complexity of even our proposed coding schema. Second, any blend of HEU and non-HEU sourced material will, as mentioned by the commenters, have reduced additional costs in proportion to the percentage of the blend. Because many commenters were concerned that $10 was small compared to the administrative effort they believed might be involved, we did not believe that a significantly smaller payment would be acceptable to that level of the supply chain.

Comment: Several commenters suggested that CMS extend the $10 additional payment for non-HEU sources for at least 5 years. The commenters stated that this period of time will be required to convert fully to non-HEU sources. Another commenter requested clarification of the proposed implementation date and methodology for calculating the total costs of radionuclide scans using claims data and the periodic recalculation of the estimated marginal cost of non-HEU Full Cost Recovery sources using models relying on the best available industry reports and projections, resulting in an adjustment in the payment of the proposed HCPCS code QXXXX accordingly, reducing the payment for the scans by the amount of cost paid through the HCPCS code QXXXX payment.

Response: Although we typically propose only the payments for the subsequent calendar year except in the case of adjustments that need to be phased in over multiple years, we did state our current expectations of the state of the industry and our expectations of a probable need for this additional payment over multiple years. We stated that our current expectation is that the transition to non-HEU sourced Mo-99 will be completed within 4 to 5 years. Therefore, we expect there may be a need to make differential payments for a period of 4 to 5 years. We will reassess, and propose, on an annual basis, whether such an adjustment under section 1833(t)(2)(E) of the Act continues to be necessary and whether any changes to the adjustment are needed. Again, our current expectation is that this additional payment will be needed for the duration of the industry's conversion to alternative methods to producing Tc-99m without HEU, which is expected to be completed within 4 to 5 years.

With respect to the request for clarification regarding future adjustments of this proposed payment, we note that the payment is being applied in addition to the standard procedure payment amount for nuclear medicine scans, including the diagnostic radioisotope and pharmaceutical, that is paid based on reported costs. As more non-HEU sourced Mo-99 is used, the costs reported by hospitals will contain costs associated with non-HEU conversion. Because the HCPCS code QXXXX is the indicator of non-HEU Mo-99 use and is also the vehicle for the additional payment, the rate at which extra payments are made will exactly follow the rate at which non-HEU sources are reported with their attendant additional costs. Therefore, even as we increase the payment for the nuclear medicine scan with radioisotope in the future due to increasing radioisotope costs, we expect to offset (reduce) the payment by the amount of the non-HEU add-on payment to avoid paying twice for non-HEU costs. This approach has the effect of using the add-on payment to make an additional payment for the cost of non-HEU sourced Mo-99 in the year that the cost appears, rather than waiting 18 months until the cost is reflected in the claims data. Consistent with our OPPS methods, though, we will still be basing the final payments for the nuclear medicine scans on the aggregate costs of the scan and its radioisotopes and pharmaceuticals as reported by hospitals. For example, suppose that 20 percent of hospitals in CY 2013 report non-HEU Tc-99m usage billed with HCPCS code QXXXX. The OPPS payment for the scan with its diagnostic radioisotope will still reflect 100 percent of the reported CY 2011 costs. The $10 from HCPCS code QXXXX will represent additional money because the higher cost non-HEU Tc-99m was not reflected in the CY 2011 cost data. However, when we set the rates for

CY 2015, those 20 percent of the hospitals who used non-HEU Tc-99m in CY 2013 will have reported higher costs for scans in the CY 2013 claims data because they had an additional cost from the non-HEU Tc-99m that they used. To eliminate a double payment, we will need to make an adjustment, such as removing the total dollars paid by HCPCS code QXXXX in CY 2013 (that is, the estimated additional cost of the non-HEU sourced isotope in those 20 percent of the claims) from the total reported procedure dollars in CY 2013 before setting the base procedure rate for CY 2015. We note that this offset does not reduce the payment for the scan below its current level; it only keeps the payment from going up as the cost of the radioisotope rises, because the increased cost of the radioisotope is being paid separately using HCPCS code QXXXX. In fact, in CY 2015, the utilization of non-HEU sourced Tc-99m should have continued to climb well beyond 20 percent. As in CY 2013, the dollars associated with increased utilization, that is, HCPCS code QXXXX billing in excess of the 20 percent, will again represent additional money over the total costs reflected in the CY 2013 claims.

Comment: A few commenters suggested that CMS alter the description of the proposed HCPCS code QXXXX by adding the word "study" into the descriptor in order to make this definition more consistent with the arcana of the radiopharmaceutical industry. The commenters stated that the descriptor for the HCPCS Q-code therefore would be HCPCS code QXXXX (Tc-99m from non-HEU source, full cost recovery add-on, per study dose). The commenters stated that it would be logical to add the word "study" because several nuclear cardiology procedures could require multiple Tc-99m doses administered alone with one CPT procedure code. Thus, they believed that

providers would purchase one to three study doses. The commenters further suggested that CMS clarify in this final rule with comment period that the add-on payment would apply to each per study dose of the complete service as described by the CPT procedure code. Therefore, the commenters stated, providers would be able to bill the HCPCS Q-code with multiple units and be paid $10 per the number of study doses provided during the procedure described by the CPT code, as appropriate.

Response: We acknowledge that it was our intent that this additional payment would be applied per study dose, such as the dose for the study performed at rest and the dose for the study performed with exercise. Therefore, we accept these recommendations and are modifying the proposed HCPCS definition to include the word "study" as follows: HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on, per study dose).

Comment: Several commenters requested that CMS clarify the proposal which requires a reduction to the payment for the scans by the amount of cost paid through the proposed HCPCS code QXXXX. The commenters were not sure whether the payment offset would be applied uniformly to all hospitals or only to those hospitals reporting non-HEU source doses. The commenters further requested that no reduction in payment for nuclear scans by made as a result of the additional $10 payment amount.

Response: Although commenters were not making this comment in the context of budget neutrality, the considerations that caused us to create a payment offset were driven by precisely that statutory constraint. As discussed above, because hospitals will not be required to separately report costs for non-HEU radioisotopes, all increased costs will be

reported as part of the charges for the nuclear scans. To preserve budget neutrality, an additional payment in one place must be accompanied by an offset somewhere else. To prevent double payment for the radioisotope, this offset will have to come from the payment for nuclear scans. Because all hospitals use the same codes for scans, and because parallel families of codes for scans using HEU and non-HEU sourced Tc-99m were not feasible, the offset will be applied to all hospitals. However, this offset will not occur until the claims data show non-HEU payments, at which time reported charges will presumably also reflect these increases in radioisotope costs. Thus, under the current expectations, if 10 percent of CY 2013 claims for a given nuclear scan show a $10 non-HEU add-on payment, $1 (10 percent of $10) will be offset in CY 2015 from the nuclear scan payment. However, if the 10 percent of hospitals claiming the $10 add-on payment also had $10 in increased costs, the calculated cost of a scan using CY 2013 data will have increased by $1 (10 percent of $10). The payment for CY 2015 would therefore increase by $1 because of the new costs in the claims data, and that new $1 will then be removed (offset) to go exclusively to the hospitals that are actually using the non-HEU sourced Tc-99m and are carrying the added cost. Therefore, we note that we are not reducing payments to all hospitals to offset the cost of this payment; rather, we are ensuring that the added costs of the non-HEU sourced Tc-99m go only to the hospitals incurring the costs and that their payments are not diluted by increased payments to uninvolved facilities. In this way, we are not offsetting the current nuclear scan payment by the $10 non-HEU add-on payment even though we currently plan to offset future

payment increases to the extent necessary to avoid double payments, as those increased costs will be included in the costs reported by hospitals.

Comment: Several commenters suggested that CMS use the average sales price (ASP) methodology to establish the additional payment amount for Tc-99m based on non-HEU sources. One commenter suggested that CMS use the ASP data when available as a benchmark for determining costs that are packaged. A few commenters suggested that payment based on the ASP methodology be applied in the same manner CMS pays for therapeutic radiopharmaceuticals. The commenters stated that this will establish transparency in the ratesetting for radioisotopes derived from non-HEU sources.

Response: We note that the ASP methodology does not apply to the Tc-99m radioisotope but only to the radiopharmaceutical that results from the combination of the isotope with the pharmaceutical moiety. Moreover, the ASP methodology is particularly unsuited to use on the radioisotope component alone because the isotope does not have an ASP. The radioisotope is typically produced by a generator and, whereas the ASP of a generator can be determined, the cost of a single dose is highly dependent on the number and timing of elutions of the generator, information that is not captured in the ASP. In fact, ASP is marginally valuable for Tc-99m radiopharmaceuticals only because the cost of the drug component is typically large compared to the cost of the isotope. This fact also argues against the comment that ASP would increase "transparency" of the cost of Tc-99m: there is no additional transparency of an isotope packaged into a payment with the drug than there is for an isotope packaged into a payment with the scan. Finally, the use of the ASP methodology would not differentiate between the cost of a non-HEU

sourced Tc-99m and the cost of using an HEU source, which is the purpose of this payment. The proposed additional payment accounts for the increased cost of the isotope, which meets both incremental payment and transparency goals.

Comment: A few commenters recommended that CMS establish parallel codes for the use of HEU and non-HEU sourced radiopharmaceuticals to collect cost data for future ratesetting. Most of the commenters were concerned with the complexity involved in adding and reporting a single code.

Response: We do not believe that an entire set of parallel codes would lessen the complexity or the administrative cost and, in fact, we believe it would significantly increase them. We acknowledge that this, like many other options we have had on other issues, could significantly improve the accuracy of our ratesetting. However, based on other comments from the hospitals that would have to use these parallel codes, we do not believe that we or the hospitals would consider the increased administrative cost to be worth the slight increase in payment precision.

Comment: A few commenters requested that CMS clarify the meaning of "calculation by 'Full Cost Recovery'". Some commenters also requested clarification of what this method encompasses.

Response: Full Cost Recovery is a concept that is well known to the producers, processors, and manufacturers but is not commonly discussed by radiopharmacies and hospitals. Unlike other supplies, radioisotopes typically require nuclear reactors for initial production, and many of the capital and environmental costs are not captured in the prices. For example, some reactors were built decades ago for other purposes and can be

used (relatively) “free of charge” because it costs almost the same to run the reactor and do nothing as it does to run the reactor and irradiate some uranium. This has implications on the accounting of capital costs, which, in many cases, were or are recovered by other uses to which the reactors were put. Similarly, moderately enriched uranium left over from previous programs may be cheaply downgraded and provided at a “low” cost because the alternative is to allow it to decay in storage with no consequent benefit. In both cases, the Tc-99m produced is obtained by hospitals at a bargain price, but not at a price that is sustainable because the old reactors will need to be replaced and the enriched uranium will be depleted. There are other unique costs for radioisotopes, such as the need to make arrangements for long-term storage of radioactive waste. Failure to account for those costs can lower the price of the radioisotope for some hospitals today but creates a long-term problem in that other hospitals must pick up the costs. Full Cost Recovery is the accounting principle that ensures that all of these long-term costs are included in cost calculations.

Full Cost Recovery is obviously not important to the hospitals although, because it is critically important in providing for the long-term supply of the radioisotope, it is actually a major underlying cause of payment inequities associated with this transition. From the standpoint of this final rule with comment period then, Full Cost Recovery is coupled to the non-HEU criterion for purposes of the additional payment. Just as manufacturers will indicate that certain Tc-99m doses are derived from non-HEU sources, it is our expectation that the irradiator (reactor) and the processor of the non-HEU Mo-99 will be able to confirm that Full Cost Recovery accounting was used in

setting the price of the non-HEU sourced Mo-99, an accounting principle that is considered integral to the conversion to non-HEU sources. We expect the generator manufacturer to affirm to the radiopharmacy that its source is non-HEU, with this designation including accounting according to Full Cost Recovery. As mentioned earlier, we consider this affirmation to be sufficient for the radiopharmacy and the hospital, regardless of whether the affirmation is in the form of a letter or statement, a notation on the invoice, or a label on the vial or tracking slip. We do not believe that independent verification is necessary or even possible for the radiopharmacy and the hospital and require only their due diligence in accepting claims made by their suppliers. The costs of new capital expenses such as new reactors, including all their associated costs, are factored into the manufacturer's price of the Tc-99m and passed down to hospitals, and the additional payment is made to account for those unique costs that the hospitals will incur.

Comment: One commenter asked that CMS delay finalizing the proposal until CY 2014 so that hospitals have adequate time to implement the proposed change. Another commenter recommended that CMS postpone the implementation of the proposed policy until CY 2015, so that hospitals could avoid the complexities of handling and segregating HEU sources versus non-HEU sources. Another commenter expressed doubt that hospitals would be able to obtain Tc-99m derived from non-HEU sources in CY 2013. Therefore, they requested that the proposal be deferred until CY 2014.

One commenter expressed concern about the availability of non-HEU sources because they were told by their suppliers that a 100 percent non-HEU source supply is

unavailable for CY 2012 and also will be unavailable by CY 2013. The commenter questioned whether this issue should be addressed by a payment system and suggested that this issue instead be addressed by the Administration as opposed to CMS. The commenter further suggested that the implementation of this proposal be delayed until there is some availability of 100 percent non-HEU sourced isotopes in this country.

Response: We considered the timing of this proposed additional payment after advice and consultation from both the Mo-99 industry and other U.S. agencies. We were initially advised that it is the understanding of the industry that conversion to non-HEU sources is already underway and is expected to be completed by the end of 2016. We understand this remains the case. We are aware that currently commercial Tc-99m is not readily available in the United States as it is in the world market, but that there also has not been a demand from within the United States. We do understand there is an expectation that it will make an appearance in CY 2013.

We acknowledge that the supply of non-HEU sourced Mo-99 may be small in CY 2013. However, we believe, as the industry believes, that conversion to non-HEU sourced Tc-99m is inevitable and will occur over the next several years. From the standpoint of the Medicare payment system, it is important for us to have some mechanism in place to mitigate any adverse impact on hospitals. If the supply is very low, hospitals will not be significantly disadvantaged and may elect to not make use of this additional payment in CY 2013. Conversely, if the supply starts to increase, some hospitals may be forced to shoulder a disproportionate share of the cost due to supplier relationships and contract status; this additional payment will create an opportunity for

those hospitals to mitigate that cost. We fully expect that utilization of this additional payment will be small in CY 2013 but will increase in CYs 2014, 2015, and 2016 as this conversion occurs. We reiterate that the normal mechanisms of the OPPS will ultimately incorporate increased costs into APC calculations with resultant increased payments for the nuclear scans that use this radioisotope that will allow us to retire or modify this payment and incorporate the entire additional cost into the base payment. This additional payment will enable hospitals to avoid any inequities caused by suddenly rising local costs that are not able to be captured in a timely fashion by usual methods. Based on the timetable for conversion and the rescue nature of the payment, we believe that a delay until CY 2014 or CY 2015 is unnecessary.

Comment: Several commenters suggested that an additional separate payment be given in other Medicare settings, including the physician's office and ASC, for radioisotopes derived from non-HEU sources. One commenter recommended that these additional payments also be made under Medicaid, the Department of Defense/Veterans Affairs, Indian Health Services health programs, and any other government health programs where nuclear medicine procedures are covered. This commenter acknowledged that its comments are outside the scope of the OPPS/ASC final rule with comment period.

Response: We agree with the commenter that addressing additional payments for radioisotopes derived from non-HEU sources in other settings and payment systems, such as the Physician's Office, Medicaid, the Department of Defense/Veterans Affairs, Indian Health Services health programs, and any other government health programs where

nuclear medicine procedures are covered, is outside the scope of the proposed rule and cannot be addressed in this final rule with comment period. In addition, we note that the Medicare authority for this additional payment is based on the need to establish equitable payments for hospitals. The authority to make equitable adjustments under section 1833(t)(2)(E) of the Act does not extend to the ASC setting. We do use a HCPCS Q-code as the vehicle for this additional payment so that other payers and other payment systems could use this code if desired.

After consideration of the public comments we received, we are finalizing our proposed policy with the modifications discussed above. Specifically, we are modifying the policy to provide that a product identified as non-HEU sourced must be at least 95 percent derived from non-HEU sources. We also are finalizing our proposal to establish a HCPCS code for Tc-99m from non-HEU sources with a revised code definition. The number and title of the new HCPCS code is HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on, per study dose) for CY 2013. HCPCS code Q9969 is assigned to APC 1442 (Non-HEU TC-99M Add-On/Dose) with a status indicator of "K" and a CY 2013 payment rate of $10.

D. OPPS APC-Specific Policies

1. Cardiovascular and Vascular Services

a. Cardiac Telemetry (APC 0213)

For CY 2013, we proposed to reassign CPT code 93229 (External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ecg data storage

(retrievable with query) with ecg triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and physician prescribed transmission of daily and emergent data reports) from APC 0209 (Level II Extended EEG, Sleep, and Cardiovascular Studies), which had a proposed rule payment rate of approximately $808, to APC 0340 (Minor Ancillary Procedures), which had a proposed rule payment rate of approximately $49.

Comment: One commenter disagreed with CMS' proposal to reassign CPT code 93229 to APC 0340 because the service described by CPT code 93229 involves the use of sophisticated technology requiring 24-hour, 7 days a week monitoring by a technician for up to 30 days, which according to the commenter, is not a minor procedure. According to the commenter, the proposed rule payment rate of approximately $49 is significantly lower than the MPFS payment rate of $694, and much lower than the average contractual arrangement charge to hospitals of $674. The commenter explained that while this procedure is performed primarily by independent diagnostic testing facilities (approximately 98 percent), this service is provided in the HOPD setting under contractual arrangements with hospitals. The commenter stated that the CPT code is fairly new because it was effective January 1, 2009, and suggested that the low geometric mean cost for the service could be attributed to miscoding by hospitals. The commenter believed that hospitals may be reporting CPT code 93229 incorrectly when they are actually performing other remote cardiac tests, such as the services described by CPT code 93226 (External electrocardiographic recording up to 48 hours by continuous

rhythm recording and storage; scanning analysis with report) or CPT code 93271 (External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; transmission and analysis), that require fewer resources. In addition, the commenter questioned the validity of the claims data, given the low number of claims billed under the OPPS. The commenter requested that CMS delay the reassignment of the service described by CPT code 93229 to APC 0340, and urged CMS to maintain CPT code 93229 in APC 0209 until more data are available to determine an appropriate payment for the service.

Response: The commenter is correct that CPT code 93229 was effective January 1, 2009. However, we believe that since that time hospitals have familiarized themselves with how to code this service appropriately. We have no reason to believe that hospitals are incorrectly reporting the service described by CPT code 93229, and note that we do not specify the methodologies that hospitals must use to set charges for this, or any other, procedure. The calculation of OPPS relative payment weights that reflect the relative resources required for HOPD services is the foundation of the OPPS. We rely on hospitals to bill all HCPCS codes accurately in accordance with their code descriptors and CPT and CMS instructions, as applicable, and to report charges on claims and charges and costs on their Medicare hospital cost report appropriately.

We do not agree with the commenter that it is necessary to delay the reassignment of CPT code 93229 to APC 0340. We examined our claims data for the last 3 years, given the concerns raised by the commenter regarding the low number of claims. Our

analysis revealed that the claims submitted for the service described by CPT code 93229 have steadily increased since CY 2009, but the cost for the procedure has been significantly lower than the APC payment rate. Specifically, the cost for the service described by CPT code 93229 in CY 2009 was approximately $287, based on 103 single claims (out of 114 total claims), approximately $260 in CY 2010, based on 184 single claims (out of 184 total claims), and approximately $172 for CY 2011, based on 1,949 single claims (out of 1,949 total claims). Based on the claims data, we have no reason to believe that the claims data used to calculate the cost for CPT code 93229 for CY 2013 does not appropriately reflect the hospitals cost for providing this service.

In addition, because of concerns raised by the commenter regarding reassigning CPT code 93229 to an APC that is labeled "Minor Ancillary Procedures," further review of our claims data for this final rule with comment period showed that CPT code 93229 would be more appropriately assigned to APC 0213 (Level I Extended EEG, Sleep, and Cardiovascular Studies) than APC 0340 based on its clinical homogeneity and resource costs in relation to the other procedures assigned to APC 0213. Our claims data show a geometric mean cost of approximately $**172** for CPT code 93229, which is relatively similar to the final geometric mean cost of approximately $178 for APC 0213.

Further, we recognize that the MPFS pays separately for CPT code 93229, but the MPFS and the OPPS are very different payment systems. Each system is established under a different set of statutory and regulatory principles, and the policies established under the MPFS do not have bearing on the payment policies under the OPPS.

In summary, after consideration of the public comment we received, we are finalizing our CY 2013 proposal, with modification. Specifically, we are reassigning CPT code 93229 from APC 0209 to APC 0213 (instead of the proposed APC 0340) for CY 2013. The final CY 2013 geometric mean cost for APC 0213 is approximately $178.

b. Mechanical Thrombectomy (APC 0653)

For CY 2013, we proposed to continue to assign CPT code 36870 (Thrombectomy, percutaneous, arteriovenous fistula, autogenous or nonautogenous graft (includes mechanical thrombus extraction and intra-graft thrombolysis)) to APC 0653 (Level I Hand Musculoskeletal Procedures), which had a proposed rule payment rate of approximately $2,445.

Comment: Some commenters expressed concern regarding the proposed 19.7 percent reduction in the payment rate for the APC in which the procedure describing a mechanical thrombectomy by arteriovenous access, CPT code 36870, is assigned. The commenters believed that such a reduction would impede Medicare beneficiary's access to the procedure. In addition, the commenters stated that CMS offered no explanation for the payment rate reduction, nor permitted adequate notice for a meaningful opportunity to comment. The commenters requested that CMS delay its proposal to reduce the payment rate for mechanical thrombectomy by AV access until stakeholders have been given a meaningful opportunity to comment.

Response: On an annual basis, CMS evaluates hospital outpatient claims data to determine the cost of procedures and services paid under the OPPS to ensure appropriate APC assignment for the following year. This evaluation generally results in establishing

new APCs, reassigning procedures and services to more appropriate APCs, or deleting APCs that are no longer applicable. In addition, this evaluation may result in revising relative payment weights, as well as wage and other adjustments, to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors. The OPPS proposed rule is published annually in the summer and is the mechanism used by CMS to inform the public of the proposed changes for the upcoming year and provide an opportunity for comment. As has been our practice, we encourage the public to submit their comments on issues addressed in the proposed rule. Comments received in response to the proposed rule are addressed in the final rule with comment period, which is also published annually in the winter.

For the CY 2013 update, our analysis of the latest hospital outpatient data for claims submitted for services provided during CY 2011 shows a geometric mean cost for CPT code 36870 of approximately $2,662, based on 539 single claims (out of 50,476 total claims), which is relatively similar to the proposed rule payment rate of approximately $2,748 for APC 0653. Based on our claims data, we believe that APC 0653 is the most appropriate APC assignment for CPT code 36870 based on its clinical homogeneity and resource costs in relation to the other procedures assigned to the APC. Consistent with our policy of reviewing APC assignments annually, we will again reevaluate the cost of CPT code 36870 and its APC assignment in CY 2013 for the CY 2014 rulemaking cycle.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal without modification. We will continue to maintain CPT code 36870 in APC 0653 for CY 2013. The final CY 2013 geometric mean cost for APC 0653 is approximately $2,748.

c. Non-Congenital Cardiac Catheterization (APC 0080)

For CY 2011, the AMA's CPT Editorial Panel restructured the Cardiac Catheterization section of the CPT codebook so that combinations of services that were previously reported using multiple codes are now reported with one CPT code. This revision deleted several non-congenital cardiac catheterization-related CPT codes from the 93500 series and created new CPT codes in the 93400 series and in the 93500 series. We discussed these coding changes in detail in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71846 through 71849), along with the process by which we assigned the new CPT codes to APCs that we believe are comparable with respect to clinical characteristics and resources required to furnish the cardiac catheterization services described by the new CPT codes. As discussed in that final rule with comment period, we were able to use the existing CY 2009 hospital outpatient claims data and the most recent cost report data to create simulated costs for the new separately payable CPT codes for CY 2011. Specifically, to estimate the hospital costs associated with the 20 new non-congenital cardiac catheterization-related CPT codes based on their CY 2011 descriptors, we used claims and cost report data from CY 2009. Because of the substantive coding changes associated with the new non-congenital cardiac catheterization-related CPT codes for CY 2011, we used our CY 2009 single and

"pseudo" single claims data to simulate the new CY 2011 CPT code definitions. We stated that many of the new CPT codes were previously reported using multiple CY 2009 CPT codes, and we provided a crosswalk of the new CY 2011 cardiac catheterization CPT codes mapped to the CY 2009 cardiac catheterization CPT codes in Table 11 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71849). Table 11 showed the criteria we applied to select a claim to be used in the calculation of the cost for the new codes (shown in Column A). As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71847 through 71848), we developed these criteria based on our clinicians' understanding of the services that were reported by the CY 2009 CPT codes that, in various combinations, reflect the services provided that are described in the new CPT codes. We used approximately 175,000 claims for the new non-congenital catheterization-related CPT codes, together with the single and "pseudo" single procedure claims for the remaining non-congenital catheterization-related CPT codes in APC 0080 (Diagnostic Cardiac Catheterization), to calculate CPT code level costs and the payment rate for APC 0080 of approximately $2,698. We noted that, because the CPT codes listed in Table 11 were new for CY 2011, they were identified with comment indicator "NI" in Addendum B to that final rule with comment period to indicate that the interim APC assignment was subject to public comment. We specifically requested public comment on our methodology for simulating the costs for these new CY 2011 CPT codes, in addition to public comments on the payment rates themselves (75 FR 71848).

For CY 2012, we continued to use the CY 2011 methodology in determining the APC assignments for the new cardiac catheterization CPT codes. That is, we continued to use the CY 2011 methodology in determining the APC assignments for the cardiac catheterization CPT codes by using the existing hospital outpatient claims and the cost report data from the predecessor cardiac catheterization CPT codes to simulate an estimated cost for the new cardiac catheterization CPT codes in determining the appropriate APC assignments. Specifically, we used the CY 2010 hospital outpatient claims data and the most recent cost report data to create simulated costs for the new separately payable CPT codes for CY 2012 to determine the payment rates for the APC to which the cardiac catheterization CPT codes were assigned. For CY 2012, we did not make any changes to the CY 2011 APC assignments of any of the CPT codes assigned to APC 0080 because the claims data supported continuation of these APC assignments.

As we discussed in the CY 2013 OPPS/ASC proposed rule, because the cardiac catheterization CPT codes were new for CY 2011, CY 2013 is the first year that claims data are available for ratesetting for these specific CPT codes (77 FR 45084 through 45085). For CY 2013, our analysis of the CY 2011 claims data available for the proposed rule showed no violation of the 2 times rule for the cardiac catheterization CPT codes because the lowest cost of a CPT code with significant claims data in APC 0080 was approximately $1,716 (for CPT code 93451), while the highest cost of a CPT code with significant claims data was approximately $3,308 (for CPT code 93461). We stated in the proposed rule that we believe that the cardiac catheterization CPT codes continue to be appropriately assigned to APC 0080 based on clinical homogeneity and resource

costs. Therefore, for CY 2013, we proposed to continue to assign the cardiac catheterization CPT codes to APC 0080.

Comment: One commenter pointed out that CPT codes 93463 (Pharmacologic agent administration (eg, inhaled nitric oxide, intravenous infusion of nitroprusside, dobutamine, milrinone, or other agent) including assessing hemodynamic measurements before, during, after and repeat pharmacologic agent administration, when performed (list separately in addition to code for primary procedure)) and 93464 (Physiologic exercise study (eg, bicycle or arm ergometry) including assessing hemodynamic measurements before and after (list separately in addition to code for primary procedure)), which appeared in Table 5 (Proposed APCs to Which Non-Congenital Cardiac Catheterization CPT Codes Would Be Assigned for CY 2013) of the CY 2013 OPPS/ASC proposed rule do not appear to represent cardiac catheterization procedures.

Response: CPT codes 93463 and 93464 are packaged procedures. These CPT codes appeared in Table 5 of the CY 2013 OPPS/ASC proposed rule because these procedures are performed in conjunction with cardiac catheterization procedures. CPT code 93463 is an add-on code that describes a pharmacologic agent that may be administered when a cardiac catherization procedure is performed. Similarly, CPT code 93464 is an add-on code that describes a physiologic exercise test that may be combined with a cardiac catheterization. Because these procedures are used in conjunction with cardiac catherization procedures, we believe that listing them in Table 5 of the CY 2013 OPPS/ASC proposed rule was appropriate.

After consideration of the public comment that we received, we are finalizing our proposal, without modification, to continue to assign the cardiac catheterization CPT codes to APC 0080 for CY 2013, as listed below in Table 20 below. The final CY 2013 geometric mean cost for APC 0080 is approximately $2,726.

TABLE 20.—APCs TO WHICH NON-CONGENITAL CARDIAC CATHETERIZATION CPT CODES ARE ASSIGNED FOR CY 2013

CY 2013 HCPCS Code	CY 2013 Short Descriptor	CY 2012 SI	CY 2012 APC	CY 2013 SI	CY 2013 APC
93451	Right heart cath	T	0080	T	0080
93452	Left hrt cath w/ventrclgrphy	T	0080	T	0080
93453	R&l hrt cath w/ventriclgrphy	T	0080	T	0080
93454	Coronary artery angio s&i	T	0080	T	0080
93455	Coronary art/grft angio s&i	T	0080	T	0080
93456	R hrt coronary artery angio	T	0080	T	0080
93457	R hrt art/grft angio	T	0080	T	0080
93458	L hrt artery/ventricle angio	T	0080	T	0080
93459	L hrt art/grft angio	T	0080	T	0080
93460	R&l hrt art/ventricle angio	T	0080	T	0080
93461	R&l hrt art/ventricle angio	T	0080	T	0080
93462	L hrt cath trnsptl puncture	T	0080	T	0080
93463	Drug admin & hemodynmic meas	N	NA	N	NA
93464	Exercise w/hemodynamic meas	N	NA	N	NA
93565	Inject l ventr/atrial angio	N	NA	N	NA
93566	Inject r ventr/atrial angio	N	NA	N	NA
93567	Inject suprvlv aortography	N	NA	N	NA
93568	Inject pulm art hrt cath	N	NA	N	NA

d. Endovascular Revascularization of the Lower Extremity (APCs 0083, 0229, and 0319)

For the CY 2011 update, the AMA's CPT Editorial Panel created 16 new CPT codes under the Endovascular Revascularization section of the 2011 CPT codebook to describe endovascular revascularization procedures of the lower extremity performed for occlusive disease. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71841 through 71845), we discussed the process and methodology by which we assigned the CY 2011 endovascular revascularization CPT codes to APCs that we believe are comparable with respect to clinical characteristics and resources required to furnish the services. Specifically, we were able to use the existing CY 2009 hospital outpatient claims data and the most recent cost report data to create simulated costs for 12 of the 16 new separately payable CPT codes for CY 2011. Because the endovascular revascularization CPT codes were new for CY 2011, we used our CY 2009 single and "pseudo" single claims data to simulate the new CY 2011 CPT code definitions. As shown in Table 7 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71844), many of the new endovascular revascularization CPT codes were previously reported using a combination of CY 2009 CPT codes. In order to simulate costs, we selected claims that we believe met the definition for each of the new endovascular revascularization CPT codes. Table 7 showed the criteria we applied to select a claim to be used in the calculation of the costs for the new CPT codes (shown in Column A). As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71842), we developed these criteria based on our clinicians' understanding of services

that were reported by the CY 2009 CPT codes that, in various combinations, reflect the services provided that are described by the new CPT codes for CY 2011.

After determining the simulated costs for the procedures, we assigned each CPT code to appropriate APCs based on their clinical homogeneity and resource use. Of the 16 CPT new codes, we assigned 9 CPT codes to APC 0083 (Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty) and 5 CPT codes to APC 0229 (Transcatheter Placement of Intravascular Shunts), and created new APC 0319 (Endovascular Revascularization of the Lower Extremity) for the remaining 2 CPT codes. Table 8 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71845) displayed their final CY 2011 APC assignments and CPT code costs. We noted that, because these CPT codes were new for CY 2011, they were assigned comment indicator "NI" in Addendum B to the CY 2011 OPPS/ASC final rule with comment period to identify them as new interim APC assignments for CY 2011, and subject to public comment. We specifically requested public comment on our methodology for simulating the costs for these new CY 2011 CPT codes in addition to public comments on the payment rates themselves (75 FR 71845).

As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74156), for CY 2012, we continued to use the CY 2011 methodology to determine the APC assignments for the CPT codes that describe endovascular revascularization of the lower extremity. Because previous endovascular revascularization CPT codes were in existence prior to CY 2011 and assigned to designated APCs, we continued to use existing hospital outpatient claims and cost report

data from the established CPT codes to simulate estimated costs for the endovascular revascularization CPT codes to determine the appropriate APC assignments for CY 2012, as we did for CY 2011. In the CY 2012 OPPS/ASC final rule with comment period, we also revised the title of APC 0083 from "Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty" to "Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization of the Lower Extremity"; revised the title of APC 0229 from "Transcatheter Placement of Intravascular Shunts and Stents" to "Level II Endovascular Revascularization of the Lower Extremity"; and revised the title of APC 0319 from "Endovascular Revascularization of the Lower Extremity" to "Level III Endovascular Revascularization of the Lower Extremity".

Because the endovascular revascularization of the lower extremity CPT codes were new for CY 2011, CY 2013 is the first year of claims data that are available for ratesetting for these specific CPT codes. For CY 2013, review of the procedures with significant claims data in APCs 0083, 0229, and 0319 did not show 2 times rule violations in these APCs. In the CY 2013 OPPS/ASC proposed rule, we stated that we believe that the endovascular revascularization CPT codes assigned to APCs 0083, 0229, and 0319 continue to be appropriately assigned based on clinical homogeneity and resource costs. Therefore, we proposed to continue to assign the endovascular revascularization CPT codes to APCs 0083, 0229, and 0319 for CY 2013 (77 FR 45083 through 45084).

Comment: Several commenters believed that the assignment of CPT code 37183 (Revision of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous

access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract recanulization/dilatation, stent placement and all associated imaging guidance and documentation) and 37210 (Uterine fibroid embolization (ufe, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the procedure) to APC 0229 (Level II Endovascular Revascularization of the Lower Extremity) violated the 2 times rule. The commenter believed that these two codes should be reassigned to APC 0083 (Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization of the Lower Extremity).

Response: As stated above, in determining whether a 2 times rule violation exists in an APC, we consider only those HCPCS (both CPT and Level II Alphanumeric HCPCS codes) codes that are significant based on the number of claims. For purposes of identifying significant HCPCS codes for examination to determine if they violate 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 definition of when a code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a code for which there are fewer than 99 single claims and

which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost.

For this CY 2013 OPPS/ASC final rule with comment period, our analysis of the CY 2011 claims data showed that CPT code 37183 had 211 single claims (out of 302 total claims) while CPT code 37210 had 211 single claims (out of 254 total claims). Of the 12 procedures assigned to APC 0229, only 5 procedures meet the definition of significant claims. Specifically, CPT codes 37205 (Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; initial vessel), 37221 (Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed), 37225 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed), 37226 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed), and 37229 (Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed) have significant claims data to determine whether a violating of the 2 times rule exists within APC 0229. Review of the procedures assigned to APC 0229 revealed that the range of the CPT geometric mean costs for the procedures with significant claims data is between approximately $7,013 (for CPT code 37205, which represents 14 percent of the single claims) and

approximately $9,915 (for CPT code 37229, which represents 5 percent of the single claims). Taking into consideration all of the codes with significant claims that are assigned to APC 0229, CPT codes 37183 and 37210 do not meet the definition of significant claims to determine if there is a violation of the 2 times rule within APC 0229.

Therefore, based on the clinical similarity to other procedures currently assigned to APC 0229, and because there is no determination of a violation of the 2 times rule, we are continuing to assign CPT codes 37183 and 37210 to APC 0229 for CY 2013. For CY 2013, APC 0229 has a final geometric mean cost of approximately $8,905.

Comment: Several commenters recommended the reassignment of add-on CPT code 37223 (Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure)) from APC 0083 to APC 0229 because the proposed geometric mean cost of the procedure is similar to the geometric mean costs of procedures assigned to APC 0229 (although the commenters also pointed out that the cost data calculated from single claims for CPT code 37223 are unreliable because CPT code 37223 is an add-on code and would not appear by itself on a claim). Some commenters also argued that the assignment of CPT code 37223 to APC 0083 results in a violation of the 2 times rule. The commenters stated that the reassignment of CPT code 37223 to APC 0229 would be consistent with CMS' policy of assigning add-on codes to the same APC as their base codes. In addition, the commenters asserted that this reassignment would not only ensure patient access for this therapeutic procedure, but also would promote clinical

homogeneity and similar resource cost of procedures assigned to APC 0229 and provide accurate payment for the procedure.

Response: Although there are many add-on codes that have been assigned to the same APC as their base code, there are some procedures that are add-on codes that have been assigned to different APCs from their base or primary codes. In establishing an appropriate APC assignment, we take into consideration the clinical homogeneity and similarity in resource use associated with the procedure or service. This determination may result in the same APC assignment for both the base code and the add-on code, or in different APC assignments, as illustrated in Table 21 below. Therefore, we disagree with the commenters' assertion that we should reassign CPT code 37223 to APC 0229 so that it is in the same APC as its base code.

We also do not agree with commenters that the composition of APC 0083 constitutes a violation of the 2 times rule because CPT code 37223 does not have sufficient single claims to qualify as a significant procedure for purposes of applying the 2 times rule, as described earlier in this section. Based on our understanding of the procedure, we continue to believe that APC 0083 is the most appropriate assignment for CPT code 37223 based on clinical considerations and similarity in resource use to other procedures assigned to APC 0083, as we have stated in the past (76 FR 74156).

TABLE 21.—EXAMPLES OF BASE AND ADD-ON CPT CODES THAT ARE ASSIGNED TO DIFFERENT APCs

CY 2013 CPT Code	CY 2013 Short Descriptor	CY 2013 SI	CY 2013 APC
11000	Debride infected skin	T	0016
11001*	Debride infected skin add-on	T	0013

CY 2013 CPT Code	CY 2013 Short Descriptor	CY 2013 SI	CY 2013 APC
11044	Deb bone 20 sq cm/<	T	0020
11047*	Deb bone add-on	T	0019
11100	Biopsy skin lesion	T	0015
11101*	Biopsy skin add-on	T	0013
13101	Repair of wound or lesion	T	0135
13102*	Repair wound/lesion add-on	T	0134
56605	Biopsy of vulva/perineum	T	0189
56606*	Biopsy of vulva/perineum	T	0188
64479	Inj foramen epidural c/t	T	0207
64480*	Inj foramen epidural add-on	T	0206

*Add-on procedure code.

Further, in response to the commenters' concerns regarding providing accurate payment for the procedure described by CPT code 37223 to ensure patient access, we believe that the payment rate for the procedure does not inhibit HOPDs from performing the procedure. The OPPS, like other Medicare payment systems, is budget neutral and overall increases in payments are limited to the hospital inpatient market basket increase. We believe that our payment rates generally reflect the costs that are associated with providing care to Medicare beneficiaries in cost efficient settings, and we believe that our payment rates are adequate to ensure access to services.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to assign CPT code 37223 to APC 0083 for CY 2013.

Comment: One commenter believed that CPT codes 37234 (Revascularization, endovascular, open or percutaneous, tibial/ peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel,

when performed (list separately in addition to code for primary procedure)), and 37235 (Revascularization, endovascular, open or percutaneous, tibial/ peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure)) are inappropriately assigned to APC 0083, and recommended that they be reassigned to APC 0229. The commenter indicated that these procedures involve both angioplasty with stent placements, similar to the procedure described by CPT code 37221 (Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed), which is assigned to APC 0229. The commenter also stated that CPT codes 37234 and 37235 are similar to the stent procedures described by CPT codes 37205 (Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; initial vessel) and 37206 (Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; each additional vessel (list separately in addition to code for primary procedure)), which are assigned to APC 0229. The commenter concluded that the payment rate for APC 0083 does not reflect the resources associated with placement of a cardiovascular stent; therefore, CPT codes 37234 and 37235 should be reassigned to APC 0229.

Response: We continue to believe that APC 0083 is the most appropriate assignment for these CPT codes based on clinical and resource considerations. We do not agree that the procedures described by CPT codes 37234 and 37235 are dissimilar to

other procedures in APC 0083 because they involve a stent. In addition, an analysis of CY 2011 claims data shows only one single claim for CPT code 37234 (out of 153 total claims) and no single claims (out of 31 total claims) for CPT code 37235. Therefore, the outpatient claims data do not support an APC reassignment of these CPT codes. Because these CPT codes were made effective January 1, 2011, CY 2011 is the first year of claims data available for CPT codes 37234 and 37235. Consistent with CMS' policy of reviewing APC assignments annually, we will reevaluate the cost of these procedures and their APC assignments next year for the CY 2014 rulemaking cycle.

After consideration of the public comment we received, we are finalizing our CY 2013 proposal, without modification, to continue to assign CPT codes 37234 and 37235 to APC 0083, which has a CY 2013 final geometric mean cost of approximately $4,139.

Table 22 below provides the list of endovascular revascularization CPT codes assigned to APCs 0083, 0229, and 0319 for CY 2013.

TABLE 22.—APCs TO WHICH ENDOVASCULAR REVASCULARIZATION OF THE LOWER EXTREMITY CPT CODES WILL BE ASSIGNED FOR CY 2013

CY 2013 CPT Code	CY 2013 Short Descriptor	CY 2012 SI	CY 2012 APC	CY 2013 SI	CY 2013 APC
37220	Iliac revasc	T	0083	T	0083
37221	Iliac revasc w/stent	T	0229	T	0229
37222	Iliac revasc add-on	T	0083	T	0083
37223	Iliac revasc w/stent add-on	T	0083	T	0083
37224	Fem/popl revas w/tla	T	0083	T	0083
37225	Fem/popl revas w/ather	T	0229	T	0229

CY 2013 CPT Code	CY 2013 Short Descriptor	CY 2012 SI	CY 2012 APC	CY 2013 SI	CY 2013 APC
37226	Fem/popl revasc w/stent	T	0229	T	0229
37227	Fem/popl revasc stnt & ather	T	0319	T	0319
37228	Tib/per revasc w/tla	T	0083	T	0083
37229	Tib/per revasc w/ather	T	0229	T	0229
37230	Tib/per revasc w/stent	T	0229	T	0229
37231	Tib/per revasc stent & ather	T	0319	T	0319
37232	Tib/per revasc add-on	T	0083	T	0083
37233	Tibper revasc w/ather add-on	T	0229	T	0229
37234	Revsc opn/prq tib/pero stent	T	0083	T	0083
37235	Tib/per revasc stnt & ather	T	0083	T	0083

e. External Electrocardiographic Monitoring (APC 0097)

In the CY 2012 OPPS/ASC final rule with comment period, we assigned new CPT codes 0296T (External electrocardiographic recording) and 0297T (External electrocardiographic recording; scanning analysis with report) on an interim basis to APC 0097 (Level I Non-Invasive Physiologic Studies), which has a CY 2012 payment rate of approximately $68 and a CY 2013 proposed payment rate of approximately $67.

Comment: One commenter who responded to the CY 2012 OPPS/ASC final rule with comment period supported our placement of CPT code 0296T in APC 0097. The commenter stated that the service described by CPT code 0296T is clinically similar to other services in that APC. However, the commenter believed that CPT code 0297T would be more appropriately assigned to APC 0692 (Level II Electronic Analysis of Devices), which has a CY 2013 proposed rule cost of approximately $113). The commenter argued that CPT code 0297T is similar in nature and in required resources to

CPT code 93271 (Electrocardiographic monitoring and analysis), which is assigned to APC 0692, because it has a similar monitoring period and requires similar network and information technology resources.

Response: Based on our understanding of the resources that are required to furnish the services described by CPT codes 93271 and 0297T, we do not agree with the commenter. The service described by CPT code 93271 includes 24-hour attended monitoring, while the service described by CPT 0297T does not. Therefore, we believe that CPT code 0297T is more clinically similar to the services assigned to APC 0097. Therefore, for CY 2013, we will continue to assign this service to APC 0097, which has a final CY 2013 geometric mean cost of approximately $68. We will reevaluate the APC placement using our standard ratesetting methodology when we receive claims data for these services.

f. Echocardiography (APCs 0177, 0178, 0269, 0270, and 0697)

Under the OPPS, echocardiography services are reported using a combination of CPT codes and HCPCS C-codes. Hospitals report the echocardiography CPT codes when performing echocardiography procedures without contrast. Alternatively, hospitals report the HCPCS C-codes when performing echocardiography procedures with contrast, or procedures without contrast followed by procedures with contrast. In addition to the HCPCS C-codes, hospitals should also report the appropriate units of the HCPCS codes for the contrast agents used in the performance of the echocardiograms.

Currently, there are four APCs that describe echocardiography services:

- APC 0128 (Echocardiogram With Contrast)

- APC 0697 (Level I Echocardiogram Without Contrast)
- APC 0269 (Level II Echocardiogram Without Contrast)
- APC 0270 (Level III Echocardiogram Without Contrast)

For CY 2013, we proposed payment rates for these APCs of approximately $571, $212, $392, and $558, respectively.

Comment: One commenter expressed concern regarding the APC assignment of the procedures for fetal echocardiography to APC 0697. The commenter believed that this APC classification and payment rate are inconsistent with the resources required to perform fetal echocardiography studies. These resources, the commenter noted, substantially exceed the resources generally needed for adult services. Therefore, the commenter recommended that CMS reassign fetal echocardiography CPT codes 76825 (Echocardiography, fetal, cardiovascular system, real time with image documentation (2d), with or without m-mode recording;) and 76826 (Echocardiography, fetal, cardiovascular system, real time with image documentation (2d), with or without m-mode recording; follow-up or repeat study) to the same APC as adult echocardiography procedures, APC 0269 (Level II Echocardiogram Without Contrast).

Response: For the CY 2013 OPPS/ASC proposed rule, we proposed to assign CPT codes 76825 and 76826 to APC 0697, which had a proposed payment rate of $211.71. As we stated in the CY 2012 OPPS/ASC final rule with comment period, because these codes have been in existence for almost 20 years, and have been reportable under the OPPS since it was implemented in 2000, we believe that the low frequency of these services is the result of infrequent use of this procedure on Medicare beneficiaries.

Analysis of our claims data from past years revealed that these procedures are relatively low volume procedures. CPT code 76825 has had fewer than 330 single claims for ratesetting for each year with a cost that has ranged between approximately $88 and approximately $140. Similarly, CPT code 76826 has had fewer than 50 single claims for ratesetting for each year with a cost that has ranged between approximately $85 and approximately $92. For this CY 2013 OPPS/ASC final rule with comment period, CPT codes 76826 and 76825 are assigned APCs with payment rates that exceed their respective individual geometric mean costs. Therefore, based on our claims data, we believe that CPT codes 76825 and 76826 are appropriately assigned to APC 0697 for CY 2013 based on their clinical homogeneity and resource costs of the other procedure assigned to APC 0697.

Comment: Several commenters expressed concern regarding a violation of the 2 times rule for APC 0128 and urged CMS not to finalize an exemption from the 2 times rule for APC 0128. The commenters stated that the assignment of HCPCS codes C8924 (Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, follow-up or limited study) and C8930 (Transthoracic echocardiography, with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with physician supervision) to APC 0128 results in a

violation of the 2 times rule in particular, and that the other procedures assigned to APC 0128 are not clinically comparable in nature, therefore resulting in an APC payment rate that does not reflect the wide range of resources utilized for the procedures assigned to APC 0128. The commenters further recommended that CMS reconfigure APC 0128 so that the procedures are clinically similar with respect to resources. One commenter recommended that CMS adopt three levels of contrast-enhanced APCs that parallel the three APCs that have been established for non-contrast enhanced procedures.

Response: As stated above, we have four separate APCs to which echocardiography services are assigned. Procedures that utilize contrast agents are currently assigned to APC 0128, while procedures without contrast agents are assigned to one of three APCs, specifically APC 0270, APC 0269, or APC 0697. In the CY 2013 OPPS/ASC proposed rule, we proposed a payment rate for APC 0128 of approximately $571 for CY 2013. As we do every year, we reviewed our claims data for the services assigned to APC 0128. Based on our review, and taking into consideration the public comments received in response to the final rule with comment period, we agree with commenters that APC 0128 has a 2 times violation that cannot be exempted for this CY 2013 OPPS/ASC final rule with comment period. As we have stated in section III.B. of this final rule with comment period, we make exemptions to the 2 times rule's limit on the variation of costs within each APC group in unusual cases, such as low volume items and services. In deciding to propose exemptions to the 2 times rule, we look at the respective APC's resource homogeneity, clinical homogeneity, hospital outpatient setting, frequency of service (volume), and opportunity for upcoding and code

fragmentation. We believe that, for this CY 2013 OPPS/ASC final rule with comment period, it would be inappropriate to exempt APC 0128 from the 2 times rule and to continue to assign echocardiography services utilizing contrast agents to one APC, based on our evaluation of the aforementioned criteria. Therefore, for CY 2013, we are splitting APC 0128 to create two new level APCs: APC 0177 (Level I Echocardiogram with Contrast) and APC 0178 (Level II Echocardiogram with Contrast).

After consideration of the public comments we received, we are finalizing our proposals, with the modifications mentioned above, to continue to calculate the costs of the HCPCS codes describing the non-contrast echocardiography procedures based on APCs 0697, 0269, and 0270, and to calculate the costs for the HCPCS codes describing contrast echocardiography procedures based on new APCs 0177 and 0178. For a more detailed discussion and history of the OPPS payment for echocardiography services, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66644 through 66646), the CY 2009 OPPS/ASC final rule with comment period (72 FR 68542 through 68544), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60374 through 60383).

Table 23 below shows the procedure assignments and the final geometric mean cost assigned to echocardiography APCs, including the new Level I and Level II Echocardiogram with Contrast APCs.

TABLE 23.—APC ASSIGNMENTS FOR ECHOCARDIOGRAPHY PROCEDURES FOR CY 2013

APC	HCPCS Code	Short Descriptor	Final CY 2013 Geometric Mean Cost
0177 (Level I Echocardiogram With Contrast)	C8924	2D TTE w or w/o fol w/con,fu	$446.38
	C8922	TTE w or w/o fol w/cont, f/u	
	C8923	2D TTE w or w/o fol w/con,co	
	C8927	TEE w or w/o fol w/cont, mon	
0178 (Level II Echocardiogram With Contrast)	C8921	TTE w or w/o fol w/cont, com	$594.96
	C8925	2D TEE w or w/o fol w/con,in	
	C8926	TEE w or w/o fol w/cont,cong	
	C8928	TTE w or w/o fol w/con,stres	
	C8929	TTE w or wo fol wcon,Doppler	
	C8930	TTE w or w/o contr, cont ECG	
0697 (Level I Echocardiogram Without Contrast)	76825	Echo exam of fetal heart	$218.76
	76826	Echo exam of fetal heart	
	93308	Tte f-up or lmtd	
0269 (Level II Echocardiogram Without Contrast)	93304	Echo transthoracic	$401.69
	93306	Tte w/doppler complete	
	93307	Tte w/o doppler complete	
	93313	Echo transesophageal	
	93315	Echo transesophageal	
	93350	Stress tte only	
0270 (Level II Echocardiogram Without Contrast)	93303	Echo transthoracic	$574.69
	93312	Echo transesophageal	
	93316	Echo transesophageal	
	93318	Echo transesophageal intraop	
	93351	Stress tte complete	

2. Gastrointestinal Services

a. Laparoscopic Adjustable Gastric Band (APC 0132)

Effective January 1, 2006, the AMA's CPT Editorial Panel established CPT code 43770 (Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)) to describe the bariatric placement of an adjustable band by laparoscopy. From January 1, 2006 through December 31, 2011, CPT code 43770 was assigned to status indicator "C" to indicate that the procedure was not paid separately under the OPPS because the procedure was considered an "inpatient" procedure. However, in the CY 2012 OPPS/ASC final rule (76 FR 74355), we stated that we received a comment requesting that this CPT code be removed from the inpatient list and assigned to a separately payable APC, effective January 1, 2012. Based on input from our physicians and review of our claims data, we determined that it was appropriate to remove CPT code 43770 from the inpatient list because patients undergoing this procedure can typically be managed postoperatively as outpatients. Consequently, we assigned CPT code 43770 to APC 0131 (Level II Laparoscopy), effective January 1, 2012.

At the August 2012 HOP Panel meeting, a presenter requested that the Panel recommend to CMS the reassignment of CPT code 43770 from APC 0131 to a new APC. The commenter expressed concern about the existing APC assignment and indicated that APC 0131 does not adequately cover the costs of performing the procedure. After discussion of the procedure and review of the hospital outpatient claims data, the Panel recommended that CPT code 43770 remain in APC 0131 for the CY 2013 update.

For CY 2013, we proposed to continue to assign CPT code 43770 to APC 0131, which had a proposed rule payment rate of approximately $3,497.

Comment: Several commenters disagreed with the proposal to continue to assign CPT code 43770 to APC 0131 because the procedure is different from other procedures assigned to this APC. According to one commenter, the procedures assigned to APC 0131 are less intensive (for example, resource cost) than CPT code 43770. Another commenter stated that the procedures assigned to APC 0131 are not similar to CPT code 43770 because this procedure includes the implantation of a gastric band device as well as a port device, while the other procedures assigned to this APC do not. In addition, some commenters believed that assignment of CPT code 43770 to APC 0131 violates the 2 times rule. According to the commenters, there is no existing APC that includes procedures that are comparable to the procedures described by CPT code 43770, both clinically and in terms of resource utilization. Therefore, they requested that CMS establish a new APC for CPT code 43770 to ensure the most appropriate payment for this procedure.

However, we received conflicting statements on the issue of clinical comparability from some of the commenters. One commenter stated that, although there is no existing APC that accurately fits with CPT code 43770, the commenter mentioned that APC 0132 (Level III Laparoscopy) does include some procedures that are more clinically comparable to CPT code 43770 than the procedures assigned to APC 0131, and suggested that APC 0132 would be an appropriate APC assignment for this procedure. Another commenter considered suggesting a reassignment of CPT code 43770 to APC

0132 but stated that the procedures assigned to APC 0132 are not comparable in terms of resource utilization. Although most of the commenters agreed that establishing a new APC for CPT code 43770 would be more appropriate, some commenters suggested assigning the procedure to APC 0132 as an interim APC assignment if a new APC cannot be established for the CY 2013 update.

Response: We do not agree with the commenters' assertion that assigning CPT code 43770 to APC 0131 violates the 2 times rule. In determining whether a 2 times rule violation exists in an APC, we consider only those HCPCS codes that are significant based on the number of claims. 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 comprise at least 2 percent of the single major claims used to establish the costs of the procedures assigned to an APC to be significant (75 FR 71832). This longstanding definition of when a HCPCS code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a HCPCS code for which there are fewer than 99 single claims and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the costs of the procedures in an APC. For the CY 2013 OPPS/ASC proposed rule, claims data for CPT code 43770 showed 171 single claims out of 216 total claims and comprised less than 1 percent of the claims for procedures within APC 0131. Although CPT code 43770 had more than 99 single major claims, it did not contribute to

at least 2 percent of the single major claims for procedures within APC 0131. Therefore, in the CY 2013 OPPS/ASC proposed rule, we determined that assigning CPT code 43770 to APC 0131 did not violate the 2 times rule because it did not meet the definition of a significant HCPCS code.

As stated above, the HOP Panel made a recommendation to continue to assign CPT code 43770 to APC 0131 for the CY 2013 update. However, after the Panel meeting, we reviewed our more recent claims data for this final rule with comment period, and our analysis revealed that the procedure would be more appropriately assigned to APC 0132 (Level III Laparoscopy). Specifically, our analysis showed 213 single claims (out of 262 total claims) for CPT code 43770 with a geometric mean cost of approximately $7,410. Furthermore, our analysis revealed that CPT code 43770 meets the definition of significant claims because the procedure represents more than 99 single major claims and contribute to at least 2 percent of the claims for procedures within APC 0132. Consequently, we do not agree with the Panel's recommendation, and are reassigning CPT code 43770 to APC 0132.

In summary, after consideration of the public comments we received, we are revising the APC assignment for CPT code 43770 from APC 0131 to 0132 for CY 2013. The final CY 2013 geometric mean cost for APC 0132 is approximately $5,268.

b. Transoral Incisionless Fundoplication (APC 0422)

For CY 2013, we proposed to continue to assign CPT code C9724 (Endoscopic full-thickness plication in the gastric cardia using endoscopic plication system (eps);

includes endoscopy) to APC 0422 (Level III Upper GI Procedures), which had a proposed payment rate of approximately $1,878.

We note that at the August 2012 HOP Panel meeting, a presenter requested that the Panel recommend to CMS the reassignment of HCPCS code C9724 from APC 0422 to a new APC, or alternatively, to establish a new APC with a descriptor of "Level IV Upper GI Procedures." The commenter stated that the payment rate for APC 0422 does not cover the cost of providing the procedure. After discussion of the procedure and review of the hospital outpatient claims data, the Panel recommended that HCPCS code C9724 remain in APC 0422 for the CY 2013 update.

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 would not cover the cost of performing the procedure. According to the commenters, the cost of performing the procedure is approximately $5,000. The commenters urged CMS to either reassign HCPCS code C9724 to APC 1565 (New Technology - Level XXVIII ($5000-$5500)), which had a proposed payment rate of approximately $5,250, or establish a new APC titled "Level IV Upper GI Procedures" with a payment rate of approximately $5,000.

Response: 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. Because this code has been in existence since April 2005, we have claims data for several years. For this final rule with comment

period, which is based on claims submitted from January 1, 2011 through December 31, 2011, our data show a geometric mean cost of approximately $5,728 based on 24 single claims (out of 120 total claims) for HCPCS code C9724. In addition, we agree with the Panel's recommendation to maintain HCPCS code C9724 in APC 0422 for the CY 2013 update. Based on the clinical similarity to other procedures currently assigned to APC 0422, and because there is no violation with the 2 times rule, we will continue to assign HCPCS code C9724 to APC 0422. Consistent with CMS' policy of reviewing APC assignments annually, we will reevaluate the cost of HCPCS code C9724 and its APC assignment for the CY 2014 rulemaking cycle.

In addition, because of concerns related to the current descriptor for HCPCS code C9724, we are revising the long descriptor to read "Endoscopic full-thickness plication of the stomach using endoscopic plication system (eps); includes endoscopy," effective January 1, 2013. This change in the long descriptor is necessary to accurately describe how the procedure is currently performed.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal without modification and will continue to maintain HCPCS code C9724 in APC 0422. The final CY 2013 geometric mean cost for APC 0422 is approximately $1,921.

c. Gastrointestinal Transit and Pressure Measurement (APC 0361)

The AMA's CPT Editorial Panel created CPT code 0242T (Gastrointestinal tract transit and pressure measurement, stomach trough colon, wireless capsule, with interpretation and report) effective January 1, 2011. For CY 2011, we initially assigned

CPT code 0242T to APC 0361 (Level II Alimentary Tests), with a payment rate of $282.48.

For CY 2012, we maintained the assignment of CPT code 0242T to APC 0361 with a payment rate of $285.59. We noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74242) that we routinely make assignments of new CPT codes to clinical APCs before we have claims data that are indicative of the resource costs of a procedure. 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 stated in the CY 2012 OPPS/ASC final rule with comment period that, as was the case when we made the initial assignment for CY 2011, we continued to believe that there are relevant clinical similarities between the service described by CPT code 0242T and other services assigned to APC 0361 to continue to justify this APC assignment. The service described by CPT code 0242T and the services assigned to APC 0361 all involve tests of the alimentary canal. We believed that the clinical attributes and CY 2012 costs of the services assigned to APC 0361 supported the initial assignment of CPT code 0242T to APC 0361. We indicated that we routinely make assignments of new CPT codes to clinical APCs before we have claims data to indicate the procedural resource costs, and that we generally wait until claims data are available before reassignment to a new APC. For CY 2012, we maintained our assignment of CPT code 0242T to APC 0361, which has a final median cost of $285.89, and we stated that we would review this assignment for CY 2013 when some claims data should be available for this procedure.

For CY 2013, we proposed to maintain the assignment of CPT code 0242T to APC 0361, which had a proposed rule geometric mean cost of approximately $311 and a proposed payment rate of approximately $303. We now have a small number of claims for use in CY 2013 for CPT code 0242T, which had a proposed rule geometric mean cost of approximately $613. The range of procedure level costs in APC 0361 for the CY 2013 proposed rule was approximately $214 to approximately $633. This range of costs does not constitute a 2 times rule violation because the range of costs for procedures with significant volume in the APC is approximately $302 to approximately $406.

We did not receive any public comments on our proposed APC assignment of CPT code 0242T to APC 0361.

At the August 2012 meeting of the HOP Panel, the Panel recommended that CMS assign CPT code 0242T to APC 0142 (Level I Small Intestine Endoscopy), based on the procedure's proposed rule mean cost of approximately $613, with a frequency of 8 claims.

Our CY 2013 final rule claims data show a cost of approximately $497 for CPT code 0242T, based on 8 claims. Our analysis comparing the proposed rule data and the final rule data for CPT code 0242T shows that one claim was dropped and another added, resulting in the fluctuation in geometric mean costs for the small number of claims between the proposed rule dataset and the final rule dataset for this procedure. The CY 2013 final geometric mean cost for APC 0361 is approximately $311, which includes a range of costs for procedures in the APC of approximately $209 to approximately $633. The CY 2013 final geometric mean cost for APC 0142 is approximately $772, which

includes a range of costs for procedures in the APC of approximately $569 to approximately $826. Therefore, based on the final rule geometric mean cost for CPT code 0242T, assignment of the code to APC 0361 is appropriate. We also continue to believe that CPT code 0242T is similar clinically to other procedures assigned to APC 0361. Therefore we are maintaining our assignment of the CPT code 0242T procedure to APC 0361 for CY 2013.

We note that the CPT Editorial Panel is replacing the CPT code for the procedure described by CPT code 0242T with a Category I CPT code, CPT code 91112 (Gastrointestinal transit and pressure measurement, stomach trough colon, wireless capsule, with interpretation and report), effective January 1, 2013. Therefore, we are deleting CPT code 0242T from the OPPS effective January 1, 2013, and assigning replacement CPT code 91112 to APC 0361 for this procedure.

3. Integumentary System Services

a. Extracorporeal Shock Wave Wound Treatment (APC 0340)

In the CY 2012 OPPS/ASC final rule with comment period, we assigned new CPT codes 0299T (Extracorporeal shock wave for integumentary wound healing, initial wound) and 0300T (Extracorporeal shock wave for integumentary wound healing, each additional wound) on an interim basis to APC 0340 (Minor Ancillary Procedures), which has a CY 2012 payment rate of approximately $46 and a CY 2013 proposed rule payment rate of approximately $49.

Comment: One commenter objecting to the interim APC assignment of CPT codes 0299T and 0300T believed that the assignment is not consistent clinically or in

terms of the resources associated with the shock wave treatment procedures. The commenter stated that these services are more similar clinically and in related resources to the high-energy shock wave procedure for musculoskeletal conditions that is assigned to APC 0050 (Level II Musculoskeletal Procedures Except Hand and Foot), which has a CY 2012 payment rate of approximately $2,269. The commenter believed that assignment of these codes to a New Technology APC would be appropriate to gather cost data, and indicated that they would submit an application for new technology payments for these codes to CMS.

We received other similar comments to the proposed rule from several clinicians in the field who were involved in the initial clinical trial of the extracorporeal shock wave procedure. These commenters discussed the clinical trial and the clinical attributes of this treatment, indicating that it offers significantly greater clinical benefit than other wound healing therapies at a considerably lower cost. They objected to CMS' assignment of CPT codes 0299T and 0300T to APC 0340. The commenters believed that the payment rate for this APC would inhibit the use of this emerging technology and would prevent patient access to the treatment.

Response: We agree with the commenters that it may be more appropriate in terms of clinical and resource similarity to assign CPT codes 0299T and 0300T to an APC other than APC 0340. However, we do not agree that CPT codes 0299T and 0300T should be assigned to APC 0050. Having considered the information provided by the commenters, and based on our evaluation of clinical and resource similarity to existing services, we believe that placement in APC 0133 (Level I Skin Repair) would be more

appropriate for these services until claims data are available. For CY 2013, we are placing CPT codes 0299T and 0300T in APC 0133, which has a final geometric mean cost of approximately $88**.** We will reevaluate the APC placement when claims data are available for CY 2014.

b. Application of Skin Substitute (APCs 0133 and 0134)

For CY 2012, we made assignments for several new (replacement) CPT codes for the application of skin substitutes. We assigned CPT code 15272 (Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm or part thereof) and CPT code 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 or part thereof) to APC 0133 (Level I Skin Repair), which has a CY 2012 payment rate of approximately $84 and a CY 2013 proposed payment rate of approximately $86. We assigned CPT code 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 or part thereof) and CPT code 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 or part thereof) to APC 0134 (Level II Skin Repair), which has a CY 2012 payment rate of approximately $228 and a CY 2013 proposed payment rate of approximately $252.

Comment: One commenter stated that CMS should have assigned the new codes to the APC that includes their predecessor base codes so that a 2 times rule violation is

avoided. They requested that for CY 2013, CMS reassign CPT codes 15272 and 15276 to APC 0134, crosswalking them to the predecessor add-on CPT code 15341 and assign them to the same APC as the former base CPT code 15340. Similarly, the commenter requested that CMS reassign CPT codes 15274 and 15278 to APC 0135 (Level III Skin Repair) which includes their applicable base codes (CPT codes 15273 and 15277).

Response: As we indicated in the CY 2012 OPPS/ASC final rule (76 FR 74269), we assigned these four replacement CPT codes for CY 2012 based on their clinical and estimated resource similarity to the services in their assigned APCs. We also took into account the size descriptions in the new codes' long descriptors. There was not a one-to-one crosswalk between the old skin substitute application codes and the new CPT codes, as suggested by the commenter. Several of the old CPT codes map to a single new code. Therefore, we made the most appropriate assignment based on clinical homogeneity and estimated resource similarity, taking into account all of the former procedures that are now encompassed by a single code and the new coding structure for the family of codes.

For CY 2013, we will continue to assign CPT codes 15272 and 15276 to APC 0133, which has a final geometric mean cost of approximately **$**88**,** and CPT codes 15274 and 15278 to APC 0134, which has a final geometric mean cost of approximately $259. We will reevaluate the placement of these codes when claims data become available in the CY 2014 rulemaking cycle.

c. Low Frequency, Non-Contact, Non-Thermal Ultrasound (APC 0015)

Effective January 1, 2008, the CPT Editorial Panel created CPT code 0183T (Low Frequency, Non-Contact, Non-Thermal Ultrasound). Since that time, we have assigned this service to either APC 0013 (Level II Debridement and Destruction) or APC 0015 (Level III Debridement and Destruction). Initially, for CY 2008 and CY 2009, we placed this service in the higher Level III APC 0015, with a payment rate of approximately $100. Based on our review of the first year of hospital claims data (CY 2008 claims), for CY 2010 we reassigned the service to the lower Level II APC 0013, with a payment rate of approximately $59. For CY 2011 and CY 2012, due to a change in the estimated cost of CPT code 0183T, we reassigned it to the higher level APC 0015, with a payment rate of approximately $105 in CY 2011 and approximately $103 in CY 2012.

For CY 2013, we proposed to reassign CPT 0183T to APC 0013 because its proposed rule geometric mean cost of approximately $89 was closer to the proposed rule geometric mean cost of APC 0013 (approximately $73) than the proposed rule geometric mean cost of APC 0015 (approximately $110).

Comment: One commenter objected to the reassignment of CPT code 0183T to APC 0013 because the commenter's estimated cost of furnishing this service of approximately $101 would be greater than its proposed payment. The commenter believed that procedures currently assigned to APC 0013 and those assigned to APC 0015 are not homogeneous clinically or in terms of resource requirements. The commenter requested that CMS split APC 0013 and APC 0015 to create a third APC, such that APC 0013 would include the services with costs less than $80; the new APC

would include services with costs between $80 and $110; and APC 0015 would include services with costs greater than or equal to $110.

Another commenter recommended that CMS merge APC 0013 and APC 0015, arguing that both APCs are for skin procedures and noting that the proposed cost for the highest volume service in APC 0013, described by CPT code 17000 (Destruction of premalignant lesions; first lesion), is more than half of the cost of the highest volume service in APC 0015, described by CPT code 97597 (Open wound debridement; first 20 sq cm or less).

Response: The final rule geometric mean cost of CPT code 0183T and APC 0013 (approximately $88 and $74, respectively) did not change significantly from their proposed rule costs and remain very similar. There also is no significant change in the final rule geometric mean cost of APC 0015 (approximately $110). We note that merging the two APCs as one commenter suggested would create several 2-times rule violations, and we see no clinical or other need to further split the APCs. Therefore, because the geometric mean cost of CPT code 0183T continues to be closer to the geometric mean cost of APC 0013 than that of APC 0015, and because merging the APCs would create several 2 times rule violations, for CY 2013, we are finalizing our proposal to reassign CPT code 0183T to APC 0013.

4. Nervous System Services

a. Scrambler Therapy (APC 0275)

For the CY 2012 update, the AMA's CPT Editorial Panel established Category III CPT code 0278T (Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes)) effective

January 1, 2012. CPT code 0278T describes a transcutaneous electrical modulation pain reprocessing procedure and involves the use of four to five electrodes that deliver electrical stimulation to treat chronic chemo-induced neuropathic pain. Based on the nature of the procedure, which can be performed by physicians, nurses, or physical therapists, the therapy involves 10 sessions (1 session per day for 10 days), and each session takes approximately between 30 and 45 minutes.

In Addendum B of the CY 2012 OPPS/ASC final rule with comment period, we assigned CPT code 0278T to APC 0215 (Level I Nerve and Muscle Tests) which has a CY 2012 payment rate of approximately $44. We also assigned this CPT code comment indicator "NI" to indicate that the code was new for CY 2012 with an interim APC assignment that was subject to public comment following the publication of the final rule with comment period. Specifically, the code's APC assignment and status indicator were subject to public comment. We received one public comment regarding the interim APC assignment for CPT code 0278T which we address below in this section.

We note that we do not discuss APC or status indicator assignments for new codes for the upcoming year in the proposed rule because the new codes are not available when we publish the proposed rule. Rather, as has been our practice in the past, we implement new HCPCS codes in the OPPS final rule with comment period, at which time we invite public comments regarding the treatment of the new codes. We subsequently respond to those comments in the final rule with comment period for the following year's OPPS update.

As has been our practice since the implementation of the OPPS in 2000, we carefully review all new procedures before assigning them to an APC. In determining the APC assignment for CPT code 0278T, we took into consideration the clinical and resource characteristics involved with Scrambler Therapy. Based on our initial review of the components of these services and consultation with our medical advisors, we assigned CPT code 0278T to APC 0215 for CY 2012.

At the February 2012 HOP Panel meeting, a presenter requested the reassignment of CPT code 0278T from APC 0215 to APC 0206 (Level II Nerve Injections) based on resource cost and clinical homogeneity. The presenter stated that the assignment of CPT code 0278T to APC 0215 is not appropriate because the procedures in this APC are primarily diagnostic in nature, whereas CPT code 0278T represents a therapeutic procedure. The presenter further added that the time and cost involved with providing the service associated with CPT code 0278T is considerably greater than the time and cost involved for procedures assigned to APC 0215, and recommended that the Scrambler Therapy would be more appropriately assigned to APC 0206 because the procedures in APC 0206 are mostly therapeutic in nature and represent similar costs. At the February 2012 meeting, the Panel made no recommendation to reassign CPT code 0278T from its current APC 0215 assignment for CY 2013.

In Addendum B of the CY 2013 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 0278T to APC 0215. At the August 2012 HOP Panel meeting, the same presenter at February 2012 Panel meeting made the same request to the Panel to recommend to CMS to reassign CPT code 0278T to a more appropriate APC.

Specifically, at the August 2012 HOP Panel meeting, the requester recommended that CPT code 0278T be reassigned to APC 0204 (Level I Nerve Injections) based on clinical and cost considerations. During the discussion, one of the Panel members pointed out that the procedures assigned to APC 0204 represent nerve injections, which is in contrast to how the procedure described by CPT code 0278T is delivered because the procedure associated with the Scrambler Therapy does not involve injections. After discussion of the issue, the HOP Panel recommended that CMS assign CPT code 0278T to APC 0218 (Level II Nerve and Muscle Tests).

Comment: One commenter to the CY 2012 OPPS/ASC final rule with comment period recommended the reassignment of CPT code 0278T from APC 0215 to APC 0206 based on the commenter's cost analysis. Alternatively, the commenter recommended assignment of CPT code 0278T to APC 0204 because this is the APC assigned to unlisted CPT code 64999 (Unlisted procedure, nervous system), which would be used to report the Scrambler Therapy if CPT code 0278T had not been established.

Response: As a new Category III CPT code for CY 2012, we do not yet have hospital claims data for the procedure. Category III CPT codes are temporary codes that describe emerging technology, procedures, and services, and are created by the AMA to allow for data collection for new services or procedures. Under the OPPS, we generally assign a payment rate to a new Category III CPT code based on input from a variety of sources, including but not limited to, review of resource costs and clinical homogeneity of the service to existing procedures, information from specialty societies, input from CMS medical advisors, and other information available to us. Based on our review of the

clinical characteristics of the service described by CPT code 0278T and the information provided by the commenter, we do not believe that we have sufficient clinical or cost information to justify a reassignment to a different APC at this time. As we do every year for other services and procedures under the OPPS, we will review the claims data for CPT code 0278T for CY 2012 for the CY 2014 rulemaking cycle. Because CPT code 0278T was a new code for CY 2012, the first time we will have claims data for this procedure is next year for the CY 2014 update, and at which time we will reevaluate the APC assignment for this code.

Comment: Some commenters recommended a range of the appropriate payment for CPT code 0278T based on their internal analysis. One commenter recommended that CPT code 0278T be assigned to an APC that has a payment rate of between $124 to $144 based on their analysis, by taking into consideration the site of service, staff time involved, and system costs associated with providing the therapy. Another commenter stated that the total cost of providing Scrambler Therapy is approximately $274; however, an initial payment of approximately $184 may be adequate for hospitals to initiate treatment. The commenter further stated that the proposed payment rate of approximately $81 for APC 0218, which was recommended by the HOP Panel at the August 2012 meeting, is adequate. However, the commenter asserted that the proposed payment rate of approximately $150 for New Technology APC 1540 (New Technology - Level III ($100 - $200)) would be more appropriate.

Response: After further review of the HOP Panel recommendation at the August 2012 meeting and consideration of the public comments that we received on this

particular procedure, we believe that we should continue to assign the Scrambler Therapy to APC 0215. Therefore, we are not accepting the Panel's recommendation to reassign CPT code 0278T to APC 0218. In addition, we do not agree with the commenter that CPT code 0278T should be assigned to New Technology APC 1540. Based on our understanding of the procedure, we believe that APC 0215 is the most appropriate APC assignment for CPT code 0278T based on its similarity to other procedures assigned to APC 0215. We will review the claims data for CPT 0278T next year for the CY 2014 rulemaking to determine whether an APC reassignment for the Scrambler Therapy is necessary.

After consideration of the public comments received, we are finalizing our CY 2013 proposal, without modification, to continue to assign CPT code 0278T to APC 0215 for CY 2013. The final CY 2013 geometric mean cost for APC 0215 is approximately $44.

b. Transcranial Magnetic Stimulation Therapy (TMS) (APC 0216)

Since July 2006, CPT codes have existed to describe Transcranial Magnetic Stimulation Therapy (TMS) therapy. The initial CPT codes were temporary Category III CPT codes, specifically, CPT code 0160T (Therapeutic repetitive transcranial magnetic stimulation treatment planning) and 0161T (Therapeutic repetitive transcranial magnetic stimulation treatment delivery and management, per session), that were effective July 1, 2006. For CY 2011, the CPT Editorial Panel deleted CPT code 0160T on December 31, 2010, and replaced it with CPT code 90867 (Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; initial, including cortical mapping, motor threshold determination, delivery and management) effective January 1, 2011.

Similarly, CPT code 0161T was deleted on December 31, 2010, and was replaced with CPT code 90868 (Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent delivery and management, per session) effective January 1, 2011. In CY 2012, the AMA's CPT Editorial Panel established an additional TMS therapy code, specifically CPT code 90869 (Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent motor threshold re-determination with delivery and management), that was effective January 1, 2012.

In Addendum B of the CY 2013 OPPS/ASC proposed rule, we proposed to continue to assign CPT codes 90867, 90868, and 90869 to APC 0218 (Level II Nerve and Muscle Tests), which had a proposed payment rate of approximately $81.

Comment: One commenter disagreed with the proposed APC assignment and stated that the TMS therapy codes are not similar to the services assigned to APC 0218. The commenter recommended three options on the appropriate APC assignment.

Under the first option, the commenter recommended the reassignment of CPT codes 90867, 90868, and 90869 to APC 0216 (Level III Nerve and Muscle Tests), which had a proposed payment rate of approximately $182. The commenter also recommended the revision of the APC title description to read "Level III Nerve and Muscle Tests & TMS". The commenter stated that the TMS therapy services are similar to the services described by CPT codes 95961 (Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; initial hour of physician attendance), 95962 (Functional cortical and subcortical mapping by stimulation and/or recording of

electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; each additional hour of physician attendance (list separately in addition to code for primary procedure)), and 96000 (Comprehensive computer-based motion analysis by video-taping and 3d kinematics), which are assigned to APC 0216.

Under the second option, the commenter recommended the establishment of a new APC for the three TMS therapy CPT codes, and further recommended revising the APC title description to read “Transcranial Magnetic Stimulation”.

Under the third option, the commenter suggested assigning CPT codes 90867, 90868, and 90869 to APC 0320 (Electroconvulsive Therapy), which had a proposed payment rate of approximately $441. Although TMS therapy is clinically related to electroconvulsive therapy (ECT), the commenter stated that its resource costs are lower than ECT.

Response: We appreciate the commenter's thoughtful suggestions on the APC assignments for CPT codes 90867, 90868, and 90869. We do not agree with the commenter that the procedures described by CPT codes 90867, 90868, and 90869 would be appropriately assigned to APC 0320 from a clinical perspective because the provision of electroconvulsive therapy generally requires more extensive monitoring and services (for example, muscle blockade) than transcranial magnetic treatment delivery and management. However, based on the latest claims data used for this rulemaking, we do agree with the commenter's suggestion that APC 0216 would be the more appropriate APC assignment for the three TMS therapy CPT codes. Analysis of our more recent claims data revealed that the resources associated with CPT codes 90867, 90868, and

90869 are similar to those services assigned to APC 0216. Specifically, for claims submitted during CY 2011, which were used for this final rule with comment period, CPT code 90867 showed a geometric mean cost of approximately $190 based on 15 single claims (out of 18 total claims), and a geometric mean cost of approximately $233 for CPT code 90868 based on 609 single claims (out of 614 total claims). In addition, review of the procedures assigned to APC 0216 showed that the range of the geometric mean cost for the procedures with significant claims data is between approximately $146 (for CPT code 92584 (Electrocochleography)) and approximately $233 (for CPT code 90868 (Tcranial magn stim tx deli)). Based on the clinical and resource similarity to other procedures currently assigned to this APC, we believe it is appropriate to reassign the TMS therapy services to APC 0216. Although CPT code 90869 is a new code for CY 2012, we believe that it is appropriate to reassign this service to APC 0216, similar to the APC assignment of CPT codes 90867 and 90868. Because of this reassignment, we also are revising the APC title descriptions of APCs 0215, 0216, and 0218 to appropriately reflect the services within each APC. Specifically, we are revising the APC title description of APC 0215 from "Level I Nerve and Muscle Tests" to "Level I Nerve and Muscle Services"; the title description of APC 0218 from "Level II Nerve and Muscle Tests" to "Level II Nerve and Muscle Services"; and the title description of APC 0216 from "Level III Nerve and Muscle Tests" to "Level III Nerve and Muscle Services".

After consideration of the public comment we received, we are finalizing our CY 2013 proposal, with modification. That is, we are reassigning CPT codes 90867, 90868, and 90869 from APC 0218 to APC 0216, which has a final CY 2013 geometric

mean cost of approximately $189. Table 24 below shows the final APC assignments for CPT codes 90867, 90868, and 90869 for CY 2013.

TABLE 24.—FINAL APC ASSIGNMENTS FOR TMS THERAPY FOR CY 2013

CY 2012 HCPCS Code	CY 2012 Short Descriptor	CY 2012 SI	CY 2012 APC	Final CY 2013 SI	Final CY 2013 APC
90867	Tcranial magn stim tx plan	S	0218	S	0216
90868	Tcranial magn stim tx deli	S	0218	S	0216
90869	Tcran magn stim redetemine	S	0218	S	0216

c. Paravertebral Neurolytic Agent (APC 0207)

Effective January 1, 2012, the AMA's CPT Editorial Panel created CPT code 64633 (Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or ct); cervical or thoracic, single facet joint). For CY 2012, we assigned new CPT code 64633 on an interim basis to APC 0207 (Level III Nerve Injections). This interim APC assignment was consistent with our standard process for dealing with new CPT codes effective on January 1 for the upcoming calendar year, which is to assign each code to the APC that we believe contains services that are comparable with respect to clinical characteristics and resources required to furnish the service. CPT code 64633 was assigned a comment indicator of "NI" in Addendum B to the CY 2012 OPPS/ ASC final rule with comment period to identify it as a new interim APC assignment for the new year and the APC assignment for this new code was open to public comment for 60 days following the publication of the CY 2012 OPPS/ ASC final

rule with comment period. For CY 2013, we proposed to continue to assign CPT code 64633 to APC 0207, which had a proposed payment rate of approximately $568.

Comment: One commenter who responded to the CY 2012 OPPS/ ASC final rule with comment period objected to the assignment of CPT code 64633 to APC 0207 because the commenter believed that the payment rate for APC 0207 substantially underpays providers for this service.

Response: Due to the lack of any claims data for CPT code 64633, we have no way to validate or substantiate the claim made by the commenter. We expect to have CY 2012 claims data for CPT code 64633 available in CY 2013 in preparation for the CY 2014 rulemaking cycle and will reevaluate the APC assignment of CPT code 64633 at that time.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal, without modification, to continue to assign CPT code 64633 to APC 0207, which has a final CY 2013 APC geometric mean cost of approximately $582.

d. Programmable Implantable Pump (APC 0691)

Effective January 1, 2012, the AMA's CPT Editorial Panel created two new CPT codes that combine pump refill and programming/analysis procedures: CPT code 62369 (Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drub prescription status); with reprogramming and refill) and CPT code 62370 (Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drub prescription status); with reprogramming

and refill (requiring physician's skill)). For CY 2012, CPT codes 62369 and 62370 received a new interim APC assignment to APC 0691 (Level III Electronic Analysis of Devices), consistent with our standard process for dealing with new CPT codes effective on January 1 for the upcoming calendar year, which is to assign each code to the APC that we believe contains services that are comparable with respect to clinical characteristics and resources required to furnish the service. CPT codes 62369 and 62370 were both given a comment indicator of "NI" in Addendum B to the CY 2012 OPPS/ASC final rule with comment period to identify it as a new interim APC assignment for the new year and the APC assignment for these two new codes was open to public comment for 60 days following the publication of the CY 2012 OPPS/ASC final rule with comment period. For CY 2013, we proposed to continue to assign CPT codes 62369 and 62370 to APC 0691, which had a proposed payment rate of approximately $192.

Comment: Commenters who responded to the CY 2012 OPPS/ ASC final rule with comment period objected to the assignment of CPT codes 62369 and 62370 to APC 0691 because they believed that the payment rate for APC 0691 substantially underpays providers for these services.

Response: Due to the lack of any claims data for CPT codes 62369 and 62370, we have no way to validate or substantiate the claim made by commenters. We expect to have CY 2012 claims data for CPT codes 62369 and 62370 in CY 2013 in preparation for the CY 2014 rulemaking cycle and will reevaluate the APC assignment of CPT codes 62369 and 62370 at that time.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal, without modification, to continue to assign CPT codes 62369 and 62370 to APC 0691, which has a final CY 2013 APC geometric mean cost of approximately $197.

e. Revision/Removal of Neurostimulator Electrodes (APC 0687)

For CY 2013, we proposed to continue to assign CPT code 64569 (Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator) to APC 0687 (Revision/Removal of Neurostimulator Electrodes), which had a proposed CY 2013 payment rate of approximately $1,576.

Comment: Commenters objected to the assignment of CPT code 64569 in APC 0687 because they stated that this code is used to report both the revision and the replacement of neurostimulator electrodes. The commenters believed that hospital resources are substantially greater when neurostimulator electrodes are being replaced rather than revised. The commenters asked CMS to reassign CPT code 64569 to device-dependent APC 0040 (Level I Implantation/ Revision/ Replacement of Neurostimulator Electrodes) or assign new HCPCS codes to differentiate between electrode replacements (with a new electrode) and electrode revisions (without a new electrode) so that electrode revisions map to APC 0687 and electrode replacements map to APC 0040. The commenters noted that, like CPT code 64569, the procedures currently assigned to APC 0040 involve the implantation of a new electrode, either as an initial implant or as a replacement, while all of the procedures currently assigned to APC

0687, with the exception of CPT code 64569, are defined as "revision or removal" or simply "removal" of electrodes. The commenters stated that the resources associated with the procedure described by CPT code 64569 are similar to the resources associated with the procedures assigned to APC 0040.

Response: We agree with the commenters that the resources associated with the procedure described by CPT code 64569 are similar to the resources associated with procedures assigned to APC 0040, and that these procedures share clinical characteristics. We note that the CY 2013 final rule geometric mean cost for CPT code 64569 of approximately $5,473 is more consistent with the CY 2013 final rule geometric mean cost of APC 0040 of approximately $4,526 than with the CY 2013 final rule geometric mean cost of APC 0687 of approximately $1,554. Therefore, we are modifying our proposal and assigning CPT code 64569 to APC 0040 for CY 2013.

5. Ocular Services: Placement of Amniotic Membrane (APC 0233)

In CY 2011, the AMA CPT Editorial Panel revised the long descriptor for CPT code 65780 (Ocular surface reconstruction; amniotic membrane transplantation, multiple layers) to include the words "multiple layers" to further clarify the code descriptor. In addition, the AMA's CPT Editorial Panel created two new CPT codes that describe the placement of amniotic membrane on the ocular surface without reconstruction: one describing the placement of a self-retaining (non-sutured/non-glued) device on the surface of the eye; and the other describing a single layer of amniotic membrane sutured to the surface of the eye. Specifically, the AMA's CPT Editorial Panel established CPT codes 65778 (Placement of amniotic membrane on the ocular surface for wound healing;

self-retaining) and 65779 (Placement of amniotic membrane on the ocular surface for wound healing; single layer, sutured), effective January 1, 2011.

As has been our practice since the implementation of the OPPS in 2000, we review all new procedures before assigning them to an APC. In determining the APC assignments for CPT codes 65778 and 65779, we took into consideration the clinical and resource characteristics involved with placement of amniotic membrane products on the eye for wound healing via a self-retaining device and a sutured, single-layer technique. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72402), we assigned CPT code 65778 to APC 0239 (Level II Repair and Plastic Eye Procedures), which had a payment rate of approximately $559, and CPT code 65779 to APC 0255 (Level II Anterior Segment Eye Procedures), which had a payment rate of approximately $519.

In addition, consistent with our longstanding policy for new codes, we assigned these two new CPT codes to interim APCs for CY 2011. Specifically, we assigned CPT codes 65778 and 65779 to comment indicator "NI" in Addendum B of the CY 2011 OPPS/ASC final rule with comment period to indicate that the codes were new with interim APC assignments that were subject to public comment. In accordance with our longstanding policy, our interim APC assignment for each code was based on our understanding of the resources required to furnish the service as defined in the code descriptor and input from our physicians.

At the Panel's February 28-March 1, 2011 meeting, a presenter requested the reassignment of CPT codes 65778 and 65779 to APC 0244 (Corneal and Amniotic Membrane Transplant), which is the same APC to which CPT code 65780 is assigned.

The presenter indicated that, prior to CY 2011, the procedures described by CPT codes 65778 and 65779 were previously reported under the original version of CPT code 65780, which did not specify "multiple layers," and as such these new CPT codes should continue to be assigned to APC 0244. Further, the presenter stated that the costs of the procedures described by CPT codes 65778 and 65779 are very similar to the cost of the procedure described by CPT code 65780.

The Panel recommended that CMS reassign the APC assignments for both CPT codes 65778 and 65779. Specifically, the Panel recommended the reassignment of CPT code 65778 from APC 0239 to APC 0233 (Level III Anterior Segment Eye Procedures), and the reassignment of CPT code 65779 from APC 0255 to APC 0233. In addition, the Panel recommended that CMS furnish data when data become available for these two codes. We noted at that time that because these CPT codes were effective January 1, 2011, the first available claims data for these codes would be for the CY 2013 OPPS rulemaking cycle.

We accepted the Panel's recommendations. However, in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74247), we indicated that, while we agreed with the Panel's recommendation to reassign CPT codes 65778 and 65779 to APC 0233, we believed that CPT code 65778 should be assigned to a conditionally packaged status indicator of "Q2" to indicate that the procedure would be packaged when it is reported with another procedure that is also assigned to status indicator "T"; but in all other circumstances, the CPT code would be paid separately. Because the procedure described by CPT code 65778 would rarely be provided as a separate, stand-alone service

in the HOPD, and because the procedure would almost exclusively be provided in addition to and following another procedure or service, we proposed to reassign CPT code 65778 a conditionally packaged status indicator of "Q2." In addition, our medical advisors indicated that the procedure described by CPT code 65778 is not significantly different than placing a bandage contact lens on the surface of the eye to cover a corneal epithelial defect. CPT code 65778 describes the simple placement of a special type of bandage (a self-retaining amniotic membrane device) on the surface of the eye, which would most commonly be used in the HOPD to cover the surface of the eye after a procedure that results in a corneal epithelial defect.

At the August 10-11, 2011 Panel meeting, a presenter urged the Panel to recommend to CMS not to conditionally package CPT code 65778 for CY 2012, and instead, assign it status indicator "T." Based on information presented at the meeting, and after further discussion of the issue, the Panel recommended that CMS reassign the status indicator for CPT code 65778 from conditionally packaged "Q2" to status indicator "T." Several commenters also urged CMS not to finalize its proposal to conditionally package CPT code 65778 by assigning it status indicator "Q2" and instead adopt the Panel's recommendation to assign status indicator "T."

After consideration of the Panel's August 2011 recommendation and the public comments that we received in response to the CY 2012 OPPS/ASC proposed rule, we finalized our proposal and reassigned the status indicator for CPT code 65778 from "T" to "Q2" effective January 1, 2012 (76 FR 74246). Given the clinical characteristics of

this procedure, we believed that conditionally packaging CPT code 65778 was appropriate under the OPPS.

For the CY 2013 OPPS update, we proposed (77 FR 45123) to continue to assign CPT code 65778 a conditionally packaged status indicator of "Q2." Similarly, we stated that we believe that we should assign CPT code 65779 to a conditionally packaged status indicator of "Q2." Therefore, for CY 2013, we proposed to revise the status indicator for CPT code 65779 from status indicator "T" to "Q2" to indicate that the procedure would be packaged when it is reported with another procedure that is also assigned status indicator "T," but in all other circumstances, the CPT code would be paid separately. This reassignment would enable hospitals to perform either procedures (CPT code 65778 or 65779) when appropriate, and would not differentiate one procedure from the other because of the status indicator assignment under the OPPS.

As indicated at the February 28-March 1, 2011 Panel meeting, because CPT codes 65778 and 65779 were effective January 1, 2011, the first available claims data for these codes would be in CY 2012 for the CY 2013 OPPS rulemaking. We now have claims data for CPT codes 65778 and 65779, and our data show that both procedures are performed in the HOPD setting. Analysis of the CY 2011 claims data available for the proposed rule, which was based on claims processed from January 1 through December 31, 2011, revealed that the estimated cost for CPT code 65778 is approximately $1,025 based on 33 single claims (out of 130 total claims), and the estimated cost for CPT code 65779 is approximately $2,303 based on 35 single claims (out of 260 total claims). Based on the clinical similarity to other procedures currently

assigned to APC 0233, and because there was no violation with the 2 times rule, we stated that we believe that we should continue to assign both CPT codes 65778 and 65779 to APC 0233, which had a payment rate of approximately $1,150. Review of the procedures assigned to APC 0233 showed that the range of the cost for the procedures with significant claims data is between approximately $859 (for CPT code 65400 (Removal of eye lesion)) and approximately $1,397 (for CPT code 66840 (Removal of lens material)).

In summary, for CY 2013, we proposed to continue to assign CPT code 65778 to a conditionally packaged status indicator of "Q2" and to reassign the status indicator for CPT code 65779 from "T" to "Q2," similar to CPT code 65778. In addition, we proposed to continue to assign both CPT codes 65778 and 65779 to APC 0233, which had a proposed geometric mean cost of approximately $1,150. Both procedures and their CY 2013 APC assignments were displayed in Table 19 of the proposed rule.

At the August 2012 HOP Panel Meeting, a presenter urged the Panel to recommend to CMS not to conditionally package CPT code 65779 for CY 2013, and instead, assign status indicator "T" to the code. Based on the information presented at the meeting, and after further discussion of the issue, the HOP Panel made no recommendation to revise the status indicator assignment for CPT code 65779.

Comment: One commenter urged CMS not to finalize its proposal to conditionally package CPT code 65779 by assigning it status indicator "Q2," and recommended that CMS continue to assign the code status indicator "T." The commenter expressed concern that assigning a "Q2" status indicator to CPT code 65779 would

impede access to this procedure because, in a majority of the cases (84 percent), hospitals perform this procedure with another procedure. Consequently, a "Q2" status indicator would result in no payment for CPT code 65779. The commenter further recommended that CMS assign CPT code 65779 to APC 0244, or another APC that better reflects the resources associated with the procedure, such as APC 0241 (Level IV Repair and Plastic Eye Procedures) or APC 0234 (Level IV Anterior Segment Eye Procedures).

Response: We believe that the revision in status indicator for CPT code 65779 would enable hospitals to perform either procedures (CPT code 65778 or 65779) when appropriate, and would not differentiate one procedure from the other because of the status indicator assignment under the hospital OPPS. In addition, because CPT codes 65778 and 65779 were new for CY 2011, CY 2013 is the first year of claims data that we have available for ratesetting for both CPT codes. Analysis of the CY 2011 claims data revealed a geometric mean cost of approximately $989 for CPT code 65778 based on 36 single claims (out of 142 total claims), and approximately $2,314 for CPT code 65779 based on 37 single claims (out of 280 total claims). Review of the procedures assigned to APC 0233 showed that the range of the CPT geometric mean cost for the procedures with significant claims data is between approximately $867 (for CPT code 65400 (Removal of eye lesion)) and approximately $1,390 (for CPT code 66840 (Removal of lens material)). Based on the clinical similarity to other procedures currently assigned to APC 0233, and because there is no violation with the 2 times rule, we believe that we should continue to assign CPT code 65779 to APC 0233, which has a final geometric mean cost of approximately $1,162 for CY 2013.

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. For CPT codes 65778 and 65779, we will again reevaluate their APC assignments for the CY 2014 OPPS rulemaking cycle.

After consideration of the public comment that we received, we are finalizing our CY 2013 proposal, without modification, to assign status indicator "Q2" to CPT code 65779. When the service is furnished with a separately payable surgical procedure with status indicator "T" on the same day, payment for CPT code 65779 is packaged. Otherwise, payment for CPT code 65779 is made separately through APC 0233, which has a final CY 2013 geometric mean cost of approximately $1,162. The amniotic membrane procedures and their CY 2013 final APC assignments are displayed in Table 25 below.

TABLE 25.—FINAL APC ASSIGNMENTS FOR CPT CODES 65778 AND 65779 FOR CY 2013

CY 2012 HCPCS Code	CY 2012 Short Descriptor	CY 2012 SI	CY 2012 APC	Final CY 2013 SI	Final CY 2013 APC
65778	Cover eye w/membrane	Q2	0233	Q2	0233
65779	Cover eye w/membrane suture	T	0233		

6. Radiology Oncology

a. 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), which had a CY 2013 proposed rule cost of approximately $331 (based on 185 single claims of 185 total claims submitted for CY 2011); and CPT code 77522 (Proton treatment delivery; simple, with compensation), which had a proposed rule cost of approximately $1,191 (based on 14,279 single claims of 15,405 total claims submitted for CY 2011). APC 0667 (Level II Proton Beam Radiation Therapy) also includes two procedures: CPT code 77523 (Proton treatment delivery, intermediate), which had a proposed rule cost of approximately $920 (based on 3,009 single claims out of 3,202 total claims submitted for CY 2011), and CPT code 77525 (Proton treatment delivery, complex), which had a proposed rule cost of approximately $483 (based on 1,400 single claims out of 1,591 total claims submitted for CY 2011). Based on these CY 2011 claims data, under the current APC structuring the proposed rule cost of APC 0664 was approximately $1,171, and the proposed rule cost of APC 0667 was approximately $750.

Because only a few hospitals bill Medicare for these services, their payment rates, which are set annually based on claims data according to the standard OPPS ratesetting methodology, may fluctuate significantly from year to year. For CY 2013, under the current APC assignments, the proposed rule cost of APC 0664 was approximately the same as its CY 2012 payment rate of $1,184. However, the proposed rule cost of APC 0667 decreased substantially from the CY 2012 payment rate. We also observed that for

CY 2013, as in several prior years, the lower level APC 0664 did not include the lower cost services among the four CPT codes. For CY 2013, we proposed to improve the resource homogeneity within the proton beam therapy APCs by including the services requiring fewer resources in APC 0664 (Level I) and the services requiring greater resources in APC 0667 (Level II). Specifically, we proposed to reassign CPT code 77522 to APC 0667 and to reassign CPT code 77525 to APC 0664. Under the proposed reassignment, the estimated cost of APC 0664 was approximately $462, and the estimated cost of APC 0667 was approximately $1,138. We invited public comments on this proposal.

Comment: Several commenters indicated that the decrease in the cost of APC 0667 is attributable to inaccurate coding and cost reporting during part of CY 2010 and part of CY 2011, on the part of one hospital. The commenters stated that one hospital's services that should have been billed as CPT code 77523 were instead billed as CPT code77525, which has a lower estimated cost. They stated that these services were also reported under an unintended cost center in the hospital's cost report, and argued that the current APC configuration better reflects the clinical similarity and relative resources used to furnish proton beam therapy services. We received a comment from the hospital in question indicating the same. This provider also stated that these issues were corrected and do not affect any claims in CY 2012. These commenters requested that we therefore forego using the CY 2011 claims data to set CY 2013 rates because they are based in part on inaccurate data reported by one of the few billing providers. They requested that CMS maintain both the CY 2012 payment rates and the current CY 2012 APC configuration

through CY 2013, and the HOP Panel agreed with this recommendation at its August 2012 public meeting.

One commenter recommended that CMS obtain corrected data from the provider in question and use the corrected data in updating the CY 2012 proton beam therapy payment rates for CY 2013. The commenter recommended that if CMS could not accomplish this in time for publication of the CY 2013 final rule, CMS exclude the reportedly erroneous data from its ratesetting process and update the CY 2012 payments for proton beam services for CY 2013 using the remaining claims data. In either event, the commenter recommended that we not restructure the APCs this year because despite what the cost data show, simple and complex proton beam therapy services are not clinically homogenous.

Another commenter supported the proposed reduction in payments for proton beam services. The commenter stated that given the cost of establishing and staffing proton beam centers, proton beam therapy does not yield commensurate benefit over other therapies.

Response: We appreciate the public comments and the HOP Panel's recommendation. After consideration of the public comments we received, we are updating the payment rates for proton beam therapy for CY 2013 to reflect the most recently available claims data from all providers. Therefore, we are not maintaining the CY 2013 payment rates at CY 2012 levels, and we are not excluding the reportedly erroneous data from the ratesetting process. However, we are maintaining the current APC structure for CY 2013 and will reevaluate the costs and appropriateness of the APC

structuring for proton beam services next year. Using the current APC assignments for proton beam services, the CY 2013 final geometric mean cost of APC 0664 (including CPT codes 77520 and 77522) is approximately $1,169. The CY 2013 final geometric mean cost of APC 0667 (including CPT codes 77523 and 77525) is approximately $702.

b. Device Construction for Intensity Modulated Radiation Therapy (IMRT) (APC 0305)

Effective January 1, 2010, the CPT Editorial Panel created CPT code 77338 (Construction of multi-leaf collimator (MLC) device(s) for IMRT per IMRT plan) to report all of the devices furnished under a single IMRT treatment plan. The code was created as part of an effort to consolidate the reporting of multiple services or units of service into a single code. For CY 2011, we assigned CPT 77338 to APC 0310 (Level III Therapeutic Radiation Treatment Preparation) based on a simulated cost of approximately $792 that we calculated using CY 2009 claims data for the predecessor CPT code 77334 ((Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)).

For CY 2012, using our standard ratesetting methodology and the first year of available claims data for CPT code 77338, and based upon a final rule cost of approximately $188, we reassigned this service from APC 0310 to APC 0305 (Level II Therapeutic Radiation Treatment Preparation) with a final payment rate of approximately $264. In our response to public comments, we noted several possible reasons for the discrepancy in the reported cost of the service relative to its predecessor code. We stated that it is not unusual for providers to bill a given service in a manner that is inconsistent with what we would expect based on the definition of a new code. We also noted

potential clinical reasons for the apparent anomaly, such as the inclusion of labor-intensive physical blocks, shields, and molds in the service described by CPT code77334, and accounting rationales such as the crosswalking of a single collimator setting to the charges for the construction of a physical block, also in the service described by CPT code 77334. We stated that we saw no basis to ignore our robust set of single procedure claims submitted by a significant number of hospitals by continuing to simulate a cost for CPT code 77338.

In the CY 2013 OPPS/ASC proposed rule Addenda, based on a proposed rule cost of approximately $293, we proposed to continue the current assignment of CPT code 77338 for CY 2013 to APC 0305, and to add this service to the bypass list which would increase the number of claims that could be used in setting its payment rate.

Comment: One commenter objected to the continued assignment of CPT code 77338 to APC 0305. The commenter again noted the low estimated cost of this service compared to its predecessor code, and continued to believe that providers are inappropriately coding the service. They requested that for CY 2013, we simulate the cost of this service using the alternative methodology that we used in CY 2011, and that we reassign the service to APC 0310, which has a final rule cost of approximately $1,013.

Response: As we noted last year, we see no reason to discard the reported claims data for CPT code 77338, which has a CY 2013 final rule geometric mean cost of approximately $297. For the reasons previously discussed, for CY 2013 we will continue assigning this CPT code to APC 0305, which has a final geometric mean cost of

approximately $299. We will reevaluate whether this placement is appropriate next year when additional claims data are available.

c. Other Radiation Oncology Services (APCs 0310 and 0412)

Comment: One commenter addressed the proposed payment rates for the following services: CPT code 77418 (Radiation treatment delivery intensity modulated radiotherapy), which is assigned to APC 0412 (Level II Radiation Therapy) and is separately paid; CPT code 77295 (3-D Therapeutic radiology simulation-aided field setting), which is assigned to APC 0310 (Level III Therapeutic Radiation Treatment Preparation) and is also separately paid; CPT code 77373 (Stereotactic body radiation therapy delivery), which has a status indicator of "B" (Not covered under the OPPS); and CPT code 77014 (CT scan for therapy guidance), which has status indicator of "N" and is packaged. The commenter expressed concern about perceived decreases in payment for these services.

Response: Under our standard ratesetting methodology, we proposed a slight payment increase for CPT 77418 from approximately $459 in CY 2012 to approximately $484 in CY 2013, based on a CY 2013 proposed rule geometric mean cost of $497. Similarly, we proposed a slight payment increase for CPT 77295 from approximately $953 in CY 2012 to approximately $985 in CY 2013, based on a CY 2013 proposed rule geometric mean cost of $988. The final CY 2013 geometric mean cost of CPT 77418 is approximately $498, and the final CY 2013 geometric mean cost of CPT 77295 is approximately $991.

Since 2007, we have not recognized CPT code 77373 under the OPPS, and hospitals should instead report this service using HCPCS code G0251 (Linear accelerator based stereotactic radiosurgery, delivery). HCPCS code G0251 is assigned to APC 0065 (Level I Stereotactic Radiosurgery, MRgFUS, and MEG), whose payment rate also increased from CY 2012 (final CY 2012 payment of approximately $902) to CY 2013 (final CY 2013 geometric mean cost of approximately $1,007). CPT code 77014 has been packaged under the OPPS since 2008 when we implemented our guidance services policy.

d. Stereotactic Radiosurgery (SRS) Treatment Delivery Services (APCs 0065, 0066, 0067, and 0127)

For CY 2013, we proposed to continue to assign CPT code 77371 (Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based) to APC 0127 (Level IV Stereotactic Radiosurgery, MRgFUS, and MEG), which had a CY 2013 proposed payment rate of approximately $8,011.

We also proposed to continue to recognize four existing HCPCS G-codes that describe linear accelerator-based SRS treatment delivery services for separate payment in CY 2013. Specifically, we proposed the following: to assign HCPCS code G0173 (Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session) and HCPCS code G0339 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment) to APC 0067 (Level III Stereotactic Radiosurgery, MRgFUS, and MEG),

which had a CY 2013 proposed payment rate of approximately $3,294; to assign HCPCS code G0251 (Linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum five sessions per course of treatment) to APC 0065 (Level I Stereotactic Radiosurgery, MRgFUS, and MEG), which had a CY 2013 proposed payment rate of approximately $967; and to assign HCPCS code G0340 (Image-guided robotic linear accelerator based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment) to APC 0066 (Level II Stereotactic Radiosurgery, MRgFUS, and MEG), which had a CY 2013 proposed payment rate of approximately $2,361.

Further, we proposed to continue to assign SRS CPT codes 77372 (Radiation treatment delivery, stereotactic radiosurgery (SRS) (complete course of treatment of cerebral lesion(s) consisting of 1 session); linear accelerator based) and 77373 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions) status indicator “B” (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) under the OPPS, to indicate that these CPT codes are not payable under the OPPS.

Comment: One commenter urged CMS to reevaluate the APC assignments for the linear accelerator-based (LINAC) and robotic Cobalt-60 based stereotactic radiosurgery (r-SRS) HCPCS codes. The commenter stated that no clinical data exist to

support the need for differential payments for LINAC-based and Cobalt-60 r-SRS procedures. The commenter further explained that there is no clinical evidence to suggest that one system is superior to the other, and the costs of purchasing and maintaining the devices are similar. The commenter recommended that CMS assign HCPCS code G0339 and CPT code 77371 to the same APC, thereby establishing payment parity for the complete course of treatment for intracranial and other head and neck r-SRS, regardless of equipment or energy source. In addition, the commenter argued that this APC reevaluation is necessary to protect the Medicare program and beneficiaries from excessive costs associated with Cobalt-60-based system, when both the LINAC-based and Cobalt-60-based systems are similar in clinical homogeneity and resource costs.

Response: We disagree with the commenter's argument that the LINAC-based and Cobalt-60 based systems have similar resource costs. For the past several years, we have seen resource differences based on the geometric mean costs for the LINAC-based and Cobalt-60-based systems, and analysis of our claims data show that the geometric mean costs for LINAC-based and Cobalt-60-based SRS procedures differ significantly. Since CY 2007, when CPT code 77371 became effective, our claims data have shown consistently a cost of more than $7,000 for the service associated with the Cobalt-60-based system, which is higher than the mean cost of approximately $3,500 for the LINAC-based system (described by HCPCS G-code G0339).

Analysis of the updated CY 2011 claims data used for this final rule with comment period indicates that the code-specific geometric mean costs for the LINAC-based and Cobalt-60-based systems continue to differ. Our updated claims data

on the hospital outpatient claims available for CY 2013 ratesetting show a geometric mean cost of approximately $8,138 for CPT code 77371 based on 410 single claims (out of a total of 4,598 claims), which is significantly higher than the geometric mean costs associated with HCPCS codes G0173, G0251, G0339, and G0340. Specifically, our claims data indicate a geometric mean cost of approximately $2,605 for HCPCS code G0173 based on 923 single claims (out of a total of 1,597 claims), a geometric mean cost of approximately $1,007 for HCPCS code G0251 based on 12,965 single claims (out of a total of 13,746 claims), a geometric mean cost of approximately $3,497 for HCPCS code G0339 based on 8,287 single claims (out of a total of 10,462 claims), and a geometric mean cost of approximately $2,423 for HCPCS code G0340 based on 25,444 single claims (out of a total of 25,708 claims). Because the geometric mean costs of HCPCS code G0339 and CPT code 77371 differ significantly, we do not believe it would be appropriate to provide OPPS payment through a single APC for these r-SRS treatment delivery services in CY 2013. We continue to believe that APC 0127 is an appropriate APC assignment for CPT code 77371, and, similarly, that APC 0067 is an appropriate APC assignment for HCPCS code G0339 based on consideration of the clinical characteristics associated with these procedures and based on the geometric mean costs for these services calculated from the most recently available hospital outpatient claims and cost report data. Consistent with our current policy to annually assess the appropriateness of the APC assignments for all services under the hospital OPPS, we will continue to monitor our claims data for the SRS treatment delivery services in the future.

As we have stated in the past (74 FR 60456), the OPPS is a prospective payment system, where APC payment rates are based on the relative costs of services as reported to us by hospitals according to the most recent claims and cost report data as described in section II.A. of this final rule with comment period. The 2 times rule specifies that the mean cost of the highest cost item or service within a payment group may be no more than 2 times greater than the mean cost of the lowest cost item or service within the same group. Based on the 2 times rule, HCPCS code G0339 and CPT code 77371 could not be assigned to the same APC and, because hospitals continue to report very different costs for these services, we believe it is appropriate to maintain their assignments to different payment groups for CY 2013. As a matter of payment policy, the OPPS does not set payment rates for services based on considerations of clinical effectiveness. Furthermore, in accordance with the statute, we budget neutralize the OPPS each year in the annual update so that projected changes in spending for certain services are redistributed to payment for other services.

After consideration of the public comments we received, we are finalizing our CY 2013 proposals, without modification, to continue to assign CPT code 77371 to APC 0127, which has a final CY 2013 APC geometric mean cost of approximately $8,138, and to continue to assign HCPCS code G0339 to APC 0067, which has a final CY 2013 APC geometric mean cost of approximately $3,395.

e. Intraoperative Radiation Therapy (IORT) (APC 0412)

(1) Background

The AMA's CPT Editorial Panel created three new Category I CPT codes for intraoperative radiation therapy (IORT), effective January 1, 2012: CPT codes 77424 (Intraoperative radiation treatment delivery, x-ray, single treatment session); 77425 (Intraoperative radiation treatment delivery, electrons, single treatment session); and 77469 (Intraoperative radiation treatment management). As with all new CPT codes for CY 2012, these three codes were included in Addendum B to the CY 2012 OPPS/ASC final rule with comment period (available via the CMS Web site), effective on January 1, 2012. In accordance with our standard practice each year, our clinicians review the many CPT code changes that will be effective in the forthcoming year and make decisions regarding status indicators and/or APC assignments based on their understanding of the nature of the services. We are unable to include proposed status indicators and/or APC assignments in the proposed rule for codes that are not announced by the AMA's CPT Editorial Panel prior to the issuance of the proposed rule. Therefore, in accordance with our longstanding policy, we include, in the final rule with comment period, interim status indicators and/or APC assignments for all new CPT codes that are announced by the AMA's CPT Editorial Panel subsequent to the issuance of the OPPS/ASC proposed rule to enable payment for new services as soon as the codes are effective.

We identified the new codes for IORT for CY 2012 in Addendum B to the CY 2012 OPPS/ASC final rule with comment period as being open to public comment by

showing a comment indicator of "NI" and made interim status indicator assignments for each of these new IORT codes, based on our understanding of the clinical nature of the services they describe. Specifically, for CY 2012, we packaged these IORT service codes with the surgical procedures with which they are billed, assigning them interim status indicators of "N" (Items and Services Packaged into APC Rates). We did so based on a policy that was adopted in the CY 2008 OPPS final rule with comment period (72 FR 66610 through 66659) to package services that are typically ancillary and supportive of a principal diagnostic or therapeutic procedure, which would generally include intraoperative services. Because IORT are intraoperative services furnished as a single dose during the time of the related surgical session, we packaged them into the payment for the principal surgical procedures with which they are performed based on claims data used for the CY 2012 OPPS/ASC final rule with comment period.

Subsequent to issuance of the CY 2012 OPPS/ASC final rule with comment period, stakeholders provided comments on the interim status of these IORT service codes for CY 2012, asserting that these services are not ancillary to the surgical procedures, urging us to unpackage these codes, and requesting that we assign them to an APC reflective of the resources used to provide the IORT services. Commenters who responded to the CY 2012 OPPS/ASC final rule with comment period argued that IORT services described by CPT codes 77424 and 77425 are separate, distinct, and independent radiation treatment services from the surgical services to remove a malignant growth. According to the commenters, IORT is performed separately by a radiation oncologist and a medical physicist when there is concern for residual unresected cancer because of

narrow margins related to the surgical resection. A number of the commenters provided varied estimates of the cost of IORT as between $4,000 and $7,000 per treatment, and some commenters cited a hospital survey of per treatment costs for the procedure described by CPT code 77424 of $4,441.17 and for the procedure described by CPT code 77425 of $6,897.50.

One commenter stated that the x-ray intraoperative service described by CPT code 77424 has previously been reported with CPT code 0182T (High dose rate electronic brachytherapy, per fraction), which is a separately paid OPPS service. However, the commenter pointed out that it would not be proper to report intraoperative radiation therapy with CPT code 0182T because now CPT codes 77424 and 77425 more specifically and accurately describe the intraoperative radiation services. One commenter recommended that CPT code 77425 be mapped to a new technology APC.

(2) CY 2013 Proposals for CPT Codes 77424, 77425, and 77469

Based on the public comments and information received on the IORT policies contained in the CY 2012 OPPS/ASC final rule with comment period, and after further review and consideration of those public comments and the clinical nature of the IORT procedures, we agreed that IORT services are not the typical intraoperative services that we package, as they are not integral to or dependent upon the surgical procedure to remove a malignancy that precedes IORT. Therefore, for CY 2013, we proposed to unpackage CPT codes 77424 and 77425 and assign them to APC 0412, currently titled "IMRT Treatment Delivery" (77 FR 45124). We stated that IORT treatment services are clinically similar to other radiation treatment forms, such as IMRT treatment, which are

assigned to APC 0412. Furthermore, we proposed to change the title of APC 0412 to "Level III Radiation Therapy" to encompass a greater number of clinically similar radiation treatment modalities. The CY 2013 proposed rule geometric mean cost for APC 0412, based on CY 2011 claims data, was approximately $496. We also proposed to monitor hospitals' costs for furnishing the services described by CPT codes 77424 and 77425.

In the CY 2013 proposed rule, we stated that we believe that CPT code 77469 should receive equal treatment to other radiation management codes, such as CPT code 77431 (Radiation therapy management with complete course of therapy consisting of 1 or 2 fractions only) and CPT code 77432 (Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of 1 session)), which are assigned status indicator "B" (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) and are not paid under the OPPS. Therefore, we proposed that the appropriate status indicator code assignment for CPT code 77469 be "B" for nonpayable status under the OPPS for CY 2013, a change from its current CY 2012 status indicator assignment of "N" for packaged payment status.

At its August 2012 meeting, the HOP Panel recommended that CMS assign CPT code 77424 and CPT code 77425 to APC 0313 (Brachytherapy), and consider renaming the APC "Brachytherapy and Intraoperative Radiation Therapy." The Panel also recommended that CMS present to the Panel cost data regarding CPT codes 77424 and 77425, when available or by the August 2013 Panel meeting.

Comment: Many commenters supported the proposal to unpackage CPT codes 77424 and 77425, but objected to the proposed assignment of these codes to APC 0412. The commenters asserted that APC 0412 is neither reflective of the clinical characteristics nor the resources needed to perform the IORT services described by CPT codes 77424 and 77425. The commenters pointed out the clinical differences between IORT and IMRT, in that IORT provides a much higher dose of radiation during a single fraction (session) lasting about 45 minutes, while IMRT provides lower doses over multiple fractions lasting about 15 minutes. The commenters asserted that IMRT's cost over the full course of therapy is $17,000 to $20,000, much higher than IORT's cost.

Many commenters requested that CMS assign CPT codes 77424 and 77425 to an appropriate APC based on clinical similarity to other radiation treatments and suggested that CMS use external cost data to estimate the costs of IORT, because cost data from hospital claims are not yet available for these new CPT codes. Some commenters recommended that CPT codes 77424 and 77425 be assigned to APC 0313 (Brachytherapy), which has a proposed payment rate of approximately $685, because the IORT services are more similar to brachytherapy services than the IMRT services currently assigned to APC 0412. These commenters asserted that both IORT and brachytherapy involve placement of a radiation source inside or next to the area of the body requiring treatment, while IMRT, which is a form of external beam radiation therapy, delivers radiation from outside the body. The commenters opined that CPT codes 77424 and 77425 and the APC 0313 brachytherapy procedures have similar resource costs, particularly because the X-ray based IORT procedure is comparable to

high dose rate (HDR) brachytherapy, and the X-ray based IORT system may be used for the delivery of fractionated breast brachytherapy, often billed with CPT code 0182T (High dose rate electronic brachytherapy, per fraction), which is assigned to APC 0313.

Several other commenters stated that IORT is very different than HDR brachytherapy, as well as IMRT and multi-fraction stereotactic radiosurgery, in terms of both clinical characteristics and resource costs. Commenters stated that IORT capital equipment can only be used for IORT in the operating room, and not for other forms of radiation therapy, resulting in less patient utilization over which to spread costs. These commenters recommended that CMS assign CPT codes 77424 and 77425 to APC 0067 (Level III Stereotactic Radiosurgery, MRgFUS, and MEG), which has a proposed payment rate of approximately $3,294. These commenters believed that IORT is more similar clinically to stereotactic radiosurgery (SRS) than IMRT, pointing out that SRS may be delivered in single or multiple fraction therapy and has many fewer (that is, 2 to 5) fractions, making it more similar to IORT, in that regard. A few commenters recommended that CMS assign IORT to a New Technology APC, with a wide range of recommended payment rates, from approximately $4,000 to approximately $7,000, citing various data estimates and sources including a survey of hospitals.

Regarding our proposal to change the status indicator for CPT code 77469 to “B” and make the service non-payable, one commenter supported the proposed change on the basis that it is consistent with our policy regarding other radiation treatment management codes.

Response: We appreciate all of the feedback we received on the CY 2012 interim status indicator assignment of "N" to CPT codes 77424 and 77425 and the CY 2013 proposal to assign these CPT codes to APC 0412. As stated in the CY 2013 OPPS/ASC proposed rule and described above, we agree with the commenters that IORT services are not the typical intraoperative services that we package, as they are not integral to or dependent upon the surgical procedure to remove a malignancy that precedes IORT.

We agree with commenters that the resource costs of APC 0412 do not fit well with single fraction radiation therapy technologies, such as IORT. However, we believe the resource costs of IORT can be accommodated by one of the existing APCs for radiation therapy, and therefore, a new technology APC assignment is not needed. From a clinical standpoint, we agree with commenters that the procedures described by CPT codes 77424 and 77425 share important characteristics with SRS, particularly because SRS may be a single fraction therapy or involve many fewer fractions than IMRT. Based on the range of claimed costs provided by the commenters, which are all based on external costs, as we do not yet have claims data, there is clearly a wide range of reported or estimated costs for IORT services, and, as some commenters indicate, there may be a difference in the cost structures of CPT codes 77424 and 77425.

After consideration of the public comments we received, we believe that an appropriate initial APC assignment for CPT codes 77424 and 77425 is APC 0065 (Level I Stereotactic Radiosurgery, MRgFUS, and MEG), in terms of clinical characteristics, and the range of estimated costs for IORT services. Therefore, for CY 2013, we are assigning CPT codes 77424 and 77425 to APC 0065, which has a CY 2013 final

geometric mean cost of approximately $1,006. We will review the APC assignment of CPT codes 77424 and 77425, individually, once we have OPPS hospital claims data. Regarding the Panel recommendation that we present to the Panel cost data regarding CPT codes 77424 and 77425, we agree to provide cost data from claims for these service codes when available.

7. Imaging

a. Non-Ophthalmic Fluorescent Vascular Angiography (APC 0397)

Effective April 1, 2012, we created HCPCS code C9733 (Non-ophthalmic fluorescent vascular angiography (FVA)) for a service that became known to us via the new technology APC application process. We assigned HCPCS code C9733 to APC 0397 (Vascular Imaging), which has a CY 2012 payment rate of $154.87 and a status indicator assignment of "Q2." The "Q2" status indicator provides that the service will have packaged APC payment if billed on the same date of service as a HCPCS code assigned status indicator "T"; and in all other circumstances, there is a separate APC payment for the service. We proposed to continue to assign HCPCS code C9733 to APC 0397 for CY 2013, which had a CY 2013 proposed payment rate of $192.21, and to continue the assignment of the code to the "Q2" status indicator.

The HOP Panel, at its August 2012 meeting, recommended that CMS maintain a status indicator of "Q2" for HCPCS code C9733, while making no recommendation as to its APC assignment. The proposed payment rate for APC 0397 was $197.08, with a range in individual procedure geometric mean costs from $140.78 to $202.97. We proposed the assignment of HCPCS code C9733 to APC 0397 because we believed that the service described by HCPCS code C9733 is similar in clinical characteristics to other

vascular imaging services. We do not have claims cost data available for HCPCS code C9733 because it was made effective on April 1, 2012. For new HCPCS codes, our longstanding policy is to wait until we have claims data on new services before considering them for reassignment to clinical APCs other than the originally assigned APC.

Comment: A number of commenters were appreciative that CMS created a new HCPCS code for non-ophthalmic FVA, but were concerned with the packaged status that would result from assigning HCPCS code C9733 status indicator "Q2" because the procedure is usually performed with a service having a "T" status indicator. A few commenters pointed out that FVA is effective in assessing perfusion in tissue, and is particularly useful when vascular function is diminished. A number of commenters pointed out that the procedure is performed intraoperatively for this purpose, and is a valuable tool to assist the surgeon with clinical decision-making. Commenters also pointed out that the non-ophthalmic FVA procedure has been used primarily in the hospital inpatient setting, and only recently offered in the hospital outpatient setting; therefore, outpatient data are only beginning to accumulate. However, commenters believed that because the "Q2" status indicator will typically result in packaging the cost of the procedure, the procedure will not be performed at many hospitals. The commenters asserted that it was very important that CMS change the status indicator of HCPCS code C9733 to "S," which is the same status indicator as all other procedures assigned to APC 0397. Moreover, some commenters stated that other vascular imaging procedures, such as Doppler Ultrasound, fluoroscopy, and magnetic resonance

angiography (MRA), are alternatives to the procedure described by HCPCS code C9733 and are assigned status indicator "S" rather than status indicator "Q2." Another commenter noted that other modalities used for tissue perfusion screening in the hospital outpatient setting are assigned to APC 0096 (Level II Noninvasive Physiologic Studies), and these procedures also are assigned status indicator "S." The commenter opined that assignment of status indicator "Q2" will encourage outpatient clinics to schedule multiple visits to avoid the packaging of HCPCS code C9733. One commenter claimed that only a small number of APCs have more than one status indicator for their assigned procedures, and that no other HCPCS C-codes have a status indicator of "Q2." The commenter asserted that packaged status should only be assigned to procedures where data indicate that the costs and services associated with the procedure are integral to existing procedures.

One commenter asserted that the assignment of HCPCS code C9733 to APC 0397 is not appropriate based on the costs of the procedure, and estimated that the cost is approximately $2,100 per procedure. The commenter stated that this estimate is based on a $6,000 monthly lease payment of the system's capital with 5 times per month use, disposable kit costs of approximately $800, plus $100 in indirect costs. The commenter recommended the assignment of HCPCS code C9733 to APC 0279 (Level II Angiography and Venography), which has a CY 2013 proposed payment rate of approximately $2,219, or assignment of the C-code to New Technology APC 1522 (Level XXII New Technology), which has a CY 2013 proposed payment rate of $ 2,250,

for at least a 3-year transitional period, until the costs to perform the non-ophthalmic FVA procedure are known, in order to package the procedure.

A few commenters were concerned that the HOP Panel, and perhaps CMS as well, were confusing the HCPCS code C9733 technology with a "Wood's Lamp." The commenters explained the differences in the two technologies, indicating that there are clinically significant differences as a result of the properties of the fluorescent dyes with which they are used.

Response: We believe that, when the non-ophthalmic FVA procedure is performed with a surgical procedure, it is ancillary to the surgical service, providing imaging services that are supportive and adjunctive to the surgical service. As a number of commenters stated, the procedure is used intraoperatively to assist the surgeon. In those instances when the service described by HCPCS code C9733 is performed as a stand-alone service, it is separately paid. Therefore, we believe the "Q2" status indicator is appropriate. Regarding the comment that there are only a few APCs that have more than one status indicator, we assign status indicators to HCPCS codes, not to APCs. APCs are sometimes composed of procedures that have similar roles in the overall provision of services (for example, they are either major or minor services, serve an adjunct role), but this is not always the case. We disagree that the "Q2" status indicator will encourage multiple clinic visits. In cases where surgery requires intraoperative imaging to assess tissue perfusion, the procedure described by HCPCS code C9733 cannot be provided separate from the surgery. Regarding the estimated cost of the procedure that a commenter provided, we note that the assumptions regarding the use of

the capital equipment markedly affects the estimate of the cost of the procedure. The commenter's assumed use of the equipment at 5 times per month, results in the $1,200 monthly capital cost. However, an assumed monthly use of 20 times results in $300 monthly costs, and 30 times per month results in $200 monthly capital costs, and so on. Low utilization of a new technology can result in aberrantly high per case cost estimates and illustrates why it is important for us to wait until hospital outpatient claims data become available to us for use in ratesetting. We understand the differences between the non-ophthalmic FVA and Wood's Lamp technologies, and assure the commenters that our decision is not based on any confusion regarding the two technologies.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal to assign HCPCS code C9733 to APC 0397 and to continue to assign the code to status indicator "Q2." APC 0397 has a CY 2013 final geometric mean cost of approximately $340, which we note is a significant increase over the CY 2012 proposed rule mean cost.

b. Level II Nervous System Imaging (APC 0402)

For CY 2013, we proposed to continue to assign CPT code 78607 (Brain imaging, tomographic (spect)) in APC 0402 (Level II Nervous System Imaging), which had a proposed payment rate of approximately $477.

Comment: Some commenters requested that CMS assess the accuracy of the payment rate calculation for APC 0402. One commenter stated that the proposed 22-percent payment reduction does not appear to be due to any significant reduction in hospital charges for the procedures included in the APC or the shift from the use of

medical charges to the use of the geometric mean cost. Another commenter requested that CMS reassess its APC payment rate calculation, including the proposed geometric mean cost of brain SPECT, which is described by CPT code 78607, and only phase in a change to the APC payment rate if the data support a reduction.

Response: We reviewed our claims data and, for the CY 2013 update, used more claims to determine the payment rate for APC 0402, as compared to the CY 2012 update. For the CY 2012 final rule with comment period, there were 2,593 single claims (out of 4,643 total claims), while for the CY 2013 proposed rule, there were 3,062 single claims (out of 4,793 total claims) used to calculate the proposed payment rate for APC 0402. Also, as indicated in the file that we made available with the proposed rule entitled "CY 2013 OPPS Comparison Between Proposed Geometric Mean and Median Based Payments," the proposed payment rate using either payment methodology shows a decrease in the payment rate for APC 0402 for the CY 2013 update. That is, the CY 2013 proposed payment rate for APC 0402, based on the median cost methodology, was approximately $497, while the geometric mean cost methodology resulted in a CY 2013 proposed payment rate of approximately $477. While the proposed payment rate decreased for APC 0402, overall, the use of the geometric mean methodology has been positive for many services. In addition, basing the OPPS payment calculations on geometric means aligns the metric used in the ratesetting methodology for the OPPS with that used for the IPPS.

Further examination of the claims data used for this final rule with comment period revealed an increase in services assigned to APC 0402. Specifically, our claims

data show a geometric mean cost of approximately $472 based on 3,446 single claims (out of 5,345 total claims). Similarly, we saw the same pattern of increase in services and cost for CPT code 78607 from the proposed rule claims data to this final rule claims data. That is, for the CY 2013 OPPS/ASC proposed rule, the proposed geometric mean cost for CPT code 78607 was approximately $490 based on 2,295 single claims (out of 2,573 total claims), while the final rule geometric mean cost is approximately $468 based on 2,592 single claims (out of 2,902 total claims). We note that CPT code 78607 represents 75 percent of the claims for services assigned to APC 0402. Because of the robust claims, we believe that our claims data accurately reflect the resource costs of the procedures assigned to APC 0402, including the service described by CPT code 78607. We do not believe that applying a phase-in change to the APC payment rate for the brain SPECT CPT code 78607 is necessary, given the significant claims data for this procedure.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal, without modification, to continue to assign CPT code 78607 to APC 0402. The final CY 2013 geometric mean cost for APC 0402 is approximately $472.

c. Computed Tomography of Abdomen/Pelvis (APCs 0331 and 0334)

For CY 2011, the AMA's CPT Editorial Panel established three new CPT codes to describe computed tomography of the abdomen and pelvis. CPT codes 74176 (Computed tomography, abdomen and pelvis; without contrast material), 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)), and 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both

body regions, followed by contrast material(s) and further sections in one or both body regions) were effective January 1, 2011. As shown in Table 26, for CY 2011, these services were paid under one of two methods under the OPPS. They were either paid separately through a single APC or through a composite APC. We assigned CPT code 74176 to APC 0332 (Computed Tomography Without Contrast), CPT code 74177 to APC 0283 (Computed Tomography With Contrast), and CPT code 74178 to APC 0333 (Computed Tomography Without Contrast Followed By Contrast). We also assigned CPT code 74176 to composite APC 8005 (CT and CTA Without Contrast Composite), and CPT codes 74177 and 74178 to composite 8006 (CT and CTA With Contrast Composite). We assigned the CPT codes to status indicator "Q3" to indicate that they were eligible for composite payment under the multiple imaging composite APC methodology when they are furnished with other computed tomography procedures performed on the same patient on the same day.

TABLE 26.—CY 2011 OPPS APC ASSIGNMENTS FOR THE COMPUTED TOMOGRAPHY OF ABDOMEN AND PELVIS CPT CODES

CY 2011 CPT Code	CY 2011 Short Descriptor	CY 2011 SI	CY 2011 Single Code APC	CY 2011 Single Code APC Payment Rate	CY 2011 Composite APC	CY 2011 Composite APC Payment Rate
74176	Ct abd & pelvis	Q3	0332	$193.85	8005	$420.85
74177	Ct abd & pelv w/contrast	Q3	0283	$299.81	8006	$628.61
74178	Ct abd & pelv 1/> regns	Q3	0333	$334.24	8006	$628.61

Consistent with our longstanding policy for new codes, in Addendum B of the CY 2011 OPPS/ASC final rule with comment period, we assigned these new CPT codes

to interim APCs for CY 2011, with comment indicator "NI" to denote that the codes were new and the interim APC assignment would be open to public comment. In accordance with our longstanding policy to provide codes to enable payment to be made for new services as soon as the code is effective, our interim APC assignment for each code was based on our understanding of the resources required to furnish the service and its clinical characteristics as defined in the code descriptor.

As we described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74259), in general, stakeholders who provided comments on the interim APC assignments of these CPT codes for CY 2011 stated that the most appropriate approach to establishing payment for these new codes was to assign the procedures described by the codes to APCs that recognize that each of the new codes reflects the reporting, under a single code, of two services that were previously reported under two separate codes and that, therefore, payments would be more accurate and better reflective of the services under the OPPS than if we were to establish payment rates for the codes for CY 2012 using claims data that reflect the combined cost of the two predecessor codes. In addition, at the February 28-March 1, 2011 Panel meeting, several presenters expressed their concern and disagreement with our single APC assignments for these new codes. The presenters stated that the payment rates for the single APC assignments reflected only half of the true costs of these services based on their internal calculated costs. Similar to the public commenters, the presenters indicated that, prior to CY 2011, these services were reported using a combination of codes, and suggested that CMS revise the methodology to include these combinations of codes to determine accurate payment rates

for these services. Specifically, the presenters indicated that simulating the costs for CPT codes 74176, 74177, and 74178 using historical claims data from the predecessor codes would result in the best estimates of costs for these CPT codes and, therefore, the most accurate payment rates.

After examination of our claims data for the predecessor codes, and after considering the various concerns and recommendations that we received on this issue (specifically, the views of the stakeholders who met with us to discuss this issue, the comments received in response to the CY 2011 OPPS/ASC final rule with public comment period, and input from the Panel at its February 28-March 1, 2011 meeting), we proposed to revise our payment methodology for CPT codes 74176, 74177, and 74178 for CY 2012 (76 FR 42235). That is, we proposed to simulate the costs for CPT codes 74176, 74177, and 74178 using historical claims data from the predecessor codes to determine the most accurate payment rates for these CPT codes. This new proposed payment methodology necessitated establishing two new APCs, specifically, APC 0331 (Combined Abdominal and Pelvis CT Without Contrast) to which CPT code 74176 would be assigned, and APC 0334 (Combined Abdominal and Pelvis CT With Contrast) to which CPT codes 74177 and 74178 would be assigned. In addition, we proposed to continue to assign CPT code 74176 to composite APC 8005 and CPT codes 74177 and 74178 to composite APC 8006 for CY 2012.

Based on the feedback that we received from the Panel at its August 10-11, 2011 meeting, and the public comments received in response to the CY 2012 OPPS/ASC proposed rule in support of the proposed revised payment methodology for CPT codes

74176, 74177, and 74178, we finalized our proposals in the CY 2012 OPPS/ASC final rule with comment period. Specifically, we reassigned CPT code 74176 from APC 0332 to APC 0331, CPT code 74177 from APC 0283 to APC 0334, and CPT code 74178 from APC 0333 to APC 0334. (We refer readers to the CY 2012 OPPS/ASC final rule with comment period for a detailed description of the methodology we used to simulate the costs of these procedures using claims data for the predecessor CPT codes (76 FR 74259 through 74262).) We also continued with our composite APC assignments for these codes. Specifically, we continued to assign CPT code 74176 to composite APC 8005 and CPT codes 74177 and 74178 to composite APC 8006. Table 27 below shows the payment rates for these CPT codes for the CY 2012 update.

TABLE 27.—CY 2012 OPPS APC ASSIGNMENTS FOR THE COMPUTED TOMOGRAPHY OF ABDOMEN AND PELVIS CPT CODES

CY 2012 CPT Code	CY 2012 Short Descriptor	CY 2012 SI	CY 2012 Single Code APC	CY 2012 Single Code APC Payment Rate	CY 2012 Composite APC	CY 2012 Composite APC Payment Rate
74176	Ct abd & pelvis	Q3	0331	$405.17	8005	$431.60
74177	Ct abd & pelv w/contrast	Q3	0334	$580.54	8006	$721.12
74178	Ct abd & pelv 1/> regns	Q3	0334	$580.54	8006	$721.12

We stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74262) that we would reassess whether there is a continued need for these APCs for the CY 2013 OPPS/ASC update once we have actual charges for these services. Because CPT codes 74176, 74177, and 74178 became effective on January 1, 2011, we have hospital claims data available for these codes that we can use for ratesetting for the first time. In the CY 2013 OPPS/ASC proposed rule (77 FR 45086), we stated that analysis of the latest CY 2011 hospital outpatient claims data for the CY 2013 OPPS/ASC proposed rulemaking update, which was based on claims processed with dates of service from January 1, 2011 through December 31, 2011, revealed a decrease in costs for the three procedures, compared to the costs simulated using the predecessor CPT codes for CY 2012. CPT code 74176 showed a proposed geometric mean cost of approximately $314 based on 312,493 single claims (out of 713,662 total claims), while CPT code 74177 showed a proposed geometric mean cost of approximately $476 based on 367,002 single claims (out of 951,296 total claims). In addition, CPT code 74178

showed a proposed geometric mean cost of approximately $537 based on 184,580 single claims (out of 267,401 total claims). Because we used hospital claims data specific to CPT codes 74176, 74177, and 74178, we stated that we believe these costs accurately reflect the resources associated with providing computed tomography of the abdomen and pelvis as described by these CPT codes in the HOPD.

Furthermore, our analysis of the CY 2011 claims data available for the proposed rule showed no 2 times rule violation for either APC 0331 or APC 0334. Therefore, for CY 2013, we proposed to continue to assign CPT code 74176 to APC 0331 and CPT codes 74177 and 74178 to APC 0334. (Because we have claims data available for these three CPT codes, we will no longer simulate their costs using the predecessor codes as we did in CY 2012.) In addition, we proposed to continue to assign these codes to their existing composite APCs for CY 2013. Specifically, we proposed to continue to assign CPT code 74176 to composite APC 8005, and to assign CPT codes 74177 and 74178 to composite APC 8006.

Comment: Several commenters expressed concern with the decreased payment rates for APCs 0331 and 0334, and suggested that the coding changes that occurred in CY 2011 for CPT codes 74176, 74177, and 74178, attributed to the payment reduction. Some of the commenters believed that because the codes were new in CY 2011, hospitals have not had enough time to appropriately adjust their charge masters to accurately reflect the CY 2011 coding changes. One commenter urged CMS to take whatever action necessary to mitigate the payment cuts for CY 2013. Some of commenters requested that

CMS delay the use of claims data and continue the use of historical data for an additional year to give more time for education and adjustment of hospital charge masters.

Response: We believe that hospitals have a process in place to adjust to the numerous coding changes that occur annually. There are hundreds of coding changes (that is, CPT, Level II Alphanumeric HCPCS, and ICD-9-CM codes) that occur every year, and hospitals make changes to their internal systems (for example, coding, charge masters, grouper, business office systems, among other) accordingly to capture these changes so that their claims are processed timely and accurately.

Because of the substantial claims data that we have for these procedures, we see no reason to delay the use of the claims data in determining the costs for CPT codes 74176, 74177, and 74178. Specifically, we were able to use at least 1 million claims that were submitted during CY 2011 in determining the payment rates for CPT codes 74176, 74177, and 74178. Our analysis for this final rule with comment period revealed a geometric mean cost of approximately $315 for CPT code 74176 based on 333,144 single claims (out of 769,757 total claims), a geometric mean cost of approximately $477 for CPT code 74177 based on 388,506 single claims (out of 1,024,117 total claims), and a geometric mean cost of approximately $538 for CPT code 74178 based on 194,216 single claims (out of 283,435 total claims). We have no reason to believe that our claims data, as reported by hospitals, do not accurately reflect the hospital costs for CPT codes 74176, 74177 and 74178.

After consideration of the public comments received, we are finalizing our CY 2013 proposal, without modification. Specifically, for CY 2013, we are continuing

to assign CPT code 74176 to APC 0331 and CPT codes 74177 and 74178 to APC 0334. In addition, we are continuing to assign these CPT codes to their existing composite APCs for CY 2013. Specifically, we are continuing to assign CPT code 74176 to composite APC 8005, and to assign CPT codes 74177 and 74178 to composite APC 8006.

Table 28 below lists the computed tomography of the abdomen and pelvis CPT codes along with their status indicators, and single and composite APC assignments for CY 2013.

TABLE 28.—APC ASSIGNMENTS FOR THE COMPUTED TOMOGRAPHY OF ABDOMEN AND PELVIS CPT CODES FOR CY 2013

CY 2013 CPT Code	CY 2013 Short Descriptor	CY 2013 SI	CY 2013 Single Code APC	CY 2013 Composite APC
74176	Ct abd & pelvis	Q3	0331	8005
74177	Ct abd & pelv w/contrast	Q3	0334	8006
74178	Ct abd & pelv 1/> regns	Q3	0334	8006

8. Respiratory Services

a. Bronchoscopy (APC 0415)

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)) was established by the AMA's CPT Editorial Panel in 1987. CPT code 31634 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with

administration of occlusive substance (eg, fibrin glue), if performed) was established effective January 1, 2011. CPT code 31629 has been assigned to APC 0076 (Level I Endoscopy Lower Airway) since August 2000, when the hospital OPPS was implemented, while CPT code 31634 has been assigned to APC 0076 since the code was effective on January 1, 2011.

In the CY 2013 OPPS/ASC proposed rule, we proposed to reassign both CPT codes 31629 and 31634 from APC 0076 to APC 0415 (the Level II Endoscopy Lower Airway). Consistent with CMS' policy of reviewing APC assignments annually for any 2 times rule violations and appropriateness of APC assignments based on the latest hospital outpatient claims data, we evaluated the resource cost associated with the procedures assigned to APC 0076 for the CY 2013 rulemaking update. Based on our analysis, we determined that the configuration of APC 0076 violated the 2 times rule. To eliminate the 2 times rule violation, we proposed to reassign CPT codes 31629 and 31634 from APC 0076 to APC 0415 because we believe this APC appropriately reflects these services based on their resource costs as well as clinical homogeneity.

At the August 2012 HOP Panel meeting, a presenter requested that the Panel recommend to CMS not to reassign CPT codes 31629 and 31634 to APC 0415 for CY 2013. The presenter stated that including both procedures in APC 0415 would result in a 2 times rule violation. In addition, the presenter recommended that CPT codes 31629 and 31634 be reassigned to APC 0074 (Level IV Endoscopy Upper Airway) instead of APC 0415. After discussion of the procedures and review of the hospital

outpatient claims and cost report data, the Panel recommended that CPT codes 31629 and 31634 be reassigned from APC 0076 to APC 0415 for the CY 2013 OPPS update.

Comment: Some commenters disagreed with the proposal to include CPT codes 31629 and 31634 in APC 0415, and indicated that including both procedures reduces the proposed payment rate for APC 0415 by at least 23 percent. One commenter specified that adding CPT codes 31629 and 31634, which have greater volumes of lower geometric mean costs than other services assigned to APC 0415, reduces the overall payment of APC 0415. One commenter indicated that the reduction in payment would hinder patient access to the pulmonary services listed under APC 0415 and recommended alternative endoscopy lower airway APC configurations, such as establishing a new APC titled "Level III Endoscopy Lower Airway" for six lower endoscopy procedures, that would include both CPT codes 31629 and 31634 as well as four other lower endoscopy procedures. Specifically, the commenter suggested including CPT codes 31626 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple), 31631 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of tracheal stent(s) (includes tracheal/bronchial dilation as required)), 31636 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of bronchial stent(s) (includes tracheal/bronchial dilation as required), initial bronchus), 31638 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with revision of tracheal or bronchial stent inserted at previous session (includes tracheal/bronchial dilation as required)), and CPT codes 31629 and 31634. The

commenter explained that CPT codes 31626, 31631, 31636, and 31638 are different from other procedures assigned to APC 0415 because they require implanting medical devices in the patient (fiducial markers, stents), which results in extra cost. Another commenter requested that CMS reevaluate the endoscopy lower airway APCs (0076 and 0415) as more claims data become available for newer procedures, and to meet with stakeholders to discuss the future reconfiguration of APCs for endoscopy lower airway.

Response: As indicated above, we proposed to revise the APC assignments for CPT codes 31629 and 31634 after our analysis of the claims data for the CY 2013 rulemaking revealed a 2 times rule violation in APC 0076. Based on the latest hospital outpatient claims data for this final rule with comment period, we do not agree with the commenters that we should implement an alternative configuration for endoscopy lower airway APCs because the existing APCs are sufficient to reflect the costs of all of the procedures assigned to these APCs. We continue to believe that APC 0415 is the most appropriate APC assignment for CPT codes 31629 and 31634 because their resource costs are relatively similar to the procedures assigned to APC 0415. Therefore, we are accepting the Panel's recommendation and will assign both procedures to APC 0415. For the CY 2013 update, our analysis of the claims data submitted during CY 2011 and used for this final rule with comment period show a geometric mean cost of approximately $1,381 based on 2,699 single claims (out of 12,209 total claims) for CPT code 31629, and a relatively similar geometric mean cost of approximately $1,394 for CPT code 31634 based on 10 single claims (out of 16 total claims). Consistent with CMS' policy of reviewing APC assignments annually, we will again reevaluate the clinical similarity and

resource use of the procedures in APC 0415 for the CY 2014 rulemaking cycle. Finally, we note that we regularly accept meetings from interested parties throughout the year, and we encourage stakeholders to continue a dialogue with us during the rulemaking cycle and throughout the year on this issue.

After consideration of the public comments we received, we are finalizing our CY 2013 proposal, without modification, to reassign CPT codes 31629 and 31634 from APC 0076 to APC 0415. The final CY 2013 geometric mean cost for APC 0415 is approximately $1,617.

b. Upper Airway Endoscopy (APC 0075)

For CY 2013, we proposed to continue to assign 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), which had a CY 2013 proposed payment rate of approximately $2,039. In addition, we proposed to reassign CPT code 31541 (Laryngoscopy, direct, operative, with excision of tumor and/ or stripping of vocal cords or epiglottis; with operating microscope or telescope) from APC 0074 (Level IV Endoscopy Upper Airway) to APC 0075.

Comment: Commenters objected to the assignment of CPT codes 31295, 31296, and 31297 to APC 0075 because the commenters believed that the payment rate for APC 0075 substantially underpays providers. The commenters recommended that CMS create

split APCs for sinus surgery with balloon catheter and without balloon catheter, the former of which should be deemed device-dependent to appropriately account for the cost of such procedures. The commenters also requested that CMS not finalize its proposal to reassign CPT 31541 to APC 0075 and, instead, maintain the code in APC 0074 for CY 2013.

Response: We believe that the most clinically appropriate APC assignment for CPT codes 31295, 31296, and 31297 is APC 0075, which includes other nasal and sinus endoscopy procedures. When assigning procedures to an APC, we first consider the clinical and resource characteristics of a procedure and determine the most appropriate APC assignment. Regarding the resource costs of the procedures in question, the commenters asserted costs of approximately $4,000 for these procedures, which are currently assigned to the highest paying clinically appropriate APC (APC 0075), which is Level 5 out of 5 levels of APCs for "endoscopy upper airway." The highest geometric mean cost of all of the procedures assigned to APC 0075 is approximately $4,000. Therefore, even the nonclaims data-based cost estimate for these procedures offered by the commenters is within the approximate range (although on the high end of the range) of the geometric mean costs for procedures assigned to APC 0075. We do not agree with the commenters that new APCs should be created to differentiate between sinus surgery with balloon catheter and without balloon catheter, as APC 0075 accurately reflects a reasonable distribution of resource costs reflected in the group of clinically similar services currently assigned to the APC. We note that there is currently no 2 times rule violation in APC 0075. We do not agree with the commenters that CPT code 31541

should continue to be assigned to APC 0074, as CPT code 31541's geometric mean cost of approximately $1,962 is higher than the geometric mean cost for any service currently assigned to APC 0074 and would result in a 2 times rule violation for APC 0074 as well. We believe that the geometric mean cost and clinical characteristics of CPT code 31541 justify its assignment to APC 0075 for CY 2013.

After consideration of the public comments we received, we are finalizing our CY 2013 proposals, without modification, to continue to assign CPT codes 31295, 31296, and 31297 to APC 0075, and reassign CPT code 31541 to APC 0075, which has a final CY 2013 APC geometric mean cost of approximately $2,085.

9. Other Services

a. Payment for Molecular Pathology Services

For the January 2012 update, the AMA's CPT Editorial Panel established 101 new molecular pathology services CPT codes that were designated as either Molecular Pathology Procedures Tier 1 or Molecular Pathology Procedures Tier 2 effective January 1, 2012. Tier 1 consisted of CPT codes 81200 through 81383, while Tier 2 consisted of CPT codes 81400 through 81408. However, these new molecular pathology CPT codes are not valid for payment under Medicare for CY 2012.

Instead, molecular pathology tests for CY 2012 are billed using combinations of longstanding CPT codes that describe each of the various steps required to perform a given test. This billing method is called "stacking" because different "stacks" of codes are billed depending on the components of the furnished test. Currently, all of the stacking codes are paid under the Clinical Laboratory Fee Schedule (CLFS) and one

stacking code, CPT code 83912 (Molecular diagnostics; interpretation and report), is paid on both the CLFS and the Medicare Physician Fee Schedule (MPFS). Payment for the interpretation and report of a molecular pathology test when furnished and billed by a physician is made under the MPFS using the professional component (PC, or modifier "26") of CPT code 83912 (83912-26). Payment for the interpretation and report of a molecular pathology test when furnished by nonphysician laboratory staff is made under the CLFS using CPT code 83912. Thus, under Medicare, molecular pathology services are paid under a fee schedule other than the OPPS.

In Addendum B of the CY 2012 OPPS/ASC final rule with comment period, we assigned the 101 molecular pathology services CPT codes to status indicator "B" to indicate that Medicare recognizes another more specific HCPCS code for the service, as well as to comment indicator "NI" to indicate that the CPT code was new for CY 2012 and that public comments would be accepted on the interim APC assignment for the new code, if applicable. We subsequently corrected the status indicator assignment for these CPT codes from "B" to "E" to indicate that they are not paid by Medicare in Addendum B of the CY 2012 OPPS/ASC final rule with comment period that was posted on the CMS Web site. In the CY 2013 OPPS/ASC proposed rule, we proposed to reassign the status indicator for the 101 molecular pathology services CPT codes from "E" to "A" for CY 2013 to indicate that the codes would be paid under a Medicare fee schedule and not under the OPPS. The public comments that we received in response to the CY 2012 OPPS/ASC final rule with comment period and the CY 2013 OPPS/ASC proposed rule are addressed below.

Comment: One commenter to the CY 2012 OPPS/ASC final rule with comment period requested that CMS consider paying separately for the molecular pathology services under the OPPS, and recommended that CMS reassign the services to status indicator "X" (Paid under OPPS; separate APC payment).

Several commenters who responded to the CY 2013 OPPS/ASC proposed rule requested clarification of the status indicator assignment and payment status for the molecular pathology services. One commenter indicated that CMS did not specify whether CPT codes 81200 through 81299, 81300 through 81383, and 81400 through 81408 will continue to be assigned status indicator "E" under the OPPS.

Another commenter pointed out that CMS did not specifically discuss the 101 molecular pathology services CPT codes in the CY 2013 OPPS/ASC proposed rule, but did propose to assign status indicator "A" to the new molecular pathology services CPT codes. The commenter believed that CMS is unsure as to how these services will be paid, whether they will be paid under the MPFS or under the CLFS. The commenter recommended that CMS pay for the molecular pathology services codes under the MPFS to cover the professional interpretation and work components, and under the OPPS to cover the technical component of the services when provided in a HOPD.

Response: Molecular pathology services are not paid under the OPPS. As explained above, molecular pathology services currently are billed using stacking codes that are paid under the CLFS with one stacking code, specifically, CPT code 83912, being paid under both the CLFS and the MPFS. For the CY 2013 update, the CPT "stacking" codes 83890 through 83914 will be deleted on December 31, 2012, and will

be replaced with 115 new molecular pathology CPT codes. Specifically, this includes the 101 molecular pathology services CPT codes discussed above plus an additional 14 new Tier I Molecular Pathology Procedure CPT codes that the AMA's CPT Editorial Panel established effective January 1, 2013. In addition, CMS established one HCPCS G-code effective January 1, 2013. With the exception of the HCPCS G-code, the 115 molecular pathology CPT codes will be paid under the CLFS. Payment for the interpretation and report of a molecular pathology test when furnished and billed by a physician will be made under the MPFS using the professional component-only HCPCS code G0452 (Molecular pathology procedure; physican interpretation and report). We refer readers to the CY 2013 MPFS final rule with comment period for further information on the molecular pathology services CPT codes.

Although we did not discuss this issue in the preamble of the CY 2013 OPPS/ASC proposed rule, we proposed to assign the 101 molecular pathology services CPT codes to status indicator "A" for the CY 2013 update. Specifically, we assigned the 101 molecular pathology services CPT codes to status indicator "A" in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site). We note that HCPCS codes listed in Addenda A and B are subject to comment, and responses to the comments received are addressed in the final rule with comment period.

For CY 2013, the 101 molecular pathology services CPT codes will be assigned to status indicator "A" because they will be paid under the CLFS. Consistent with the OPPS assignment for the 101 molecular pathology services, the 14 new CPT codes also will be assigned to status indicator "A" for CY 2013. Specifically, CPT codes 81201

through 81203, 81235, 81252 through 81254, 81321 through 81326, and 81479 will be assigned to status indicator "A" because they will be paid under the CLFS. In addition, HCPCS code G0452 will be assigned to status indicator "B" to indicate that the HCPCS code describes a professional component-only service that is paid under the MPFS.

In summary, after consideration of the public comments we received, we are finalizing our proposal, without modification, to assign the 101 molecular pathology services CPT codes to status indicator "A" for CY 2013. Consistent with the OPPS assignment for the 101 molecular pathology services, the 14 new CPT codes also will be assigned to status indicator "A" for CY 2013. In addition, HCPCS code G0452 will be assigned to status indicator "B" under the OPPS for the CY 2013 update.

b. Bone Marrow (APC 0112)

For CY 2013, we proposed to continue to assign CPT code 38240 (Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic) and CPT code 38241 (Bone marrow or blood-derived peripheral stem cell transplantation; autologous) to APC 0112 (Apheresis and Stem Cell Procedures), which had a CY 2013 proposed payment rate of approximately $2,878.

Comment: One commenter requested that CMS create separate APCs for autologous and allogeneic transplants in recognition of the cost difference between the two procedures. In addition, the commenter urged CMS to develop an alternate ratesetting methodology for low volume services or services performed by a small number of providers to more accurately capture their costs.

Response: We believe that CPT codes 38240 and 38241 are both appropriately assigned to APC 0112 based on clinical homogeneity. We note that there is no 2 times rule violation in APC 0112; therefore, we do not agree with the commenter's suggestion that we need to create separate APCs for autologous and allogeneic transplants. We appreciate the commenter's interest in developing an alternate ratesetting methodology for low-volume services as we are always eager to find improved methods to more accurately capture costs of services performed in the hospital outpatient setting.

After consideration of the public comment we received, we are finalizing our CY 2013 proposal, without modification, to continue to assign CPT codes 38240 and 38241 to APC 0112, which has a final CY 2013 APC geometric mean cost of approximately $2,972.

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 four device categories eligible for pass-through payment. These device categories are described by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (implantable)), which we made effective for

pass-through payment October 1, 2010; HCPCS codes C1830 (Powered bone marrow biopsy needle) and C1840 (Lens, intraocular (telescopic)), which we made effective for pass-through payment October 1, 2011; and HCPCS code C1886 (Catheter, extravascular tissue ablation, any modality (insertable)), which we made effective for pass-through payment January 1, 2012. In the CY 2012 OPPS/ASC final rule with comment period, we finalized the expiration of pass-through payment for HCPCS code C1749, which will expire after December 31, 2012 (76 FR 74278). Therefore, after December 31, 2012, we will package the costs of the HCPCS code C1749 device into the costs of the procedures with which the devices are reported in the hospital claims data used in OPPS ratesetting.

b. CY 2013 Policy

As stated above, 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. Device pass-through categories C1830 and C1840 were established for pass-through payments on October 1, 2011, and will have been eligible for pass-through payments for more than 2 years but less than 3 years as of the end of CY 2013. Also, device pass-through category C1886 was established for pass-through payments on January 1, 2012, and will have been eligible for pass-through payments for at least 2 years but less than 3 years as of the end of CY 2013. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45125), we proposed a pass-through payment expiration date for device categories C1830, C1840, and C1886 of December 31, 2013. Under our proposal, beginning January 1, 2014, device categories C1830, C1840, and C1886 will no longer be eligible for pass-through payments, and their respective device

costs would be packaged into the costs of the procedures with which the devices are reported in the claims data.

Comment: One commenter expressed concern that under the CMS proposal to expire device HCPCS code C1886 from pass-through payment, CMS will have difficulty in establishing a payment rate that will reflect all costs associated with bronchial thermoplasty, the procedure with which the HCPCS code C1886 device is used. The commenter indicated that the two bronchial thermoplasty 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) are subject to noncoverage policies for all Category III CPT codes for all but two MACs, resulting in few Medicare claims for CY 2012, the year for which CPT codes 0276T and 0277T are reported for bronchial thermoplasty, and which will be used for CY 2014 ratesetting. The commenter estimated that there are nine Medicare claims for bronchial thermoplasty in CY 2011, available for CY 2013 ratesetting, which were billed with HCPCS codes C9730 and C9731. The commenter requested that CMS delay the expiration of pass-through status for HCPCS code C1886 because of limited data available for CY 2014 ratesetting, and because two Category 1 CPT codes related to bronchial thermoplasty are expected to become effective January 1, 2013, which would result in these procedures being removed from the MAC local coverage determinations for noncovered services.

Response: We created HCPCS code C1886 as a new device category effective January 1, 2012. As such, there are no claims for HCPCS code C1886 in our CY 2011 claims data. However, although we have no claims data for CY 2011, we have over 300 units of HCPCS code C1886 reported in the first 8 months of CY 2012, with robust cost data. Therefore, we believe that we will have sufficient CY 2012 claims on which to base payment rates for the bronchial thermoplasty procedures with which HCPCS code C1886 is billed.

After consideration of the public comment we received, we are finalizing our proposal to expire from pass-through payment HCPCS C1886 on December 31, 2013, and to package its costs with the costs of the procedures with which it is billed.

We did not receive any public comments regarding our proposals to expire pass-through payment eligibility for device categories C1830 and C1840 and to package their respective costs into the costs of the procedures with which the devices are reported. Therefore, we are finalizing our proposals to expire from pass-through payment these device categories, and to package their costs with the costs of the procedures with which they are billed.

We also received a number of comments related to packaging the costs of HCPCS code C1749 into the costs of the procedures with which the HCPCS code C1749 device are reported, a policy we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74278). We are discussing these public comments in this section instead of the section on packaging because of their relationship to device pass-through payment.

Comment: A few commenters asserted that packaging payment for the HCPCS code C1749 device (retrograde colonoscope or Third Eye Retroscope) into the costs of colonoscopy procedure codes, with which it is billed, after the period of pass-through payment ends on December 31, 2012, will not provide adequate payment for use of the device.

One commenter based this assertion on a study of CY 2011 Medicare claims data (which the commenter summarized in its comment letter) for 7 diagnostic colonoscopy procedures found in APC 0143 (Lower GI endoscopy) performed with HCPCS code C1749, finding that the weighted geometric mean costs of procedures in which HCPCS code C1749 was used is approximately $969; the cost of the same 7 colonoscopy procedures without HCPCS code C1749 is approximately $437, showing a cost difference of approximately $532, which it attributed to the cost of the HCPCS code C1749 device. At the same time, the commenter pointed out that it identified 688 claims for these 7 colonoscopy procedure codes that included units of HCPCS code C1749, while there were 1,067,828 claims for the same 7 procedure codes that did not include HCPCS code C1749 on the claim, or only 0.064 percent of the total claims for these 7 codes that included HCPCS code C1749. Therefore, the commenter claimed that the proposed rates for existing colonoscopy procedures do not fairly reflect the costs of HCPCS code C1749. The commenter further asserted that the proposed APC 0143 payment rate of $691.58 would not pay hospitals adequately for the cost of a procedure using the HCPCS code C1749 device. The commenter claimed that the payment shortfall would be even greater in the ASC setting, where the proposed payment rate for

colonoscopies is $389.60. The commenter requested that CMS create a G-code (entitled "colonoscopy, flexible, proximal to splenic flexure; with continuous retrograde examination") to be billed along with existing colonoscopy procedure codes when using the HCPCS code C1749 device; assign the new G-code and its costs to a unique device dependent APC under the OPPS and a device-intensive APC under the ASC payment system; and require that HCPCS code C1749 be billed with the new G-code.

Some commenters suggested that CMS continue to pay for HCPCS code C1749 separately, based on OPPS claims data, from the APC payment for the procedure under a unique device-dependent APC in the OPPS and a device-intensive APC for ASC payment because the HCPCS code C1749 device represents the primary cost of this procedure. Another commenter requested that CMS extend the pass-through payment for HCPCS code C1749 through CY 2013 to help further data collection for the device regarding its clinical role and to ensure access to the device for endoscopists' use.

A number of commenters, including those who were patients or relatives of patients, emphasized the importance of being examined by the Third Eye Retroscope, the device upon which HCPCS code C1749 is based, because it provides dramatically improved detection rates of pre-cancerous adenomas, and urged CMS to improve payment for the HCPCS code C1749 procedure. Several commenters claimed that the proposal did not provide a code or payment to report use of the HCPCS code C1749 device.

Response: HCPCS code C1749 was created for device pass-through payment of the retrograde colonoscope effective October 1, 2010. Under the statute, hospitals are

paid for devices eligible for pass-through payment, which is payment for the device in addition to the usual APC payment rate, for at least 2 but not more than 3 years from the date we establish pass-through payment. We finalized the expiration of pass-through payment eligibility for HCPCS code C1749 on December 31, 2012, and, consistent with our normal ratesetting methodology for expired device pass-through payment, we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74278) our policy to package the costs of the HCPCS code C1749 device with the procedures with which it is billed, effective January 1, 2013 (76 FR 74278). For CY 2013, there are 692 units of HCPCS code C1749 reported in our CY 2011 OPPS claims data, with a geometric mean cost of approximately $536. For CY 2013, these costs would be packaged into the procedures with which HCPCS code C1749 are billed. CY 2011 was the first complete year that HCPCS code C1749 was effective, and we assume that utilization of this new device will grow over time.

We do not agree with the commenter that using the HCPCS code C1749 retrograde colonoscope during a colonoscopy is a separate procedure, and therefore would require a G-code to describe a separate procedure. We believe that the retrograde colonoscopic portion of the procedure entails a small incremental amount of colonoscopy procedure time, as it is primarily used during withdrawal of the colonoscope, and there are few additional resource costs (such as procedure room time, equipment costs) other than the HCPCS code C1749 device itself, according to the commenter in its study of the 7 colonoscopy procedure codes. Therefore, the retrograde portion of the procedure is not a separate procedure on which to base a new G-code. Therefore, we will package costs

for HCPCS code C1749 with the colonoscopic procedures with which they are billed according to our standard policy. Because we are declining to create a G-code to describe the retrograde colonoscopic portion of colonoscopy procedures, there is no need to create a new, dedicated device-dependent APC, as requested by the commenter.

We also do not agree with the commenter's alternate suggestion that separate payment is needed for HCPCS code C1749 at this time. HCPCS code C1749 is currently under separate payment under the pass-through provision, and once pass-through status expires, device costs are packaged into the payment for the procedure.

Regarding the commenter's request that we extend the eligibility for pass-through payment of HCPCS code C1749 through CY 2013, based on the statutory limits at section 1833(t)(6)(B)(iii) of the Act and related payment policies not permitting partial year rate changes, we are not able to further extend pass-through payment for HCPCS code C1749. Moreover, we will be able to track the HCPCS code C1886 device utilization in CY 2013 even without the pass-through payment eligibility because HCPCS code C1749 will still be required to be reported with the procedures with which it is billed.

The commenters who believe that HCPCS codes for pass-through devices become inactive when pass-through status for a device expires are incorrect. Under our longstanding policy, once the period of device pass-through payment is complete, we package the costs of the devices with the procedures with which they are billed. In the case of HCPCS code C1749, as stated previously, it is our proposal to package the device costs with the colonoscopy procedures with which the retrograde colonoscope is billed,

effective January 1, 2013, to maintain HCPCS code C1749 for the device, and to require hospitals to include HCPCS code C1749 and its costs on the claims for the procedures with which it is billed. This will provide assurance that the costs of HCPCS code C1749 will be represented in our claims data and accounted for in the relevant APC payment rates.

After consideration of the public comments we received, we are finalizing our proposals concerning the expiration for pass-through payment eligibility for device category codes C1830, C1840, and C1886 as of December 31, 2013, and to package the device costs with the respective procedures with which these devices are billed. Furthermore, we are maintaining our previous decision to package the costs of HCPCS code C1749 with the procedures with which it is billed, as of January 1, 2013.

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

We currently have published a list of all procedural APCs with the CY 2012 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 2013 Policy

In the CY 2013 OPPS/ASC proposed rule (77 FR 45125), we proposed to continue, for CY 2013, 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 rates. We proposed to continue our policy, for CY 2013, 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)).

For CY 2013, 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 a new device pass-through category that includes a newly eligible implantable biological beginning in CY 2013 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.

In addition, we proposed to 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 2013 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 2013 device pass-through payment applications and by CMS in reviewing those applications.

Comment: One commenter recommended that all biologicals, including implantable biologicals that are approved by the FDA under biological license applications (BLAs), be treated as drugs, rather than as devices, for pass-through payment purposes for CY 2013. The commenter claimed that when Congress enacted the current payment system for SCODs that previously had pass-through status, it intended for biologicals approved under BLAs to be paid under the specific statutory provisions for drugs. The commenter argued that it is only logical, then, that Congress would have intended for these BLA-approved therapies to be paid as pass-through drugs as well. The commenter requested that, if CMS continues to evaluate implantable biologicals under the pass-through device criteria, CMS clarify its policy that the device pass-through criteria apply only to biologicals if they are solely surgically implanted according to their FDA approved indications. The commenter stated that the current regulation at 42 CFR 419.64(a)(4) is unclear how we would evaluate pass-through eligibility of a biological that has both surgically implanted and nonimplantable indications. The commenter stated that the explanation CMS provided in the CY 2012 OPPS/ASC final rule with comment period, that "we mean to exclude from consideration for drug and biological pass-through status any biological that has an indication such that it may function as a surgically implanted or inserted biological, even if there are also indications in which the biological is not surgically implanted or inserted" (76 FR 74280), is unclear and inconsistent with what CMS has stated previously in policy and billing instructions.

The commenter recommended that CMS revise the regulation text so that if refers to "a biological that is not always surgically implanted into the body."

Response: As stated in previous OPPS/ASC final rules with comment period, we evaluate implantable biologicals that function as, and are substitutes for, implantable devices for OPPS payment purposes. This is done regardless of their category of FDA approval (74 FR 60476; 75 FR 71924; 76 FR 74279 through 74280). We do not believe 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 the safety and effectiveness of medical products.

We do not agree with the commenter who asserted that Congress intended biologicals approved under BLAs to be paid under the specific OPPS statutory provisions that apply to SCODs, including the pass-through provisions. Moreover, as we stated in previous OPPS/ASC final rules with comment period, Congress did not specify in the statute that we must pay for implantable biologicals as biologicals rather than devices, if they also meet our criteria for payment as a device (74 FR 60476; 75 FR 71924; and 76 FR 74280). We continue to believe that implantable biologicals meet both the definitions of a device and a biological and that, for payment purposes, it is appropriate for us to consider implantable biologicals as implantable devices in all cases, and not as biologicals.

We do not agree with the commenter's assertion that the explanation offered in the CY 2012 OPPS/ASC final rule with comment period of the regulation text at 42 CFR 419.64(a)(4)(iii) which indicates that a biological for drug pass-through payment

purposes must not be surgically implanted or inserted into the body, is inconsistent with our prior description of this policy, the application of this policy to date, and billing instruction to hospitals. Our policy and application process have consistently reflected that implantable biologicals are subject to the device application process since the beginning of CY 2010. For CYs 2010, 2011, and 2012, we finalized the same 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 as of January 1, 2010, be the device pass-through process and payment methodology only (74 FR 60476, 75 FR 71924, and 76 FR 74280, respectively). We have not established a policy in any year that stated that implantable biologicals needed to be solely surgically inserted or implanted to be subject to the device pass-through process and payment methodology. Furthermore, there is no inconsistency with our policy and billing instructions regarding pass-through devices or implantable biologicals because there are no billing instructions regarding the device pass-through application process. Rather, application instructions are found on the CMS Web site (currently at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf). The language on the device application web site is consistent with the language in the CYs 2010, 2011, and 2012 final rules with comment period, stating that, as of January 1, 2010, implantable biologicals that are surgically inserted or implanted (through a surgical incision or natural orifice) are being evaluated for device pass-through payment under the instructions using

the device pass-through process. We reiterate our explanation provided in the CY 2012 final rule with comment period (76 FR 74280) regarding the regulatory language at 42 CFR 419.64(a)(4), that we mean to exclude from consideration for drug and biological pass-through status any biological that has an indication such that it may function as a surgically implanted or inserted biological, even if there also are indications in which the biological is not surgically implanted or inserted. We will add similar language to our device and drug pass-through application Web sites as well.

We are finalizing the following proposals for CY 2013: to continue our established methodology to estimate the portion of each APC payment rate that could reasonably reflect the cost of an associated device eligible for pass-through payment; to continue our policy 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; to continue our established policies for calculating and setting the device APC offset amounts for each device category eligible for pass-through payment; and 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, and, if device costs packaged into the existing APC structure are associated with the new category, to deduct the device APC offset amount from the pass-through payment for the device category.

For CY 2013, we also are finalizing our proposal and continuing our policy established in CY 2010 to include implantable biologicals in our calculation of the device APC offset amounts, and to continue to calculate and set any device APC offset amount for a new device pass-through category that includes a newly eligible implantable biological beginning in CY 2013 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.

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 2013 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 2013 device pass-through payment applications and by CMS in reviewing those applications.

3. Clarification of Existing Device Category Criterion

a. Background

Section 1833(t)(6)(B)(ii)(IV) of the Act directs the Secretary to establish a new device category for pass-through payment for which none of the pass-through categories in effect (or that were previously in effect) is appropriate. Commenters who responded to our various proposed rules, as well as applicants for new device categories, had expressed concern that some of our existing and previously in effect device category descriptors

were overly broad, and that the device category descriptors as they are currently written may preclude some new technologies from qualifying for establishment of a new device category for pass-through payment (70 FR 68630 through 68631). As a result of these comments, we finalized a policy, effective January 1, 2006, to create an additional category for devices that meet all of the criteria required to establish a new category for pass-through payment in instances where we believe that an existing or previously in effect category descriptor does not appropriately describe the new device. Accordingly, effective January 1, 2006, we revised § 419.66(c)(1) of the regulations to reflect this policy change. In order to determine if a new device is appropriately described by any existing or previously in effect category of devices, we apply two tests based upon our evaluation of information provided to us in the device category application. First, an applicant for a new device category must show that its device is not similar to devices (including related predicate devices) whose costs are reflected in the currently available OPPS claims data in the most recent OPPS update. Second, an applicant must demonstrate that utilization of its device provides a substantial clinical improvement for Medicare beneficiaries compared with currently available treatments, including procedures utilizing devices in any existing or previously in effect device categories. We consider a new device that meets both of these tests not to be appropriately described by any existing or previously in effect pass-through device categories (70 FR 68630 through 68631).

b. Clarification of CY 2013 Policy

In the CY 2013 OPPS/ASC proposed rule (77 FR 45126), we proposed, for CY 2013, to clarify the test that requires an applicant for a new device category to show that its device is not similar to devices (including related predicate devices) whose costs are reflected in the currently available OPPS claims data in the most recent OPPS update. We clarified that this test includes showing that a new device is not similar to predicate devices that once belonged in any existing or previously in effect pass-through device categories. Under this test, a candidate device may not be considered to be appropriately described by any existing or previously in effect pass-through device categories if the applicant adequately demonstrates that the candidate device is not similar to devices (including related predicate devices) that belong or once belonged to an existing or any previously in effect device category, and that the candidate device is not similar to devices whose costs are reflected in the OPPS claims data in the most recent OPPS update. The substantial clinical improvement criterion, which also must be satisfied in every case, as indicated in § 419.66(c)(2) of our regulations, is separate from the criterion that a candidate device not be similar to devices in any existing or previously in effect pass-through categories. We invited public comments regarding this proposed clarification.

We did not receive any public comments on our proposal to clarify the test that requires an applicant for a new device category to show that its device is not similar to devices (including related predicate devices) whose costs are reflected in the currently

available OPPS claims data. Therefore, we are clarifying our existing policy as noted above.

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. APCs and Devices Subject to the Adjustment Policy

In the CY 2013 OPPS/ASC proposed rule (77 FR 45126), we proposed, for CY 2013, to continue the existing policy of reducing OPPS payment for specified APCs 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. (We refer readers to section II.A.2.d.(1) of this final rule with comment period for a description of our standard ratesetting methodology for device-dependent APCs.)

For CY 2013, we also proposed to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which this 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 in the CY 2013 OPPS/ASC proposed rule (77 FR 45127) that we continue to believe these criteria are appropriate because free devices and device credits are likely to be associated with particular cases only when the device must be reported on the claim and is of a type that is implanted and remains in the body when the beneficiary leaves the hospital. We believe that the reduction in payment is appropriate only when the cost of the device is a significant part of the total cost of the APC into which the device cost is packaged, and that the 40-percent threshold is a reasonable definition of a significant cost.

As indicated in the CY 2013 OPPS/ASC proposed rule (77 FR 45127), we examined the offset amounts calculated from the CY 2013 proposed rule data and the clinical characteristics of APCs to determine whether the APCs to which the no cost/full credit and partial credit device adjustment policy applied in CY 2012 continue to meet the criteria for CY 2013, and to determine whether other APCs to which the policy did not apply in CY 2012 would meet the criteria for CY 2013. Based on the CY 2011 claims data available for the proposed rule, we did not propose any changes to the APCs and devices to which this policy applies.

Table 20 of the CY 2013 OPPS/ASC proposed rule (77 FR 45127) listed the proposed APCs to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2013, and displayed the proposed payment adjustment percentages for both no cost/full credit and partial credit circumstances. We proposed that the no cost/full credit adjustment for each APC to which this policy would continue to apply would be the device offset percentage for the APC (the estimated percentage of

the APC cost that is attributable to the device costs that are already packaged into the APC). We also proposed that the partial credit device adjustment for each APC would continue to be 50 percent of the no cost/full credit adjustment for the APC.

Table 21 of the CY 2013 OPPS/ASC proposed rule (77 FR 45128) listed the proposed devices to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2013. We stated in the CY 2013 proposed rule (77 FR 45127) that we would update the lists of APCs and devices to which the no cost/full credit and partial credit device adjustment policy would apply for CY 2013, consistent with the three criteria discussed earlier in this section, based on the final CY 2011 claims data available for the CY 2013 OPPS/ASC final rule with comment period. The updated lists of APCs and devices appear below in Table 29 and Table 30, respectively, of this final rule with comment period. We note that there are no changes to the lists of APCs and devices compared to the proposed rule for CY 2013.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45127), we proposed, for CY 2013, that OPPS payments for implantation procedures to which the "FB" modifier is appended are reduced by 100 percent of the device offset for no cost/full credit cases when both a device code listed in Table 21 of the proposed rule is present on the claim, and the procedure code maps to an APC listed in Table 20 of the proposed rule. We also proposed that OPPS payments for implantation procedures to which the "FC" modifier is appended are reduced by 50 percent of the device offset when both a device code listed in Table 21 of the proposed rule is present on the claim and the procedure code maps to an APC listed in Table 20 of the proposed rule. Beneficiary copayment is based on the

reduced amount when either the "FB" modifier or the "FC" modifier is billed and the procedure and device codes appear on the lists of procedures and devices to which this policy applies.

Comment: Commenters reported that there are some instances in which the hospital receives a full credit for only one component of a pacemaker or ICD replacement procedure that involves both a lead and a generator. Specifically, the commenters noted that the 2012 CPT Code Book states that when a pulse generator insertion involves the insertion or replacement of one or more lead(s), use system CPT codes 33206 (Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial), 33207 (Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular), and 33208 (Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular) for pacemakers or CPT code 33249 (Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber) for pacing cardioverter-defibrillators. The commenters noted that hospitals would still be required to assign an "FB" or "FC" modifier to the procedure code representing the replacement procedure, and the applicable offset would be applied to the entire APC payment, even when only one of the devices involved in the procedure was received at no cost or with full or partial credit. According to the commenters, the offset reduction may actually be much greater or much less than the credit received by the hospital, depending upon the component that was credited. The commenters requested that CMS alleviate this issue by allowing hospitals to bill individual CPT codes for each component of the replacement procedure,

rather than requiring the reporting of a full system as suggested by the CPT guidance. The commenters stated that this would allow the FB or FC modifiers and the respective offsets to be applied accurately to the payment for the individual component receiving the credit, rather than being broadly applied to the APC payment for the entire replacement.

Response: We agree with the commenters that hospitals would be required to assign an "FB" or "FC" modifier to the procedure code representing the pacemaker or ICD replacement procedure as they describe, and that the applicable offset would be applied to the entire APC payment, even when just one of the devices involved in the procedure (that is, a lead or a generator) was received at no cost or with full or partial credit. However, we do not agree that this is problematic. As the commenter noted, the offset reduction may actually be much greater or much less than the credit received by the hospital, depending upon the component that was credited. As we have stated in the past (76 FR 74282), we recognize that, in some cases, the estimated device cost and, therefore, the amount of the payment reduction will be more or less than the cost a hospital would otherwise incur. However, because averaging is inherent in a prospective payment system, we do not believe this is inappropriate. Therefore, we do not agree that we should allow hospitals to bill individual CPT codes for each component of the replacement procedure, rather than requiring the reporting of a full system as suggested by the CPT guidance, as the commenters suggested.

Comment: One commenter noted that the no cost/full credit and partial credit adjustment policy applies only when expensive devices are replaced and requested clarification regarding the assignment of the "FB/FC" modifier to devices that providers

receive at no cost or at an "inexpensive" cost. According to the commenter, providers lack clear guidelines to determine what is meant by "inexpensive." The commenter also noted that there are inconsistencies between the "FB/FC" modifier list and the list of device-dependent APCs in the CY 2013 OPPS/ASC proposed rule, specifically that the FB/FC listing is not an inclusive listing of all device-dependent APCs.

Response: As we stated in the Medicare Claims Processing Manual (Pub. 100-04, Chapter 4, Section 61.3.1), when a hospital furnishes a device received without cost or with full credit from a manufacturer, the hospital must append modifier "–FB" to the procedure code (not the device code) that reports the service provided to furnish the device. As we stated in the Medicare Claims Processing Manual (Pub. 100-04, Chapter 4, Section 61.3.3), when a hospital receives a partial credit of 50 percent or more of the cost of a new replacement device due to warranty, recall, or field action, the hospital must append modifier "–FC" to the procedure code (not on the device code) that reports the service provided to replace the device. This guidance does not instruct providers to determine whether a no cost/full credit or partial credit device is "expensive" or "inexpensive." Rather, providers should append the "FB" and "FC" modifiers to all procedures that meet the requirements of these instructions. The I/OCE determines, on a claim by claim basis, when to apply the no cost/full credit and partial credit device adjustment policy (that is, when both a specified device code is present on the claim, and the procedure code to which the "FB" or "FC" modifier is appended maps to a specified APC, as described previously in this section).

Regarding the comment that there are inconsistencies between the "FB/FC" modifier list and the list of device-dependent APCs in the CY 2013 OPPS/ASC proposed rule, we believe that the commenter is referring to the fact that Table 20 in the CY 2013 OPPS/ASC proposed rule (the list of proposed APCs to which the no cost/full credit and partial credit device adjustment policy would apply (77 FR 45127)) and Table 4A (the list of proposed device-dependent APCs (77 FR 45082)) are not identical. The commenter is correct that the list of APCs to which the no cost/full credit and partial credit device adjustment policy will apply in CY 2013 in this section and the list of device-dependent APCs in section II.A.2.d.(1) of the proposed rule and this final rule with comment period are not the same. We believe this is appropriate because, as we describe earlier in this section, we use the following criteria to determine the list of APCs to which this policy will apply: (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. Not all device-dependent APCs meet these criteria, and therefore are appropriately excluded from the list of APCs to which the no cost/full credit and partial credit device adjustment policy applies.

After consideration of the public comments we received, we are finalizing our CY 2013 proposals, without modification, to continue the established no cost/full credit and partial credit adjustment policies. Table 29 below lists the APCs to which the payment adjustment policy for no cost/full credit and partial credit devices will apply in

CY 2013 and displays the final adjustment percentages for both no cost/full credit and partial credit circumstances. Table 30 below lists the devices to which the no cost/full credit and partial credit device adjustment policy will apply for CY 2013, consistent with the three selection criteria discussed earlier in this section and based on the CY 2011 claims data available for this final rule with comment period.

TABLE 29.—APCs TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WILL APPLY IN CY 2013

CY 2013 APC	CY 2013 APC Title	CY 2013 Device Offset Percentage for No Cost/ Full Credit Case	CY 2013 Device Offset Percentage for Partial Credit Case
0039	Level I Implantation of Neurostimulator Generator	87%	43%
0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	56%	28%
0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes	69%	34%
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	69%	35%
0090	Insertion/Replacement of Pacemaker Pulse Generator	71%	36%
0106	Insertion/Replacement of Pacemaker Leads and/or Electrodes	48%	24%
0107	Level I Implantation of Cardioverter-Defibrillators (ICDs)	84%	42%

CY 2013 APC	CY 2013 APC Title	CY 2013 Device Offset Percentage for No Cost/ Full Credit Case	CY 2013 Device Offset Percentage for Partial Credit Case
0108	Level II Implantation of Cardioverter-Defibrillators (ICDs)	84%	42%
0227	Implantation of Drug Infusion Device	82%	41%
0259	Level VII ENT Procedures	84%	42%
0315	Level II Implantation of Neurostimulator Generator	88%	44%
0318	Implantation of Cranial Neurostimulator Pulse Generator and Electrode	89%	44%
0385	Level I Prosthetic Urological Procedures	62%	31%
0386	Level II Prosthetic Urological Procedures	70%	35%
0425	Level II Arthroplasty or Implantation with Prosthesis	59%	30%
0648	Level IV Breast Surgery	50%	25%
0654	Insertion/Replacement of a permanent dual chamber pacemaker	74%	37%
0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode	73%	37%
0680	Insertion of Patient Activated Event Recorders	74%	37%

TABLE 30.—DEVICES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WILL APPLY IN CY 2013

CY 2013 Device HCPCS Code	CY 2013 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

CY 2013 Device HCPCS Code	CY 2013 Short Descriptor
L8600	Implant breast silicone/eq
L8614	Cochlear device/system
L8680	Implt neurostim elctr each
L8685	Implt nrostm pls gen sng rec
L8686	Implt nrostm pls gen sng non
L8687	Implt nrostm pls gen dua rec
L8688	Implt nrostm pls gen dua non
L8690	Aud osseo dev, int/ext comp

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

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

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biologicals (also referred to as biologics). As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999 (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 for the treatment of cancer; and current radiopharmaceutical drugs and biologicals. For those drugs and biologicals referred to as "current," the transitional pass-through payment began on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain "new" drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996, and whose cost is "not insignificant" in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as "drugs." Under the 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 product's first payment as a hospital outpatient service under Medicare Part B. Proposed

CY 2013 pass-through drugs and biologicals and their designated APCs were assigned status indicator "G" in Addenda A and B to the proposed rule and in this final rule with comment period, which are available via the Internet on the CMS Web site.

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. If the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, the pass-through payment amount is determined by the Secretary to be equal to the average price for the drug or biological for all competitive acquisition areas and the year established under such section as calculated and adjusted by the Secretary. However, we note that the Part B drug CAP program has been postponed since CY 2009, and such a program has not been reinstated for CY 2013.

This methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological. Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including

the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this final rule with comment period, the term "ASP methodology" and "ASP-based" are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.

For CYs 2005, 2006, and 2007, we estimated the OPPS pass-through payment amount for drugs and biologicals to be zero based on our interpretation that the "otherwise applicable Medicare OPD fee schedule" amount was equivalent to the amount to be paid for pass-through drugs and biologicals under section 1842(o) of the Act (or section 1847B of the Act if the drug or biological is covered under a competitive acquisition contract). We concluded for those years that the resulting difference between these two rates would be zero. For CYs 2008 and 2009, we estimated the OPPS pass-through payment amount for drugs and biologicals to be $6.6 million and $23.3 million, respectively. For CY 2010, we estimated the OPPS pass-through payment estimate for drugs and biologicals to be $35.5 million. For CY 2011, we estimated the OPPS pass-through payment for drugs and biologicals to be $15.5 million. For CY 2012, we estimated the OPPS pass-through payment for drugs and biologicals to be $19 million. Our OPPS pass-through payment estimate for drugs and biologicals in CY 2013 is $22 million, which is discussed in section VI.B. of this final rule with comment period.

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 2012

In the CY 2013 OPPS/ASC proposed rule (77 FR 45128), we proposed that the pass-through status of 23 drugs and biologicals would expire on December 31, 2012, as listed in Table 22 of the proposed rule (77 FR 45129). All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2012. These drugs and biologicals were approved for pass-through status on or before January 1, 2011. 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 and contrast agents, our standard methodology for providing payment for drugs and biologicals with expiring pass-through status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is $80), as discussed further in section V.B.2. of this final rule with comment period. If the drug's or biological's estimated per day cost is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we would provide separate payment at the applicable relative ASP-based payment amount (which is ASP+6 percent for CY 2013, as discussed further in section V.B.3. of this final

rule with comment period). Section II.A.3.e. of this final rule with comment period discusses the packaging of all nonpass-through contrast agents and diagnostic radiopharmaceuticals.

Comment: Several commenters recommended that CMS continue pass-through status for new drugs, specifically diagnostic radiopharmaceuticals and contrast agents, for 3 years. The commenters asserted that providing pass-through status for 3 years would help provide a more current and accurate data set on which to base payment amounts of the procedure when the diagnostic radiopharmaceutical or contrast agent is subsequently packaged. The commenters further recommended that CMS expire pass-through status for drugs and biologicals on a quarterly as opposed to an annual basis. One commenter disagreed with a prior CMS proposal to begin the pass-through payment eligibility period on the date of first sale of the drug in the United States following FDA approval. The commenter however approved of the concurrent proposal made at that time that would require CMS to accept and expire pass-through applications for drugs and biologicals on a quarterly basis.

Response: As we stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74287), 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 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, which has been generally supported by commenters, we begin pass-through payment on a quarterly basis that depends on when applications are submitted to us for consideration and because we expire pass-through status only on an annual basis, there is no way to ensure that all pass-through drugs and biologicals receive pass-through payment for a full 3 years, while also providing pass-though payment for no more than 3 years as the statute requires. Further, 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 adequate 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. As noted in section V.A.1. of this final rule with comment period, when a product's pass-through status expires, it is either packaged into an APC if it is a relatively low-cost product that does not exceed the packaging threshold or is "policy packaged", or if it is a relatively high-cost product, it is paid separately on the basis of the product's ASP (we

refer readers to section V.B.3. of this final rule with comment period for more details regarding our payment policy for separately payable drugs). Because our policies for drugs with expiring pass-through status recognize products' relative costliness and establish either separate or bundled payment as appropriate, based on such costliness, we disagree with commenters that certain relatively high cost products currently receiving pass-through payment would not be adequately paid if taken off pass-through, and as a result should continue on such status. We expire pass-though status on an annual basis. Depending on when a drug is initially approved for pass-through status, the drug receives pass-through payment for at least 2 but not more than 3 years.

Comment: Commenters, including several medical societies, individual practitioners, and a manufacturer, requested that CMS appropriately pay for HCPCS code C9275 (Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose). Some commenters believed that payment would be eliminated for HCPCS code C9275 and requested that CMS evaluate its statutory authority and establish appropriate payment as necessary. One commenter recommended that CMS either continue to pay separately for HCPCS code C9275 because, the commenter argued, an insufficient amount of claims data have been collected, or assign HCPCS code C9275 to a new technology APC with the accompanying blue light cystoscopy procedure until sufficient claims are gathered to determine assignment of an appropriate clinical APC category. The commenter further argued that because C9275 will always be used with the blue light cystoscopy procedure, packaging C9275 will result in zero payment for the imaging agent, since current cystoscopy APCs do not include costs of imaging agents.

The commenter stated that if CMS chooses to not provide payment for HCPCS code C9275 as a separately billable product, CMS should use its "waiver authority" under section 1833(t)(2)(E) of the Act to ensure that equitable payments are made under the OPPS for C9275. The commenter noted that, for CY 2013, CMS used this statutory authority to propose an additional payment for radioisotopes derived from non-HEU sources.

Response: We proposed for CY 2013 to package the payment, for all contrast agents, that are not on pass-through status, into the payment for the associated service. We continue to believe that all nonpass-through contrast agents function effectively as supplies that are ancillary and supportive to an independent service. The product described by HCPCS code C9275 is a contrast agent that was approved for pass-through status beginning on January 1, 2011. For the CY 2013 OPPS/ASC proposed rule (77 FR 45128 through 45129), we proposed to expire pass-through status for this product because it had received at least 2 and no more than 3 years, as permitted by the Act in section 1833(t)(6). We note that because we expire pass-through status on an annual basis and not a quarterly basis, we cannot extend the pass-through status for HCPCS code C9275 for an additional number of years because it would be counter to our current policy. Therefore, we believe that our proposal to expire pass-through status for HCPCS code C9275 for CY 2013 is appropriate.

We disagree with the commenter that a sufficient amount of data was not collected for HCPCS code C9275 during its period under pass-through status. As we stated previously, we believe this pass-through period of payment facilitates

dissemination for new products into clinical practice and facilitates the collection of hospital claims data, reflective of their costs for future OPPS ratesetting. 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, where the product is being used, into their chargemasters based on the utilization and costs observed in our claims data. We believe a sufficient amount of claims data has been collected in this case and we see no reason to exempt C9275 as an extraordinary case from our longstanding packaging policy to package payment for nonpass-through contrast agents.

We also do not believe that it is appropriate to extend separate payment for HCPCS code C9275 based on section 1833(t)(2)(E) of the Act. We believe that all hospitals have the opportunity to bill for and receive equitable payment for HCPCS code C9275. Hospitals can bill for an appropriate unlisted code for the cystoscopy procedure and include the costs of the product currently reported by HCPCS code C9275 in that specific claim, in order to receive payment for the procedure and the product. Therefore, we do not believe that there is an inequity that should be adjusted. Additionally, we do not believe that an additional payment amount should be made for HCPCS code C9275, for the reasons given in this final rule with comment period, to ensure equitable payments are made to hospitals. Further, extending the pass-through status for HCPCS code C9275 beyond 3 years would not be permitted under the statutory requirements of section 1833(t)(6) of the Act.

We believe that commenters have erroneously stated that payment will not be made under the OPPS or that an insufficient amount of payment will be given to the product described by HCPCS code C9275. We remind commenters that products that are packaged under the OPPS receive payment that is packaged into the payment for the associated procedure. 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 in establishing payment rates for the separately payable services. Payment for the packaged product is then included in the payment for the independent service. For HCPCS code C9275, hospitals may bill an unlisted code for the cystoscopy procedure and include the costs for HCPCS code C9275 on that claim. These costs will additionally be included in future ratesetting for these products.

We continue to believe that packaging payment for ancillary and dependent services creates appropriate incentives for hospitals to seriously consider whether a new service or a new technology offers a benefit that is sufficient to justify the cost of the new service or new technology. Therefore, we believe that HCPCS code C9275 is appropriately packaged for CY 2013 and we are finalizing our proposal to expire pass-through status for C9275 and assign this HCPCS code to a status indicator of "N" for CY 2013.

We note that comments pertaining to a potential future new technology APC assignment or new technology APC application for HCPCS code C9275 and the

accompanying blue light cystoscopy procedure are outside the scope of this final rule with comment period.

Comment: One commenter requested that CMS review the claims used in calculating the packaging status of HCPCS code J7183 (Injection, von willebrand factor complex (human), wilate, 1 i.u. vwf:rco) and assign HCPCS code J7183 to status indicator "K" as pass-through status has expired, but the cost per day exceeds $80.

Response: We appreciate the commenter's diligence. HCPCS code J7183 was erroneously assigned to a status indicator of "N" for the CY 2013 OPPS/ASC proposed rule (77 FR 45129). The per day cost for HCPCS code J7183 for this final rule with comment period exceeds the $80 packaging threshold for CY 2013. Therefore, we are finalizing our proposal, with modification, to expire the pass-through status for HCPCS code J7183 and assign it to a status indicator of "K" for CY 2013.

After consideration of the public comments we received, we are finalizing our proposal, with modification as described above, to expire the pass-through status of the 23 drugs and biologicals listed in Table 31 below. We are assigning HCPCS code J7183 to status indicator "K" for CY 2013. Table 31 lists the drugs and biologicals for which pass-through status will expire on December 31, 2012, the status indicators, and the assigned APCs for CY 2013.

TABLE 31.—DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS WILL EXPIRE DECEMBER 31, 2012

CY 2013 HCPCS Code	CY 2013 Long Descriptor	CY 2013 SI	CY 2013 APC

CY 2013 HCPCS Code	CY 2013 Long Descriptor	CY 2013 SI	CY 2013 APC
C9275	Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose	N	N/A
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	K	9367
J0221	Injection, alglucosidase alfa, (lumizyme), 10 mg	K	1413
J0588	Injection, incobotulinumtoxin A, 1 unit	K	9278
J0597	Injection, C-1 esterase inhibitor (human), Berinert, 10 units	K	9269
J0775	Injection, collagenase clostridium histolyticum, 0.01 mg	K	1340
J0840	Injection, crotalidae polyvalent immune fab (ovine), up to 1 gram	K	9274
J0897	Injection, denosumab, 1 mg	K	9272
J1290	Injection, ecallantide, 1 mg	K	9263
J1557	Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg	K	9270
J1741	Injection, ibuprofen, 100 mg	N	N/A
J3095	Injection, telavancin, 10 mg	K	9258
J3262	Injection, tocilizumab, 1 mg	K	9264
J3357	Injection, ustekinumab, 1 mg	K	9261
J3385	Injection, velaglucerase alfa, 100 units	K	9271
J7183	Injection, von Willebrand factor complex (human), Wilate, per 100 IU VWF: RCO	K	1352
J7335	Capsaicin 8% patch,per 10 square centimeters	K	9268
J8562	Fludarabine phosphate, oral, 10 mg	K	1339
J9043	Injection, cabazitaxel, 1 mg	K	1339
J9302	Injection, ofatumumab, 10 mg	K	9260
J9307	Injection, pralatrexate, 1 mg	K	9259
J9315	Injection, romidepsin, 1 mg	K	9265

CY 2013 HCPCS Code	CY 2013 Long Descriptor	CY 2013 SI	CY 2013 APC
Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion	K	9273

3. Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2013

In the CY 2013 OPPS/ASC proposed rule (77 FR 45129), we proposed to continue pass-through status in CY 2013 for 21 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, 2012. These drugs and biologicals, which were approved for pass-through status between April 1, 2011 and July 1, 2012, were listed in Table 23 of the proposed rule (77 FR 45130 through 45131). The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through April 1, 2012 were assigned status indicator "G" in Addenda A and B of the proposed rule. Addenda A and B for the proposed rule were available via the Internet on the CMS Web site.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. Payment for drugs and biologicals with pass-through status under

the OPPS is currently made at the physician's office payment rate of ASP+6 percent. We believe it is consistent with the statute and we proposed to continue to provide payment for drugs and biologicals with pass-through status at a rate of ASP+6 percent in CY 2013, the amount that drugs and biologicals receive under section 1842(o) of the Act.

Thus, for CY 2013, 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 2013. We proposed that a $0.00 pass-through payment amount would be paid for most pass-through drugs and biologicals under the CY 2013 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 pass-through contrast agents and diagnostic radiopharmaceuticals, their pass-through payment amount would be equal to ASP+6 percent because, if not on pass-through status, payment for these products would be packaged into the associated procedure. Therefore, we proposed that the difference between ASP+6 percent and the "policy-packaged" drug APC offset amount for the associated clinical APC in which the drug or biological is utilized would be the CY 2013 pass-through payment amount for these policy-packaged products.

In addition, we proposed to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2013 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).

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. We specifically reviewed drugs with pass-through status for CY 2013 that will change from C-codes to J-codes for CY 2013. For our CY 2013 review, we have determined that HCPCS code J1741 (Injection, ibuprofen, 100 mg) describes the product reported under HCPCS code C9279 (Injection, ibuprofen, 100 mg), HCPCS code J0485 (Injection, belatacept, 1 mg) describes the product reported under HCPCS code C9286 (Injection, belatacept, 1 mg), HCPCS code J9042 (Injection, brentuximab vedotin, 1 mg) describes the code reported under HCPCS code C9287 (Injection, brentuximab vedotin, 1 mg), HCPCS code J0716 (Injection, centruroides immune f(ab)2, up to 120 milligrams) describes the code reported under HCPCS code C9288 (Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial), and HCPCS code J9019 (Injection, asparaginase (erwinaze), 1,000 iu) describes the code reported under HCPCS code C9289 (Injection, asparaginase Erwinia chrysanthemi, 1,000 international units (I.U.)).

In CY 2013, as is consistent with our CY 2012 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 2013, 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: Several commenters supported CMS' proposal to provide payment at ASP+6 percent for drugs, biologicals, contrast agents, and radiopharmaceuticals that are granted pass-through status. A few commenters approved of the proposal to use the ASP methodology that would provide payment based on WAC if ASP information is not available, and payment at 95 percent of AWP if WAC information is not available. Another commenter requested that CMS provide an additional payment for radiopharmaceuticals that are granted pass-through status. The commenter gave an example amount of ASP+10 percent. Finally, one commenter, in response to both the proposal to continue to pay for drugs and biologicals on pass-through status and those not on pass-through status at ASP+6 percent, suggested that CMS explore alternative payment mechanisms that reward the pharmaceutical care provided by specialty trained pharmacists who ensure safe and effective medication use and provide for screening of drug interactions and contraindications.

Response: As discussed above, the statutorily mandated pass-through payment for pass-through drugs and biologicals for CY 2013 generally equals the amount determined under section 1842(o) of the Act minus the portion of the otherwise applicable APC payment that CMS determines is associated with the drug or biological. Therefore, the pass-through payment is determined by subtracting the otherwise applicable payment amount under the OPPS (ASP+6 percent for CY 2013) from the amount determined under section 1842(o) of the Act (ASP+6 percent).

Regarding the comments that CMS should provide an additional payment for radiopharmaceuticals that are granted pass-through status, we note that for CY 2013, consistent with our CY 2012 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 2013, we proposed to follow the standard ASP methodology to determine its pass-through payment rate under the OPPS to account for the acquisition and pharmacy overhead costs, including compounding costs. We continue to believe that a single payment is appropriate for diagnostic radiopharmaceuticals with pass-through status in CY 2013, and

that the payment rate of ASP+6 percent (or payment based on the ASP methodology) is appropriate to provide payment for both the radiopharmaceutical's acquisition cost and any associated nuclear medicine handling and compounding costs. We refer readers to section V.B.3. of this final rule with comment period for further discussion of payment for therapeutic radiopharmaceuticals based on ASP information submitted by manufacturers, and readers may also refer to the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

Finally, we note that the comment that suggested that CMS explore alternative payment mechanisms that reward the pharmaceutical care provided by specialty trained pharmacists who ensure safe and effective medication use and provide for screening of drug interactions and contraindications is outside the scope of this final rule with comment period.

Comment: One commenter stated that HCPCS code J1572 (Injection, immune globulin (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg) received an approval for a labeling change for the extraction process on January 20, 2012, but that this did not constitute the approval of a "new drug." The commenter requested that CMS reevaluate the status indicator for HCPCS code J1572 and assign it to a status indicator of "K" instead of "G" for CY 2013, because the original FDA approval date for the product of December 15, 2003 does not meet the criteria for pass-through status.

Response: For the CY 2013 OPPS/ASC proposed rule (77 FR 45129 through 45131), we proposed to continue pass-through status for HCPCS code J1572 for the remainder of CY 2013. HCPCS code J1572 replaced HCPCS code Q4091 on January 1, 2008. The product described by HCPCS code J1572 also received FDA approval on December 15, 2003. When we reviewed the drug pass-through application for the product described by HCPCS code J1572, we concluded that the product described by HCPCS code J1572 had not previously received pass-through payment under the OPPS and had a cost that was not insignificant in relation to the OPD fee schedule amount. Therefore, we approved pass-through status for HCPCS code J1572 beginning on July 1, 2011. We believe that we appropriately assigned pass-through status to HCPCS code J1572 and we continue to believe that pass-through status should continue through CY 2013.

We disagree with the commenter that HCPCS code J1572 does not meet the criteria for pass-through status because the original FDA approval date for this product was December 15, 2003. We note that section 1833(t)(6)(A)(iv)(I) of the Act allows for pass-through payment for a device, drug, or biological as long as payment for such item was not being made as an outpatient hospital service as of December 31, 1996. Furthermore, we reiterate that the statute provides in section 1833(t)(6)(B)(iii) of the Act that pass-through status shall be in effect for a period of at least 2 but no more than 3 years of pass-through payment. Therefore, we believe continuing pass-through status for HCPCS code J1572 is appropriate.

Comment: One commenter who responded to the CY 2012 OPPS/ASC final rule with comment period requested clarification on the dosage descriptor for HCPCS code J9179 (Injection, eribulin mesylate, 0.1 mg). The commenter noted that the final rule display version referenced inconsistent dosage size.

Response: As displayed in Table 32 below, the correct dosage descriptor for HCPCS code J9179 is 0.1mg. HCPCS code J9179 will continue on pass-through status, with a status indicator of "G," for CY 2013.

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 2013, 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.d. of this final rule with comment period, over the last 5 years, we implemented a policy whereby payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents is packaged into payment for the associated procedure. We proposed to continue the packaging of these

items, regardless of their per day cost, in CY 2013. 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 either a diagnostic radiopharmaceutical or a contrast agent (identified as a "policy-packaged" drug, first described in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68639)) 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 2012, we proposed to continue to set the associated copayment amount for pass-through diagnostic radiopharmaceuticals and contrast agents that would otherwise be packaged if the item did not have pass-through status to zero for CY 2013. Similarly,

we proposed that the associated copayment amount for pass-through anesthesia drugs that would otherwise be packaged if the item did not have pass-through status would be zero for CY 2013. As discussed in further detail in section II.3.c.(2) of this final rule with comment period, we are clarifying that our general policy is to package drugs used for anesthesia, and that those anesthesia drugs with pass-through status will be packaged upon the expiration of pass-through status.

The separate OPPS payment to a hospital for the pass-through diagnostic radiopharmaceutical, contrast agent, or anesthesia drug 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 were available via the Internet on the CMS Web site).

Comment: Commenters supported the CY 2013 proposal to continue to set the associated copayment amounts for pass-through diagnostic radiopharmaceuticals and contrast agents that would otherwise be packaged if the product did not have pass-through status to zero. The commenters noted that this policy is consistent with statutory requirements and provides cost-saving benefits to beneficiaries.

Response: We appreciate the commenters' support of our proposal. As discussed in the CY 2013 OPPS/ASC proposed rule (77 FR 45129 through 45130), we believe that for drugs and biologicals that are "policy-packaged," the copayment for the nonpass-through payment portion of the total OPPS payment for this subset of drugs and biologicals is accounted for in the copayment of the associated clinical APC in which the drug or biological is used. According to section 1833(t)(8)(E) of the Act, the amount of

copayment associated with pass-through items is equal to the amount of copayment that would be applicable if the pass-through adjustment was not applied. Therefore, we believe that the copayment amount should be zero for drugs and biologicals that are "policy-packaged," including diagnostic radiopharmaceuticals and contrast agents. We also believe that the copayment amount should be zero for anesthesia drugs that would otherwise be packaged if the item did not have pass-through 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 and contrast agents that would otherwise be packaged if the item did not have pass-through status to zero for CY 2013. We are also finalizing our proposal to extend this policy to anesthesia drugs that have pass-through status, and to set a copayment amount of zero for these drugs for CY 2013.

The 26 drugs and biologicals that we are continuing on pass-through status for CY 2013 or have been granted pass-through status as of January 2013 are displayed in Table 32 below.

TABLE 32.—DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN CY 2013

CY 2012 HCPCS Code	CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 SI	Final CY 2013 APC
A9584	A9584	Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries	G	9406
C9285	C9285	Lidocaine 70 mg/tetracaine 70 mg, per patch	G	9285
C9286	J0485	Injection, belatacept, 1 mg	G	9286
C9287	J9042	Injection, brentuximab vedotin, 1 mg	G	9287
C9288	J0716	Injection, centruroides immune f(ab)2, up to 120 milligrams	G	1431
C9289	J9019	Injection, asparaginase (erwinaze), 1,000 iu	G	9289
C9290	C9290	Injection, bupivicaine liposome, 1 mg	G	9290
C9292	C9292	Injection, pertuzumab, 10 mg	G	9292
C9293	C9293	Injection, glucarpidase, 10 units	G	9293
N/A	C9294*	Injection, taliglucerase alfa, 100 units	G	9294
N/A	C9295*	Injection, carfilzomib, 1 mg	G	9295
N/A	C9296*	Injection, ziv-aflibercept, 1 mg	G	9296
C9366	Q4131	EpiFix, per square centimeter	G	9366
C9368	Q4132	Grafix core, per square centimeter	G	9368
C9369	Q4133	Grafix prime, per square centimeter	G	9369
J0131	J0131	Injection, acetaminophen, 10 mg	G	9283
J0490	J0490	Injection, belimumab, 10 mg	G	1353
J0638	J0638	Injection, canakinumab, 1mg	G	1311
J0712	J0712	Injection, ceftaroline fosamil, 10 mg	G	9282
J1572	J1572	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg	G	0947
J2507	J2507	Injection, pegloticase, 1 mg	G	9281
J7180	J7180	Injection, factor xiii (antihemophilic	G	1416

CY 2012 HCPCS Code	CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 SI	Final CY 2013 APC
		factor, human), 1 i.u		
J9179	J9179	Injection, eribulin mesylate, 0.1 mg	G	1426
J9228	J9228	Injection, ipilimumab, 10 mg	G	9284
Q2046	J0178	Injection, aflibercept, 1 mg	G	1420
Q4124	Q4124	Oasis Ultra Tri-Layer matrix, per square centimeter	G	9365

*HCPCS codes C9294, C9295, and C9296 are effective January 1, 2013.

4. Provisions for Reducing Transitional Pass-Through Payments for Diagnostic Radiopharmaceuticals and Contrast Agents to Offset Costs Packaged into APC Groups

a. Background

Prior to CY 2008, diagnostic radiopharmaceuticals and contrast agents were paid separately under the OPPS if their mean per day costs were greater than the applicable year's drug packaging threshold. In CY 2008 (72 FR 66768), we began a policy of packaging payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents as ancillary and supportive items and services into their associated nuclear medicine procedures. Therefore, beginning in CY 2008, nonpass-through diagnostic radiopharmaceuticals and contrast agents were not subject to the annual OPPS drug packaging threshold to determine their packaged or separately payable payment status, and instead all nonpass-through diagnostic radiopharmaceuticals and contrast agents were packaged as a matter of policy. For CY 2013, in the CY 2013 OPPS/ASC proposed rule (77 FR 45131), we proposed to continue to package payment for all nonpass-through

diagnostic radiopharmaceuticals and contrast agents, as discussed in section II.A.3.e. of the proposed rule and this final rule with comment period.

b. Payment Offset Policy for Diagnostic Radiopharmaceuticals

As previously noted, radiopharmaceuticals are considered to be drugs for OPPS pass-through payment purposes. As described above, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. There is currently one radiopharmaceutical with pass-through status under the OPPS, HCPCS code A9584 (Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries). This product, which is presently referred to using HCPCS code A9584, was granted pass-through status using HCPCS code C9406 beginning July 1, 2011, and we proposed that it continue receiving pass-through status in CY 2013. We currently apply the established radiopharmaceutical payment offset policy to pass-through payment for this product. 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 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 OPPS/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 OPPS/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, rather than drugs. To determine the actual APC offset amount for pass-through diagnostic radiopharmaceuticals that takes into consideration the otherwise applicable OPPS payment amount, we multiply the "policy-packaged" drug offset fraction by the APC payment amount for the nuclear medicine procedure with which the pass-through

diagnostic radiopharmaceutical is used and, accordingly, reduce the separate OPPS payment for the pass-through diagnostic radiopharmaceutical by this amount.

Beginning in CY 2011 and as discussed in the CY 2011 OPPS/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 when the diagnostic radiopharmaceutical is received at no cost/full credit. These instructions are contained within the I/OCE CMS specifications on the CMS Web site at http://www.cms.gov/Medicare/Coding/OutpatientCodeEdit/index.html.

For CY 2013 and future years, we proposed to continue to require hospitals to append modifier "FB" to specified nuclear medicine procedures when the diagnostic radiopharmaceutical is received at no cost/full credit. In addition, we proposed to continue to require that when a hospital bills with an "FB" modifier with the nuclear medicine scan, the payment amount for procedures in the APCs listed in Table 24 of the proposed rule (77 FR 45132) would be reduced by the full "policy-packaged" offset amount appropriate for diagnostic radiopharmaceuticals. Finally, we also proposed to continue to require hospitals to report a token charge of less than $1.01 in cases in which the diagnostic radiopharmaceutical is furnished without cost or with full credit.

We did not receive any public comments on this proposal. Therefore, we are finalizing our policy, without modification, to continue requiring hospitals to append modifier "FB" to specified nuclear medicine procedures when the diagnostic radiopharmaceutical is received at no cost/full credit in CY 2013 and future years. In addition, we will continue to reduce the payment amount for procedures in the APCs

listed in Table 33 in this final rule with comment period by the full "policy-packaged" offset amount appropriate for diagnostic radiopharmaceuticals. Finally, we also will continue to require hospitals to report a token charge of less than $1.01 in cases in which the diagnostic radiopharmaceutical is furnished without cost or with full credit.

For CY 2012, we finalized a policy to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals, as described above. For CY 2013, we proposed to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals.

Comment: Commenters recommended that CMS continue to apply radiopharmaceutical edits for nuclear medicine procedures using radiopharmaceuticals as long as diagnostic radiopharmaceuticals are packaged. The commenters noted that the proposed rule was silent on whether CMS will continue this policy for CY 2013 and they requested that CMS confirm in the final rule that it will continue to apply the radiopharmaceutical edits and use only claims with a radiopharmaceutical code in determining nuclear medicine APC rates.

Response: Beginning in CY 2008, we implemented nuclear medicine procedure-to-radiolabeled product claims processing edits in the I/OCE that required a diagnostic radiopharmaceutical to be present on the same claim as a nuclear medicine procedure for payment under the OPPS to be made. These edits ensure that hospitals submit correctly coded claims that report the HCPCS codes for the products and their charges that are necessary for performance of nuclear medicine procedures. Although we

do not discuss our policy regarding nuclear medicine-to-radiolabeled product claims processing edits in this final rule with comment period, we will continue to annually update and implement this list in accordance with our original finalized policy. We refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60384 through 60390) for a detailed discussion of the nuclear medicine procedure-to-radiolabeled product edits and the evolution of our edit policy. In addition, specific instructions for the nuclear medicine procedure-to-radiolabeled product claims processing edits are contained within the I/OCE CMS specifications on the CMS Web site at http://www.cms.gov/OutpatientCodeEdit/02OCEQtrReleaseSpecs.asp#TopOfPage.

Comment: A few 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 2013 OPPS 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/HhospitalOutpatientPPS/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.

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 2013 OPPS/ASC proposed rule (77 FR 45131).

Table 33 below displays the APCs to which nuclear medicine procedures will be assigned in CY 2013 and for which we expect that an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

TABLE 33.—APCs TO WHICH NUCLEAR MEDICINE PROCEDURES WILL BE ASSIGNED FOR CY 2013

CY 2013 APC	CY 2013 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.

CY 2013 APC	CY 2013 APC Title
0397	Vascular 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. There currently are no contrast agents with pass-through status under the OPPS. As described in section V.A.3. of the proposed rule, we proposed that new pass-through contrast agents would be paid at ASP+6 percent, while those 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.

Although there are 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 2013, in order to provide an appropriate transitional pass-through payment for them 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 2013 OPPS/ASC proposed rule (77 FR 45132), we proposed for CY 2013 to deduct from the payment for new pass-through contrast agents that are approved for pass-through status as a drug or biological during CY 2013, an amount that reflects the portion of the APC payment associated with predecessor contrast agents, in order to ensure no duplicate contrast agent payment is made.

In CY 2010, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor contrast agents when considering new contrast agents for pass-through payment (74 FR 60482 through 60484). For CY 2013, as we did in CY 2012, we proposed to continue to apply this same policy to contrast agents. Specifically, we proposed to utilize the "policy-packaged" drug offset fraction for clinical APCs calculated as 1 minus (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 CY 2010, we finalized a policy to redefine "policy-packaged" drugs as only nonpass-through diagnostic radiopharmaceuticals and contrast agents (74 FR 60495 through 60499). To determine the actual APC offset amount for pass-through contrast 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 contrast agent is used and, accordingly, reduce the separate OPPS payment for the pass-through contrast agent by this amount. We proposed to continue to apply this methodology for CY 2013 to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 25 of the proposed rule

(77 FR 45132 through 45133), a specific offset based on the procedural APC would be applied to payments 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 OPPS clinical APC.

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 33 above, and these APCs are displayed in Table 34 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 OPPS/ASC final rule with comment period (70 FR 60483 through 60484). For CY 2013, we proposed to continue to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 25 of the proposed rule (77 FR 45132 through 45133), 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.

Comment: One commenter urged CMS to publish the proposed offset amount for contrast agents in the proposed rule to allow interested stakeholders the opportunity to review the data and comment on the amount of the offset.

Response: As we stated previously, the exact data used to calculate all of the proposed and final payment rates, including the associated offset amounts, for the CY 2013 OPPS 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 because we assign services to APCs based on our estimate of their full resource cost, including, but not limited to, packaged contrast agents. The offset amount is the portion of each APC payment rate that could reasonably be attributed to the cost of a predecessor contrast agent when considering a new diagnostic radiopharmaceutical and contrast agent for pass-through payment and has no bearing on APC assignment.

After consideration of the public comments we received, we are finalizing our proposal for CY 2013 without modification.

TABLE 34.—APCs TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2013

CY 2013 APC	CY 2013 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 without Device.
0104	Transcathether 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.

CY 2013 APC	CY 2013 APC Title
8006	CT and CTA with Contrast Composite.
8008	MRI and MRA with Contrast Composite.

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

1. Background

Under the CY 2012 OPPS, 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 OPPS final rule with comment period (65 FR 18450) that we generally package the cost of drugs and radiopharmaceuticals into the APC payment rate for the procedure or treatment with which the products are usually furnished. Hospitals do not receive separate payment for packaged items and supplies, and hospitals may not bill beneficiaries separately for any packaged items and supplies whose costs are recognized and paid within the national OPPS payment rate for the associated procedure or service. (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 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $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; and for CY 2012, we set the packaging threshold at $75.

Following the CY 2007 methodology, for the CY 2013 OPPS/ASC proposed rule (77 FR 45133), 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 2013 and rounded the resulting dollar amount ($81.59) to the nearest $5

increment, which yielded a figure of $80. 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 note that we did not propose a change to the PPI that is used to calculate the threshold for CY 2013; rather, this change in terminology reflects a change to the BLS naming convention for this series.) We refer below to this series generally as the PPI for Prescription Drugs.

We chose this PPI 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 OPPS/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 2013 of $80. (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, Nonimplantable Biologicals, and Therapeutic Radiopharmaceuticals ("Threshold-Packaged Drugs")

In the CY 2013 OPPS/ASC proposed rule (77 FR 45134), to determine the proposed CY 2013 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, nonimplantable biologicals, and therapeutic radiopharmaceuticals (collectively called "threshold-packaged" drugs) that had a HCPCS code in CY 2011 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2011 claims processed before January 1, 2012 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages as described in section V.B.2.c. of this final rule with comment period or for diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals that we proposed to continue to package in CY 2013, as discussed in section V.B.2.d. of this final rule with comment period.

In order to calculate the per day costs for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2013, 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 nonimplantable 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

nonimplantable biologicals for CY 2013, as discussed in more detail in section V.B.3.b. of this final rule with comment period) to calculate the CY 2013 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2011 (data that were used for payment purposes in the physician's office setting, effective April 1, 2012) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2013 we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2011 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the proposed rule (which was 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 were also the bases for drug payments in the physician's office setting, effective April 1, 2012. 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 2011 hospital claims data to determine their per day cost.

We proposed to package items with a per day cost less than or equal to $80, and identify items with a per day cost greater than $80 as separately payable. Consistent with our past practice, we crosswalked historical OPPS claims data from the CY 2011 HCPCS codes that were reported to the CY 2012 HCPCS codes that we displayed in Addendum B of the proposed rule (which was available via the Internet on the CMS Web site) for payment in CY 2013.

Comment: The majority of commenters objected to the proposed increase in the OPPS packaging threshold to $80 for CY 2013. 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 $75 for CY 2013. Many commenters objected to the use of a packaging threshold under the OPPS when one is not used for physician's office payment. These commenters argued for parity across the payment systems and they expressed concern that the packaging threshold may impede beneficiary access to lower cost packaged drugs in the HOPD setting. A few commenters suggested that CMS limit increases in the packaging threshold amount to the hospital update factor for the year, reflective of all statutory adjustments. One commenter believed that these dollar figures are arbitrary and recommended that CMS tie the threshold for separate payment to the annual market basket rather than randomly assigning thresholds for separate payment for these products.

One commenter noted that increasing the packaging threshold could have the unintended impact of undermining conversion to LEU sources of diagnostic radiopharmaceuticals if CMS adopts a proposal to unbundle diagnostic radiopharmaceuticals from the APC rate under the policy packaging rule without also waiving the dollar threshold for radiopharmaceuticals produced from LEU sources.

Response: As discussed in detail in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66758 through 66767), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68643), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60485 through 60487), the CY 2011 OPPS/ASC final rule with comment period (75 FR 71940 through 71943), and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74300 through 74301), we continue to believe that unpackaging payment

for all drugs, biologicals and radiopharmaceuticals is inconsistent with the concept of a prospective payment system and that such a change could create an additional reporting burden for hospitals. The OPPS and the MPFS (which applies to physician's services) are fundamentally different payment systems with essential differences in their payment policies and structures. Specifically, the OPPS is a prospective payment system based on the concept of payment for groups of services that share clinical and resource characteristics. Payment is made under the OPPS according to prospectively established payment rates that are related to the relative costs of hospital resources for services. When physician's services are furnished in an office setting, they are paid under the MPFS, which is a fee schedule based on the relative value of each component. Under the MPFS, separate payment is made for each service provided in the physician's office; when individual drugs are administered to beneficiaries in the physician's office, they are generally paid under the ASP methodology. In contrast, the OPPS includes various drugs within a prospective payment system, where payment for certain drugs is packaged into the associated procedure payment for the APC group. Given the fundamental differences in the way payment is made in an HOPD and a physician's office setting for these drugs, differences in payment are to be expected.

In general, we do not believe that our packaging methodology under the OPPS results in limited beneficiary access to drugs because packaging is a fundamental component of a prospective payment system that accounts for the cost of certain items and services in larger payment bundles, recognizing that some cases may be more costly and others less costly, but that, on average, OPPS payment is appropriate for the services

provided. The growing utilization associated with packaged drugs and biologicals in our claims data suggests Medicare beneficiaries have sufficient access to these items.

We note that, in CYs 2005 and 2006, the statutorily mandated drug packaging threshold was set at $50, and we continue to believe that it is appropriate to continue a drug packaging threshold for the CY 2013 OPPS for the reasons set forth below. 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 packaging these items does not lead to beneficiary access issues and does not create a problematic site of service differential, 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 2013 or to eliminate or to freeze the packaging threshold at $75.

We disagree with the commenters who suggested that CMS should 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 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.

Additionally, we strongly disagree with the commenter who suggested that our methodology for updating the packaging threshold is arbitrary and recommended that CMS tie the threshold for separate payment to the annual market basket rather than randomly assigning thresholds for separate payment for these products. As we have stated above, 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 manufacturer, we believe that the PPI for Prescription Drugs is an appropriate price index to use to update the packaging threshold

for CY 2007 and subsequent years. Therefore, we believe that our continued methodology of updating the CY 2005 $50 packaging threshold for inflation based on the PPI for Prescription Drugs is not arbitrary in nature nor does it have the effect of randomly assigning a payment threshold for drugs. Our methodology continues to be an accurate way to apply an annual inflation adjustment factor that is consistent with the practices of many health care payment policy areas, and many other areas of government policy, that acknowledge real costs by using an inflation adjustment factor instead of a static dollar value.

Finally, we disagree with commenters that increasing the packaging threshold could have the unintended impact of undermining conversion to LEU sources. As we discuss in section II.A.3.e. of this final rule with comment period, we are finalizing our proposals for CY 2013 to continue to package payment for all nonpass-through diagnostic radiopharmaceuticals. Therefore, diagnostic radiopharmaceuticals will not be subject to the packaging threshold and will instead be packaged regardless of their per day cost. Additionally, as we discuss in section III.A.C.3., removing the diagnostic radiopharmaceutical so that this cost is passed through directly to Medicare is not consistent with the fundamental concept of packaging under the OPPS. Moreover, the diagnostic radiopharmaceutical is never separately billed, being a supply in the diagnostic procedure it supports, so the true cost cannot be captured by single service claims. Most significantly from the standpoint of payment for non-HEU sources, however, a separate payment for the diagnostic radiopharmaceutical does not unbundle the cost of the isotope from the much larger cost of the drug component, nor does it differentiate between HEU

and non-HEU sources, so it does not create a differential payment to further the CMS goals of payment equity or the Administration's goal of promoting non-HEU conversion.

Comment: Several commenters suggested that CMS reinstate its policy of separate payment for 5-HT3 antiemetics, which are a class of drugs often used as part of an anticancer treatment regiment to treat nausea. One commenter believed that CMS packaged all 5-HT3 antiemetic drugs (HCPCS codes J1260 (Injection, dolasetron mesylate, 10 mg), J1626 (Injection, granisetron hydrochloride, 100 mcg), J2405 (Injection, ondansetron hydrochloride, per 1 mg), J2469 (Injection, palonosetron hcl, 25 mcg), Q0166 (Granisetron hydrochloride, 1 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 24 hour dosage regimen), Q0180 (Dolasetron mesylate, 100 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 24 hour dosage regimen)). The commenter opposed the packaging of these drugs.

Response: We continue to believe that use of these antiemetics is an integral part of an anticancer treatment regimen and that OPPS claims data demonstrate their increasingly common hospital outpatient utilization. As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60488), we no longer believe that a specific exemption to our standard drug payment methodology is necessary to ensure access to the most appropriate antiemetic products for Medicare beneficiaries. We continue to believe that our analysis conducted in the CY 2010 OPPS/ASC proposed rule

on 5-HT3 antiemetics (74 FR 35320), along with the historical stability in prescribing patterns for these products and the availability of generic alternatives for several of these products, allows us to continue our policy of not specifically exempting these products from the OPPS drug packaging threshold.

Additionally, we clarify that we did not propose to assign a packaged payment status indicator to all 5-HT3 antiemetic codes in the CY 2013 OPPS/ASC proposed rule. HCPCS code J2469 (Injection, palonosetron hcl, 25 mcg) had a per day cost above the proposed $80 packaging threshold and was assigned a separately payable status indicator of "K" for the proposed rule. HCPCS code J2469 has a CY 2013 estimated per day cost, from the CY 2011 claims data, above the CY 2013 drug packaging threshold and therefore will receive separate payment in CY 2013.

Comment: One commenter recommended that CMS not package any drugs used in anticancer regimens.

Response: We disagree with the commenter for the reasons mentioned above. We believe that packaging certain items, including items used in anticancer regimens, is a fundamental component of a prospective payment system, and is an essential feature that distinguishes a prospective payment system from a fee schedule. We do not believe that packaging drugs used in an anticancer regimen or in outpatient treatment of other significant disease leads to beneficiary access issues. This finding is confirmed by our analysis of hospital claims data in which we have found that beneficiaries appear to have adequate access to cancer treatments, as is signified by ongoing volume growth in cancer-related APCs and stability in prescribing products for anticancer drugs such as 5-HT3

antiemetics, for which CMS has continued to observe volume growth, even after we ended our multiyear exemption from the packaging threshold for these products. In summary, after consideration of the public comments we received, we are not providing any exceptions to the standard drug packaging methodology for any class of drugs, including anticancer therapies, for CY 2013.

Since publication of the CY 2013 OPPS/ASC proposed rule, consistent with our policy of updating the packaging threshold with more recently available data for the final rule, we have again followed the CY 2007 methodology for CY 2013 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 2013. We then rounded the resulting updated dollar amount ($81.91) to the nearest $5 increment, which yielded a figure of $80. 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 2013 packaging threshold of $80. Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of

HCPCS codes for drugs and nonimplantable biologicals in this CY 2013 OPPS/ASC final rule with comment period, we proposed to use ASP data from the first quarter of CY 2012, 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, 2012, along with updated hospital claims data from CY 2011. We note that we also proposed to use these data for budget neutrality estimates and impact analyses for this CY 2013 OPPS/ASC final rule with comment period.

Payment rates for HCPCS codes for separately payable drugs and nonimplantable 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 2012. 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, 2012. These physician's office payment rates will then be updated in the January 2013 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2013. For items that do not currently have an ASP-based payment rate, we proposed to recalculate their mean unit cost from all of the CY 2011 claims data and updated cost report information available for this CY 2013 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals in this CY 2013 OPPS/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 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose cost fluctuates relative to the proposed CY 2013 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2012. Specifically, for CY 2013, consistent with our historical practice, we proposed to apply the following policies to these HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals whose relationship to the proposed $80 drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and nonimplantable biologicals that were paid separately in CY 2012 and that were proposed for separate payment in CY 2013, and that then have per day costs equal to or less than $80, based on the updated ASPs and hospital claims data used for this CY 2013 final rule with comment period, would continue to receive separate payment in CY 2013.

- HCPCS codes for drugs and nonimplantable biologicals that were packaged in CY 2012 and that are proposed for separate payment in CY 2013, and that then have per day costs equal to or less than $80, based on the updated ASPs and hospital claims data used for this CY 2013 final rule with comment period, would remain packaged in CY 2013.

- HCPCS codes for drugs and nonimplantable biologicals for which we proposed packaged payment in CY 2013 but then have per day costs greater than $80, based on the

updated ASPs and hospital claims data used for this CY 2013 final rule with comment period, would receive separate payment in CY 2013.

We did not receive any public comments on our proposal to apply the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose cost fluctuates relative to the CY 2013 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2012. Therefore, we are finalizing our proposal, without modification, for CY 2013.

We note that HCPCS codes J2700 (Injection, oxacillin sodium, up to 250 mg) and J9218 (Leuprolide acetate, per 1 mg) were paid separately for CY 2012 and were proposed for separate payment in the CY 2013 OPPS/ASC proposed rule and had final per day costs of less than the $80 drug packaging threshold, based on updated ASPs and the CY 2011 hospital claims data available for this CY 2013 final rule with comment period. Therefore, HCPCS codes J2700 and J9218 will continue to be paid separately in CY 2013 according to the established methodology set forth above.

In addition, we proposed to package HCPCS codes J0365 (Injection, aprotonin, 10,000 kiu), J1460 (Injection, gamma globulin, intramuscular, 1 cc), J1560 (Injection, gamma globulin, intramuscular, over 10 cc), J7183 (Injection, von willebrand factor complex (human), wilate, 1 i.u. vwf:rco), and Q4105 (Integra dermal regeneration template (drt), per square centimeter) for CY 2013. Using updated ASPs and the CY 2011 hospital claims data available for this final rule with comment period, HCPCS codes J0365, J1460, J1560, J7183, and Q4105 now have per day costs greater than $80.

In accordance with our established policy for such cases, for CY 2013 we will pay for HCPCS codes J0365, J1460, J1560, J7183, and Q4105 separately.

Finally, because we did not have claims data for HCPCS codes J1452 (Injection, fomivirsen sodium, intraocular, 1.65 mg) and J1835 (Injection, itraconazole, 50 mg) in the CY 2013 OPPS/ASC proposed rule, we had proposed a status indicator of "E" for these products in CY 2013. However, since publication of the proposed rule, we have received claims data and the per day cost for these products are more than the $80 CY 2013 packaged threshold. These products will be paid separately and will be assigned a status indicator of "K" for CY 2013.

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

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66776), we began recognizing, for OPPS payment purposes, multiple HCPCS codes reporting different dosages for the same covered Part B drugs or biologicals in order to reduce hospitals' administrative burden by permitting them to report all HCPCS codes for drugs and biologicals. In general, prior to CY 2008, the OPPS recognized for payment only the HCPCS code that described the lowest dosage of a drug or biological. We extended this recognition to multiple HCPCS codes for several other drugs under the CY 2009 OPPS (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 OPPS/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 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages. 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 2013, 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 2013 OPPS/ASC proposed rule (77 FR 45135), 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 2013.

For CY 2013, 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 2011 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 2013 OPPS/ASC final rule 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 2011 claims data to make the packaging determinations for these drugs: HCPCS codes 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), 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), 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 dosages, 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 $80 (whereupon all HCPCS codes for the same drug or biological would be packaged) or greater than $80 (whereupon 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 2013 proposal, without modification. The packaging status of each drug and biological HCPCS code to which this methodology would apply is displayed in Table 35 below.

TABLE 35.—HCPCS CODES TO WHICH THE CY 2013 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2013 HCPCS Code	CY 2013 Long Descriptor	CY 2013 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1070	Injection, testosterone cypionate, up to 100 mg	N
J1080	Injection, testosterone cypionate, 1 cc, 200 mg	N
J1440	Injection, filgrastim (g-csf), 300 mcg	K
J1441	Injection, filgrastim (g-csf), 480 mcg	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	N
J1560	Injection, gamma globulin, intramuscular over 10 cc	N
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N

CY 2013 HCPCS Code	CY 2013 Long Descriptor	CY 2013 SI
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.)	K
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	K
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
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

CY 2013 HCPCS Code	CY 2013 Long Descriptor	CY 2013 SI
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	N

CY 2013 HCPCS Code	CY 2013 Long Descriptor	CY 2013 SI
	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	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

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" is 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 "specified covered outpatient drugs," known as 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) of the Act provides for an adjustment in OPPS payment rates for 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)(I) 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 choice rather than a statutory requirement. In the CY 2013 OPPS/ASC proposed rule, we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals. Although we did not distinguish SCODs in that discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we are choosing to apply it to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

In the CY 2006 OPPS proposed rule (70 FR 42728 through 42731), we discussed the June 2005 report by MedPAC regarding pharmacy overhead costs in HOPDs and summarized the findings of that study. In response to the MedPAC findings, in the CY 2006 OPPS proposed rule (70 FR 42729), we discussed our belief that, because of the

varied handling resources required to prepare different forms of drugs, it would be impossible to exclusively and appropriately assign a drug to a certain overhead category that would apply to all hospital outpatient uses of the drug. Therefore, our CY 2006 OPPS proposal included a proposal to establish three distinct Level II HCPCS C-codes and three corresponding APCs for drug handling categories to differentiate overhead costs for drugs and biologicals (70 FR 42730). We also proposed: (1) to combine several overhead categories recommended by MedPAC; (2) to establish three drug handling categories, as we believed that larger groups would minimize the number of drugs that may fit into more than one category and would lessen any undesirable payment policy incentives to utilize particular forms of drugs or specific preparation methods; (3) to collect hospital charges for these HCPCS C-codes for 2 years; and (4) to ultimately base payment for the corresponding drug handling APCs on CY 2006 claims data available for the CY 2008 OPPS.

In the CY 2006 OPPS final rule with comment period (70 FR 68659 through 68665), we discussed the public comments we received on our proposal regarding pharmacy overhead. The overwhelming majority of commenters did not support our proposal regarding pharmacy overhead and urged us not to finalize this policy, as it would be administratively burdensome for hospitals to establish charges for HCPCS codes for pharmacy overhead and to report them. Therefore, we did not finalize this proposal for CY 2006. Instead, we established payment for separately payable drugs and biologicals at ASP+6 percent, which we 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). Hereinafter, we refer to this methodology as our standard drug payment methodology. We concluded that payment for drugs and biologicals and pharmacy overhead at a combined ASP+6 percent rate would serve as an acceptable proxy for the combined acquisition and overhead costs of each of these products.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68091), we finalized our proposed policy to provide a single payment of ASP+6 percent for the hospital's acquisition cost for the drug or biological and all associated pharmacy overhead and handling costs. The ASP+6 percent rate that we finalized was higher than the equivalent average ASP-based amount calculated from claims of ASP+4 percent according to our standard drug payment methodology, but we adopted payment at ASP+6 percent for stability while we continued to examine the issue of the costs of pharmacy overhead in the HOPD and awaited the accumulation of CY 2006 data as discussed in the prior year's rule.

In the CY 2008 OPPS/ASC proposed rule (72 FR 42735), in response to ongoing discussions with interested parties, we proposed to continue our methodology of providing a combined payment rate for drug and biological acquisition and pharmacy overhead costs while continuing our efforts to improve the available data. We also proposed to instruct hospitals to remove the pharmacy overhead charge for both packaged and separately payable drugs and biologicals from the charge for the drug or biological and report the pharmacy overhead charge on an uncoded revenue code line on the claim.

We believed that this would provide us with an avenue for collecting pharmacy handling cost data specific to drugs in order to package the overhead costs of these items into the associated procedures, most likely drug administration services. Similar to the public response to our CY 2006 pharmacy overhead proposal, the overwhelming majority of commenters did not support our CY 2008 proposal and urged us to not finalize this policy (72 FR 66761). At its September 2007 meeting, the APC Panel recommended that hospitals not be required to separately report charges for pharmacy overhead and handling and that payment for overhead be included as part of drug payment. The APC Panel also recommended that CMS continue to evaluate alternative methods to standardize the capture of pharmacy overhead costs in a manner that is simple to implement at the organizational level (72 FR 66761). Because of concerns expressed by the APC Panel and public commenters, we did not finalize the proposal to instruct hospitals to separately report pharmacy overhead charges for CY 2008. Instead, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66763), we finalized a policy of providing payment for separately payable drugs and biologicals and their pharmacy overhead at ASP+5 percent as a transition from their CY 2007 payment of ASP+6 percent to payment based on the equivalent average ASP-based payment rate calculated from hospital claims according to our standard drug payment methodology, which was ASP+3 percent for the CY 2008 OPPS/ASC final rule with comment period. Hospitals continued to include charges for pharmacy overhead costs in the line-item charges for the associated drugs reported on claims.

For CY 2009, we proposed to pay separately payable drugs and biologicals at ASP+4 percent, including both SCODs and other drugs without CY 2009 OPPS pass-through status, based on our standard drug payment methodology. We also continued to explore mechanisms to improve the available data. We proposed to split the "Drugs Charged to Patients" cost center into two cost centers: one for drugs with high pharmacy overhead costs and one for drugs with low pharmacy overhead costs (73 FR 41492). We noted that we expected that CCRs from the proposed new cost centers would be available in 2 to 3 years to refine OPPS drug cost estimates by accounting for differential hospital markup practices for drugs with high and low overhead costs. After consideration of the public comments received and the APC Panel recommendations, we finalized a CY 2009 policy (73 FR 68659) to provide payment for separately payable nonpass-through drugs and biologicals based on costs calculated from hospital claims at a 1-year transitional rate of ASP+4 percent, in the context of an equivalent average ASP-based payment rate of ASP+2 percent calculated according to our standard drug payment methodology from the final rule claims data and cost report data. We did not finalize our proposal to split the single standard "Drugs Charged to Patients" cost center into two cost centers largely due to concerns raised by hospitals about the associated administrative burden. Instead, we indicated in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68659) that we would continue to explore other potential approaches to improve our drug cost estimation methodology, thereby increasing payment accuracy for separately payable drugs and biologicals.

In response to the CMS proposals for the CY 2008 and CY 2009 OPPS, a group of pharmacy stakeholders (hereinafter referred to as the pharmacy stakeholders), including some cancer hospitals, some pharmaceutical manufacturers, and some hospital and professional associations, commented that CMS should pay an acquisition cost of ASP+6 percent for separately payable drugs, should substitute ASP+6 percent for the packaged cost of all packaged drugs and biologicals on procedure claims, and should redistribute the difference between the aggregate estimated packaged drug cost in claims and payment for all drugs, including packaged drugs at ASP+6 percent, as separate pharmacy overhead payments for separately payable drugs. They indicated that this approach would preserve the aggregate drug cost observed in the claims data, while significantly increasing payment accuracy for individual drugs and procedures by redistributing drug cost from packaged drugs. Their suggested approach would provide a separate overhead payment for each separately payable drug or biological at one of three different levels, depending on the pharmacy stakeholders' assessment of the complexity of pharmacy handling associated with each specific drug or biological (73 FR 68651 through 68652). Each separately payable drug or biological HCPCS code would be assigned to one of the three overhead categories, and the separate pharmacy overhead payment applicable to the category would be made when each of the separately payable drugs or biologicals was paid.

In the CY 2010 OPPS/ASC proposed rule (74 FR 35332), we acknowledged the limitations of our data and our availability to find a method to improve that data in a way that did not impose unacceptable administrative burdens on providers. Accepting that

charge compression was a reasonable but unverifiable supposition, we proposed to redistribute between one-third and one-half of the estimated overhead cost associated with coded packaged drugs and biologicals with an ASP, which resulted in our proposal to pay for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that did not have pass-through payment status at ASP+4 percent. We calculated estimated overhead cost for coded packaged drugs and biologicals by determining the difference between the aggregate claims cost for coded packaged drugs and biologicals with an ASP and the ASP dollars (ASP multiplied by the drug's or biological's units in the claims data) for those same coded drugs and biologicals; this difference was our estimated overhead cost for coded packaged drugs and biologicals. In our rationale described in the CY 2010 OPPS/ASC proposed rule (74 FR 35326 through 35333), we stated that we believed that approximately $150 million of the estimated $395 million total in pharmacy overhead cost, specifically between one-third and one-half of that cost, included in our claims data for coded packaged drugs and biologicals with reported ASP data should be attributed to separately payable drugs and biologicals and that the $150 million serves as the adjustment for the pharmacy overhead costs of separately payable drugs and biologicals. As a result, we also proposed to reduce the costs of coded drugs and biologicals that are packaged into payment for procedural APCs to offset the $150 million adjustment to payment for separately payable drugs and biologicals. In addition, we proposed that any redistribution of pharmacy overhead cost that may arise from the CY 2010 final rule data would occur only from some drugs and biologicals to other drugs and biologicals, thereby maintaining the estimated total cost of

drugs and biologicals that we calculate based on the charges and costs reported by hospitals on claims and cost reports. As a result of this approach, no redistribution of cost would occur from other services to drugs and biologicals or vice versa.

While we had no way of assessing whether this current distribution of overhead cost to coded packaged drugs and biologicals with an ASP was appropriate, we acknowledged that the established method of converting billed charges to costs had the potential to "compress" the calculated costs to some degree. Further, we recognized that the attribution of pharmacy overhead costs to packaged or separately payable drugs and biologicals through our standard drug payment methodology of a combined payment for acquisition and pharmacy overhead costs depends, in part, on the treatment of all drugs and biologicals each year under our annual drug packaging threshold. Changes to the packaging threshold may result in changes to payment for the overhead cost of drugs and biologicals that do not reflect actual changes in hospital pharmacy overhead cost for those products. For these reasons, we stated that we believed some portion, but not all, of the total overhead cost that is associated with coded packaged drugs and biologicals (the difference between aggregate cost for those drugs and biologicals on the claims and ASP dollars for the same drugs and biologicals), based on our standard drug payment methodology, should, at least for CY 2010, be attributed to separately payable drugs and biologicals.

We acknowledged that the observed combined payment for acquisition and pharmacy overhead costs of ASP-2 percent for separately payable drugs and biologicals may be too low and ASP+247 percent for coded packaged drugs and biologicals with

reported ASP data in the CY 2010 claims data may be too high (74 FR 35327 and 35328). Therefore, we stated that a middle ground would represent the most accurate redistribution of pharmacy overhead cost. Our assumption was that approximately one-third to one-half of the total pharmacy overhead cost currently associated with coded packaged drugs and biologicals in the CY 2008 claims data offered a more appropriate allocation of drug and biological cost to separately payable drugs and biologicals (74 FR 35328). One third of the $395 million of pharmacy overhead cost associated with packaged drugs and biologicals was $132 million, whereas one-half was $198 million.

Within the one-third to one-half parameters, we proposed reallocating $150 million in drug and biological cost observed in the claims data from coded packaged drugs and biologicals with an ASP to separately payable drugs and biologicals for CY 2010 for their pharmacy overhead costs. Based on this redistribution, we proposed a CY 2010 payment rate for separately payable drugs and biologicals of ASP+4 percent.

In the CY 2010 OPPS final rule with comment period, we adopted a transitional payment rate of ASP+4 percent based on a pharmacy overhead adjustment methodology for CY 2010 that redistributed $200 million from packaged drug and biological cost to separately payable drug cost (74 FR 60499 through 60518). This $200 million included the proposed $150 million redistribution from the pharmacy overhead cost of coded packaged drugs and biologicals for which an ASP is reported and an additional $50 million dollars from the total uncoded drug and biological cost to separately payable drugs and biologicals as a conservative estimate of the pharmacy overhead cost of

uncoded packaged drugs and biologicals that should be appropriately associated with the cost of separately payable drugs and biologicals (74 FR 60517). We stated that this was an intentionally conservative estimate as we could not identify definitive evidence that uncoded packaged drug and biological cost included a pharmacy overhead amount comparable to that of coded packaged drugs and biologicals with an ASP. We stated that we could not know the amount of overhead associated with these drugs without making significant assumptions about the amount of pharmacy overhead cost associated with the drugs and biologicals captured by these uncoded packaged drug costs (74 FR 60511 through 60513). In addition, as in prior years, we reiterated our commitment to continue in our efforts to refine our analyses.

For CY 2011, we continued the CY 2010 pharmacy overhead adjustment methodology (74 FR 60500 through 60512). Consistent with our supposition that the combined payment for average acquisition and pharmacy overhead costs under our standard methodology may understate the cost of separately payable drugs and biologicals and related pharmacy overhead for those drugs and biologicals, we redistributed $150 million from the pharmacy overhead cost of coded packaged drugs and biologicals with an ASP and redistributed $50 million from the cost of uncoded packaged drugs and biologicals, for a total redistribution of $200 million from costs for coded and uncoded packaged drugs to separately payable drugs and biologicals, with the result that we pay separately paid drugs and biologicals at ASP+5 percent for CY 2011. The redistribution amount of $150 million in overhead cost from coded packaged drugs and biologicals with an ASP and $50 million in costs from uncoded packaged drugs and

biologicals without an ASP were within the parameters established in the CY 2010 OPPS/ASC final rule. In addition, as in prior years, we described some of our work to improve our analyses during the preceding year, including an analysis of uncoded packaged drug and biological cost and our evaluation of the services with which uncoded packaged drug cost appears in the claims data. We conducted this analysis in an effort to assess how much uncoded drugs resemble coded packaged drugs (75 FR 71966). We stated that, in light of this information, we were not confident that the drugs captured by uncoded drug cost are the same drugs captured by coded packaged drug cost, and therefore, we did not believe we could assume that they are the same drugs, with comparable overhead and handling costs. Without being able to calculate the ASP for these uncoded packaged drugs and biologicals and without being able to gauge the magnitude of overhead complexity associated with these drugs and biologicals, we did not believe that we should have assumed that the same amount of proportional overhead should be redistributed between coded and uncoded packaged drugs, and therefore, we redistributed $50 million from uncoded packaged drugs and $150 million from coded packaged drugs (75 FR 71966). We reiterated our commitment to continue to refine our drug pricing methodology and noted that we would continue to pursue the most appropriate methodology for establishing payment for drugs and biologicals under the OPPS and continue to evaluate the appropriateness of this methodology when we establish each year's payment for drugs and biologicals under the OPPS (75 FR 71967).

For CY 2012, we continued our overhead adjustment methodology of redistributing 1/3 to 1/2 of allocated overhead for coded packaged drugs or $150 million

plus an additional $50 million in allocated overhead for uncoded packaged drugs. Additionally, we finalized a policy to update these amounts by the PPI for pharmaceuticals and redistributed $161 million in allocated overhead from coded packaged drugs and $54 million from uncoded packaged drugs. We further finalized a policy to hold the redistributed proportion of packaged drugs constant between the proposed and the final rule, which increased the final redistribution amount in the CY 2012 final rule to $240.3 million ($169 million from coded packaged drugs and $71.3 million from uncoded packaged drugs). This approach resulted in a final payment rate of ASP+4 percent for separately payable drugs.

b. CY 2013 Payment Policy

In reexamining our current drug payment methodology for the CY 2013 OPPS/ASC proposed rule, we reviewed our past efforts to determine an appropriate payment methodology for drugs and biologicals, as described above. Since the inception of the OPPS, we have remained committed to establishing a drug payment methodology that is predictable, accurate, and appropriate. Pharmacy stakeholders and the hospital community have also, throughout the years, continually emphasized the importance of both predictable and accurate payment rates for drugs, noting that a payment methodology that emphasizes predictability and accuracy leads to appropriate payment rates that reflect the cost of drugs and biologicals (including overhead) in HOPDs. Pertinent stakeholders also have noted that predictable and accurate payment rates minimize the effect of anomalies in the claims data that may incorrectly influence the

future payment for services. We understand that, with predictable payment rates, hospitals are better able to plan for the future.

As discussed above, 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). As we previously stated, we refer 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 keep the redistribution ratio constant between the proposed rule and the final rule.

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 believe 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 are concerned that the continued use of our current standard drug payment methodology (including the overhead adjustment) still may not appropriately account for average acquisition and pharmacy overhead cost and, therefore, may result in payment rates that are not as predictable, accurate, or appropriate as they could be.

Section 1833(t)(14)(A)(iii)(II) of the Act requires an alternative methodology for determining payment rates for SCODs wherein, if hospital acquisition cost data are not available, payment shall be equal (subject to any adjustment for overhead costs) to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary. 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 OPPS/ASC proposed rule (77 FR 45140), we proposed 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, hereinafter referred to as the statutory default.

As noted above, 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, physician Part B drugs are paid at ASP+6 percent. We believe that proposing the statutory default of ASP+6 percent is appropriate at this time as it yields increased predictability in payment for separately payable drugs and biologicals under the OPPS. We believe that ASP+6 percent is an appropriate payment amount because it is consistent with payment amounts yielded by our drug payment methodologies over the past 7 years. 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 for CY 2013.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45140), we 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 strongly 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 than the payment rates CMS has finalized in previous years. The commenters noted that, by contrast, the current payment methodology involves complex calculations and an annual overhead adjustment in which costs are redistributed from packaged drugs to separately payable drugs. Another commenter supported CMS' proposal to pay for separately payable drugs and biologicals because it believed that this change in the payment methodology will prevent the inappropriate shifting of overhead costs from contrast agents. One commenter also expressed support for the proposal and noted the importance of finalizing the proposal, as more hospitals seek to access preferred drug pricing under the 340B program.

One commenter noted that the implementation of the survey of hospital drug costs required by section 1833(t)(14)(D)(iii), instead of the proposed statutory default rate of ASP+6 percent, would impose a costly administrative burden on both hospitals and CMS without demonstrating an equivalent benefit compared to the use of the average sales price that is based on the certified sales price of the drugs and biologicals. Other commenters supported CMS' proposal to pay for drugs and biologicals at ASP+6 percent because neither the GAO nor CMS have conducted the periodic surveys required by the statute since CY 2005 on average acquisition costs. They argued that, in the absence of current survey data on average acquisition costs, the statute requires that payment be set

at the statutory default rate of ASP+6 percent and that an additional adjustment for overhead be made.

Several commenters agreed with CMS and noted that this proposal allowed for stable and predictable payment rates for separately paid drugs and biologicals while removing the need to address charge compression and other issues. One commenter noted, in particular, that the proposal eliminates the issues related to the inclusion of 340B sales in the rate calculation. The commenter further recommended that CMS continue its policy of paying 340B and non-340B hospitals at the same rate for separately paid drugs and biologicals. Other commenters noted that payment for the acquisition and overhead costs of drugs and biologicals at ASP+6 percent will help to protect patients' access to care in the most clinically appropriate setting. The commenters also argued that this payment rate would create parity with the physician office setting.

Finally, many of the comments supported CMS' goal to establish a payment methodology that accurately and predictably estimates acquisition and overhead costs for separately paid drugs and biologicals.

Response: We appreciate the commenters' support. For several years, we have attempted to identify a methodology for paying for the average acquisition cost and pharmacy overhead costs for SCODs in a manner that is both appropriate and that is not burdensome to hospitals. After several years of refining a payment methodology, which has included the standard payment methodology and the overhead adjustment methodology, we determined in the CY 2013 OPPS/ASC proposed rule (77 FR 45140) that, 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, the continued use of our current 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. Therefore, we proposed to pay for separately payable drugs and biologicals at the statutory default rate of ASP+6 percent, as is consistent with section 1833(t)(14)(iii)(II) of the Act which 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 the 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 past, commenters, pertinent stakeholders, and the HOP Panel (previously known as the APC Panel) have strongly advocated for the use of the statutory default payment rate of ASP+6 percent. As we stated in the proposed rule, we believe that our proposal is consistent with these previous comments and we agree with the commenters that proposing a payment rate of ASP+6 percent based on the statutory default for separately payable drugs and biologicals is appropriate at this time. We agree with commenters that the statutory default obviates both the need to utilize complex calculations for acquisition and overhead costs and the requirement to collect data from hospital surveys, which would prove to be burdensome to both hospitals and to CMS. Additionally, we agree with commenters that the statutory default payment rate of ASP+6

percent eliminates the 340B program concerns many commenters have expressed in the past. Therefore, we believe that the statutory default payment rate of ASP+6 percent is appropriate for CY 2013.

Comment: Several commenters supported CMS' proposal of ASP+6 percent but stated their concerns that this level of payment is not sufficient to cover both drug acquisition and pharmacy overhead cost. The commenters stated that they considered this an improvement over the rate used in previous years and that this payment rate should be the minimum level of payment, or the payment floor, necessary to cover acquisition costs alone. Therefore, the commenters recommended that CMS finalize ASP+6 percent as the payment rate for acquisition costs alone and provide an additional, separate payment for hospital pharmacy overhead costs. One commenter also expressed concern whether ASP+6 percent is sufficient to cover both acquisition and handling. However, the commenter stated that the ASP+6 percent proposed payment rate is preferable to CMS continuing to attempt to determine what level of redistribution from packaged drugs to separately payable drugs should occur on an annual basis. One commenter reaffirmed the notion that ASP+6 percent should be the minimum level of payment that should be provided to cover hospitals' drug acquisition costs but the commenter recommended that CMS reconsider ASP+6 percent to be the minimum payment level to cover drug acquisition costs in both the physician's office and the hospital outpatient setting. The commenter argued that this would create payment parity and also enable the creation of a supplemental system to make a separate and additional ASP plus percentage amount to hospitals to cover their significant overhead costs.

One commenter supported CMS' proposal and stated that if CMS should finalize its policy to pay for separately payable drugs and biologicals at ASP+6 percent, CMS should not pay for pharmacy overhead, which is permitted but not required by section 1833(t)(14)(E)(iii) of the Act, in addition to the ASP+6 percent payment because payment at ASP+6 percent already includes payment for pharmacy overhead equal to 5 percent of ASP (the difference between ASP+6 percent and the ASP+1 percent that the OIG found to be the average acquisition cost of hospital drugs and biologicals in a study conducted by the OIG in 2010) (https://oig.hhs.gov/oei/reports/oei-03-09-00420.pdf). Moreover, the commenter further noted that payment for separately payable drugs and biologicals under section 1842(o) of the Act at 106 percent of ASP includes payment for the services of the pharmacy from which the physician purchases the drugs and biologicals. Therefore, the commenter further noted, if CMS pays hospitals ASP+6 percent for separately paid drugs and biologicals, it is also paying for the associated pharmacy overhead and should pay nothing more.

Response: We disagree with the commenters who stated that ASP+6 percent should be the payment for the acquisition cost alone and that separate payment for overhead should be made. We note that while the statute states that payment for SCODs under section 1833(t)(14)(A)(iii)(II) of the Act equals the payment rates established in the physician's office, subject to any adjustment for overhead costs, the statute does not mandate that such an adjustment for overhead be made. We believe that the payment rate of ASP+6 percent includes a sufficient amount for overhead costs for separately payable drugs and biologicals and we see no further evidence that any additional adjustment for

overhead is required. As we stated in the proposed rule, we believe 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, and we have not seen any evidence to indicate that these rates have limited beneficiary access to drugs, insufficiently paid for acquisition and overhead costs for drugs administered in the HOPD, or caused a migration of care from the hospital outpatient setting to the physician's office. To the contrary, we continue to see increases in the utilization of drugs and biologicals administered in the outpatient department in our claims data, even at payment rates of ASP+4 or 5 percent. Therefore, we believe that ASP+6 percent is an appropriate payment rate for separately payable drugs and biologicals.

Additionally, we agree with the commenter who cited the OIG study conducted in 2010, which used first quarter 2009 Medicare payment amounts compared to first quarter 2009 hospital acquisition costs for 33 separately payable drugs. The OIG concluded that, in the aggregate, Medicare payments were 1 percent higher than acquisition costs amounts for the responding non-340B hospitals for the selected separately payable drugs. This study supports our position that the ASP+6 percentage amount proposed for CY 2013 sufficiently pays for overhead and acquisition costs for drugs and requires no further adjustment.

We continue to believe that ASP+6 percent based on the statutory default is appropriate for hospitals for CY 2013 and that this percentage amount includes payment for acquisition and overhead cost. Furthermore, many hospitals and major hospital

associations supported our proposed ASP+6 percent for CY 2013 and made no request for additional payment for overhead costs in their comments to the CY 2013 OPPS/ASC proposed rule. Therefore, we believe that a payment rate of ASP+6 percent is appropriate for CY 2013.

Comment: A few commenters supported CMS' proposal, but recommended that CMS examine ways to compensate hospitals for the unique, higher overhead and handling costs associated with therapeutic radiopharmaceuticals.

Response: As we stated above, we continue to believe that ASP+6 percent based on the statutory default is appropriate for hospitals for CY 2013 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 2013.

Comment: One commenter remained concerned that the comparison of ASP to cost is not an "apple to apples" comparison because the cost data incorporate data from hospitals that receive 340B program discounts from drugs they purchase. The commenter further stated that the ASP calculation excludes 340B program sales, which underestimates the aggregate costs of drugs for most hospitals and the ASP-based rate that CMS produces by comparing aggregate costs to ASP is too low. The commenter asked that CMS review its cost calculation to ASP to ensure that 340B program drugs are not artificially reducing the CMS calculation.

Response: For CY 2013, we proposed to pay for separately payable drugs and biologicals at ASP+6 percent based on the statutory default established in section

1833(t)(14)(A)(iii)(II) of the Act. While we understand that commenters were previously concerned about the impact of 340B hospital data on our previous standard and overhead adjustment methodology calculations, we did not in fact propose to continue these methodologies for CY 2013.

Comment: One commenter supported CMS' proposal to increase the payment rate for SCODs to ASP+6 percent for CY 2013. However, the commenter believed that the law requires that SCOD payment rates, other than the ASP+6 percent default rate, must be set on a drug by drug basis, as mandated by section 1833(t)(14)(A)(iii)(I) of the Act. Therefore, the commenter recommended that CMS perform an individualized, drug by drug determination for the payment rate for each SCOD.

Response: Section 1833(t)(14)(A)(iii)(I) 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, subject to any adjustment of overhead costs. If hospital acquisition cost data are not available, section 1833(t)(14)(A)(iii)(II) of the Act 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. Previously under the standard methodology and the overhead adjustment methodology, we established ASP as a proxy for the average acquisition cost. However, we did not propose to use the authority given under section 1833(t)(14)(A)(iii)(I) of the Act to pay for SCODs for CY 2013. For CY 2013, we instead proposed to pay for separately payable drugs and biologicals based on the statutory authority established in section 1833(t)(14)(A)(iii)(II) of the Act.

Comment: One commenter recommended that CMS design a payment strategy that would maintain one formula for health care prescribers, but develop a multi-tiered reimbursement strategy that would encourage the use of generic drugs over their branded counterparts, using ASP+6 percent as an appropriate base for the most expensive drugs and providing additional reimbursement for multi-source generic drugs. Another commenter recommended that CMS adopt a new policy of assigning each "branded prescription drug" a unique HCPCS code, so that Part B utilization of these drugs can be accurately determined.

Response: We made no such proposal to develop a multi-tiered payment strategy that would encourage the use of generic drugs over their branded counterparts, using ASP+6 percent as an appropriate base for the most expensive drugs and providing additional payment for multi-source generic drugs. The commenters' recommendation to assign a unique HCPCS code for each "branded prescription drug" is outside the scope of this final rule with comment period.

Comment: One commenter asked that, for CY 2014, CMS consider paying for influenza and PPV vaccines at 106 percent of ASP.

Response: This comment is outside the scope of the CY 2013 OPPS/ASC final rule. However, we plan to address this issue in an upcoming rulemaking cycle.

Comment: One commenter supported CMS' proposal to pay for separately payable drugs at ASP+6 percent, but the commenter urged CMS to consider the effect of its coding practices on brand manufacturers' annual fee payment under section 9008 of the Patient Protection and Affordable Care Act (ACA) and asked that CMS support the

exclusion of wholesaler prompt pay discounts from the ASP calculations of separately payable drugs.

Response: Comments about individual ASP calculations for drugs and biologicals, or the inclusion or exclusion of prompt pay discounts in these calculations, are outside the scope of this final rule with comment period.

At its February 2012 Panel meeting, the Panel made four recommendations on drugs and biologicals paid under the OPPS. First, the Panel recommended that CMS require hospitals to bill all drugs that are described by Healthcare Common Procedure Coding System (HCPCS) codes under revenue code 0636. While we agree that drugs and biologicals may be reported under revenue code 0636, we believe that drugs and biologicals may also 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 OPPS/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. Additionally, 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. Therefore, we are not accepting the Panel's recommendation to require hospitals to bill all drugs that are described by HCPCS codes under revenue code 0636. However, we continue to believe that OPPS ratesetting is most accurate when hospitals report charges for all items and services that have HCPCS codes using those HCPCS codes, regardless

of whether payment for the items and services is packaged. It is our standard ratesetting methodology to rely on hospital cost report and charge information as it is reported to us through the claims data. We continue to believe that more complete data from hospitals identifying the specific drugs that were provided during an episode of care may improve payment accuracy for drugs in the future. Therefore, we continue to encourage hospitals to change their reporting practices if they are not already reporting HCPCS codes for all drugs and biologicals furnished, when specific HCPCS codes are available for those drugs and biologicals.

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. One commenter recommended that CMS not require hospitals to report the HCPCS code for each drug and biological in revenue code 0636 because to do so would impose an unreasonable burden on hospitals without a commensurate benefit to the accuracy of Medicare payment for drugs and biologicals under the OPPS if CMS finalizes its proposal to pay separately paid drugs at ASP+6 percent. Moreover, the commenter continued, in the case of packaged drugs and biologicals, the charges that are reported with revenue codes but without HCPCS codes are reduced to costs by application of the CCR for the cost center that applies to the revenue code under which the charges are reported and are packaged into the cost of the service. The commenter further stated that, therefore, to require that all drugs and biologicals be reported under any specific revenue code would require hospitals to revise their cost accounting systems to accommodate such a change because the revenue code in which charges are reported

must correspond to the cost center in which the costs are reported on the cost report for the cost report to be completed correctly and for the cost of packaged drugs and biologicals to be calculated correctly.

Response: We do not accept the commenter's recommendation that CMS require drugs and biologicals to be reported under revenue code 0636. We do agree with the commenter who recommended that CMS not require hospitals to report the HCPCS code for each drug and biological in revenue code 0636 because doing so would impose an unreasonable burden on hospitals. Further, we agree that charges that are reported with revenue codes but without HCPCS codes are reduced to costs by application of the CCR for the cost center that applies to the revenue code under which the charges are reported and are packaged into the cost of the service. As we stated in the CY 2013 OPPS/ASC proposed rule, we believe that drugs and biologicals may also 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 OPPS/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. Additionally, 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. Therefore, we are not accepting the Panel's recommendation to require hospitals to bill all drugs that are described by HCPCS codes under revenue code 0636.

However, we are reiterating once again in this CY 2013 OPPS/ASC final rule with comment period that the OPPS ratesetting as a whole, not just for drugs and biologicals, is most accurate when hospitals report charges for all items and services that have HCPCS codes using those HCPCS codes, regardless of whether payment for the items and services is packaged. Therefore, we continue to encourage hospitals to report a charge for each service they furnish, either by billing the HCPCS code and a charge for that service if separate reporting is consistent with CPT and CMS instructions or by reporting the charge for the packaged service with an appropriate revenue code but without a HCPCS code, when specific HCPCS codes are unavailable.

Second, the Panel recommended that CMS exclude data from hospitals that participate in the 340B program from its ratesetting calculations for drugs. Under the proposed statutory default payment rate of ASP+6 percent, hospitals' 340B status does not affect the drug payment rate.

Third, the Panel recommended that CMS freeze the packaging threshold at $75 until the drug payment issue is more equitably addressed. The OPPS is based on the concept of payment for groups of services that share clinical and resource characteristics. We believe that the packaging threshold is reasonable based on the initial establishment in law of a $50 threshold for the CY 2005 OPPS, that updating the $50 threshold 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, we are not accepting the Panel's recommendation to freeze the packaging threshold at $75 until the drug payment issue is more equitably addressed. Instead, as discussed in section V.B.2.

of the proposed rule and this final rule with comment period, we proposed and are finalizing an OPPS drug packaging threshold for CY 2013 of $80. However, we do believe that we have addressed the drug payment issue by proposing to pay for separately paid drugs and biologicals at ASP+6 percent for CY 2013 based upon the statutory default.

Finally, the Panel recommended that CMS pay hospitals for separately payable drugs at a rate of ASP+6 percent. This Panel recommendation is consistent with our CY 2013 proposed payment rate based upon the statutory default under section 1833(t)(14)(A)(iii)(II) of the Act, which authorizes us to pay for drugs and biologicals under the OPPS at ASP+6 percent, when hospital acquisition cost data are not available.

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, hereinafter referred to as 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 2013. As we stated in the proposed rule (77 FR 45140), our goals continue to be to develop a methodology that accurately and predictably estimates acquisition and overhead costs for separately payable drugs and biologicals in order to pay for them appropriately. If a better payment methodology is developed in the future then the proposed policy to pay ASP+6 percent according to the statutory default would be an interim step in the development of this payment policy. We recognize the challenges in doing so given the

current data sources and the object of maintaining the smallest administrative burden possible.

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 2013 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, 2012, or WAC, AWP or mean unit cost from 2011 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 2013 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2013 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of 2012 (July 1, 2012 through September 30, 2012) are used to set the payment rates that are released for the quarter beginning in January 2013 near the end of December 2012. 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 2012 are based on mean unit cost in the available CY 2011 claims data. If ASP information becomes available for payment for the quarter beginning in January 2013, 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 2012 ASP data) that do not have ASP information available for the quarter beginning in January 2013. These drugs and biologicals will then be paid based on mean unit cost data derived from CY 2011 hospital claims. Therefore, the payment rates listed in Addenda A and B to this final rule with comment period are not for January 2013 payment purposes and are only illustrative of the CY 2013 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 2012, we established a policy to pay for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. We allow manufacturers to submit the ASP data in a patient-specific dose or patient-ready form in order to properly calculate the ASP amount for a given HCPCS code. If ASP information is unavailable for a therapeutic radiopharmaceutical, then 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 2013. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45141), we proposed for CY 2013 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. We proposed to continue to set payment rates for therapeutic radiopharmaceuticals based on ASP information, if available, for a "patient ready" dose and updated on a quarterly basis for products for which manufacturers report ASP data. For a full discussion of how a "patient ready" dose is defined, 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 2011 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 is submitted to CMS. The commenters also supported CMS'

proposal to continue to set payment rates for therapeutic radiopharmaceuticals based on ASP information, if available, for a "patient ready" dose. One commenter recommended that CMS use its discretion and continue to pay on the basis of hospital specific reasonable cost-finding where ASP information is not available.

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 would 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. In addition, we do not believe that we should provide payment at charges reduced to cost or reasonable cost when ASP data are not available. We have stated previously, in the CY 2008 OPPS/ASC final rule with comment period, that we continue to believe that payment on a claims-specific basis is not consistent with the

payment of times and services on a prospective basis under the OPPS and may lead to extremely high or low payment to hospitals for radiopharmaceuticals, even when those products would be expected to have relatively predictable and consistent acquisition and holding costs across individual clinical cases and hospitals. For CY 2013, Medicare pays for only a few outpatient services at reasonable cost. These services include, but are not limited to, corneal tissue acquisition and influenza vaccines, and are paid at reasonable cost in part because the input costs for future years are highly unpredictable and to set a prospective payment rate for them may result in payment that is so deficient that hospitals would not be able to provide the services and the general public could be denied the benefits. In particular, it is not possible to forecast with confidence what the cost of influenza vaccine would be a year in advance because the composition of the vaccine is not constant from year to year. In contrast, however, the input costs of therapeutic radiopharmaceuticals are not hugely unpredictable. Therefore, we do not believe that therapeutic radiopharmaceuticals should be paid in the same manner as the few outpatient services paid at reasonable cost. We continue to believe that when ASP data are unavailable, therapeutic radiopharmaceutical payment based on mean unit cost is an appropriate proxy for hospitals' acquisition and handling data.

Comment: One commenter requested that CMS create a HCPCS J-code for tositumomab, currently provided under a radioimmunotherapy regimen and billed as part of HCPCS code G3001 (Administration and supply of tositumomab, 450 mg). The commenter argued that because tositumomab is approved by the FDA as part of the BEXXAR® regimen and has its own National Drug Code (NDC), it should be

recognized as a drug and, therefore, be paid as other drugs are paid under the OPPS methodology, instead of having a payment rate determined by hospital claims data. The commenter recommended that payment for all of the BEXXAR® drug components be paid as a SCOD.

Response: We have consistently noted that unlabeled tositumomab is not approved as either a drug or a radiopharmaceutical. It is a supply that is required as part of the radioimmunotherapy treatment regimen (as noted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68658), the CY 2008 OPPS final rule with comment period (72 FR 66765), the CY 2006 OPPS final rule with comment period (70 FR 68654), and the CY 2004 OPPS final rule with comment period (68 FR 63443)). We do not make separate payment for supplies used in services provided under the OPPS. Payments for necessary supplies are packaged into payments for the separately payable services provided by the hospital. Payment for unlabeled tositumomab is included in the payment for the administration procedure (described by HCPCS code G3001). Therefore, we do not agree with the commenter's recommendation that we should assign a separate HCPCS code to unlabeled tositumomab, which is a packaged supply.

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 based on ASP information, if available, for a "patient ready" dose and updated on a quarterly basis for products for which manufacturers report ASP data. For CY 2013, therapeutic radiopharmaceuticals will be

paid based on the statutory default payment rate of ASP+6 percent. The final CY 2013 payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to the proposed rule (which is available via the Internet on the CMS Web site).

5. Payment for Blood Clotting Factors

For CY 2012, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee. That is, for CY 2012, we provided payment for blood clotting factors under the OPPS at ASP+4 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 2012 updated furnishing fee is $0.181 per unit.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45141), we proposed to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician office and inpatient hospital setting, and first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update was based on the percentage increase in the

Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPPS/ASC proposed rules are published, we were not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we proposed to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.

Comment: Commenters supported CMS' proposal to continue to apply the furnishing fee for blood clotting factors provided in the OPD. One commenter stated that the furnishing fee helps ensure patient access to blood clotting factors by increasing the payment rate for these items. These commenters also supported CMS' proposal to pay for separately payable drugs at ASP+6 percent based on the statutory default, for CY 2013.

Response: We appreciate the commenters' support. We continue to believe that applying the furnishing fee for blood clotting factors is appropriate for CY 2013. In addition, because we recognize that there is additional work involved in acquiring the product that is neither acquisition cost nor pharmacy overhead, we believe that it continues to be appropriate to pay a furnishing fee for blood clotting factors under the OPPS as is done in the physician's office setting and the inpatient hospital setting.

Additionally, for the reasons discussed in section V.B.3. of this final rule with comment period, we agree with the commenters that ASP+6 percent based on the statutory default is an appropriate payment rate for CY 2013.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS Web site.

6. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes but without OPPS Hospital Claims Data

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) did not address the OPPS payment in CY 2005 and after 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 is no statutory provision that dictated payment for such drugs, biologicals, and radiopharmaceuticals in CY 2005, and because we had no hospital claims data to use in establishing a payment rate for them, we investigated several payment options for CY 2005 and discussed them in detail in the CY 2005 OPPS final rule with comment period (69 FR 65797 through 65799).

For CYs 2005 to 2007, we implemented a policy to provide separate payment for new drugs, biologicals, and radiopharmaceuticals with HCPCS codes (specifically those new drug, biological, and radiopharmaceutical HCPCS codes in each of those calendar years that did not crosswalk to predecessor HCPCS codes) but which did not have pass-through status, at a rate that was equivalent to the payment they received in the physician's office setting, established in accordance with the ASP methodology for drugs and biologicals, and based on charges adjusted to cost for radiopharmaceuticals. 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 OPPS hospital claims data, at ASP+5 percent and ASP+4 percent, respectively, consistent with the final OPPS 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 nonimplantable biologicals with HCPCS codes that do not have pass-through status and are without OPPS hospital claims data at ASP+4 percent, consistent with the CY 2010 payment methodology for other separately payable nonpass-through drugs and nonimplantable 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 OPPS/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 OPPS hospital claims data at ASP+4 percent. This policy was continued in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71970 through 71973), paying for new drugs, nonimplantable biologicals, and radiopharmaceuticals that do not crosswalk to CY 2010 HCPCS codes, do not have pass-through status, and are without OPPS hospital claims data at ASP+5 percent and the CY 2012 OPPS/ASC final rule with comment period at ASP+4 percent (76 FR 74330 through 74332).

In the CY 2013 OPPS/ASC proposed rule (77 FR 45142), we proposed to provide payment for new CY 2013 drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals, at ASP+6 percent, consistent with the proposed CY 2013 payment methodology for other separately payable nonpass-through drugs, nonimplantable 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, nonimplantable biologicals and therapeutic radiopharmaceuticals would be treated like other drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals under the OPPS.

We also proposed to continue to package payment for all new nonpass-through diagnostic radiopharmaceuticals and contrast agents with HCPCS codes but without claims data (those new CY 2013 diagnostic radiopharmaceuticals, contrast agents, and implantable biological HCPCS codes that do not crosswalk to predecessor HCPCS

codes). This is consistent with the proposed policy packaging all existing nonpass-through diagnostic radiopharmaceuticals and contrast agents, as discussed in more detail in section II.A.3.g. of this final rule with comment period.

In accordance with the OPPS ASP methodology, in the absence of ASP data, for CY 2013, we proposed to continue the policy we implemented beginning in CY 2005 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 and are not diagnostic radiopharmaceuticals and contrast agents. 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" (for separately paid nonpass-through drugs and nonimplantable biologicals, including therapeutic radiopharmaceuticals) to HCPCS codes for new drugs and nonimplantable biologicals without OPPS claims data and for which we have not granted pass-through status. With respect to new, nonpass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals 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 2013 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, nonimplantable biologicals, and therapeutic radiopharmaceuticals would be treated like other drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals 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, for CY 2013 we proposed to announce any changes to the payment amounts for new drugs and biologicals in this CY 2013 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2013 if later quarter ASP submissions (or more recent WACs or AWPs) indicate that changes to the payment rates for these drugs and biologicals are necessary. The payment rates for new therapeutic radiopharmaceuticals would also be changed accordingly based on later quarter ASP submissions. We note that the new CY 2013 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 2013 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 2013 OPPS/ASC final rule with comment period.

There are several nonpass-through drugs and biologicals that were payable in CY 2011 and/or CY 2012 for which we did not have CY 2011 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. We note that there are currently no therapeutic radiopharmaceuticals in this category. In order to determine the packaging status of these products for CY 2013, we calculated an estimate of the per day cost of each of these items by multiplying the payment rate of each product based on ASP+6 percent, similar to other nonpass-through drugs and biologicals paid separately under the OPPS, by an estimated average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting. This rationale was first adopted in the CY 2006 OPPS/ASC final rule with comment period (70 FR 68666 and 68667).

We did not receive any public comments on our proposal to use estimated per day costs for these drugs and biologicals or on the resulting packaging status of these drugs and biologicals. Therefore, for the reasons described in our proposed rule, we are finalizing our CY 2013 proposal, with modification, to use the estimated number of units

per day included in Table 37 below to determine estimated per day costs for the corresponding drugs and biologicals for CY 2013. For those drugs and biologicals without CY 2011 claims data that we determine to be separately payable in CY 2013, payment will be made at ASP+6 percent. If ASP information is not available, payment will be based on WAC, or 95 percent of the most recently published AWP if WAC is not available.

The proposed estimated units per day and status indicators for these items were displayed in Table 27 of the proposed rule (77 FR 45143).

In the CY 2013 OPPS/ASC proposed rule (77 FR 45143), we proposed to package items for which we estimated the per day administration cost to be less than or equal to $80, which is the general packaging threshold that we proposed for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals in CY 2013. We proposed to pay separately for items with an estimated per day cost greater than $80 (with the exception of diagnostic radiopharmaceuticals and contrast agents, which we proposed to continue to package regardless of cost as discussed in more detail in section II.A.3.d. of this final rule with comment period) in CY 2013. We proposed that the CY 2013 payment for separately payable items without CY 2011 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. However, we note that if the WAC is

also unavailable, we would make payment at 95 percent of the most recent AWP available.

Although we did not receive any specific public comments regarding our proposed payment for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes, but without OPPS hospital claims data, many commenters supported our proposal to pay for separately payable drugs at ASP+6 percent under the statutory default. However, these comments were not specific to new drugs and biologicals with HCPCS codes but without OPPS claims data. For more information regarding payment for separately payable drugs, including general public comments and our responses, we refer readers to section V.B.3.b. of this final rule with comment period. In addition, commenters responding to the CY 2013 OPPS/ASC proposed rule objected to packaging payment for diagnostic radiopharmaceuticals and contrast agents in general, but these comments were not directed to new diagnostic radiopharmaceuticals or contrast agent with HCPCS codes but without OPPS claims data. We summarize these comments and provide our response in section II.A.3.e. of this final rule with comment period. We are finalizing our CY 2013 proposal, without modification, as follows: payment for new drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals with HCPCS codes that do not crosswalk to CY 2012 HCPCS codes, but which do not have pass-through status and for which we do not have OPPS hospital claims data, will be made at ASP+6 percent for CY 2013, consistent with the final CY 2013 payment methodology for other new separately payable nonpass-through drugs, nonimplantable biologicals and therapeutic

radiopharmaceuticals, described in section V.B.3.b. of this final rule with comment period. In cases where ASP information is not available, payment will be made using WAC, and, if WAC is also unavailable, payment will be made at 95 percent of the product's most recent AWP. Further, payment for all new nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals with HCPCS codes but for which we do not have OPPS claims data will be packaged for CY 2013. Finally, we are assigning status indicator "K" to HCPCS codes for new drugs and nonimplantable biologicals for which we do not have OPPS claims data and for which we have not granted pass-through status for CY 2012. With respect to new items for which we do not have ASP data, once their ASP data become available in later quarterly submissions, their payments will be adjusted so that the rates will be based on the ASP methodology and set to the finalized ASP amount of ASP+4 percent. This policy will ensure that payment is made for actual acquisition cost and pharmacy overhead for these new products.

For CY 2013, we also proposed to continue our CY 2012 policy to base payment for new therapeutic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and for which we do not have 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 a new therapeutic radiopharmaceutical at 95 percent of the product's most recent AWP because we would not have mean costs from hospital claims data upon which to base payment. Analogous to 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.

We did not receive any public comments specific to our proposal for new therapeutic radiopharmaceuticals with HCPCS codes but without pass-through status. However, commenters responding to the CY 2013 OPPS/ASC proposed rule were generally supportive of the ASP methodology for payment for therapeutic radiopharmaceuticals in the HOPD, and we are finalizing an ASP payment methodology for separately payable therapeutic radiopharmaceuticals for CY 2013, as discussed in section V.B.3.c. of this final rule with comment period.

We are finalizing our CY 2013 proposals, without modification, to provide payment based on WAC for new therapeutic radiopharmaceuticals with HCPCS codes but without pass-through status and for which we do not have claims data, if ASP data for these therapeutic radiopharmaceuticals are not available. If WAC information is also unavailable, we will make payment for new therapeutic radiopharmaceuticals at 95 percent of the product’s most recent AWP. In addition, we are assigning status indicator “K” to HCPCS codes for new therapeutic radiopharmaceuticals without claims data in CY 2013 that do not have pass-through status.

Consistent with other ASP-based payments, for CY 2013, we proposed to announce any changes to the payment amounts for new drugs and biologicals in the CY 2013 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2013 if later quarter ASP submissions (or more recent WACs or AWPs) indicate that changes to the payment rates for these drugs and biologicals are

necessary. The payment rates for new therapeutic radiopharmaceuticals will also be changed accordingly, based on later quarter ASP submissions. We note that the new CY 2013 HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals were not available at the time of development of the proposed rule. However, they are included in Addendum B to this CY 2013 OPPS/ASC final rule with comment period. They are assigned comment indicator "NI" in Addendum B to reflect that their interim final OPPS treatment is open to public comment on this CY 2013 OPPS/ASC final rule with comment period.

We did not receive any public comments on our proposal to announce, via the CMS Web site, any changes to the OPPS payment amounts for new drugs and biologicals on a quarterly basis. Therefore, for the reasons described in the CY 2013 proposed rule, we are finalizing our proposal and will update payment rates for new drugs, biologicals, and therapeutic radiopharmaceuticals, as necessary, in association with our quarterly update process and provide this information on the CMS Web site.

TABLE 36.—DRUGS AND BIOLOGICALS WITHOUT CY 2011 CLAIMS DATA

CY 2013 HCPCS Code	CY 2013 Long Descriptor	Estimated Average Number of Units Per Day	CY 2013 SI	CY 2013 APC
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	55	K	9367
J0630	Injection, calcitonin salmon, up to 400 units	1.5	K	1433
J2793	Injection, Rilonacept	320	K	1291
J7196	Injection, antithrombin recombinant, 50 IU	268	K	1332

CY 2013 HCPCS Code	CY 2013 Long Descriptor	Estimated Average Number of Units Per Day	CY 2013 SI	CY 2013 APC
J8562	Fludarabine phosphate, oral, 10 mg	1	K	1339
J9065	Injection, cladribine, per 1 mg	10	K	0858
J9151	Injection, daunorubicin citrate, liposomal formulation, 10 mg	5	K	0821
J0205	Injection, alglucerase, per 10 units	420	K	0900
J2724	Injection, protein c concentrate, intravenous, human, 10 iu	1540	K	1139
Q0515	Injection, sermorelin acetate, 1 microgram	70	K	3050
J2513	Injection, pentastarch, 10% solution, 100 ml	4	N	N/A
J3355	Injection, urofollitropin, 75 IU	2	K	1741
90581	Anthrax vaccine, for subcutaneous or intramuscular use	1	K	1422
J2265	Injection, minocycline hydrochloride, 1 mg	300	K	1423
J8650	Nabilone, oral, 1 mg	4	K	1424

Finally, there were 19 drugs and biologicals, shown in Table 28 of the proposed rule (77 FR 45144), that were payable in CY 2011, but for which we lacked CY 2011 claims data and any other pricing information for the ASP methodology for the CY 2013 OPPS/ASC proposed rule. In CY 2009, for similar items without CY 2007 claims data and without pricing information for the ASP methodology, we stated that we were unable to determine their per day cost and we packaged these items for the year, assigning these items status indicator "N."

For CY 2010, we finalized a policy to change the status indicator for drugs and biologicals previously assigned a payable status indicator to 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. 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 in CY 2010 for the ASP methodology. If pricing information became available, we would assign the products status indicator "K" and pay for them separately for the remainder of CY 2010. We continued this policy for CY 2011 and CY 2012 (75 FR 71973 and 76 FR 74334).

For CY 2013, we proposed to continue to assign status indicator "E" to drugs and biologicals that lack CY 2011 claims data and pricing information for the ASP methodology. All drugs and biologicals without CY 2011 hospital claims data and data based on the ASP methodology that are assigned status indicator "E" on this basis at the time of the proposed rule for CY 2013 were displayed in Table 28 of the proposed rule (77 FR 45144). If pricing information becomes available, we proposed to assign the products status indicator "K" and pay for them separately for the remainder of CY 2013.

Comment: Several commenters disagreed with CMS' proposal to assign a status indicator "E" to HCPCS code Q4102 (Talymed, per square centimeter) for CY 2013. The commenters requested a status indicator of "K" to more closely align the product with others on the market, such as the products represented by HCPCS code Q4101 and Q4102. The commenters indicated that a status indicator of "E" would make it impossible for the necessary claims data and pricing to be collected.

The manufacturers of the product that is described by HCPCS code Q4101 assured CMS that they will be submitting ASP data shortly and anticipate that CMS will

replace the status indicator “E” with the status indicator “K” upon submission of this data.

Response: For this final rule with comment period, we have not received ASP pricing information in order to assign a status indicator of “K” to HCPCS code Q4101. Therefore, according to our longstanding policy, we will continue to assign HCPCS code Q4101 to a status indicator of “E.” If pricing information becomes available, we will assign HCPCS code Q4101 a status indicator “K” and pay for it separately for the remainder of CY 2013. We cannot assign a payable status indicator to products that have no available payment information.

Comment: One commenter who responded to the CY 2012 OPPS/ASC final rule with comment period expressed concern that the assignment of status indicator “E” to HCPCS code Q4128 was a technical error that should have been changed to status indicator “K” effective January 1, 2012.

Response: For the CY 2012 OPPS/ASC final rule with comment period, HCPCS code Q4128 (Flexhd or allopatch hd, per square centimeter) was not erroneously assigned a status indicator of “E” because we did not have ASP pricing information available to us at the time of the publication of the final rule. However, during CY 2012, we received pricing information for HCPCS code Q4128 and assigned status indicator “K” to this code. For CY 2013, this HCPCS code continues to have a status indicator of “K” and the price is published in Addendum B of this final rule with comment period.

After the proposed rule was published, we were able to use updated CY 2011 claims data and ASP pricing information for HCPCS code J1452 (Injection, fomivirsen

sodium, intraocular, 1.65 mg), HCPCS code J1835 (Injection, itraconazole, 50 mg), and HCPCS code J9212 (Injection, interferon alfacon-1, recombinant, 1 microgram). Therefore, we are assigning HCPCS code J1452, HCPCS code J1835, and HCPCS code J9212 a status indicator of "K" for CY 2013. The revised status indicators for these HCPCS codes are included in Addendum B to this CY 2013 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

Further, as we have used updated claims data and ASP pricing information for this final rule with comment period, we have newly identified HCPCS codes Q4134 (Hmatrix, per square centimeter), Q4135 (Mediskin, per square centimeter), and Q4136 (Ez-derm, per square centimeter) as lacking CY 2011 claims data and any other pricing information for the ASP methodology. Therefore, in addition to the HCPCS codes for which we proposed to assign status indicator "E" for CY 2013 due to a lack of claims data and any other pricing information in the proposed rule, we are assigning status indicator "E" to HCPCS codes Q4134, Q4135, and Q4136.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to assign status indicator "E" to these drugs and biologicals. As was our policy in CY 2012, if pricing information becomes available for these products in CY 2013, we will assign the products status indicator "K" and pay for them separately for the remainder of CY 2013.

All drugs and biologicals without CY 2011 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 2013 are displayed in Table 37 below.

TABLE 37.—DRUGS AND BIOLOGICALS WITHOUT CY 2011 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

CY 2013 HCPCS Code	CY 2013 Long Descriptor	CY 2013 SI
90296	Diphtheria antitoxin, equine, any route	E
90393	Vaccina immune globulin, human, for intramuscular use	E
J3305	Injection, trimetrexate glucuronate, per 25 mg	E
90706	Rubella virus vaccine, live, for subcutaneous use	E
90725	Cholera vaccine for injectable use	E
90727	Plague vaccine, for intramuscular use	E
J0190	Injection, biperiden lactate, per 5 mg	E
J2670	Injection, tolazonline hcl, up to 25 mg	E
J2940	Injection, somatrem, 1 mg	E
J3305	Injection, trimetrexate glucuronate, per 25 mg	E
J3320	Injection, spectinomycin dihydrochloride, up to 2 gm	E
J9165	Injection, diethylstilbestrol diphosphate, 250 mg	E
Q4117	Hyalomatrix, per square centimeter	E
Q4120	Matristem Burn matrix, per square centimeter	E
Q4126	Memoderm, per square centimeter	E
Q4127	Talymed, per square centimeter	E
Q4134	Hmatrix, per square centimeter	E
Q4135	Mediskin, per square centimeter	E
Q4136	Ez-derm, per square centimeter	E

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an "applicable percentage," currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year.

If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate pro rata 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 2013 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 2013. 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 2012 or beginning in CY 2013. The sum of the CY 2013 pass-through estimates for these two groups of device categories equals the total CY 2013 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 2012 OPPS/ASC final rule with comment period (76 FR 74335 through 74336). 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 nonimplantable 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 was not proposed to be reinstated for CY 2013. Because we will pay for most nonpass-through separately payable drugs and nonimplantable biologicals under the CY 2013 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 nonimplantable biologicals, and because we will pay for CY 2013 pass-through drugs and nonimplantable biologicals at ASP+6 percent, as we discussed in section V.A. of this final rule with comment period, our estimate of drug and nonimplantable biological pass-through payment for CY 2013 for this group of items is zero, 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 because these products will never be separately paid. However, all pass-through diagnostic radiopharmaceuticals and contrast agents with pass-through status approved prior to CY 2013 will be paid at ASP+6 percent like other pass-through drugs and nonimplantable biologicals. Therefore, our estimate of pass-through payment for all diagnostic radiopharmaceuticals and contrast agents with pass-through status approved prior to CY 2013 is not zero. In section V.A.4. of this final rule with comment period, we discuss our policy to determine if the cost of certain "policy-

packaged" drugs, including diagnostic radiopharmaceuticals and contrast agents, are already packaged into the existing APC structure. If we determine that a "policy-packaged" drug approved for pass-through payment resembles predecessor diagnostic radiopharmaceuticals or contrast agents already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we are offsetting the amount of pass-through payment for diagnostic radiopharmaceuticals or contrast agents. For these drugs, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through radiopharmaceuticals or contrast agents, which we refer to as the "policy-packaged" drug APC offset amount. If we determine that an offset is appropriate for a specific diagnostic radiopharmaceutical or contrast agent receiving pass-through payment, we reduce our estimate of pass-through payment for these drugs by this amount.

Similar to pass-through estimates for devices, the first group of drugs and nonimplantable biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment for CY 2012 and that will continue to be eligible for pass-through payment in CY 2013. The second group contains drugs and nonimplantable biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2012 or beginning in CY 2013. The sum of the CY 2013 pass-through estimates for these two groups of drugs and nonimplantable biologicals equals the total CY 2013 pass-through spending estimate for drugs and nonimplantable biologicals with pass-through status.

B. Estimate of Pass-Through Spending

In the CY 2013 OPPS/ASC proposed rule (77 FR 45145), we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2013, consistent with section 1833(t)(6)(E)(ii)(II) of the Act, and our OPPS policy from CY 2004 through CY 2012 (76 FR 74336).

For the first group of devices for pass-through payment estimation purposes, there currently are three device categories eligible for pass-through payment for CY 2013: C1830 (Powered bone marrow biopsy needle); C1840 (Lens, intraocular (telescopic)); and C1886 (Catheter, extravascular tissue ablation, any modality (insertable). In the proposed rule, we estimated that CY 2013 pass-through expenditures related to these three eligible device categories would be approximately $42 million. In estimating our CY 2013 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 proposed rule will be newly eligible for pass-through payment in CY 2013 (of which there are none); additional device categories that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2013; and contingent projections for new device categories established in the second through fourth quarters of CY 2013. We proposed to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For the proposed rule, the estimate of CY 2013 pass-through spending for this second group of device categories was $10 million. Using our established methodology, we proposed that the total estimated pass-through spending for device categories for

CY 2013 (spending for the first group of device categories ($42 million) plus spending for the second group of device categories ($10 million)) would be $52 million.

We did not receive any public comments regarding our proposed pass-through spending estimate for devices. Therefore, for CY 2013, we are continuing to use our established methodology for estimating pass-through spending for device categories. For this final rule with comment period, using our established methodology and updated data and information, we estimate CY 2013 pass-through spending for the first group of device categories to be $42, and the CY 2013 pass-through spending for the second group of device categories to be $10 million. The total estimated pass-through spending for device categories for CY 2013 (spending for the first group of device categories ($42 million) plus spending for the second group of device categories ($10 million)) is $52 million.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45146), to estimate CY 2013 pass-through spending for drugs and nonimplantable biologicals in the first group, specifically those drugs (including radiopharmaceuticals and contrast agents) and nonimplantable biologicals recently made eligible for pass-through payment and continuing on pass-through status for CY 2013, we proposed to utilize 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 nonimplantable biologicals, to project the CY 2013 OPPS utilization of the products.

For the known drugs and nonimplantable biologicals (excluding diagnostic radiopharmaceuticals and contrast agents) that will be continuing on pass-through status in CY 2013, in the proposed rule (77 FR 45145), we estimated the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-through drugs and nonimplantable biologicals that will be separately paid at ASP+6 percent, which is zero for this group of drugs. Because payment for a diagnostic radiopharmaceutical or contrast agent is packaged if the product was not paid separately due to its pass-through status, we proposed to include in the CY 2013 pass-through estimate the difference between payment for the 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 diagnostic radiopharmaceutical or contrast agent approved for pass-through payment resembles predecessor diagnostic radiopharmaceuticals or contrast agents already included in the costs of the APCs that are associated with the drug receiving pass-through payment. In the proposed rule, using the proposed methodology described above, we calculated a CY 2013 proposed spending estimate for this first group of drugs and nonimplantable biologicals of approximately $13 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 2013 spending estimate for the first group of drugs and nonimplantable biologicals of approximately $15 million.

In the proposed rule (77 FR 45146), to estimate CY 2013 pass-through spending for drugs and nonimplantable biologicals in the second group (that is, drugs and nonimplantable biologicals that we knew at the time of development of the proposed rule are newly eligible for pass-through payment in CY 2013, additional drugs and nonimplantable biologicals that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2013, and projections for new drugs and nonimplantable biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2013), we proposed to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2013 pass-through payment estimate. We also proposed to consider the most recent OPPS experience in approving new pass-through drugs and nonimplantable biologicals. Using our proposed methodology for estimating CY 2013 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and nonimplantable biologicals of approximately $19 million.

We did not receive any public comments on our proposed methodology for estimating CY 2013 pass-through payments for this second group of drugs and nonimplantable biologicals. Therefore, for this final rule with comment period, are

finalizing our proposed methodology. Using that methodology and updated data and information, we calculated a final CY 2013 spending estimate for this second group of drugs and implantable biologicals of approximately $7 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 2013 pass-through spending estimate for drugs and nonimplantable biologicals. Our CY 2013 estimate for total pass-through spending for drugs and nonimplantable biologicals (spending for the first group of drugs and nonimplantable biologicals ($15 million) plus spending for the second group of drugs and nonimplantable biologicals ($7 million)) equals $22 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 nonimplantable biologicals that are continuing to receive pass-through payment in CY 2013 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2013 will be approximately $74 million (approximately $52 million for device categories and approximately $22 million for drugs and nonimplantable biologicals), which represents 0.15 percent of total projected OPPS payments for CY 2013. We estimate that pass-through spending in CY 2013 will not amount to 2.0 percent of total projected OPPS CY 2013 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 visits, and critical care services, including trauma team activation. As we proposed in the CY 2013 OPPS/ASC proposed rule (77 FR 45146 through 45148), for CY 2013, we are continuing to recognize these CPT and HCPCS codes describing clinic visits, Type A and Type B emergency department visits, and critical care services, which are listed below in Table 38, for CY 2013. 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 longstanding policy on OPPS payment for hospital outpatient visits.

TABLE 38.—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

At its August 27-28, 2012 meeting, the HOP Panel recommended that CMS move HCPCS code G0379 (Direct admission of patient for hospital observation care) to APC 0608 (Level 5 Hospital Clinic Visits). We are accepting this recommendation, as discussed below in this section.

B. Policies for Hospital Outpatient Visits

We proposed in the CY 2013 OPPS/ASC proposed rule (77 FR 45147 through 45148), for CY 2013, to continue our longstanding policies related to hospital outpatient visits, which includes clinic visits, emergency department visits, and critical care services. Specifically, we proposed to continue to recognize the definitions of a new patient and an established patient, which are based on whether the patient has been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit. We also proposed to continue to apply our policy of calculating costs for clinic visits under the OPPS using historical hospital claims data through five levels of clinic visit APCs (APCs 0604 through 0608). In addition, we proposed to continue to recognize Type A emergency departments and Type B emergency departments for payment purposes under the OPPS, and to pay for Type A emergency department visits based on their costs through the five levels of Type A emergency department APCs (APCs 0609 and 0613 through 0616) and to pay for Type B emergency department visits based on their costs through the five levels of Type B emergency department APCs (APCs 0626 through 0630). 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 APC assignments and payment rates for these hospital outpatient visits. Finally, we proposed to continue to

instruct hospitals to report facility resources for clinic and emergency department hospital outpatient visits using the CPT E/M codes and to develop internal hospital guidelines for reporting the appropriate visit level. We note that our continued expectation is that hospitals' internal guidelines will comport with the principles listed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66805). We encourage hospitals with specific questions related to the creation of internal guidelines to contact their servicing fiscal intermediary or MAC. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74338 through 74346) for a full historical discussion of these longstanding policies. We note recent reports in the public media of billing inaccuracies in hospital outpatient clinic visits, and remind hospitals that we are committed to vigorously enforcing our payment policies and will pursue appropriate action against any potentially fraudulent activities we identify.

We also proposed to continue the methodology established in the CY 2011 OPPS/ASC final rule with comment period for calculating a payment rate for critical care services that includes packaged payment of ancillary services. For 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 OPPS 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 OPPS/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 OPPS/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 OPPS payment status indicated for status indicator "Q3" in Addendum D1 to the CY 2011 OPPS/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 reflect the CPT billing guidance that was in effect prior to CY 2011, in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74343 through 74344), we continued the methodology established in the CY 2011 OPPS/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 OPPS/ASC proposed rule (77 FR 45148), 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. Because our policy to establish relative payment weights based on geometric mean cost data for CY 2013 represents a change from our historical practice to base payment rates on median costs, and because we now have 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 proposed rule and determined that the data show increases in both the mean and median line item costs as well as the mean and median line item charges for CPT code 99291, when compared to CY 2010 hospital claims data. Specifically, the mean and median line item costs increased 13 percent and 16 percent, respectively, and the 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 are present on the same claims as critical care services, and also showed continued low volumes of many ancillary services. We stated in the proposed rule 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 suggests 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 proposed rule that we continue 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 proposed, to continue 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 proposed to continue to implement claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment. We stated that we will continue to monitor the hospital claims data for CPT code 99291 in order to determine whether revisions to this policy are warranted based on changes in hospitals' billing practices.

Comment: One commenter indicated that because hospitals have used internal, hospital-defined guidelines for over 10 years, CMS should not move to standard national guidelines. In the absence of national guidelines for visit reporting, some commenters urged CMS to support a request to the AMA's CPT Editorial Panel to create unique CPT codes for hospital reporting of emergency department and clinic visits.

Response: We agree with the commenter that we should not move to national guidelines for visits in CY 2013. As we have in the past (76 FR 74345 through 74346), we acknowledge that it would be desirable to many hospitals to have national guidelines. 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 while we address the problems that would be inevitable in the case of any new set of guidelines that would be applied by thousands of hospitals. As we have also stated in the past (76 FR 74346), if the AMA were to create facility-specific CPT codes for reporting visits provided in HOPDs [based on internally developed guidelines], we would consider such codes for OPPS use.

Comment: One commenter recommended that CMS reassign HCPCS code G0379 to APC 0608 (Level 5 Hospital Clinic Visits) because of the consistent 2 times rule violation in APC 0604 (Level 1 Hospital Clinic Visits) and HCPCS code G0379's similarity in both mean cost and clinical characteristics to CPT code 99205 (Office or other outpatient visit for the evaluation and management of a new patient (Level 5)). The commenter pointed out that the mean cost for HCPCS code G0379 is more similar to the mean cost for APC 0608 than it is to the mean cost for APC 0604. The commenter argued that the resources associated with HCPCS code G0379 resemble those expended for high-level clinic visits more than resources for low-level clinic visits, and noted that CMS' claims logic for composite APC 8002 (Level I Extended Assessment and Management) treats HCPCS code G0379 similarly to high-level clinic visit CPT codes

99205 and 99215 (Office or other outpatient visit for the evaluation and management of an established patient (Level 5)).

Response: We agree with the rationale set forth by the commenter and with the Panel, which recommended CMS reassign HCPCS code G0379 from APC 0604 to APC 0608. Therefore, we are reassigning HCPCS code G0379 to APC 0608 for CY 2013.

Comment: Commenters recommended that CMS, in setting the payment rate for critical care services by estimating the costs of the packaged ancillary services, establish a methodology that includes review of multiple cost report revenue centers.

Response: The methodology 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 mean cost calculation for critical care.

Comment: One commenter argued that the ancillary services associated with critical care do not meet CMS' criteria for packaging. The commenter suggested that, rather than packaging the ancillary services associated with critical care, CMS use

CY 2008 cost data for CPT code 99291 updated with an overall inflation factor to recalculate the cost of critical care exclusive of bundled ancillary services.

Response: As we discussed above in this section and in the CY 2013 OPPS/ASC proposed rule (76 45147 through 45148), the policy to package ancillary services associated with critical care was implemented in CY 2011 and resulted from a change in CPT guidance effective January 1, 2011. We packaged the ancillary services because the costs of those ancillary services were already intrinsically included in the cost calculated for critical care; to pay for the ancillary services separately result in overpayment. Because the claims data for critical care for CY 2011 do not reflect that hospitals have changed their billing practices in response to the revised CPT guidance effective January 1, 2011–that is, they have not adjusted their charging practices to reflect that the ancillary services are no longer included in the definition of critical care–we continue to believe that the costs of the ancillary services continue to be reflected in the hospitals' charges for critical care, and that to pay separately for the ancillary services would be inappropriate. We also do not agree with the commenter that we should use claims data from CY 2008 to calculate costs for critical care. We remind the commenter that the OPPS is a system of averages, in which the costs of services, calculated from the most recent year's claims data, are weighted relative to the other services in the system, for that given year. To utilize a payment rate derived from claims outside of the most recent claims data, despite any update by the overall inflation factor, would be inconsistent with the standard methodology of the OPPS, and would not allow for that service to be appropriately valued relative to the other services in the OPPS.

After consideration of the public comments we received, we are finalizing our CY 2013 proposals related hospital outpatient visits, with one modification. As described above, we are reassigning HCPCS code G0379 to APC 0608 for CY 2013.

C. Transitional Care Management

In the CY 2013 MPFS proposed rule (77 FR 44774 through 44780), we discussed a multiple year strategy exploring the best means to encourage the provision of primary care and care coordination services to Medicare beneficiaries. As part of the strategy discussed in that proposed rule, we proposed to address the non-face-to-face work involved in hospital or SNF discharge care coordination by creating a HCPCS G-code for care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital stay (inpatient, outpatient observation services, or outpatient partial hospitalization), SNF stay, or CMHC partial hospitalization program to care furnished by the beneficiary's physician or qualified nonphysician practitioner in the community. As discussed in the CY 2013 MPFS proposed rule, care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital or a SNF stay to the beneficiary's primary physician or qualified nonphysician practitioner in the community could avoid adverse events such as readmissions or subsequent illnesses, improve beneficiary outcomes, and avoid a financial burden on the health care system. Successful efforts to improve hospital discharge care coordination and care transitions could improve the quality of care while simultaneously decreasing costs.

The proposed HCPCS G-code included in the CY 2013 MPFS proposed rule, GXXX1, specifically describes post-discharge transitional care management services, which include all non-face-to-face services related to the transitional care management, furnished by the community physician or nonphysician practitioner within 30 calendar

days following the date of discharge from an inpatient acute care hospital, psychiatric hospital, LTCH, SNF, and IRF; discharge from hospital outpatient observation or partial hospitalization services; or discharge from a PHP at a CMHC, to the community-based care. The post-discharge transitional care management services include non-face-to-face care management services provided by clinical staff member(s) or office-based case manager(s) under the supervision of the community physician or qualified nonphysician practitioner.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45148 through 45159), we stated that while we do not pay for physician or nonpractitioner professional services under the OPPS (42 CFR 419.22), we recognize that certain elements of the transitional care coordination services described by proposed HCPCS code GXXX1 could be provided to a hospital outpatient as an ancillary or supportive service in conjunction with a primary diagnostic or therapeutic service that would be payable under the OPPS, such as a clinic visit. We stated that, as described in section II.A.3. of the proposed rule, we package payment for services that are typically ancillary and supportive to a primary service. While we do not make separate payment for such services, their costs are included in the costs of other services furnished by the hospital to the beneficiary on the same day. We indicated in the CY 2013 OPPS/ASC proposed rule that, because transitional care management services described by HCPCS code GXXX1 may be ancillary and supportive to a primary service provided to a hospital outpatient, we proposed to assign HCPCS code GXXX1 a status indicator of "N" (Items and Services

Packaged into APC Rates), signifying that its payment would be packaged (77 FR 45159).

Comment: The majority of commenters supported the proposed development of a HCPCS G-code to identify the non-face-to-face work involved in hospital or SNF discharge care coordination. Some commenters supported establishing a HCPCS G-code as a short-term solution to capture the non-face-to-face services, but suggested that in the long term, CMS consider generating new CPT codes specific to the post-discharge transitional care management that would also capture face-to-face components of transitional care. Some commenters also stated that the requirements for billing the post-discharge transitional care services (regardless of whether they are identified with the new HCPCS G-code or a CPT code) should not be arduous or complex. A few commenters expressed concern that the proposed HCPCS G-code for transitional care management would be duplicative of discharge day management services described by other CPT codes. Some commenters requested that CMS establish a separate APC for the proposed HCPCS G-code with a status indicator of "S" or "X" for transitional care management services or assign the HCPCS G-code to APC 0605 (Level 2 Hospital Clinic Visits).

Response: For the reasons outlined in the CY 2013 MPFS final rule with comment period, we are adopting the following CPT transitional care management codes in place of the proposed HCPCS G-code: CPT code 99495 (Transitional care management services w/ moderate medical decision complexity; Face to face visit within 14 days) and CPT code 99496 (Transitional care management services w/ high medical

decision complexity; Face to face visit within 7 days). We agree with the commenters that the requirements for billing the post-discharge transitional care management services should not be arduous or complex, and we refer readers to the CY 2013 MPFS final rule with comment period for a full discussion of the billing requirements for CPT codes 99495 and 99496. We also refer readers to the CY 2013 MPFS final rule with comment period for a full discussion of why we do not believe that recognition of the transitional care management services described by CPT codes 99495 and 99496 is duplicative of services described by other CPT codes.

The CPT transitional care management code 99495 includes the following required elements:

- Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge;
- Medical decision-making of at least moderate complexity during the service period; and
- Face-to-face visit, within 14 calendar days of discharge.

CPT code 99496 includes the following required elements:

- Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge;
- Medical decision-making of high complexity during the service period; and
- Face-to-face visit, within 7 calendar days of discharge.

As we describe in the CY 2013 MPFS final rule with comment period, the services described by CPT codes 99495 and 99496 are for an established patient whose

medical and/or psychosocial problems require moderate or high complexity medical decision-making during transitions in care from an inpatient hospital setting (including acute hospital, rehabilitation hospital, long-term acute care hospital), partial hospital, observation status in a hospital, or SNF/nursing facility, to the patient's community setting (home, domiciliary, rest home, or assisted living). Transitional care management commences upon the date of discharge and continues for the next 29 days.

Transitional care management is comprised of one face-to-face visit within the specified timeframes, in combination with non-face-to-face services that may be performed by the physician or other qualified health care professional and/or licensed clinical staff under his or her direction. Because the transitional care management services described by CPT codes 99495 and 99496 involve at least one face-to-face visit, (unlike the proposed HCPCS G-code), we believe that CPT codes 99495 and 99496 represent a primary, independent service that should be separately payable under the OPPS. We are assigning CPT code 99495 to APC 0605 (Level 2 Hospital Clinic Visit) and CPT code 99496 to APC 0606 (Level 3 Hospital Clinic Visit) on an interim basis for CY 2013. As with all new CPT codes, these interim assignments are open to public comment for a period of 60 days following the publication of this final rule with comment period.

As we discuss in the CY 2013 MPFS final rule with comment period, we are adopting these new transitional care management codes to provide a separate reporting mechanism to the community physician for these services in the context of the broader CMS multi-year strategy to recognize and support primary care and care management.

We wish to emphasize again that the policies we are finalizing in this final rule with comment period may be short-term payment strategies that may be modified and/or revised over time to be consistent with broader primary care and care management initiatives. We refer readers to the CY 2013 MPFS final rule with comment period for a full discussion of post-discharge transitional care management services in particular and, more broadly, the multiple year strategy exploring the best means to encourage primary care and care coordination services.

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 plan 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 community mental health center.

Section 1833(t)(1)(B)(i) of the Act provides the Secretary with the authority to designate the OPD services to be covered under the OPPS. The Medicare regulations that implement this provision specify, at 42 CFR 419.21, that payments under the OPPS

will be made for partial hospitalization services furnished by CMHCs as well as Medicare Part B services furnished to hospital outpatients designated by the Secretary, which include partial hospitalization services (65 FR 18444 through 18445).

Section 1833(t)(2)(C) of the Act, in pertinent part, requires the Secretary to "establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs" using data on claims from 1996 and data from the most recent available cost reports. In pertinent part, subparagraph (B) provides that the Secretary may establish groups of covered OPD services, within a classification system developed by the Secretary for covered OPD services, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we have developed the 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 in the CY 2008 update (72 FR 66670 through 66676). We made two refinements to the methodology for computing the PHP median: the first remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers; and the second refined our methodology for computing the PHP median per diem cost by computing a separate per diem cost for each day rather than for each bill. We refer readers to a complete discussion of these refinements in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676).

In CY 2009, we implemented several regulatory, policy, and payment changes, including a two-tiered payment approach for PHP services under which we paid one amount for days with 3 services (APC 0172 (Level I Partial Hospitalization)) and a higher amount for days with 4 or more services (APC 0173 (Level II Partial Hospitalization)). We refer readers to section X.B. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68693) for a full discussion of the two-tiered payment system. In addition, for CY 2009, we finalized our policy to deny payment for any PHP claims submitted for days when fewer than 3 units of therapeutic services are provided (73 FR 68694).

Furthermore, for CY 2009, we revised the regulations at 42 CFR 410.43 to codify existing basic PHP patient eligibility criteria and to add a reference to current physician certification requirements at 42 CFR 424.24 to conform our regulations to our longstanding policy (73 FR 68694 through 68695). These changes have helped to strengthen the PHP benefit. We also revised the partial hospitalization benefit to include several coding updates. We refer readers to section X.C.3. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68695 through 68697) for a full discussion of these requirements.

For CY 2010, we retained the two-tiered payment approach for PHP services and used only hospital-based PHP data in computing the APC per diem payment rates. We used only hospital-based PHP data because we were concerned about further reducing both PHP APC per diem payment rates without knowing the impact of the policy and payment changes we made in CY 2009. Because of the 2-year lag between data collection and rulemaking, the changes we made in CY 2009 were reflected for the first time in the claims data that we used to determine payment rates for the CY 2011 rulemaking (74 FR 60556 through 60559).

In CY 2011, in accordance with section 1301(b) of the Health Care and Education Reconciliation Act of 2010 (HCERA 2010), we amended the description of a PHP in our regulations to specify that a PHP must be a distinct and organized intensive ambulatory treatment program offering less than 24-hour daily care "other than in an individual's home or in an inpatient or residential setting." In addition, in accordance with section 1301(a) of HCERA 2010, we revised the definition of a CMHC in the regulations to

conform to the revised definition now set forth at 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). In the CY 2011 OPPS/ASC proposed rule, we proposed that CMHC APC medians would be based only on CMHC data and hospital-based PHP APC medians would be based only on hospital-based PHP data (75 FR 46300). 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 CY 2009 policies. 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. 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, given that hospital-based PHPs offer the widest access to PHP services because they are located across the country. 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 APC 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 medians and the CY 2011 final CMHC medians and then adding that number to the CY 2011 final CMHC medians. 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 may, based on these analyses, 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 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 APCs, as set forth in 42 CFR 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." However, we used 1996 data (plus 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."

B. PHP APC Update for CY 2013

In the CY 2013 OPPS/ASC proposed rule (77 FR 45094 through 45098 and 45151), we proposed to develop the relative payment weights that underpin the OPPS using geometric means rather than the current median-based methodology. We stated that this proposal to base the relative payment weights on geometric means would also apply to the per diem costs used to determine the relative payment weights for the four PHP APCs (77 FR 45151). We stated that, for PHP APCs, as with all other OPPS APCs, the proposal to base the relative payment weights on geometric means rather than medians would not affect the general process to establish appropriate claims for modeling. We stated that, as with the current median-based methodology, the PHP APC per diem payment rates would continue to be calculated by computing a separate per diem cost for each day of PHP service. When there are multiple days of PHP services entered on a claim, a unique cost would continue to be computed for each day of care. However, a geometric mean would be used to calculate the per diem costs rather than a median. We stated that the process would still be repeated separately for CMHCs and hospital-based PHPs using that provider's claims data for the two categories of days with 3 services and days with 4 or more services. We stated that the four PHP APC per diem

costs would continue to be included in the scaling of all APCs under the OPPS to the mid-level office visit (APC 0606). For a detailed discussion of the CY 2013 OPPS weight scaler, we refer readers to section II.A.4. of this final rule with comment period.

In the CY 2013 OPPS/ASC proposed rule, for CY 2013, using CY 2011 claims data, 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) services using only CY 2011 CMHC claims data, and hospital-based PHP APC geometric mean per diem costs for Level I and Level II services using only CY 2011 hospital-based PHP claims data. These proposed geometric mean per diem costs were shown in Table 30 of the CY 2013 OPPS/ASC proposed rule (77 FR 45151) and are reprinted below.

REPRINTED TABLE 30.--PROPOSED CY 2013 GEOMETRIC MEAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHP SERVICES, BASED ON CY 2011 CLAIMS DATA

APC	Group Title	Proposed Geometric Mean Per Diem Costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$87.76
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	111.89
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	182.66
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	232.74

Under the CY 2013 proposal to base the OPPS relative payment weights on geometric mean costs, the proposed geometric mean per diem costs for CMHCs would continue to be substantially lower than the proposed geometric mean per diem costs for hospital-based PHPs for the same units of service. For CY 2013, the proposed geometric mean per diem costs for days with 3 services (Level I) were approximately $88 for

CMHCs and approximately $183 for hospital-based PHPs. The proposed geometric mean per diem costs for days with 4 or more services (Level II) were approximately $112 for CMHCs and approximately $233 for hospital-based PHPs. We stated that this analysis indicated that there continue to be fundamental differences between the cost structures of CMHCs and hospital-based PHPs.

The CY 2013 proposed geometric mean per diem costs for CMHCs calculated under the proposed CY 2013 methodology using CY 2011 claims data also have decreased compared to the CY 2012 final median per diem costs for CMHCs established in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352), with per diem costs for Level I services decreasing from approximately $98 to approximately $88, and costs for Level II services decreasing from approximately $114 to approximately $112. In contrast, the CY 2013 proposed geometric mean per diem costs for hospital-based PHPs calculated under the proposed CY 2013 methodology using CY 2011 claims data have increased compared to the CY 2012 final median per diem costs for hospital-based PHPs, with per diem costs for Level I services increasing from approximately $161 to approximately $183, and per diem costs for Level II services increasing from approximately $191 to approximately $233.

To provide a comparison in the CY 2013 OPPS/ASC proposed rule, we also calculated PHP median per diem costs for CY 2013 using CY 2011 claims data (77 FR 45151 through 45152). We computed median per diem costs for each provider type using that provider's claims data for Level I services and for Level II services.

These comparative median per diem costs were shown in Table 31 of the CY 2013 OPPS/ASC proposed rule (77 FR 45152) and are reprinted and discussed below.

REPRINTED TABLE 31.--COMPARATIVE PHP MEDIAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHP SERVICES, BASED ON CY 2011 CLAIMS DATA AS SET FORTH IN THE CY 2013 OPPS/ASC PROPOSED RULE		
APC	**Group Title**	**Comparative Median Per Diem Costs**
0172	Level I Partial Hospitalization (3 services) for CMHCs	$87.52
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	121.27
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	163.86
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	224.57

The proposed geometric mean per diem costs for hospital-based PHPs for Level I and Level II services calculated under the proposed CY 2013 methodology using CY 2011 claims data would be higher than the median per diem costs calculated under the current median-based methodology, using CY 2011 claims data. For hospital-based PHPs, the per diem costs would increase from approximately $164 under the current median-based methodology to approximately $183 under the proposed geometric mean-based methodology for Level I services, and from approximately $225 to approximately $233 for Level II services.

The proposed geometric mean per diem costs for CMHCs for Level I services calculated under the proposed CY 2013 methodology using CY 2011 claims data would be approximately the same as the median per diem costs calculated under the current median-based methodology, using CY 2011 claims data. The proposed geometric mean

per diem costs for CMHCs for Level II services calculated under the proposed CY 2013 methodology using CY 2011 claims data would be slightly lower than the median per diem costs calculated under the current median-based methodology, using CY 2011 claims data. For CMHCs, the per diem costs would be approximately $88 under both the current median-based methodology and the proposed geometric mean-based methodology for CMHC Level I services, and would decrease from approximately $121 under the current median-based methodology to approximately $112 under the proposed geometric mean-based methodology for CMHC Level II services.

We stated that the data analysis also shows that the median per diem costs for CMHCs continue to be substantially lower than the median per diem costs for hospital-based PHPs for the same units of service provided. The median per diem costs for Level I services were approximately $88 for CMHCs and approximately $164 for hospital-based PHPs. The median per diem costs for Level II services were approximately $121 for CMHCs and approximately $225 for hospital-based PHPs. We stated that the significant difference in per diem costs between CMHCs and hospital-based PHPs emphasizes the distinct cost structures between the two provider types.

Finally, we stated that the data analysis indicates that CMHC median per diem costs for Level I services would have decreased from CY 2012 final median per diem costs (using CY 2010 claims data) (established in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352)) to CY 2013 (using CY 2011 claims data) from approximately $98 to approximately $88, using only CMHC claims data. The CMHC median per diem costs for Level II services would have slightly increased from CY 2012

final median per diem costs (using CY 2010 claims data) to CY 2013 (using CY 2011 claims data) from approximately $114 to approximately $121, using only CMHC claims data. Hospital-based PHP median per diem costs for Level I and Level II services would have increased from the CY 2012 final median per diem costs (using CY 2010 claims data) to CY 2013 (using CY 2011 claims data) from approximately $161 to approximately $164 for Level I services and from approximately $191 to approximately $225 for Level II services, using only hospital claims data.

In summary, while we have historically based the OPPS payments on median costs for services in the APC groups, for CY 2013, we proposed to calculate the relative payment weights for the OPPS APCs using geometric means, including the four PHP APCs, as discussed in section II.A.2.f. of the proposed rule. We invited public comments on these proposals.

Comment: A few commenters representing CMHCs opposed the proposed conversion from the historically applied median-based methodology to the geometric mean-based methodology and the resulting CMHC payment rates. The commenters believed that the median cost approach is more stable and less sensitive to extreme observations and, therefore, a more appropriate methodology. One CMHC commenter preferred the median-based methodology because it resulted in a higher payment rate for the CMHC APC for Level II services than when calculated using a geometric mean-based methodology. The commenters recommended that CMS continue using a median-based methodology and not change to a geometric mean-based methodology for calculating the per diem costs.

Response: We acknowledge the commenters' concern about the change from the median-based methodology to the geometric mean-based methodology and its impact on CMHCs. In the CY 2013 OPPS/ASC proposed rule, we proposed to develop the OPPS relative payment weights using geometric mean cost for all APCs that were previously calculated using median cost, including the PHP APCs (77 FR 45094 through 45098 and 45151). Under the CY 2013 proposal, OPPS payments to CMHCs for partial hospitalization also would be calculated based on geometric mean per diem costs, rather than the previous use of median per diem costs. This would help ensure that the relativity of the OPPS payment weights was properly aligned. As discussed in section II.A.2.f. of this final rule with comment period, we do not believe that paying for some services based on median costs while using geometric mean costs for other services is appropriate, equitable, or consistent with statute. Therefore, our CY 2013 proposal was to develop the OPPS relative payment weights using geometric mean costs for any services previously calculated using median costs, whether that was on a standard, per diem, or line item basis (77 FR 45097).

In the CY 2013 OPPS/ASC proposed rule, we recognized that median costs had historically served as an appropriate measure on which to establish relative payment weights. However, in our proposal to establish the CY 2013 OPPS relative payment weights using geometric mean cost, we discussed a number of reasons why we believed that changing to geometric mean cost would represent an incremental improvement as well as be appropriate. These reasons included changes CMS has made throughout the history of the OPPS with the goal of deriving more accurate information from available

claims and cost report data, as well as benefits of using a metric that more accurately describes the range of costs associated with providing services.

While commenters have suggested that medians are more appropriate because they are less sensitive to outlier observations, in particular for CMHCs, we believe that including those outlier observations in developing the weights and capturing the full range of service costs will lead to more accurate relative payment weights. In addition to better incorporating those cost values that surround the median and, therefore, describing a broader range of cost patterns, basing the relative payment weights on geometric mean costs may also promote better stability in the payment system by making OPPS payments more reflective of the range of costs associated with providing services. In the short term, geometric mean-based relative payment weights would make the relative payment weights more reflective of the service costs. However, making this change also may promote more payment stability in the long term by including a broader range of observations in the relative payment weights, making them less susceptible to gaps in estimated cost near the median observation and also making changes in the relative payment weight a better function of changes in estimated service costs.

We note that using the geometric means would increase the relative payment weights for some services and decrease the relative payment weights for others. We believe those updated relative payment weights to be more reflective of the costs associated with providing those services, which is consistent with the goal of developing relative payment weights that accurately describe service costs. As described in the CY 2013 OPPS/ASC proposed rule, we have made a number of changes in the history of

the OPPS to derive more information from what is available to us and ensure that the cost information we use for ratesetting is as accurate as possible. We believe that making changes consistent with those goals is preferable, rather than choosing one methodology or another simply due to the numeric payment rates that arise from any different methodology.

Thus, for the reasons discussed above, 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 will lead to relative payment weights that are more reflective of service cost patterns. For these reasons, we disagree with the commenters' assertion that use of the median-based methodology is a preferable option. We believe that this change is appropriate and requires all OPPS services previously paid through median-based calculations (including CMHC based per diem costs) to transition together to geometric mean cost calculations to establish accurate cost relativity in the system. Therefore, we are finalizing the geometric mean-based methodology in this final rule with comment period. For a more detailed discussion of geometric mean-based relative payment weights, we refer readers to section II.A.2.f. of this final rule with comment period.

Comment: Several hospital-based PHP providers supported the conversion from a median-based methodology to a geometric mean-based methodology and the resulting hospital-based PHP per diem payments. These commenters also recommended that CMS continue to recognize the cost structure differences between hospital-based PHPs and CMHCs by calculating four separate PHP APCs based on each providers' own unique

data, and stated that it was a necessary improvement to help ensure PHP access in hospital-based settings for the future. The commenters also encouraged CMS to continue to refine data analysis strategies that help bring payment accuracy as well as stability to the partial hospitalization benefit in order to allow programs that meet the needs of Medicare beneficiaries to exist.

Response: We appreciate the commenters' support of the two-tiered, four PHP APC per diem payment rates based on each providers' own unique data. 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, which will support continued access to quality services. We are constantly monitoring the OPPS in search of potential refinements that would improve the accuracy and stability of the payment system. Over the past several years, we have made changes to PHP APC per diem payment rates to more accurately align the payments with costs. These changes have included establishing separate APC per diem payment rates for CMHCs and hospital-based providers based on each providers' costs as well as a two-tiered APC per diem payment rate for both CMHC and hospital-based PHPs under which we pay one amount for days with 3 services and another amount for days with 4 or more services. As discussed in the CY 2013 OPPS/ASC proposed rule, we believe that the use of geometric mean costs rather than median costs in the ratesetting process is another improvement, because it allows the payment metric to consider a broader range of service costs among other factors (77 FR 45097). We will continue to monitor the impact of our payment policies on the PHP benefit and providers.

Comment: A few CMHC providers requested that CMS suspend implementation of the proposed PHP APC per diem payment rates for CMHCs and maintain the current CY 2012 CMHC PHP APC per diem payment rates as a means to preserve CMHCs. The commenters stated that many of the CMHCs throughout the country have already closed due to CMS' ongoing payment rate reductions. Another commenter stated that no business in the United States or anywhere else in the world can survive and continue to operate after such a decrease over 3 years. The commenter further stated that it appeared that the goal of CMS was to substantially reduce the total number of CMHCs participating in the Medicare program and consequentially reduce payments nationwide. One commenter expressed concern that, instead of being rewarded, CMHCs are being targeted and punished for providing more cost-effective services than the hospital-based PHPs. This same commenter was "highly offended" by the following sentence from the CY 2012 OPPS/ASC proposed rule (77 FR 45150): "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 the sentence implies "CMHCs provide less valuable services than hospital-based PHPs, hire less qualified staff, and overall perform very poorly compared to hospital based PHPs."

Several commenters expressed concern that the proposed reductions to the CMHC PHP APC per diem payment rates could further erode the viability of the safety net system, and make it more difficult for patients to receive needed mental health care and

services. One of these commenters also stated that if patients are unable to receive care in a CMHC, many will have only the emergency departments as a last resort.

Response: We understand the concerns raised by the commenters regarding CMHC APC per diem payment rate reductions. We are not targeting or trying to punish specific providers, and we are not trying to reduce the number of CMHCs participating in the Medicare program. However, 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 services. CMHCs' costs have fluctuated significantly and then generally declined over the years. CMHCs' costs also have remained significantly lower than hospital-based PHPs' costs, which have been relatively stable since the inception of the OPPS. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74347), we stated that CMHCs have a lower cost structure than hospital-based PHP providers 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 offend any of our providers. We also did not mean to imply that, in comparison to hospital-based PHPs, CMHCs provide inferior, less valuable

or poor quality services; we were only stating the differences in these providers' cost structures based on our cost analysis.

In light of these differences in cost structures between provider types, it was inappropriate to continue to treat CMHCs and hospital-based PHP providers in the same manner. We were concerned that paying hospital-based PHPs at a lower 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. 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. We believe that the CMHC APC per diem payment rates accurately reflect the cost data of the CMHCs.

The PHP APC per diem payment rates are directly related to the accuracy of the claims and cost reports submitted by providers. It is imperative that providers submit accurate claims and cost reports in order for the payment rates to most accurately reflect the providers' costs. The resulting PHP APC per diem payment rates reflect the cost of what providers expend to maintain such programs. So, it is unclear 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 any number of reasons, such as poor business management or marketing decisions, competition, over-saturation of certain geographic areas, and Federal and State fraud and abuse efforts,

among others. It does not directly imply that closure could be due to reduced payment rates alone, especially when these payment rates reflect the costs of PHP providers.

In response to the commenters' concerns that further reduction in the CMHC PHP APC per diem payment rates could further erode the viability of the safety net system and make it more difficult for patients to receive needed mental health services, we take such concerns seriously. Currently, 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. We also remain steadfast in our concern regarding access to care for all beneficiaries, while also providing appropriate payments for such care. A PHP is not the only program in which a Medicare beneficiary is able to receive needed mental health care. Although not equivalent to a PHP, Medicare provides payment for outpatient mental health services in addition to PHP services. Many beneficiaries in need of mental health treatment receive other outpatient services generally from hospital programs which are available nationwide, and no evidence suggests that there is an increase in adverse outcomes due to lack of access to care. Other forms of access to mental health services remain available. We continue to believe that it is important to calculate PHP APC per diem payment rates based on the data of each type of provider in order to appropriately pay for PHP services, which will support continued access to quality services.

Commenters also requested that we suspend implementation of the proposed CY 2013 PHP APC per diem payment rates for CMHCs, and that we pay based on the CY 2012 per diem payment rates to preserve CMHCs. As discussed above, we cannot establish payment rates that do not accurately reflect the current cost data. We believe

that having separate payment rates for CMHCs and hospital-based providers based on each providers' costs as well as a two-tiered APC per diem payment rate for both CMHC and hospital-based PHPs under which we pay one amount for days with 3 services and another amount for days with 4 or more services along with using geometric means to more accurately reflect the costs associated with providing OPPS services supports the PHP benefit and pays providers appropriately for the services that they provide. For these reasons, we are not suspending implementation of the CY 2013 PHP APC per diem payment rates for CMHCs.

Comment: One commenter stated that the database of claim payments used in calculating the new payment rates includes at least two providers indicted for fraud, and recommended that these claims be removed.

Response: We strive to ensure that the claims we use for modeling the OPPS payment rates contain accurate cost information on services. In addition, we note that providers with questionable data are subject to further investigation. We request that the commenter provide us with more details regarding those providers.

Comment: One 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. Another commenter recommended that CMS establish quality and outcome criteria to judge performance that would influence future ratesetting, and provide rewards to individual providers for outstanding quality and outcomes.

Response: Sections 1833(t)(2) and 1833(t)(9) of the Act set forth the requirements for establishing and adjusting the OPPS payment rates, including the PHP payment rates. The existing policies and procedures implementing these statutory provisions do not consider quality measures when setting base payment rates. However, we note that section 1833(t)(17) of the Act implements an outpatient quality reporting program for subsection (d) hospitals that applies a payment reduction for hospitals that fail to meet the program requirements.

Comment: One commenter requested that CMS establish a ratesetting task force to review the CMS ratesetting methodology and CMHCs' and hospital-based PHPs' costs as a means to identify fair and adequate payment rates for both. Another commenter requested an open discussion with CMS and associations whose members are PHP providers.

Response: We maintain positive working relationships with various industry leaders representing both CMHCs and hospital-based PHP providers with whom we have consistently met over the years to discuss industry concerns and ideas. These relationships have provided significant and valued input regarding PHP ratesetting. We also hold Hospital Outpatient Open Door Forum calls monthly, in which all individuals are welcome to participate and/or submit questions regarding specific issues, including questions related to PHPs.

Furthermore, we initiate rulemaking annually, through which we receive public comments on proposals set forth in a proposed rule and respond to those comments in a

final rule. All individuals are provided an opportunity to comment, and we give consideration to each comment that we receive.

Given the relationships that we have established with various industry leaders and the various means for us to receive comments and recommendations, we believe that we receive adequate input regarding ratesetting and take that input into consideration when establishing the payment rates. We continue to welcome any input and information that the industry is willing to provide.

Comment: A few commenters addressed issues related to the costs used to calculate the PHP APC per diem payment rates. One commenter expressed concern that CMS' ratesetting methodology does not take into consideration the array of services that are delivered in PHPs, such as assisting with appointments regarding social security and Medicare; housing searches; primary healthcare; eye and dental services; working with families; obtaining prescription medications; and accessing transportation, food banks and food stamps.

Two commenters expressed concern that CMHCs must retain the same level of licensed staff as hospital-based PHPs, yet the discrepancy between the proposed CMHC and hospital-based PHP per diem payment rates is now significant. The commenters stated that because all PHPs must hire psychiatrists, licensed clinicians, licensed supervisors, and bachelor-level case managers, it is difficult to understand why and how CMS calculated such different payment rates for essentially the same services.

Lastly, one commenter further questioned why a licensed therapist in a community-based treatment setting can be paid $110.27 for a 45 to 50 minute individual

counseling session, while a CMHC is expected to deliver up to 6 hours of care per day including treatment, food, transportation, among others, for $111.89 per day (for 4 or more services).

Response: Section 1861(ff) of the Act and 42 CFR 410.43 describe the items and services included in partial hospitalization services. As set forth in these sections, partial hospitalization services generally consist of a variety of group, individual, and family psychotherapy sessions, supplemented with occupational therapy, the services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients, drugs and biologicals furnished for therapeutic purposes that cannot be self-administered, diagnostic services, education and training, and certain activity therapies designed to stabilize an acute episode of mental illness. The PHP APC per diem payment rate is the bundled payment for these partial hospitalization services. Physician services that meet the requirements of § 415.102(a) for payment on a fee schedule basis, physician assistant services, nurse practitioner and clinical nurse specialist services, and qualified psychologist services are separately covered (as are services furnished to skilled nursing facility residents as defined in § 411.15(p)) and are not paid as partial hospitalization services (§ 410.43(b)). Further, section 1861(ff)(2)(I) of the Act explicitly excludes meals and transportation from the items and services included in partial hospitalization services.

Regarding the concern about the discrepancy between the proposed CMHC and hospital-based PHP per diem payment rates, as discussed above, we 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 services. We base the PHP APC per diem payment rates on claims and cost reports submitted by providers. The resulting PHP APC per diem payment rates reflect the cost of what providers expend to maintain such programs.

In response to the commenter who questioned why the payment to a CMHC for a full day of mental health treatment is about the same as the amount a therapist is paid for one individual counseling session, we believe the commenter is comparing the professional fee the therapist is paid under the MPFS for providing a therapy service ($110.27, according to the commenter) to the proposed Level II APC per diem payment rate to a CMHC under the OPPS for CY 2013 ($111.89). We believe that this is not an appropriate comparison because these payments are for completely different services. It is important to note that CMHCs receive the per diem amount per person per day. Thus, assuming the PHP has 10 patients, the facility is receiving over $1,000 for the day. That amount, which is intended to cover the facility's per diem cost for a day of PHP, includes the cost of staff who are not authorized to bill Medicare Part B as discussed above. Again, we base the PHP APC per diem payment rates on claims and cost reports submitted by providers. Thus, resulting PHP APC per diem payment rates reflect the cost of what providers expend to maintain such programs.

In summary, after consideration of the public comments we received, we are finalizing our CY 2013 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 2013 are shown in Tables 39 and 40 below. We will continue our efforts to explore payment reforms that will support quality and result in greater payment accuracy and reduction of fraud and abuse within the partial hospitalization program.

TABLE 39.--CY 2013 GEOMETRIC MEAN PER DIEM COSTS FOR CMHC PHP SERVICES

APC	Group Title	Mean Per Diem Costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$87.39
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	$112.82

TABLE 40.--CY 2013 GEOMETRIC MEAN PER DIEM COSTS FOR HOSPITAL-BASED PHP SERVICES

APC	Group Title	Mean Per Diem Costs
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	$185.90
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	$234.81

C. Coding Changes

CPT codes are established by the AMA and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. CPT and Level II HCPCS codes are used to report procedures, services, and items and supplies under the hospital OPPS. These codes are updated and changed throughout the year.

Subsequent to the publication of the CY 2013 OPPS/ASC proposed rule, the AMA's CPT Editorial Panel deleted 28 psychiatric CPT codes, including those related to PHP services, and replaced them with 12 new CPT codes, effective January 1, 2013. For a detailed explanation of the OPPS treatment of new, deleted or revised CPT and Level II HCPCS codes we refer readers to section III.A. of this final rule with comment period. As a result of the AMA's CPT coding changes to the psychiatric CPT codes, we are making corresponding changes to the PHP code set that is used for billing and documenting PHP services. Specifically, we are making the following changes:

- The initial E/M codes are being separated based on whether the service was completed by a physician (CPT code 90792 (Initial evaluation with medical services done by a physician)), or a nonphysician (CPT code 90791 (Initial evaluation done by a non-physician)). Currently, for PHPs, E/M services are billed under: CPT codes 90801 (Psychiatric diagnostic interview examination) and 90802 (Interactive psychiatric diagnostic interview). Effective January 1, 2013, CPT codes 90801 and 90802 will be deleted and the E/M services will be billed using the following CPT codes: CPT code 90791 (Psychiatric diagnostic evaluation (no medical services) when completed by a non-physician) and CPT code 90792 (Psychiatric diagnostic evaluation (with medical services) when completed by a physician).

- The psychotherapy codes will no longer be for a range of time, but for a specific period of time. The following CPT codes that are currently used to bill for and document PHP individual psychotherapies will be deleted in CY 2013: CPT code 90816 (Psytx hosp 20-30 min); CPT code 90817 (Psytx hosp 20-30 min w/e&m); CPT code

90818 (Psytx hosp 45-50 min); CPT code 90819 (Psytx hosp 45-50 min w/e&m); CPT code 90821 (Psytx hosp 75-80 min); CPT code 90822 (Psytx hosp 75-80 min w/e&m); CPT code 90823 (Intac psytx hosp 20-30 min); CPT code 90824 (Intac psytx hsp 20-30 w/e&m); CPT code 90826 (Intac psytx hosp 45-50 min); CPT code 90827 (Intac psytx hsp 45-50 w/e&m); CPT code 90828 (Intac psytx hosp 75-80 min); and CPT code 90829 (Intac psytx hsp 75-80 w/e&m). These codes will be replaced with the following new psychotherapy CPT codes: CPT codes 90832 (Psychotherapy, 30 minutes); CPT codes 90834 (Psychotherapy, 45 minutes); and CPT codes 90837 (Psychotherapy, 60 minutes). If the time spent for psychotherapy is more than half the time of the code, then that code can be used to bill for PHP services. For example, if the time spent for psychotherapy is 16 minutes up to 37 minutes, CPT code 90832 (Psychotherapy, 30 minutes) would be used. For psychotherapy lasting 38 to 52 minutes, CPT code 90834 (Psychotherapy, 45 minutes) would be used, and for psychotherapy lasting 53 minutes or more, CPT code 90837 (Psychotherapy, 60 minutes) would be used. When psychotherapy is provided during the same encounter as an E/M service, there will be timed add-on CPT codes for psychotherapy that are to be used by psychiatrists to indicate that psychotherapy was provided during the same encounter as an E/M service. When E/M services are completed with psychotherapy, the following CPT codes may be used effective January 1, 2013: Appropriate E/M code (not selected on basis of time) and CPT code +90833 (30-minute psychotherapy add-on code); Appropriate E/M code (not selected on basis of time) and CPT code +90836 (45-minute psychotherapy add-on code); and Appropriate E/M code (not selected on basis of time) and CPT code +90838 (60-minute

psychotherapy add-on code). The following table provides a list of the PHP-related individual psychotherapy CPT codes that will be deleted December 31, 2012.

TABLE 41.—INDIVIDUAL PSYCHOTHERAPY CPT CODES THAT WILL BE DELETED DECEMBER 31, 2012

CY 2012 CPT Code	Long Descriptor
90816	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient
90817	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services
90818	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient
90819	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services
90821	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient
90822	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services
90823	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient

CY 2012 CPT Code	Long Descriptor
90824	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services
90826	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient
90827	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services
90828	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient
90829	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services

- Instead of separate codes for interactive psychotherapy, there is now an add-on CPT code for interactive complexity, which may be used when the patient encounter is more complex because of the need to involve people other than the patient (CPT code +90785). This add-on CPT code can be used with initial evaluation codes, with the psychotherapy codes, with the nonfamily group psychotherapy code, and with the E/M codes when they are used in conjunction with psychotherapy services. The CPT manual

includes specific guidelines as to what constitutes interactive complexity that should be understood before this add-on CPT code is used. Documentation must clearly indicate exactly what that complexity was.

Beginning on January 1, 2013, interactive psychotherapy should be billed using the psychiatric evaluation codes, the psychotherapy and psychotherapy add-on CPT codes, and the group (nonfamily) psychotherapy CPT code +90785 (Interactive psychotherapy).

Relevant coding requirements must be followed. We recommend learning how to accurately bill for and document these new codes. More information may be found on the CPT/AMA Web site: http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.page .

All other PHP CPT and HCPCS codes will remain unchanged and active for billing and documentation of PHP services. We refer readers to the table below that highlights which PHP CPT/HCPCS codes are changing and which PHP CPT/HCPCS codes will remain unchanged and active for billing and documentation of services.

The following Table 42 provides a crosswalk between the CPT/HCPCS code options in CY 2012 and the CPT/HCPCS code options that are effective on January 1, 2013.

TABLE 42.—CROSSWALK OF DELETED AND NEW PHP CPT AND HCPCS BILLABLE CODES FOR 2013

CURRENT CPT/HCPCS CODE	NEW CPT/HCPCS CODE
90801 (Psychiatric diagnostic interview)	90791 (psychiatric diagnostic evaluation (no medical services) 90792 (psychiatric diagnostic evaluation

CURRENT CPT/HCPCS CODE	NEW CPT/HCPCS CODE
	with medical services)
90802 (Intac psychiatric diagnostic interview)	90791 or 90792, with +90785 (interactive complexity add-on code)
90816 (Psytx hosp 20-30 min)	90832 psychotherapy, 30 min. (with patient and/or family)
90817 (Psytx hosp 20-30 min w/e&m)	Appropriate inpatient E/M code (not selected on basis of time), and +90833, 30-minute psychotherapy add-on code (with patient and/or family)
90818 (Psytx hosp 45-50 min)	90834 psychotherapy, 45 min. (with patient and/or family)
90819 (Psytx hosp 45-50 min w/e&m)	Appropriate inpatient E/M code (not selected on basis of time), and +90836, 45-minute psychotherapy add-on code (with patient and/or family)
90821 (Psytx hosp 75-80 min)	90837 psychotherapy, 60 min. (with patient and/or family)
90822 (Psytx hosp 75-80 min w/e&m)	Appropriate inpatient E/M code (not selected on basis of time), and +90838, 60-minute psychotherapy add-on code (with patient and/or family)
90823 (Intac psytx hosp 20-30 min)	90832, psychotherapy, 30 min. +90785, interactive complexity add-on code (with patient and/or family)
90824 (Intac psytx hsp 20-30 w/e&m)	Appropriate inpatient E/M code (not selected on basis of time), and +90833, 30-minute psychotherapy add-on code, and +90785, interactive complexity add-on code (with patient and/or family)
90826 (Intac psytx hosp 45-50 min)	90834, psychotherapy, 45 min. +90785, interactive complexity add-on code (with patient and/or family)
90827 (Intac psytx hsp 45-50 w/e&m)	Appropriate inpatient E/M code (not selected on basis of time), and

CURRENT CPT/HCPCS CODE	NEW CPT/HCPCS CODE
	+90836, 45-minute psychotherapy add-on code, and +90785, interactive complexity add-on code (with patient and/or family)
90828 (Intac psytx hosp 75-80 min)	90837, psychotherapy, 60 min. +90785, interactive complexity add-on code (with patient and/or family)
90829 (Intac psytx hsp 75-80 w/e&m)	Appropriate inpatient E/M code (not selected on basis of time), and +90838, 60-minute psychotherapy add-on code, and +90785, interactive complexity add-on code (with patient and/or family)
90845 (Psychoanalysis)	Retained/No changes
90846 (Family psytx w/o patient)	Retained/No changes
90847 (Family psytx w/patient)	Retained/No changes
90865 (Narcosynthesis)	Retained/No changes
90880 (Hypnotherapy)	Retained/No changes
96101 (Psycho testing by psych/phys)	Retained/No changes
96102 (Psycho testing by technician)	Retained/No changes
96103 (Psycho testing admin by comp)	Retained/No changes
96116 (Neurobehavioral status exam)	Retained/No changes
96118 (Neuropsych tst by psych/phys)	Retained/No changes
96119 (Neuropsych testing by tec)	Retained/No changes
96120 (Neuropsych tst admin w/comp)	Retained/No changes
G0129 (Partial hosp prog service)	Retained/No changes
G0176 (OPPS/PHP;activity therapy)	Retained/No changes
G0177 (OPPS/PHP; train & educ serv)	Retained/No changes
G0410 (Grp psych partial hosp 45-50)	Retained/No changes
G0411 (Inter active grp psych parti)	Retained/No changes

The following Table 43 shows all of the billable PHP revenue and CPT/HCPCS codes effective on January 1, 2013. This table is also located in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 4, Section 260.1, which is available on the

CMS Web site at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf.

TABLE 43.—PARTIAL HOSPITALIZATION BILLABLE CODES

Revenue Codes	Description	CPT/HCPCS Codes
043X	Occupational Therapy	G0129
0900	Behavioral Health Treatment/Services	90791 or 90792
0904	Activity Therapy	G0176
0914	Individual Psychotherapy	90785, 90832, 90833, 90834, 90836, 90837, 90838, 90845, 90865, or 90880
0915	Group Therapy	G0410 or G0411
0916	Family Psychotherapy	90846 or 90847
0918	Psychiatric Testing	96101, 96102, 96103, 96116, 96118, 96119, or 96120
0942	Education/Training	G0177

D. Separate Threshold for Outlier Payments to CMHCs

In the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), we indicated that, given the difference in charges for PHP services provided between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Prior to that time, there was a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP services. Therefore, 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. In addition, further analysis indicated that using the same OPPS outlier threshold for both hospitals and CMHCs did not limit outlier payments to

high-cost cases and resulted in excessive outlier payments to CMHCs. Therefore, beginning in CY 2004, we established a separate outlier threshold for CMHCs. The separate outlier threshold for CMHCs has resulted in more commensurate outlier payments.

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 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.

We proposed in the CY 2013 OPPS/ASC proposed rule (77 FR 45153) to continue our policy of identifying 1.0 percent of the aggregate total payments under the OPPS for outlier payments for CY 2013. We proposed that a portion of that 1.0 percent, an amount equal to 0.12 percent of outlier payments (or 0.0012 percent of total OPPS payments) would be allocated to CMHCs for PHP outlier payments. In section II.G. of the CY 2013 OPPS/ASC proposed rule, for the hospital outpatient outlier payment policy, we proposed to set a dollar threshold in addition to an APC multiplier threshold (77 FR 45110 through 45111). 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. We proposed to set the outlier threshold for CMHCs for CY 2013 at 3.40 times the APC payment amount and the CY 2013 outlier

payment percentage applicable to costs in excess of the threshold at 50 percent. Specifically, 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 will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. We invited public comments on these proposals.

We did not receive any public comments regarding our proposed outlier policy. Therefore, we are finalizing our CY 2013 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 that 1.00 percent, an amount equal to 0.12 percent of outlier payments or 0.0012 percent of total estimated OPPS payments to CMHCs for PHP outlier payments. For CY 2013, as proposed, we are setting the outlier threshold at 3.40 multiplied by the APC payment amount and the CY 2013 outlier percentage applicable to costs in excess of the threshold at 50 percent.

IX. Procedures That Would Be Paid Only as Inpatient Procedures

A. Background

We refer readers to the CY 2012 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 2013 OPPS/ASAC proposed rule (77 FR 45153), for CY 2013, 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 are being performed a significant amount of the time on an outpatient basis, and appropriately 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 identified two procedures that potentially could be removed from the inpatient list for CY 2013: CPT code 22856 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical); and CPT code 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)). We then reviewed the clinical characteristics and related evidence for these two potential procedures for possible removal from the inpatient list and found them to be appropriate candidates for removal from the inpatient list. For CY 2013, we proposed to remove the procedures described by CPT codes 22856 and 27447 from the inpatient list because we believe that the procedures may be appropriately provided as hospital outpatient procedures for some Medicare beneficiaries, based upon the evaluation criteria mentioned above and should thus be paid under the OPPS.

The two procedures that we proposed to remove from the inpatient list for CY 2013 and their CPT codes, long descriptors, proposed APC assignments, and proposed status indictors were displayed in Table 34 of the proposed rule.

Comment: A few commenters supported CMS' proposal to remove CPT code 27447 (Total knee arthroplasty) from the list of inpatient procedures, and asserted that this procedure may be appropriately provided on an outpatient basis for some Medicare beneficiaries, given thorough preoperative screening by medical teams with significant experience and expertise involving knee replacement procedures. The commenters referenced a study presented at the American Academy of Orthopedic Surgeons 2009 annual meeting, which noted recent advances in total knee replacement procedures, including improved perioperative anesthesia, and expedited rehabilitation protocols, as well as significant enhancements to the postoperative process, such as improvements in pain management, early mobilization, careful monitoring, and that early preventive intervention for the most common medical complications have decreased the average length of hospital stays to the point that total knee arthroplasty can now be performed on an outpatient basis in certain cases. The commenters noted significant success involving same day discharge for patients who met the screening criteria and whose experienced medical teams were able to perform the procedure early enough in the day for the patients to achieve postoperative goals, allowing home discharge by the end of the day. The commenters remarked that the benefits of providing total knee arthroplasty on an outpatient basis will lead to significant enhancements in patient well-being and cost savings to the Medicare program, including shorter hospital stays resulting in fewer medical complications, improved results, and enhanced patient satisfaction.

A few commenters urged CMS to group total knee arthroplasty into a new APC with unicompartmental knee replacement or to group these two procedures with other

clinically similar orthopedic implant procedures from APC 0425 to create a more clinically homogenous APC for resource-intensive arthroplasty, if CMS finalized its proposal to remove total knee arthroplasty from the inpatient list. One commenter requested CMS to assign CPT code 27447 a status indicator of "S."

The majority of commenters asked that CMS retract its proposal to remove CPT code 27447 from the inpatient list. Commenters argued that CPT code 27447 is not being performed in numerous hospitals on an outpatient basis and noted that the published average length of stay for this procedure is over 3 days, with a recommended best practice target of 3 days when no complications exist. Commenters stated that removing CPT code 27447 from the inpatient list will create a dangerous situation for Medicare beneficiaries, who are older and more medically complex patients, as there are serious potential adverse effects, including inadequate pain management, unsafe ambulation, and risk for falls. Commenters also noted that patients undergoing total knee replacement often have several comorbidities and increased risks, such as death, loss of a limb, nerve damage resulting from neurovascular injury, myocardial infarction (MI), pulmonary embolism (PE), deep vein thrombosis (DVT), and infection and loss of mobility, as well as anaphylaxis, obstructive sleep apnea, and aspiration of stomach contents into the lungs. Several commenters stated that many patients will require some type of sub acute rehabilitation, which could include a SNF, and if these patients are not admitted, they will not meet their qualifying 3-day inpatient stay and will not be eligible for SNF care, which likely will lead to poor outcomes postoperatively. Some commenters stated that Medicare patients require greater than 24 hours of inpatient hospital care following total

knee replacement procedures for clinical reasons, including anesthesia recovery, physical therapy, blood loss monitoring, and pain control, which often includes intravenous pain medications for 24 to 48 hours following the procedure, and the outpatient setting cannot handle the high acuity for the extended postoperative care that this type of patient requires. Other commenters stated that they do not believe that the clinical characteristics of CPT code 27447 justify its selection as an appropriate candidate for removal from the inpatient list.

Commenters pointed out that, while Medicare's definition of outpatient surgery specified that it includes the care provided during the normal recovery period, which is defined as less than 24 hours, the length of stay for total knee arthroplasty patients is markedly longer than 24 hours for outpatient surgery recovery. In addition, the commenters noted that, according to the Medicare Claims Processing Manual, Chapter 4, section 180.7, '"Inpatient only' services are generally, but not always, surgical services that require inpatient care because of the nature of the procedure, the typical underlying physical condition of patients who require the service, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged." Several commenters cited the lack of any evidence-based publications supporting outpatient total knee arthroplasty in patients over the age of 65 and asserted that patients having total knee replacement surgery as outpatients were significantly more likely to die or need readmission within 90 days, compared with inpatients remaining in the hospital for 3 to 4 days, according to a study presented at the February 2012 American Association of Orthopedic Surgery meeting. Commenters also noted, according to the

same study, the rates of subsequent revision surgery were nearly doubled in patients having 1-day hospital stays compared with the 3- to-4-day standard.

Commenters further noted that performing total knee arthroplasty in the outpatient setting may impact the types of rehabilitation services available to patients upon completion of the surgery, and may make justifying the medical necessity of inpatient rehabilitation more difficult. Furthermore, commenters expressed concern that commercial carriers will change total knee arthroplasty to an outpatient procedure, thereby making it more difficult to get such a procedure authorized.

Commenters also stated that all hospitals do not have the robotics available for less invasive surgical technique and only a few centers across the country are routinely doing knee replacement as outpatients, and even those hospitals are doing them on specific patient types. One commenter remarked that, while outpatient joint replacements are possible in hospitals in major cities with large resources and an educated skilled support staff, it would be dangerous to the patient to perform outpatient total knee arthroplasties in small rural communities, as there are limited nurses, therapists, and other support staff in many communities across the country.

Some commenters expressed concern about the effects of CMS' proposed removal of CPT 27447 on participants in the CMS Innovation Center's (CMMI's) Bundled Payments for Care Improvement (BPCI) initiative.

Response: We appreciate all of the public comments we received on the removal of CPT code 27447 from the inpatient list. In light of all of these public comments, for CY 2013, we have decided not to remove CPT code 27447 from the inpatient list as we

proposed. Based on the public comments, we have concerns regarding whether this procedure may be appropriately provided as a hospital outpatient procedure for some Medicare beneficiaries based upon the evaluation criteria above.

Comment: The majority of commenters supported CMS' proposal to provide payment for CPT code 22856 in the hospital outpatient setting, but recommended assigning CPT code 22856, as well as CPT codes 22551 and 22554, to APC 0052 (Level IV Musculoskeletal Procedures Except Hand and Foot), APC 0425 (Level II Arthroplasty or Implantation of Prosthesis), or a newly created APCs in order to appropriately compensate hospitals for their costs associated with this procedure. One commenter believed that CPT code 22856, for patient safety reasons, should remain on the inpatient list.

Response: We appreciate commenters' support of our proposal to provide payment for CPT code 22856 in the hospital outpatient setting. We believe that this procedure may be appropriately provided as a hospital outpatient procedure for some Medicare beneficiaries based upon the evaluation criteria above. However, we do not agree with the commenters' recommendation to assign CPT code 22856, as well as CPT codes 22551 and 22554, to APC 0052, 0425, or a newly created APC. We believe that CPT code 22856, as well as CPT codes 22551 and 22554, are appropriately placed in APC 0208.

Comment: Several commenters requested that CMS remove 39 additional CPT codes from the CY 2012 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 the 39 additional CPT codes requested by the commenters, using more recent utilization data and further clinical review by CMS medical advisors. These codes are listed in Table 44 below. As a result of the reevaluation, we remain convinced that these procedures can be safely performed only in the inpatient setting.

TABLE 44.—ADDITIONAL PROCEDURES REQUESTED BY COMMENTERS TO BE REMOVED FROM THE INPATIENT ONLY LIST FOR CY 2013

HCPCS Code	Long Descriptor	CY 2013 Status Indicator
0075T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; initial vessel	C
20661	Application of halo, including removal; cranial	C
20664	Application of halo, including removal, cranial, 6 or more pins placed, for thin skull osteology (eg, pediatric patients, hydrocephalus, osteogenesis imperfecta), requiring general anesthesia	C
20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)	C
20937	Autograft for spine surgery only (including harvesting the graft); morselized (through separate skin or fascial incision) (list separately in addition to code for primary procedure)	C
20938	Autograft for spine surgery only (including harvesting the graft); structural, bicortical or tricortical (through separate skin or fascial incision) (list separately in addition to code for primary procedure)	C
21141	Reconstruction midface, LeFort I; single piece, segment movement in any direction, without bone graft	C
21196	Reconstruction of mandibular rami & body with sag split & int fix	C
22114	Partial excision of vertebral body, for intrinsic bony lesion,	C

HCPCS Code	Long Descriptor	CY 2013 Status Indicator
	without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar	
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure).	C
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar.	C
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure	C
22845	Anterior instrumentation; 2 to 3 vertebral segments (list separately in addition to code for primary procedure)	C
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	C
22840	Posterior nonsegmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)	C
23472	Arthroplasty, glenohumeral joint total shoulder (glenoid and proximal humeral replacement)	C
35221	Repair blood vessel, direct; intra-abdominal	C
35372	Thromboendarterectomy, including patch graft, if performed; deep (profunda) femoral	C
35721	Exploration (not followed by surgical repair), with or without lysis of artery; femoral artery	C
35800	Exploration for post op hemorrhage, thrombosis or infection; neck	C
37182	TIPS procedure	C
37617	Ligation, major artery; abdomen	C
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic	C
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury	C
44300	Open jejunostomy following a diagnostic laparoscopy	C
44314	Revision of ileostomy; complicated (reconstruction indepth) (separate procedure)	C
44345	Revision of colostomy; complicated (reconstruction indepth)	C

HCPCS Code	Long Descriptor	CY 2013 Status Indicator
	(separate procedure)	
44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)	C
44602	Suture of small intestine accidental laceration	C
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)	C
49255	Omentectomy, epiploectomy, resection of omentum	C
51840	Anterior vesicourethropexy , or urethropexy (eg, Marshall-Marchetti-Krantz, Burch); simple	C
54411	Removal and replacement of a multi-component inflatable penile prosthesis through an infected field at the same operative session	C
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	C
56630	Vulvectomy, radical, partial;	C
61624	Transcatheter permanent occlusion or embolization, percutaneous, any method; central nervous system	C
63044	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (List separately in addition to code for primary procedure)	C
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar	C
63710	Dural graft, spinal	C

Comment: Some commenters requested that CMS add CPT codes 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 note that CPT codes 44206, 44207, 44208, and 44213 have been payable in the outpatient setting for a number of years without significant concern raised by the public. Therefore, we find no reason to reassign CPT codes 44206, 44207, 44208, and 44213 to the inpatient list at this time.

Comment: A number of commenters requested that the inpatient list be eliminated in its entirety, and if the inpatient list cannot be eliminated in its entirety, an appeals process be developed. Commenters also requested that the inpatient list be reviewed clinically. In addition, commenters expressed concern about the way Recovery Audit Contractors (RACs) target procedures removed from the inpatient list and encouraged CMS to provide a period to allow hospitals to make the appropriate adjustments without being at risk of an audit. The commenters urged CMS to provide, in both regulatory language and transmittals, that procedures with APC payment rates can be performed, covered, and paid by Medicare on an inpatient basis when medical necessity is documented and the physician has ordered inpatient status.

Response: We appreciate these comments and thoughtful suggestions. We continue to believe that the inpatient list is a valuable tool for ensuring that the OPPS only pays for services that can safely and appropriately be performed in the hospital outpatient setting, and we will not eliminate the inpatient only list at this time. We do not plan to adopt a specific appeals process for claims related to inpatient procedures performed in the HOPD in light of the added administrative burden, and the existing

processes established for a beneficiary or a provider to appeal a specific claim remain in effect. We are committed to clinically reviewing the inpatient list timely to reflect changes in medical practice, and we plan to continue our current practice of reviewing procedures for removal from the inpatient list through the formal notice-and-comment rulemaking process. The inpatient list is made available to the public through the OPPS /ASC final rule with comment period at least 60 days prior to its effective date of January 1 of the upcoming year. We believe that the 60 days between the release of the OPPS/ ASC final rule with comment period and the effective date of January 1 of the upcoming year provide sufficient time for hospitals to make the appropriate adjustments to reflect the upcoming year's inpatient list. As we have stated in Section 180.7 of Chapter 4 of the Medicare Claims Processing Manual, procedures removed from the inpatient list may be appropriately furnished in either the inpatient or outpatient settings and such procedures continue to be payable when furnished in the inpatient setting.

Comment: One commenter who responded to the CY 2012 OPPS/ASC final rule with comment period supported CMS' decision to assign a status indicator of "C" to Category III codes 0293T (Insertion of left atrial hemodynamic monitor; complete system, includes implanted communication module and pressure sensor lead in left atrium including transseptal access, radiological supervision and interpretation, and associated injection procedures, when performed) and 0294T (Insertion of left atrial hemodynamic monitor; pressure sensor lead at time of insertion of pacing cardioverter-defibrillator pulse generator including radiological supervision and interpretation and

associated injection procedures, when performed (list separately in addition to primary procedure)).

Response: We appreciate the commenter's support.

At its August 27- 28, 2012 meeting, the Panel recommended that CMS remove HCPCS code 22856 from the list of inpatient procedures. We are accepting this recommendation.

After consideration of the public comments we received, we are modifying our proposal and only removing CPT code 22856 from the CY 2013 inpatient list. CPT code 27447 will remain on the inpatient list for CY 2013.

The procedure that we are removing from the inpatient list for CY 2013 and its CPT code, long descriptor, APC assignment, and status indictor are displayed in Table 45 below.

TABLE 45.—PROCEDURE REMOVED FROM THE INPATIENT ONLY LIST AND ITS APC ASSIGNMENTS FOR CY 2013

HCPCS Code	Long Descriptor	CY 2013 APC Assignment	CY 2013 Status Indicator
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical	0208	T

The complete list of codes to be paid by Medicare in CY 2013 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. Policies for the Supervision of Outpatient Services in Hospitals and CAHs

A. Conditions of Payment for Physical Therapy, Speech-Language Pathology, and Occupational Therapy Services in Hospitals and CAHs

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74360 through 74371), we clarified that hospital outpatient therapeutic services and supplies, including those described by benefit categories other than the hospital outpatient "incident to" category under section 1861(s)(2)(B) of the Act, are subject to the conditions of payment in 42 CFR 410.27 when they are paid under the OPPS or paid to CAHs under section 1834(g) of the Act. We issued this clarification in response to inquiries regarding the application of these conditions of payment to radiation therapy services that are described under section 1861(s)(4) of the Act when these services are furnished to hospital outpatients.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74369), in our response to public comments on the CY 2012 OPPS/ASC proposed rule, we indicated that the supervision and other requirements of § 410.27 do not apply to professional services or to services that are paid under other fee schedules such as the Clinical Laboratory Fee Schedule (CLFS). After the publication of the CY 2012 OPPS/ASC final rule with comment period, we continued to receive questions about the applicability of the regulations to physical therapy (PT), speech-language pathology (SLP), and occupational therapy (OT) services furnished in CAHs. Several stakeholders expressed concern that the rules could be applied differently in CAHs than in OPPS hospitals. The stakeholders were concerned that OPPS hospitals, which are paid for outpatient therapy services at the applicable amount based on the Medicare Physician Fee Schedule (MPFS), would not be subject to the regulations,

but that CAHs, which are paid for outpatient therapy services on a reasonable cost basis, would be subject to them.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45154), we clarified that it was not our intent in the CY 2012 OPPS/ASC final rule with comment period to establish different requirements for CAHs and for OPPS hospitals for the same services. We clarified that the limited set of PT/SLP/OT services that are paid under the OPPS are subject to the supervision requirements in § 410.27, whether they are furnished in OPPS hospitals or CAHs. The PT/SLP/OT services that are not paid under the OPPS and are paid instead at the applicable amount based on the MPFS are not subject to the supervision requirements in § 410.27, whether they are furnished in OPPS hospitals or in CAHs.

Comment: Commenters expressed appreciation and support for the clarification in the proposed rule. One commenter requested that CMS rescind the requirement of direct supervision for all PT/SLP/OT services, regardless of whether they are furnished as therapy services and paid at the applicable amount under the MPFS or are furnished as nontherapy services and paid under the OPPS.

Response: Stakeholders may direct requests for changes in the minimum required level of supervision for therapeutic services, including therapy or other services that are hospital outpatient services, to the independent review process that we established for considering such requests in the CY 2012 OPPS/ASC final rule with comment period. The instructions for submitting a request are discussed in the CY 2012 final rule with comment period and are available on the CMS Web site at:

http://www.cms.gov/Regulations-and-

Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.

In this final rule with comment period, we are clarifying that the supervision and other requirements of the regulation at § 410.27 apply to facility services that are paid to hospitals under the OPPS and to these same services when they are furnished in CAHs and paid on a reasonable cost basis. In OPPS hospitals, the requirements of § 410.27 do not apply to professional services that are separately billed under the MPFS or to PT, SLP, and OT services that are billed by the hospital as therapy services and are paid at the applicable amount based on the MPFS. The requirements of § 410.27 also do not apply to these same professional and PT, SLP, and OT services when they are furnished in CAHs.

In OPPS hospitals, a small subset of "sometimes therapy" PT, SLP, and OT services are paid under the OPPS when they are not furnished as therapy, meaning not under a certified therapy plan of care. Because the supervision and other conditions of payment under § 410.27 apply to this subset of "sometimes therapy" services when they are furnished in OPPS hospitals as nontherapy services (because they are paid under the OPPS and not based on the MPFS), those conditions of payment also apply to this subset of "sometimes therapy" services when they are furnished as nontherapy in CAHs. When OPPS hospitals and CAHs furnish these services as therapy services (under a therapy plan of care by a qualified therapist), the conditions of payment under § 410.27 do not apply because OPPS hospitals are paid for these services based on the MPFS and not under the OPPS. As we did in the CY 2013 OPPS/ASC proposed rule, we are providing

a list of the "sometimes therapy" services that may be paid under the OPPS in Table 46 below.

TABLE 46.--"SOMETIMES THERAPY" SERVICES THAT ARE PAID UNDER THE OPPS WHEN NOT FURNISHED AS THERAPY SERVICES

HCPCS Code	Descriptor
97597	Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less
97598	Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof (list separately in addition to code for primary procedure)
97602	Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (eg, wet-to-moist dressings, enzymatic, abrasion), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session
97605	Negative pressure wound therapy (eg, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
97606	Negative pressure wound therapy (eg, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters
0183T	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day

B. Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in CAHs and Certain Small Rural Hospitals

As we indicated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74371), we extended through CY 2012 the notice of nonenforcement of the requirement for direct supervision of outpatient therapeutic services furnished in CAHs and small rural hospitals having 100 or fewer beds (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**). We extended this enforcement instruction to our contractors for another year, through CY 2012, to allow time for the initiation of supervision reviews by the Advisory Panel on Hospital Outpatient Payment (the Panel), which began in early 2012 and are continuing in accordance with the provisions of the CY 2012 OPPS/ASC final rule with comment period.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45154), we requested that CAHs and small rural hospitals submit to CMS for potential evaluation by the Panel at its summer meeting any services for which they anticipate difficulty complying with the direct supervision standard in CY 2013. We stated that, in developing evaluation requests, hospitals should refer to the evaluation criteria that we finalized in the CY 2012 OPPS/ASC final rule with comment period. In order to give hospitals additional opportunity during CY 2012 to become familiar with the new submission and review process at the summer Panel meeting, and to allow hospitals time to meet the required supervision levels for the services that would be considered for CY 2013, we indicated

that we anticipated extending the nonenforcement instruction one additional year through CY 2013. We stated that we expect that CY 2013 will be the final year for the instruction, regardless of the services reviewed by the Panel during its summer meeting.

Comment: Most commenters supported an extension of the enforcement instruction another year through CY 2013, and reiterated requests made in previous years that we limit CAHs to the requirements in their staffing Conditions of Participation (CoPs) by making the definition of "direct supervision" in § 410.27 consistent with the CAH staffing CoPs. These CoPs require that a doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant be available to furnish patient care services at all times the CAH operates (§ 485.631) and be available on site within 30 minutes (§ 485.618). They apply to all services that are furnished by a CAH. In contrast, for payment of most outpatient therapeutic services, under § 410.27 the CAH (like all OPPS hospitals) must furnish direct supervision, meaning the supervising physician or appropriate nonphysician practitioner is immediately available to furnish assistance and direction for the duration of the service. The requirement in § 410.27 does not apply to CAH inpatient services or to CAH outpatient diagnostic services.) Some commenters similarly requested that CMS require only general supervision in CAHs and small rural hospitals, meaning the services would be furnished under the supervising physician's or appropriate nonphysician practitioner's overall direction and control but he or she need not be physically present.

One commenter stated that while the commenter understands the need to allow CAHs and small rural hospitals to become compliant with the recent clarifications

regarding the outpatient supervision requirements, and while the commenter shares the concerns of these facilities regarding the available supply of certain types of physicians, the supervision requirements should be applied uniformly across all care settings for reasons of patient safety. In addition, several commenters offered suggestions for improving the subregulatory supervision review process.

Response: We appreciate the suggestions for improving the supervision review process and will take them into consideration for future Panel meetings. Regarding the supervision requirements for payment of hospital and CAH outpatient services, we previously discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74362) that the Act applies the same regulations to hospitals and CAHs when appropriate (CAHs are included if "the context otherwise requires" under section 1861(e) of the Act). As we indicated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72000 through 72005), we elected not to limit the CAHs to their CoPs or to exclude them from the direct supervision requirement for payment because we believe that Medicare should purchase outpatient services from CAHs and other hospitals that are of the same basic level of safety and quality. In addition, while CoPs apply to all services that a hospital or a CAH furnishes, the payment rule in § 410.27 applies only to outpatient therapeutic services.

Regarding the enforcement instruction, as we discussed in the CY 2013 OPPS/ASC proposed rule, we will extend the enforcement instruction one additional year through CY 2013. This additional year, which we expect to be the final year of the extension, will provide 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 Panel held its second meeting on supervision levels for outpatient therapeutic services in August 2012, and considered several stakeholder requests for a reduction in the minimum required level of supervision for certain services. These included observation services; administration of certain drugs and agents; and selected bladder, skin/wound care, injection/infusion, intravenous and central venous access services. In accordance with the subregulatory review process finalized in the CY 2012 OPPS/ASC final rule with comment period, we are currently reviewing public comments on the agency's preliminary decisions regarding supervision levels for these services based upon the Panel's recommendations. We will issue our final decisions on these services prior to January 1, 2013 on the CMS Web site at: **http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html**.

XI. Outpatient Status: Solicitation of Public Comments in the CY 2013 OPPS/ASC Proposed Rule

A. Background

Under section 402(a)(1)(A) of the Social Security Amendments of 1967 (Pub. L. 90-248), the Secretary is permitted to engage in demonstration projects to determine whether changes in the methods of payment for health care and services under the Medicare program would increase the efficiency and economy of those services through the creation of incentives to those ends without adversely affecting the quality of such services. Under this statutory authority, CMS has implemented the Medicare Part A to Part B Rebilling (AB Rebilling) Demonstration, which allows participating hospitals to receive 90 percent of the allowable Part B payment for Part A short-stay claims that are denied on the basis that the inpatient admission was not reasonable and necessary. Participating hospitals can rebill these denied Part A claims under Part B and be paid for additional Part B services than would usually be payable when an inpatient admission is deemed not reasonable and necessary. This demonstration is slated to last for 3 years, from CY 2012 through CY 2014.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45155 through 45157), we provided an update of the status of the demonstration. In addition, we solicited public comments on a related issue: potential policy changes we could make to improve clarity and consensus among providers, Medicare, and other stakeholders regarding the relationship between admission decisions and appropriate Medicare payment, such as

when a Medicare beneficiary is appropriately admitted to the hospital as an inpatient and the cost to hospitals associated with making this decision.

In the proposed rule, we discussed that when a Medicare beneficiary arrives at a hospital in need of medical or surgical care, the physician or other qualified practitioner must decide whether to admit the beneficiary for inpatient care or treat him or her as an outpatient. In some cases, when the physician admits the beneficiary and the hospital provides inpatient care, a Medicare claims review contractor, such as the Medicare Administrative Contractor (MAC), the Recovery Audit Contractor (RAC), or the Comprehensive Error Rate Testing (CERT) Contractor, determines that inpatient care was not reasonable and necessary under section 1862(a)(1)(A) of the Act and denies the hospital inpatient claim for payment. In these cases, under Medicare's longstanding policy, hospitals may rebill a separate inpatient claim for only a limited set of Part B services, referred to as "Inpatient Part B" or "Part B Only" services (Section 10, Chapter 6 of the Medicare Benefit Policy Manual (Pub. 100-02)). The hospital also may bill Medicare Part B for any outpatient services that were provided in the 3-day payment window prior to the admission (Section 10.12, Chapter 4 of the Medicare Claims Processing Manual (Pub. 100-04)). These claims are subject to the timely filing restrictions.

Once a Medicare beneficiary is discharged from the hospital, the hospital cannot change the beneficiary's patient status from inpatient to outpatient and then submit an outpatient claim because of the potentially significant impact on beneficiary liability. As we discuss below, hospital inpatients have significantly different Medicare benefits and

liabilities than hospital outpatients, notably coverage of self-administered drugs and, for patients who are admitted to the hospital as inpatients for 3 or more consecutive calendar days, Medicare coverage of postacute SNF care (to the extent all other SNF coverage requirements are met). To enable beneficiaries to make informed financial and other decisions prior to hospital discharge, Medicare allows the hospital to change a beneficiary's inpatient status to outpatient (using condition code 44 on an outpatient claim) and bill all medically necessary services that it provided to Part B as outpatient services, but only if the change in patient status is made prior to discharge, the hospital has not submitted a Medicare claim for the admission, and both the practitioner responsible for the care of the patient and the utilization review committee concur with the decision (Section 50.3, Chapter 1 of the Medicare Claims Processing Manual (Pub. 100-04); MLN Matters article SE0622, Clarification of Medicare Payment Policy When Inpatient Admission Is Determined Not To Be Medically Necessary, Including the Use of Condition Code 44: "Inpatient Admission Changed to Outpatient," September 2004). Medicare beneficiaries are provided with similar protections, which are outlined in the Hospital Conditions of Participation (CoPs). For example, in accordance with 42 CFR 482.13(b), Medicare beneficiaries have the right to participate in the development and implementation of their plan of care and treatment, to make informed decisions, and to accept or refuse treatment. Informed discharge planning between the patient and the physician is important for patient autonomy and for achieving efficient outcomes.

In the proposed rule, we stated that while the limited scope of allowed rebilling for "Inpatient Part B" services protects Medicare beneficiaries and provides disincentives for hospitals to admit patients inappropriately, hospitals have expressed concern that this policy provides inadequate payment for resources that they have expended to take care of the beneficiary in need of medically necessary hospital care, although not necessarily at the level of inpatient care. A significant proportion of the Medicare CERT error rate consists of short (1- or 2-day) stays where the beneficiary received medically necessary services that the CERT contractor determined should have been provided as outpatient services and not as inpatient services. Hospitals have indicated that often they do not have the necessary staff (for example, utilization review (UR) staff or case managers) on hand after normal business hours to confirm the physician's decision to admit the beneficiary. Thus, for a short-stay admission, the hospital may be unable to timely review and change a beneficiary's patient status from inpatient to outpatient prior to discharge in accordance with the condition code 44 requirements.

In the proposed rule, we indicated that we have heard from various stakeholders that hospitals appear to be responding to the financial risk of admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review by electing to treat beneficiaries as outpatients receiving observation services, often for longer periods of time, rather than admitting them as inpatients. In recent years, the number of cases of Medicare beneficiaries receiving observation services for more than 48 hours, while still small, has increased from approximately 3 percent in 2006 to approximately 7.5 percent in 2010. This trend is concerning because of its effect on

Medicare beneficiaries. There could be significant financial implications for Medicare beneficiaries of being treated as outpatients rather than being admitted as inpatients, of which CMS has informed beneficiaries.[1] For instance, if a beneficiary is admitted as an inpatient, the beneficiary pays a one-time deductible for all hospital services provided during the first 60 days in the hospital. As a hospital inpatient, the beneficiary would not pay for self-administered drugs or have any copayments for the first 60 days; whereas if the beneficiary is treated as an outpatient, the beneficiary has a copayment for each individual outpatient hospital service received. While the Medicare copayment for a single outpatient hospital service cannot be more than the inpatient hospital deductible, the beneficiary's total copayment for all outpatient services received may be more than the inpatient hospital deductible. In addition, usually self-administered drugs provided in an outpatient setting are not covered by Medicare Part B and hospitals may charge the beneficiary for them. Also, the time spent in the hospital as an outpatient is not counted towards the 3-day qualifying inpatient stay that section 1861(i) of the Act requires for Medicare Part A coverage of postacute care in a SNF.

As a result of these concerns related to the impact of extended time as an outpatient on Medicare beneficiaries, the CERT error rate, and the impact on hospitals of a later inpatient denial, CMS initiated the AB Rebilling Demonstration for a 3-year period for hospitals. This demonstration is voluntary and allows participating hospitals to rebill outside of the usual timely filing requirements for services relating to all inpatient short-stay claims that are denied for lack of medical necessity because the inpatient

[1] CMS Pamphlets: "Are You a Hospital Inpatient or Outpatient? If You Have Medicare - Ask!", CMS Product No. 11435, Revised, February 2011; "How Medicare Covers Self-Administered Drugs Given in Hospital Outpatient Settings," CMS Product No. 11333, Revised, February 2011.

admission was not medically necessary. Under the demonstration, hospitals may receive 90 percent of the Medicare allowable payment for all Part B services that would have been medically necessary had the beneficiaries originally been treated as outpatients and not admitted as inpatients. We note that hospitals cannot rebill for observation services, which, by definition, must be ordered prospectively to determine whether an inpatient admission is necessary (Chapter 1, Section 50.3.2 of the Medicare Claims Processing Manual (Pub. 100-04); FAQ 2723, available on the CMS Web site at https://questions.cms.gov/faq.php?id=5005&faqId=2723). Hospitals that participate in the AB Rebilling Demonstration will waive any appeal rights associated with the denied inpatient claims eligible for rebilling. Under the demonstration, Medicare beneficiaries are protected from any adverse impacts of expanded rebilling. For example, hospitals cannot bill beneficiaries for self-administered drugs or additional cost-sharing that would be required under Medicare Part B. The demonstration will inform us on the impact that expanded rebilling may have on the Medicare Trust Funds, beneficiaries, hospitals, and the CERT error rate. The demonstration is designed to evaluate potential impacts of expanded rebilling on admission and utilization patterns, including whether expanded rebilling would reduce hospitals' incentive to make appropriate initial admission decisions.

Hospitals expressed significant interest in the AB Rebilling Demonstration, which began on January 1, 2012. The demonstration was approved to accept up to 380 hospitals. In order to participate in the demonstration, a hospital must not be receiving periodic interim payments from CMS, and must be a Medicare-participating hospital as

defined by section 1886(d) of the Act, a category that includes all hospitals paid under the Medicare IPPS, but excludes hospitals paid under the IPF PPS, the IRF PPS, and the LTCH PPS, and cancer hospitals, CAHs, and children's hospitals.

The hospitals that volunteered to participate and were accepted in the demonstration began rebilling in early spring of 2012. More information about the demonstration is available on the CMS Web site at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/Part_A_to_Part_B_Rebilling_Demonstration.html. We stated in the proposed rule that we plan to conduct an evaluation of the demonstration during and after its completion.

B. Summary of Public Comments Received

While we are implementing the AB Rebilling Demonstration, we also solicited public comments in the CY 2013 OPPS/ASC proposed rule on other actions that we could potentially undertake to address stakeholders' concerns. In the proposed rule, we stated that there may be several ways of approaching the multifaceted issues that have been raised in recent months around a beneficiary's patient status and Medicare hospital payment. Given the complexity of this topic, we sought public perspectives on potential options the agency might adopt to provide more clarity and consensus regarding patient status for purposes of Medicare payment. We invited commenters to draw on their knowledge of these issues to offer any suggestions that they believe would be most helpful to them in addressing the current challenges, while keeping in mind the various impacts in terms of recently observed increases in the length of time for which patients

receive observation services, beneficiary liability, Medicare spending, and the feasibility of implementation of any suggested changes for both the Medicare program and hospitals.

We received approximately 350 public comments in response to our solicitation in the CY 2013 OPPS/ASC proposed rule from hospitals and hospital associations, physician associations, rehabilitative and long-term care facilities, beneficiaries, beneficiary advocacy organizations, Quality Improvement Organizations (QIOs), organizations specializing in medical necessity review, and other interested parties. The commenters provided significant input, and the majority requested that CMS not implement a comprehensive solution or set of solutions regarding patient status in the CY 2013 OPPS/ASC final rule with comment period. Instead, many commenters recommended that CMS develop an informed course of action in the upcoming months through a formal, ongoing dialogue with all interested stakeholders (for example, through open door forums or a task force). A few commenters recommended a more immediate course of action to limit beneficiary liability for SNF care and for the difference in beneficiary cost-sharing between hospital inpatient and outpatient services.

In this section, we summarize the feedback we received in response to our solicitation of public comments in the CY 2013 OPPS/ASC proposed rule. We are not providing responses to the public comments we received because in the proposed rule we strictly solicited public comments, and did not propose any changes in policy. We will consider the feedback we received from the public as we move forward. We structured our summary of the public comments around key suggestions that we have heard from

stakeholders in the following areas: (1) Part A to Part B Rebilling; (2) Clarifying Current Admission Instructions or Establishing Specified Clinical Criteria; (3) Hospital Utilization Review; (4) Prior Authorization; (5) Time-Based Criteria for Inpatient Admission; (6) Payment Alignment; and (7) Public Comments on Other Topics (including Rules for External Review of Inpatient Claims, Improving Beneficiary Protections, and Revising the Qualifying Criteria for SNF Coverage). We summarize the public comments below in the context of each of these suggestions.

1. Part A to Part B Rebilling

Some stakeholders have suggested that, when a Part A inpatient claim is denied because an inpatient level of care was not reasonable and necessary although some medical care was necessary, CMS allow hospitals to rebill Medicare and receive payment for all Part B services that would have been payable had the patient originally been treated as an outpatient rather than an inpatient. As we describe above, the AB Rebilling Demonstration allows participating providers to receive 90 percent of the allowable payment amount for such services (except observation services) as Part B Inpatient services. Because establishing such a policy on a national basis could result in increases in Medicare expenditures and could affect beneficiary liability for hospital care, CMS implemented the demonstration to assess Medicare spending and other outcomes while protecting beneficiaries from any increase in liability.

Comments: Commenters expressed some support for the AB Rebilling Demonstration as an important step in determining what types of policy clarifications are needed. The commenters noted that the beneficiary protections against changes in

liability are a key benefit of the demonstration. While some commenters expressed appreciation for the opportunity for increased Part B payment to hospitals, they disagreed with the demonstration's requirement to forego appeals of the denied inpatient claims eligible for rebilling. One commenter requested that CMS provide interim reports to stakeholders describing the demonstration's evaluation criteria and its progress towards meeting its goals.

Some commenters recommended that CMS establish a national policy allowing the rebilling of all Part B services that would have been payable if the patient had been treated as an outpatient rather than admitted as an inpatient because, according to the commenters, outpatient and inpatient services are sometimes indistinguishable. The commenters believed that the Medicare statute does not preclude such a policy and that, due to the recent focus on claims audit and review, hospitals would have no incentive to admit beneficiaries inappropriately in response to a more generous rebilling policy. However, other commenters expressed concern that there would be such an incentive. They indicated that allowing expanded rebilling with a change in bill type from a Part A claim to a Part B claim would remove the incentive to bill accurately, as hospitals would file more inpatient claims under Part A in order to receive the (typically higher) Diagnosis-Related Group (DRG) payment under the IPPS, knowing that, in the event of the inpatient claim being denied, they could rebill under Part B and receive the same (typically lower) OPPS payment they would have received if they had billed an outpatient claim initially.

Several commenters suggested that allowing full Part B rebilling would negate and undermine the designs of the OPPS and the IPPS. The commenters stated that OPPS payments are established to compensate hospitals for the care provided in the outpatient setting, and that they act as a natural complement to the IPPS. They indicated that making the two payment systems retroactively interchangeable would result in the payment rates calculated under each system being miscalibrated and failing to adjust appropriately over time to migration of services from the inpatient to the outpatient setting. In addition, according to the commenters, a national policy allowing full Part B rebilling would provide an unfair market advantage to providers who make inappropriate inpatient admission determinations over those who do not. The commenters reasoned that Medicare's current policies are well-founded, longstanding, widely known and largely followed, and that the current challenges do not warrant the extensive resources that full rebilling and other policy changes would entail.

Some commenters indicated that a national policy allowing full Part B rebilling following the denial of an inpatient claim would have limited utility because typically the timely filing period has lapsed by the time the inpatient claim is denied, providers could not appeal the inpatient claim, and providers would not receive the Part A payment that they seek. In addition, according to the commenters, the manual process of recoding the inpatient claim as an outpatient claim is costly. A few commenters suggested that CMS allow rebilling of all Part B services but apply a penalty by limiting payment to a discounted amount. Other commenters were concerned about the significant financial

burden of Part B rebilling for beneficiaries who have Part A coverage but do not have coverage for Part B services.

Some commenters also suggested that CMS allow hospitals to change a beneficiary's inpatient status to outpatient after discharge in order to submit a Part B outpatient claim either prior to or after submitting an inpatient claim. Other commenters recommended that CMS extend the timely filing deadline to 1 year from the date of service or 6 months to 1 year from the date of the inpatient claim denial, whichever is later. Some commenters suggested that CMS extend the timely filing deadline only for claims that are denied after a significant amount of time has passed since the date of service.

Commenters suggested mechanisms to protect beneficiaries from increases in their liability associated with any of these policy changes. For example, several commenters believed that hospitals could waive any increases in beneficiary cost-sharing or that CMS could provide coverage for self-administered drugs in the outpatient department, cap the sum of outpatient services at the inpatient deductible, or establish annual maximum out-of-pocket costs. Many commenters also recommended the modernization and reform of the SNF qualification criteria (we describe these comments further below).

2. Clarifying Current Admission Instructions or Establishing Specified Clinical Criteria

In recent months, we have heard from some stakeholders who suggested a need for us to clarify our current instructions regarding the circumstances under which Medicare will pay for an admission in order to improve hospitals' ability to make

appropriate admission decisions. Stakeholders have suggested the establishment of more specific clinical criteria for admission and payment such as adopting specific clinical measures because, according to the commenters, the current criteria are not clear-cut. We have issued longstanding instructions that the need for admission is a complex medical judgment that depends upon multiple factors, including an expectation that the beneficiary will require an overnight stay in the hospital or need more than 24 hours of care, the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's policies, the relative appropriateness of outpatient and inpatient treatment, and other factors (Section 10, Chapter 1 of the Medicare Benefit Policy Manual (Pub. 100-02)). We stated in the CY 2013 OPPS/ASC proposed rule that we are interested in receiving public comments and suggestions regarding whether and how we might improve our current instructions and clarify the application of Medicare payment policies for both hospitals and physicians, keeping in mind the challenges of implementing national standards that are broad enough to contemplate the range of clinical scenarios but prescriptive enough to provide greater clarity.

Comments: The public comments reflected a widespread understanding and agreement with CMS' guidance that the inpatient admission decision is ultimately a complex medical judgment that involves the consideration of many factors. Many commenters indicated that if Medicare adopted more specific guidelines or criteria, the clinical judgment of the treating physician should have primacy. A recurrent comment was that this judgment would always be necessary in certain cases, and should take

precedence over other criteria that may be used. Many commenters were concerned that decision-making tools (such as Interqual Clinical Decision Support or the Milliman Care Guidelines, alternatively described by commenters as commercial or proprietary screening tools), which are designed for use as guidelines rather than prescriptive tools, do not take into account patient "risk" and may undermine the physician's judgment.

In addition, many commenters believed that any selected criteria must apply equally to Medicare contractors, hospitals, and others and should match the audit review criteria. Many commenters expressed concern that Medicare's claims review contractors inappropriately disregard the physician's judgment, and do not employ a physician in making their determinations. (We describe the comments on external review criteria in further detail below). One commenter indicated that commercial screening tools do not always comport with Medicare rules. The commenter provided as an example that one popular tool fails to distinguish scheduled replacement pacemaker procedures from the placement of a new pacemaker on an emergency basis. Some of the public comments received from physicians identified what they characterized as significant problems with the accuracy, validity, and transparency of proprietary screening tools, including use of appropriateness standards that are not accepted by the relevant physician specialties and failure to follow Medicare payment policy.

Nevertheless, many commenters expressed support for various types of national criteria. These criteria included evidence-based guidelines such as the Agency for Healthcare Research and Quality's National Clearinghouse Guidelines or other rules developed in consultation with physician societies. Some commenters supported the use

of specific proprietary screening tools such as Interqual Clinical Decision Support or the Milliman Care Guidelines. Other commenters favored more transparent criteria similar to the Correct Coding Initiative (CCI) that are adapted for Medicare and are developed using physician input. One commenter indicated that the CCI edits have proven more cost-effective than proprietary tools. A few commenters suggested that use of the Program for Evaluating Payment Patterns Electronic Report (PEPPER) reports, which provide hospital-specific Medicare data statistics for discharges that are vulnerable to improper payments, would allow for continuous improvement in utilization and coding. One commenter noted that it would be useful to choose the set of criteria that are used by Medicaid and other payers, in order to facilitate uniform documentation that supports the specific criteria required by the various screening tools.

Some commenters pointed out process improvements that hospitals and physicians should make, regardless of whether CMS adopts specific clinical criteria or issues more specific admission instructions. Several commenters stated that physicians should improve their documentation in support of the patient status that they order, and that sometimes it is not clear whether the physician ordered inpatient admission or outpatient observation services. The commenters suggested that physicians document the need for admission in a standardized field on electronic health records or elsewhere. Other commenters emphasized the importance of the role of the hospital in selecting patient status for purposes of billing because they believed that the physician is focused on ordering the necessary care and, for good reason according to the commenters, is not occupied with the nuances of patient status designation for payment purposes.

3. Hospital Utilization Review

In the proposed rule, we asked commenters to consider the responsibility of hospitals to utilize all of the tools necessary to make appropriate initial admission decisions. We stated that we believe this is important because some hospitals have indicated that simply having case management and UR staff available to assist in decision-making outside of regular business hours may improve the accuracy of admission decisions.

Comments: Several commenters stated that some hospitals do not have UR staff on hand outside normal business hours or on weekends to assist with patient status determinations, and that this is especially problematic for patients with short inpatient stays. The commenters expressed varying opinions on hospital UR. Some commenters recognized that Medicare's regulations require the collaboration of the treating physician and the hospital's UR staff in making the appropriate patient status determination, and believed that neither party is dispensable. Several commenters indicated that 24-hour, 7 days a week availability of hospital UR and/or case management staff should be a hospital best practice, as it assists in making appropriate admission determinations for short-stay cases where the need for admission is unclear. Several commenters opined that Medicare should require the availability of hospital UR on a 24-hour/7 days a week basis. One commenter stated that CMS should develop a certification process of "deeming" acceptable individual hospital UR processes, using a standard of 24-hour/7 days a week availability, confirmation by an external physician, and adherence to the hospital CoPs. Another commenter recommended the use of a condition code on claims

to track whether UR confirmation of appropriate patient status is associated with fewer claim denials. Some commenters preferred reinforcement of hospital UR over the institution of external guidelines for admission.

However, several commenters indicated that Medicare's current UR requirements in the CoPs should be eliminated because of the administrative cost to the hospital, or because they do not result in more accurate admission determinations that are commensurate with their associated cost. One association believed that hospital UR will have limited utility as long as admission criteria are unclear. Yet another physician professional association stated that hospitals should be required to submit their claims based on the admitting physician's judgment rather than the opinion of another physician in the hospital.

4. Prior Authorization

In our proposed rule, we also invited public comments on the potential use of prior authorization for payment of a hospital inpatient admission.

Comments: Many commenters believed that the concept of using prior authorization on a targeted basis was promising and worthy of consideration. To facilitate administrative feasibility, many commenters suggested that it be used selectively for elective procedures, specific services that are not designated as inpatient-only services under the OPPS, or conditions that are at high-risk for inappropriate inpatient admission. The commenters were concerned that mandatory prior authorization could become a barrier to the provision of urgent care, and some recommended that CMS exclude patients in the emergency department or those receiving critical care.

Alternatively, the commenters suggested that prior authorization be used as an adjunct method for cases not meeting the admission criteria of commercial screening tools.

Several commenters believed that prior authorization is feasible because hospitals already have an infrastructure for obtaining prior authorization for commercial insurers. The commenters suggested that CMS could similarly redirect current resources towards a prior authorization program. Several commenters suggested an online tool for prior authorization.

A few commenters opposed prior authorization altogether based on administrative burden, and many commenters believed that it would need to result in guaranteed payment in order to be useful. One commenter observed that retrospective review is still required in many cases when prior authorizations are obtained from commercial insurers, due to incomplete or inaccurate prior authorization information and changes in what was planned or expected when the initial clinical information was submitted. The commenter stated that for this reason, commercial insurers reserve the right to perform, and often do perform, retrospective audits based on the completed medical record. In addition, the commenter stated that the CERT error rate evidences that the vast majority of providers understand and follow the current Medicare statutes and rules. Thus, according to the commenter, requiring prior authorization will add significant cost to the program without eliminating the inpatient error rate, at a time when the Medicare Trust Fund is at risk.

5. Time-Based Criteria for Inpatient Admission

In the proposed rule, we stated that some stakeholders have suggested that CMS has authority to define whether a patient is an inpatient or an outpatient. They believed

that it may be permissible and appropriate for us to redefine "inpatient" using parameters in addition to medical necessity and a physician order that we currently use, such as length of stay (LOS) or other variables. For example, currently a beneficiary's anticipated LOS at the hospital may be a factor in determining whether the beneficiary should be admitted to the hospital, but is not the only factor. We have issued instructions that state that, typically, the decision to admit should be made within 24 to 48 hours, and that expectation of an overnight stay may be a factor in the admission decision (Section 20.6, Chapter 6 and Section 10, Chapter 1 of the Medicare Benefit Policy Manual (Pub. 100-02)). However, we stated in the proposed rule that we are interested in hearing from stakeholders regarding whether it may be appropriate and useful to establish a point in time after which the encounter becomes an inpatient stay if the beneficiary is still receiving medically necessary care to treat or evaluate his or her condition. We indicated that such a policy could potentially limit the amount of time that a beneficiary is treated as an outpatient receiving observation services before the hospital encounter becomes inpatient, provided the additional time in the hospital is medically necessary. Currently, we do not specify a limit on the time a beneficiary may be an outpatient receiving observation services, although, in the past, we have limited payment of observation services to a specific timeframe, such as 24 or 48 hours. Some in the hospital community have indicated that it may be helpful for the agency to establish more specific criteria for patient status in terms of how many hours the beneficiary is in the hospital, or to provide a limit on how long a beneficiary receives observation services as an outpatient. We invited public comments regarding whether there would be more clarity regarding patient

status under such alternative approaches to defining inpatient status. We also noted that it is important for CMS to maintain its ability to audit and otherwise carry out its statutory obligation to ensure that the Medicare program pays only for reasonable and necessary care. We asked that commenters consider opportunities for inappropriately taking advantage of the Medicare system that time-based and other changes in criteria for patient status may create.

Comments: Some commenters expressed interest and support for criteria that are strictly time-based, based largely on a primary goal of eliminating extended observation cases. These commenters supported defining a patient as an inpatient after 24, 48, or 72 hours, and noted that such a policy could improve the problem of beneficiaries not qualifying for needed SNF care due to their outpatient status. One commenter believed that a 48-hour benchmark made sense because it is consistent with the activities that are required under the CoPs within the first 48 hours of a hospital stay. Another commenter suggested establishing a second decision point during the observation period, when the physician must reevaluate whether the patient needs to be admitted as an inpatient. However, the commenter noted that this may increase administrative complexity without commensurate benefit.

Some commenters representing the hospital community believed that patients who have been actively monitored for more than 24 to 48 hours as outpatients under observation and cannot be safely discharged are likely sufficiently complex cases that would benefit from being admitted as an inpatient, regardless of whether they technically meet inpatient admission criteria. The commenters posited that observation services are

more comparable to inpatient care than they are to other outpatient services, and that this fact would be more accurately reflected by a time-based admission policy. A few commenters suggested that CMS limit observation care to 24 hours, with exceptions for physician discretion. Several commenters suggested that CMS clarify the definition and parameters of outpatient observation services to help stakeholders determine when it is appropriate to furnish observation services and for how long. Another commenter suggested that CMS limit a patient's time in observation by requiring additional assessments and increased documentation of involvement by the physician.

In contrast, many commenters expressed reservations about a time-based approach. Some commenters posited that inpatient and outpatient services are different in nature. One physician association stated that the primary difference between the inpatient and outpatient setting is the availability of nurses (and related staff) and advanced technology in the inpatient setting, which accounts for the added cost of inpatient care. The commenter recommended structuring an inpatient DRG payment around short-stay admissions where the physician believes that these added components of care are necessary. Other commenters were concerned that under a time-based policy, the level of service would no longer be taken into account in hospital payment and that such a policy would inappropriately negate the need for medical necessity review. Some commenters stated that the medical review would simply shift to assessing the necessity of the patient's LOS as an outpatient or whether the patient needed continuing hospital care at the time they became an inpatient. Some commenters believed that a time-based policy would result in additional short inpatient stays than under current Medicare

guidance. Therefore, these commenters believed that hospitals would continue to be subject to audit risk and that short-stay audits would simply increase.

Another commenter expressed concern that hospitals may be substituting outpatient observation services for inpatient admissions in order to maximize their outpatient drug revenues under the Federal 340B Drug Pricing Program. The commenter recommended that CMS modify the definitions of "outpatient" and "inpatient" to explicitly clarify that a patient's status determination should be based solely on appropriate clinical judgment, and should not be influenced by financial motives under programs such as the 340B Drug Pricing Program.

Some commenters opposed time-based rules because, according to the commenters, it would undermine the judgment of the treating physician. Other commenters noted that the absence of objective clinical criteria for choosing a timeframe would render time-based criteria for admission arbitrary. Several commenters opposed limiting observation services to 24 hours because hospitals often need more time (particularly up to 48 hours) to evaluate diagnostic testing and develop the right treatment plan. They noted that practice patterns vary widely nationally and among facilities in the same region. Other commenters were concerned that a policy of never counting certain days as inpatient days could actually reduce beneficiary access to SNF care. Other commenters believed that a time-based policy would need refinement around issues like requirement of a physician order for inpatient admission.

Several commenters opposed time-based criteria because such criteria may conflict with the provision of inpatient surgical care for patients who require only short

admissions. The commenters pointed out that such a policy could conflict with Medicare's inpatient only list, and that as the standard of practice evolves to enable longer inpatient services to be furnished during short (1- or 2-day) inpatient stays, those services would no longer qualify as inpatient services. One commenter stated that there are some procedures that are so inherently complex that they may be performed only on an inpatient basis, regardless of how long (or short) the time was that the patient spent in the hospital. The commenter stated that establishing a bright-line time rule could create a situation whereby these services could be denied solely on the basis of the time spent in the hospital while ignoring the level of service required for subjecting a patient to an inherently risky procedure. The commenter expressed concern that CMS might require that all patients, regardless of clinical presentation, first undergo a period of 48 hours of observation before being admitted as inpatients to the hospital, despite the fact that their medical condition and treatment plan may be wholly consistent with an inpatient admission upon presentation to the hospital.

Several commenters recommended that rather than limiting the timeframe for observation services, observation care should be furnished in dedicated observation units in emergency departments rather than on floor units. They cited studies showing that the dedicated units save costs compared to inpatient care and demonstrate shorter timeframes than the floor units for diagnosing or discharging.

6. Payment Alignment

In the proposed rule, we asked commenters to consider how aligning payment rates more closely with the resources expended by a hospital when providing outpatient

care versus inpatient care of short duration might reduce payment disparities and influence financial incentives and disincentives to admit.

Comments: Commenters expressed significant interest in various means of improving the alignment of payment for what they termed equivalent outpatient and short inpatient hospital stays. Most of the commenters who supported payment alignment suggested developing a DRG for short inpatient stays, although several commenters recommended an expanded outpatient APC payment in addition to or in lieu of a short-stay DRG. Some commenters suggested basing the payment for short-stay inpatient admissions on a percentage of the related DRG by mean LOS. For example, if the mean LOS for a given DRG is 3 days, then the hospital would be paid one-third of that DRG for an inpatient admission with a 1-day stay. Several commenters suggested a short-stay outlier policy similar to the LTCH PPS, or a policy similar to the IPPS transfer policy. Other commenters more broadly suggested developing a resource-based payment structure specifically for short-stay, lower acuity admissions.

Some commenters noted, however, that aligning payment rates would reduce but not eliminate the financial risk of claim denial. According to the commenters, a payment alignment approach would not eliminate the potential for continued use of observation care over inpatient admission. One commenter asserted that the resources expended by a hospital for inpatient and outpatient care are already aligned when the care is billed appropriately.

7. Public Comments on Other Topics

We received a number of public comments on other related issues.

a. Rules for the External Review of Inpatient Claims

Comments: Many commenters expressed concerns about the criteria that are used by Medicare's contractors to determine the medical necessity of hospital inpatient admissions. The commenters were concerned that the review criteria being utilized by contractors do not match the admission criteria set forth in Medicare's guidance. In particular, according to the commenters, contractors are not employing physicians in making their medical necessity determinations, even though Medicare instructs that the admission decision is a complex medical judgment that involves forecasting a potential (not definite) need for an overnight stay or more than 24 hours of hospital care, or the risk of harm to the patient if not admitted (predictability of an adverse event). The commenters asserted that, as a result, claims reviewers inappropriately base their judgment on information that was not predictable or available to the physician at the time of admission.

Many commenters recommended that CMS increase its oversight of the Agency's medical review contractors, and ensure that its review rules are being followed. Commenters asked that CMS require all review contractors to use the same criteria to determine medical necessity that physicians and hospitals are required to use in making the inpatient admission decision; to use a physician reviewer in accordance with the QIO claim review standard, or to consult with the treating physician or a physician in the same specialty as the admitting physician; and to provide justification to the treating physician in support of a claim denial. According to the commenters, the review criteria that are used should apply uniformly to Medicare contractors, hospitals, and others.

Several commenters indicated that physician payment for professional services should be denied whenever inpatient hospital payment is denied, due to the role of the physician in the admission decision. In contrast, some physician commenters were concerned that they already are often inappropriately at risk for denial of their Part B claim when a hospital inpatient claim is denied, or when a hospital changes a patient's status to outpatient without their knowledge such that the place of service on the physician claim does not match that claimed by the hospital. They stated that, in some cases, the hospital does not bill Medicare, so there is no companion claim at all. Similarly, some physicians expressed concern that hospitals use "black box" proprietary tools to identify allegedly inappropriate admissions and change the patient's status to outpatient without the knowledge of the patient or the physician. These commenters also expressed concern for any adverse impact on beneficiary liability.

b. Improving Beneficiary Protections

Comments: Many commenters suggested means of improving beneficiary protections against unforeseen changes in his or her liability. These included providing Medicare coverage for self-administered drugs in the hospital outpatient department, waiving beneficiary coinsurance, capping the sum of outpatient services at the inpatient deductible, or establishing annual maximum out-of-pocket costs. Some commenters suggested that Medicare clarify and strengthen beneficiary notification and appeal rights regarding changes in patient status and the receipt of observation care. For example, according to the commenters, Medicare should require a straightforward explanation to beneficiaries of the cost-sharing implications of being an outpatient receiving observation

services compared to being an inpatient. One QIO noted that as part of their case review activities, QIOs review beneficiary appeals of inpatient hospital discharges to assure that patients are medically ready to move to the next level of care. The QIO believed that if a beneficiary receives only outpatient observation services and is not an inpatient, he or she has no right to appeal his or her discharge from the hospital to the QIO. The QIO stated that it often receives complaints from beneficiaries who believe they are being discharged prematurely, only to find out that the QIO cannot review that care because the hospital classified the stay as observation rather than inpatient.

Some commenters suggested means of penalizing hospitals for inappropriate admission patterns. They provided examples such as developing quality measures with payment penalties to identify instances of inappropriate use of observation care for patients meeting inpatient admission criteria, or counting time spent receiving observation services as inpatient time for the purposes of hospital readmission penalties. Other commenters recommended improving physician education regarding the beneficiary liabilities that are associated with patient status to facilitate patient status determinations that take beneficiary cost-sharing into account.

c. Revising the Qualifying Criteria for Skilled Nursing Facility (SNF) Coverage

Comments: Many commenters recommended that Congress and/or CMS modernize and revise the SNF qualification rules. Many beneficiaries, beneficiary representatives, SNFs, and others requested that CMS count the time a beneficiary spends as an outpatient receiving observation services towards the 3-day hospital inpatient stay that is required for coverage of SNF care. Many commenters indicated that the statutory

time-based rule that requires a beneficiary to have a 3-day inpatient hospital stay in order to qualify for SNF care is obsolete, given the advances in medical care, the trend towards reduced LOS, and the migration of services from inpatient to outpatient over the course of the Medicare program's history. These commenters recommended that this rule be replaced with clinically meaningful criteria that are not time-based or based on patient status.

A few commenters asserted that CMS could use its statutory authority under section 1812(f) of the Act (as enacted by section 123 of the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248) to waive the 3-day qualification rule. Some commenters asserted that the criteria for using this authority would be met, namely that there would be no increase in associated costs to the Medicare program and that the acute nature of the SNF benefit would be maintained. The Act provides that the Secretary shall provide for coverage of extended care services which are not post-hospital extended care services at such time and for so long as the Secretary determines that the inclusion of such services will not result in any increase in the total payments made under Title XVIII, and will not alter the acute care nature of the SNF benefit. Other commenters believed that new statutory authority would be required to change the SNF criteria, and they expressed their support for bills they stated have been introduced in the Congress to count time in observation as inpatient time for purposes of SNF qualification. Some commenters recommended waiving the 3-day rule for certain diagnoses that benefit from short inpatient stays and speedy access to postacute rehabilitative services. They indicated that some beneficiaries require only a brief hospital assessment, rather than a

lengthy stay in acute care, prior to long-term skilled care, and that it is not uncommon for patients with hospital stays of less than 3 days to require follow up care in a SNF.

C. Summary

We appreciate all of the public comments that we received on this multi-faceted topic. We will take all of the public comments that we received into consideration as we consider future actions that we could potentially undertake to provide more clarity and consensus regarding patient status for purposes of Medicare payment.

XII. CY 2013 OPPS Payment Status and Comment Indicators

A. CY 2013 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs play an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code. The CY 2013 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. We note that, in the past, a majority of the Addenda referred to throughout the preamble of our OPPS/ASC proposed and final rules appeared in the printed version of the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, the Addenda will no longer appear in the printed version of the OPPS/ASC rules that are found in the **Federal Register**. Instead, these Addenda will be published and available only via the Internet on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

We did not receive any public comments related to the definitions of the OPPS status indicators, and therefore, as we proposed in the CY 2013 OPPS/ASC proposed rule (77 FR 45157), for CY 2013, we are not making any changes to the definitions of status indicators that were listed in Addendum D1 of the CY 2012 OPPS/ASC final rule with

comment period. We believe that these definitions of the OPPS status indicators continue to be appropriate for CY 2013.

The complete list of the final CY 2013 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.

B. CY 2013 Comment Indicator Definitions

In the CY 2013 OPPS/ASC proposed rule (77 FR 45158), for the CY 2013 OPPS, we proposed to use the same two comment indicators that are in effect for the CY 2012 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 2013 OPPS/ASC proposed rule to indicate HCPCS codes for which the status indicator or APC assignment, or both, are proposed for change in CY 2013 compared to their assignment as of June 30, 2012. We stated that we believed that using the "CH" indicator in the CY 2013 OPPS/ASC proposed rule would facilitate the public's review of the changes that

we were proposing for CY 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 is proposed to be changed in the CY 2013 OPPS/ASC final rule with comment period.

We proposed to use the "CH" comment indicator in the CY 2013 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 2013 compared to their assignment as of December 31, 2012.

In addition, any existing HCPCS codes with substantial revisions to the code descriptors for CY 2013 compared to the CY 2012 descriptors are labeled with comment indicator "NI" in Addendum B to the CY 2013 OPPS/ASC final rule with comment period. However, as we stated in the proposed rule, in order to receive the comment indicator "NI," the CY 2013 revision to the code descriptor (compared to the CY 2012 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 are open for comment as part of the CY 2013 OPPS/ASC final rule with comment period. Like all codes labeled with comment indicator "NI," as we stated in the CY 2013 OPPS/ASC proposed rule, we will respond to public comments and finalize their OPPS treatment in the CY 2014 OPPS/ASC final rule with comment period.

In accordance with our usual practice, CPT and Level II HCPCS codes that are new for CY 2013 are also labeled with comment indicator "NI" in Addendum B to the CY 2013 OPPS/ASC final rule with comment period.

Only HCPCS codes with comment indicator "NI" in this CY 2013 OPPS/ASC final rule with comment period are subject to comment. HCPCS codes that do not appear with comment indicator "NI" in this CY 2013 OPPS/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. The CY 2013 treatment of HCPCS codes that appear in this CY 2013 OPPS/ASC final rule with comment period to which comment indicator "NI" is not appended was open for public comment during the comment period for the proposed rule, and we indicated that we would respond to those comments in this CY 2013 OPPS/ASC final rule with comment period.

We did not receive any public comments on the proposed comment indicators. We believe that the CY 2012 definitions of the OPPS status indicators continue to be appropriate for CY 2013, and therefore, as proposed, we are continuing to use those definitions without modification for CY 2013. The final definitions are listed in Addendum D2 on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatient PPS/index.html.

XIII. OPPS Policy and Payment Recommendations

A. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act to advise the Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to Congress no later than March and June of each year that contain its Medicare payment policy recommendations. In our CY 2013 OPPS/ASC proposed rule, we noted several recommendations regarding the OPPS from the March 2012 report ("Report to the Congress: Medicare Payment Policy," available on MedPAC's Web site at: http://www.medpac.gov/documents/Mar12_EntireReport.pdf). Since the publication of the proposed rule, MedPAC has not made any other recommendations regarding the OPPS, although we discuss MedPAC's public comments to our proposed rule in the applicable sections of this final rule with comment period.

In its March report, MedPAC recommended that Congress increase payment rates for the OPPS in CY 2013 by 1.0 percent. We discuss our final policy to follow the statutory requirements for the CY 2013 OPD fee schedule increase factor in section II.B of this final rule with comment period.

In addition, MedPAC recommended that Congress enact legislation to reduce payment rates for evaluation and management office visits provided in hospital outpatient departments to the rates paid for these services in physician offices. MedPAC recommended that the change be phased in over 3 years. During the phase-in, MedPAC stated that the associated payment reductions to hospitals with a disproportionate share

patient percentage at or above the median should be limited to 2 percent of overall Medicare payments. MedPAC also recommended that the Secretary of Health and Human Services conduct a study by January 2015 to examine whether this policy change would reduce access to ambulatory physician and other services for low-income patients. Congress has not enacted such legislation.

B. GAO Recommendations

Congress established the U.S. Government Accountability Office (GAO) under the Budget and Accounting Act of 1921 (Pub. L. 67-13) as an independent agency that advises Congress and the heads of Executive agencies regarding Federal program expenditures. The GAO conducts audits and other analyses to ensure that Federal funds are being spent efficiently and effectively. Since the issuance of the CY 2012 OPPS/ASC final rule with comment period, the GAO has not released any reports regarding the OPPS.

C. OIG Recommendations

The mission of the Office of the Inspector General (OIG) as mandated by Pub. L. 95–452 (as amended) is to protect the integrity of the Department of Health and Human Services programs and the health and welfare of program beneficiaries. The OIG conducts independent audits, inspections, and investigations to improve the efficiency of these programs and to identify and prevent fraud, waste and abuse. Since the issuance of the CY 2012 OPPS/ASC final rule with comment period, the OIG has not made any recommendations regarding the OPPS.

XIV. 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 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74378 through 74379).

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 are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and 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 for 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 OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. These covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment (72 FR 42495). Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (§ 416.173; 72 FR 42535). In addition, as discussed in detail in section XIV.B. of this final rule with comment period, because we base ASC payment policies for covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, 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, the 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 OPPS/ASC proposed rule for the process used to update the HCPCS and CPT codes (76 FR 42291).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures (including all procedures newly proposed for removal from the OPPS inpatient list), new procedures, and procedures for which there is revised coding, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a

regular, predictable, and timely manner. We did not receive any public comments on this process. Therefore, we are continuing our established process without modification for determining the list of codes and payment rates for ASC covered surgical procedures and covered ancillary services.

B. Treatment of New Codes

1. Process for Recognizing New Category I and Category III CPT Codes and Level II HCPCS Codes

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; (2) Category III CPT codes, which describe new and emerging technologies, services, and procedures; and (3) Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule to evaluate each year all new Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures (72 FR 42533 through 42535). In addition, we identify new codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system.

We have separated our discussion below into two sections based on whether we proposed to solicit public comments in the CY 2013 OPPS/ASC proposed rule (and respond to those comments in this CY 2013 OPPS/ASC final rule with comment period) or whether we are soliciting public comments in this CY 2013 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2014 OPPS/ASC final rule with comment period).

We note that we sought public comment in the CY 2012 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2012. We also sought public comments in the CY 2012 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2011. These new codes, with an effective date of October 1, 2011, or January 1, 2012, were flagged with comment indicator "NI" in Addenda AA and BB to the CY 2012 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2012 OPPS/ASC final rule with comment period. In the proposed rule, we stated that we would respond to public comments and finalize the ASC treatment of these codes in this CY 2013 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding our process for recognizing new Category I and Category III CPT codes and Level II HCPCS codes under the ASC payment system and are implementing our proposed policy as final, without modification, for CY 2013.

2. Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April and July 2012 for Which We Solicited Public Comments in the CY 2013 OPPS/ASC Proposed Rule

In the April and July CRs, we made effective for April 1, 2012 or July 1, 2012, respectively, a total of 12 new Level II HCPCS codes and 5 new Category III CPT codes that were not addressed in the CY 2012 OPPS/ASC final rule with comment period. The 12 new Level II HCPCS codes describe covered ancillary services.

In the April 2012 ASC quarterly update (Transmittal 2425, CR 7754, dated March 16, 2012), we added one new radiology Level II HCPCS code and four new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 36 of the CY 2013 OPPS/ASC proposed rule (77 FR 45160), we added the following codes to the list of covered ancillary services:

- HCPCS code C9288 (Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial);
- HCPCS code C9289 (Injection, asparaginase Erwinia chrysanthemi, 1,000international units (I.U.));
- HCPCS code C9290 (Injection, bupivacaine liposome, 1 mg);
- HCPCS code C9291 (Injection, aflibercept, 2 mg vial); and
- HCPCS code C9733 (Non-ophthalmic fluorescent vascular angiography).

In the July 2012 quarterly update (Transmittal 2479, Change Request 7854, dated May 25, 2012), we added seven new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 37 of the CY 2013

OPPS/ASC proposed rule (77 FR 45161), we added the following codes to the list of covered ancillary services:

- HCPCS code C9368 (Grafix core, per square centimeter);
- HCPCS code C9369 (Grafix prime, per square centimeter);
- HCPCS code Q2034 (Influenza virus vaccine, split virus, for intramuscular use (Agriflu));
- HCPCS code Q2045 (Injection, human fibrinogen concentrate, 1 mg);
- HCPCS code Q2046 (Injection, aflibercept, 1 mg);
- HCPCS code Q2048 (Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg); and
- HCPCS code Q2049 (Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg).

We noted that HCPCS code Q2045 replaced code J1680, HCPCS code Q2046 replaced code C9291, and HCPCS code Q2048 replaced code J9001 beginning July 1, 2012.

We assigned payment indicator "K2" (Drugs and biologicals paid separately when provided integral to a surgical procedure on the ASC list; payment based on OPPS rate) to the 10 new 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) or payment indicator "N1" (Packaged service/item; no separate payment made) to the two new Level II HCPCS codes that are packaged when provided in ASCs. In the CY 2013 OPPS/ASC proposed rule

(77 FR 45160), we solicited public comment on the proposed CY 2013 ASC payment indicators and payment rates for the covered ancillary services listed in Tables 36 and 37 of the proposed rule (77 FR 45160 through 45161). Those HCPCS codes became payable in ASCs, beginning in April or July 2012, 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 36 of the proposed rule were included in Addendum BB to the proposed rule (which was available via the Internet on the CMS Web site). We noted 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 for July 2012 (listed in Table 37 of the proposed rule) were not available to us in time for incorporation into the Addenda to the OPPS/ASC proposed rule, our policy is to include these HCPCS codes and their proposed payment indicators and payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. These codes and their final payment indicators and rates are included in the appropriate Addendum to this CY 2013 OPPS/ASC final rule with comment period. Thus, the codes implemented by the July 2012 ASC quarterly update CR and their proposed CY 2013 payment rates (based on July 2012 ASP data) that were displayed in Table 37 were not included in Addendum BB to the proposed rule (which was available via the Internet on the CMS Web site). The final list of covered ancillary services and the associated payment weights and payment indicators is included in Addendum BB to this

CY 2013 OPPS/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 ancillary services in April and July 2012 through the quarterly update CRs, as listed in Tables 36 and 37 of the proposed rule. We proposed to finalize their payment indicators and their payment rates in this CY 2013 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding our proposals. We are adopting as final for CY 2013 the ASC payment indicators for the ancillary services described by the new Level II HCPCS codes implemented in April and July 2012 through the quarterly update CRs as shown below, in Tables 47 and 48, respectively. These new HCPCS codes are also displayed in Addendum BB to this final rule with comment period. We note that after publication of the CY 2013 OPPS/ASC proposed rule, the CMS HCPCS Workgroup created permanent HCPCS J-codes for CY 2013 to replace certain temporary HCPCS C-codes made effective for CY 2012. These permanent CY 2013 HCPCS J-codes are listed alongside the temporary CY 2012 HCPCS C-codes in Tables 47 and 48 below.

TABLE 47.—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2012

CY 2012 HCPCS Code	CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 Payment Indicator
C9288	J0716	Injection, centruroides immune f(ab)2, up to 120 milligrams	K2

CY 2012 HCPCS Code	CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 Payment Indicator
C9289	J9019	Injection, asparaginase (Erwinaze), 1,000 IU	K2
C9290	C9290	Injection, bupivacaine liposome, 1 mg	K2
C9291*	J0178	Injection, aflibercept, 1 mg	K2
C9733	C9733	Non-ophthalmic fluorescent vascular angiography	N1

*Note: Level II HCPCS code C9291 (Injection, aflibercept, 2 mg vial) was deleted June 30, 2012, and replaced with HCPCS code Q2046 (Injection, aflibercept, 1 mg), effective July 1, 2012. HCPCS code Q2046 was deleted December 31, 2012, and replaced with HCPCS code J0178 effective January 1, 2013.

TABLE 48.—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2012

CY 2012 HCPCS Code	CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 Payment Indicator
C9368	Q4132	Grafix core, per square centimeter	K2
C9369	Q4133	Grafix prime, per square centimeter	K2
Q2034	Q2034	Influenza virus vaccine, split virus, for intramuscular use (Agriflu)	L1
Q2045*	J7178	Injection, human fibrinogen concentrate, 1 mg	K2
Q2046*	J0178	Injection, aflibercept, 1 mg	K2
Q2048*	J9002	Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg	K2
Q2049	Q2049	Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg	K2

*Note: HCPCS code Q2045 replaced HCPCS code J1680, HCPCS code Q2046 replaced HCPCS code C9291, and HCPCS code Q2048 replaced HCPCS code J9001 beginning July 1, 2012.

Through the July 2012 quarterly update CR, we also implemented ASC payment for five new Category III CPT codes as ASC covered surgical procedures, effective July 1, 2012. These codes were listed in Table 38 of the CY 2013 OPPS/ASC proposed

rule (77 FR 45161), along with their proposed payment indicators and proposed payment rates for CY 2013. 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 38 of the proposed rule and their final payment indicators and rates are included in Addendum AA to this CY 2013 OPPS/ASC final rule with comment period.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45161), we proposed to assign payment indicator "G2" (Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) to three of the five new Category III CPT codes implemented in July 2012 and to assign payment indicator "J8" (Device-intensive procedure added to ASC list in CY 2008 or later; paid at adjusted rate) to the remaining two new Category III CPT codes implemented in July 2012. We believe that these procedures would not be expected to pose a significant safety risk to Medicare beneficiaries or would not be expected to require an overnight stay if performed in ASCs. We solicited public comment on these proposed payment indicators and the payment rates for the new Category III CPT codes that were newly recognized as ASC covered surgical procedures in July 2012 through the quarterly update CR, as listed in Table 38 of the proposed rule (77 FR 45161). We proposed to finalize their payment indicators and their payment rates in this CY 2013 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding this proposal. We are adopting as final for CY 2013 the ASC payment indicators for the covered surgical procedures described by the new Category III CPT codes implemented in the July 2012 CR as shown below in Table 49. The new CPT codes implemented in July 2012 are also displayed in Addendum AA to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 49.—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2012 AS ASC COVERED SURGICAL PROCEDURES

CY 2013 CPT Code	CY 2013 Long Descriptor	Final CY 2013 Payment Indicator
0302T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode)	J8
0303T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only	G2
0304T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only	J8
0307T	Removal of intracardiac ischemia monitoring device	G2
0308T*	Insertion of ocular telescope prosthesis including removal of crystalline lens	G2

*CPT code 0308T replaced HCPCS code C9732 beginning July 1, 2012.

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 2013 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 2013 OPPS/ASC proposed rule (77 FR 45161 through 45162), we proposed to continue this process for CY 2013. Specifically, for CY 2013, we proposed to include in Addenda AA and BB to the CY 2013 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2013, that would be incorporated in the January 2013 ASC quarterly update CR and the new Level II HCPCS codes, effective October 1, 2012 or January 1, 2013, that would be released by CMS in its October 2012 and January 2013 ASC quarterly update CRs. We stated that these codes would be flagged with comment indicator "NI" in Addenda AA and BB to this CY 2013 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 2013 OPPS/ASC final rule with comment period and would be finalized in the CY 2014 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding this proposed process. For CY 2013, 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 for the following year, 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 changed the clinical appropriateness of these procedures for the ASC setting. In the CY 2013 OPPS/ASC proposed rule (77 FR 45162), we proposed to update the list of ASC covered surgical procedures by adding 16 procedures to the list. We determined that these 16 procedures would not be expected to pose a significant safety risk to Medicare beneficiaries and would not be expected to require an overnight stay if performed in ASCs.

The 16 procedures that we proposed to add to the ASC list of covered surgical procedures, including their HCPCS code long descriptors and proposed CY 2013 payment indicators, were displayed in Table 39 of the proposed rule (77 FR 45162). We invited public comment on this proposal.

Comment: Many commenters supported the addition of the procedures listed in Table 39 of the CY 2013 OPPS/ASC proposed rule to the list of ASC covered surgical procedures.

One commenter believed that CPT codes 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound) and 0300T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care) should not be added to the list of ASC covered surgical procedures. The commenter agreed with CMS that these codes would not pose a significant safety risk to Medicare beneficiaries and would not be expected to require an overnight stay if performed in an ASC. However, the commenter believed that additional information on the clinical efficacy and outcomes of these services should be collected before adding these procedures to the list of ASC covered surgical procedures.

Response: We appreciate commenters' support of the proposed addition of the procedures listed in Table 39 of the CY 2013 OPPS/ASC proposed rule to the list of ASC covered surgical procedures for CY 2013. With regard to the commenter's belief that CPT codes 0299T and 0300T should not be added to the list of ASC covered surgical procedures until additional information regarding the clinical efficacy and outcomes of these services is collected, our policy is to review all HCPCS codes that are currently paid under the OPPS to identify any procedures that are currently excluded from the ASC list of covered procedures that we believe would not pose a safety risk to Medicare beneficiaries and would not require an overnight stay if performed in an ASC (42 CFR

416.166). We do not make our assessment regarding what codes should be included on the list of covered surgical procedures based on data regarding the clinical efficacy and outcomes of the services. Because it is our expectation that the procedures identified by CPT codes 0299T and 0300T would not pose a significant safety risk to Medicare beneficiaries or require an overnight stay if performed in an ASC, we do not agree with the commenter that these procedures should continue to be excluded from the list of ASC covered surgical procedures.

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; and 76 FR 74380, and 74399), procedures that are reported by the CPT unlisted codes are not eligible for addition to the ASC list because our charge requires us to evaluate each surgical procedure for potential safety risk and expected need for overnight monitoring and to exclude such procedures from ASC payment. 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: In addition to the procedures listed in Table 39 of the CY 2013 OPPS/ASC proposed rule, commenters requested that CMS add the procedures described by the 57 CPT codes displayed in Table 50 below to the list of ASC covered surgical procedures. 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.

TABLE 50.--PROCEDURES REQUESTED FOR ADDITION TO THE CY 2013 LIST OF ASC COVERED SURGICAL PROCEDURES

CY 2013 CPT Code	CY 2013 Short Descriptor
0274T	Perq lamot/lam crv/thrc
0275T	Perq lamot/lam lumbarbar
21141*	Reconstruct midface lefort
21142*	Reconstruct midface lefort
22551	Neck spine fuse&remov bel c2
22552*	Addl neck spine fusion
22554	Neck spine fusion
22612	Lumbar spine fusion
22845*	Insert spine fixation device
22846*	Insert spine fixation device
22851	Apply spine prosth device
23470	Reconstruct shoulder joint
22856	Cerv artific diskectomy
27096	Inject sacroiliac joint
27125*	Partial hip replacement
27130*	Total hip arthroplasty
27415	Osteochondral knee allograft
27447*	Total knee arthroplasty
27524	Treat kneecap fracture

CY 2013 CPT Code	CY 2013 Short Descriptor
27556*	Treat knee dislocation
27558*	Treat knee dislocation
27702*	Reconstruct ankle joint
27703*	Reconstruct ankle joint
27715*	Revision of lower leg
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)
57310	Repair urethrovaginal lesion
58541	Lsh uterus 250 g or less
58542	Lsh w/t/o ut 250 g or less
58570	Tlh uterus 250 g or less
58571	Tlh w/t/o 250 g or less
63001	Removal of spinal lamina
63003	Removal of spinal lamina
63005	Removal of spinal lamina
63012	Removal of spinal lamina
63015	Removal of spinal lamina
63017	Removal of spinal lamina
63020	Neck spine disk surgery
63030	Low back disk surgery
63035	Spinal disk surgery add-on
63042	Laminotomy single lumbar
63043*	Laminotomy addl cervical
63047	Removal of spinal lamina
63048	Remove spinal lamina add-on
63050*	Cervical laminoplasty
63056	Decompress spinal cord
63075	Neck spine disk surgery
63076	Neck spine disk surgery
63081*	Removal of vertebral body
63265*	Excise intraspinal lesion
63267*	Excise intraspinal lesion
63275*	Biopsy/excise spinal tumor
63277*	Biopsy/excise spinal tumor

*Indicates that these procedures are paid only as inpatient 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 57 requested procedures, we did not review the 22 procedures that are reported by CPT codes that are on the OPPS inpatient list. These procedures are not paid under the OPPS and, therefore, are not eligible for addition to the list of ASC covered procedures. The procedures that are paid only as inpatient procedures are identified with an asterisk in Table 50. In addition, the procedure that is identified by CPT code 27096 (Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or ct) including arthrography when performed) is not paid under the OPPS and, therefore, is not eligible for addition to the list of ASC covered procedures.

With regard to the remaining procedures in Table 50 that commenters requested be added to the list of ASC covered surgical procedures, we do not agree that most 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 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 50, we found that most of the procedures either may 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. Several of the urology procedures appear to require major invasion of a body cavity. However, we agree with commenters that the procedures described by CPT codes 0274T, 0275T, 58541, 58542, 58570, 58571, 63001, 63003, and 63005 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 2013.

After consideration of the public comments we received, we are finalizing the addition of the 16 procedures that we proposed to add to the list of ASC covered surgical procedures for CY 2013. We are also adding 9 of the procedures requested by the

commenters to the CY 2013 list of ASC covered surgical procedures. The procedures, their descriptors, and payment indicators are displayed in Table 51 below.

TABLE 51.—NEW ASC COVERED SURGICAL PROCEDURES FOR CY 2013

CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 ASC Payment Indicator**
0274T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, ct), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic	G2
0275T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, ct), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar	G2
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2*
0300T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care	R2*
37205	Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; initial vessel	G2
37206	Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; each additional vessel (list separately in addition to code for primary procedure)	G2
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty	G2
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed	G2

CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 ASC Payment Indicator**
37226	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	G2
37227	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed	J8
37228	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty	G2
37229	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed	G2
37230	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	G2
37231	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed	J8
37232	Revascularization, endovascular, open or percutaneous, tibial/ peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (list separately in addition to code for primary procedure)	G2
37233	Revascularization, endovascular, open or percutaneous, tibial/ peroneal artery, unilateral, each additional vessel; with atherectomy, includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure)	G2
37234	Revascularization, endovascular, open or percutaneous, tibial/ peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure)	G2

CY 2013 HCPCS Code	CY 2013 Long Descriptor	Final CY 2013 ASC Payment Indicator**
37235	Revascularization, endovascular, open or percutaneous, tibial/ peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure)	G2
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less	G2
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	G2
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less	G2
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	G2
63001	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; cervical	G2
63003	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; thoracic	G2
63005	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; lumbar, except for spondylolisthesis	G2

*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. At the time this final rule with comment period was being developed for publication, current law authorizes a negative update to the MPFS payment rates for CY 2013. For a discussion of those rates, we refer readers to the CY 2013 MPFS final rule with comment period.

b. Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as "office-based" those procedures that are added to the ASC list of covered surgical

procedures in CY 2008 or later years that we determine are performed predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC list of covered surgical procedures beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator "P2" (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); "P3" (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or "R2" (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated it would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the list of surgical procedures eligible for payment in ASCs, each year we identify surgical procedures as either temporarily office-based, permanently office-based, or non-office-based, after taking into account updated volume and utilization data.

(2) Changes for CY 2013 to Covered Surgical Procedures Designated as Office-Based

In developing the CY 2013 OPPS/ASC proposed rule, we followed our policy to annually review and update the surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. We reviewed CY 2011 volume and utilization data and the clinical characteristics for all surgical procedures that are assigned payment indicator "G2" (Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in CY 2012, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically "P2*," "P3*," or "R2*" in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74400 through 74408).

In the CY 2013 OPPS/ASC proposed rule (77 FR 45163), we stated that our review of the CY 2011 volume and utilization data resulted in our identification of six covered surgical procedures that we believe meet the criteria for designation as office-based. We stated that the data indicated that the procedures are performed more than 50 percent of the time in physicians' offices, and that our medical advisors believed the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The six CPT codes we proposed to permanently designate as office-based were listed in Table 40 of the CY 2013 OPPS/ASC proposed rule (77 FR 45163), and are listed in Table 52 below. We invited public comments 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, and CY 2012 OPPS/ASC final rules with comment period (74 FR 60605 through 60607; 75 FR 72034 through 72036; and 76 FR 74401, respectively).

After consideration of the public comments we received, we are finalizing our CY 2013 proposal to designate the procedures displayed in Table 52 below as permanently office-based for CY 2013.

TABLE 52.—ASC COVERED SURGICAL PROCEDURES NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2013

CY 2013 CPT Code	CY 2013 Long Descriptor	CY 2012 ASC Payment Indicator	Proposed CY 2013 ASC Payment Indicator*	Final CY 2013 ASC Payment Indicator*
31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa	G2	P2	P2
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)	G2	P2	P2
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)	G2	P2	P2
53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence	G2	P2	P2
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming	G2	P3	P3
G0365	Vessel mapping of vessels for hemodialysis access (services for preoperative vessel mapping prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous outflow)	G2	P2	P2

*Final payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates. At the time this final rule with comment period was being developed for publication, current law authorizes a negative update to the MPFS payment rates for CY 2013. For a discussion of those rates, we refer readers to the CY 2013 MPFS final rule with comment period.

We also reviewed CY 2011 volume and utilization data and other information for the eight procedures finalized for temporary office-based status in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74404 through 74408). Among these eight procedures, there were very few claims data for six procedures: CPT code 0099T (Implantation of intrastromal corneal ring segments); CPT code 0124T (Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication)); 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 0227T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)); 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 (eg, retinopathy of prematurity), photocoagulation or cryotherapy). Consequently, we proposed in the CY 2013 OPPS/ASC proposed rule (77 FR 45163) to maintain their temporary office-based designations for CY 2013.

The volume and utilization data for the remaining two procedures that have temporary office-based designations for CY 2012 are sufficient to indicate that these procedures are not performed predominantly in physicians' offices and, therefore, should

not be assigned an office-based payment indicator in CY 2013. Consequently, we proposed to assign payment indicator "G2" to the following two covered surgical procedure codes in CY 2013:

- CPT code 37761 (Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg); and
- CPT code 0232T (Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed).

The proposed CY 2013 payment indicator designations for the eight procedures that were temporarily designated as office-based in CY 2012 were displayed in Table 41 of the CY 2013 OPPS/ASC proposed rule (77 FR 45164). The procedures for which the proposed office-based designations for CY 2013 are temporary also were indicated by asterisks in Addendum AA to the proposed rule (which was available via the Internet on the CMS Web site). We invited public comments on this proposal.

We did not receive any public comments that addressed our proposal to continue to designate six of the eight procedures, which were designated as temporarily office-based for CY 2012, as temporarily office-based for CY 2013. Therefore, we are finalizing our proposal to designate the six procedures listed in Table 41 of the CY 2013 OPPS/ASC proposed rule (77 FR 45164) and restated in Table 53 below, which were designated as temporarily office-based for CY 2012, as temporarily office-based for CY 2013. In addition, we did not receive any public comments that addressed our proposal to not designate as office-based in CY 2013 the two remaining procedures that were designated as temporarily office-based for CY 2012. Therefore, we are finalizing

our proposal to not provide an office-based designation to the 2 procedures listed in Table 41 of the CY 2013 OPPS/ASC proposed rule (77 FR 45164), and restated below in Table 53, which were designated as temporarily office-based for CY 2012.

TABLE 53.—CY 2013 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2012 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2013 CPT Code	CY 2013 Long Descriptor	CY 2012 ASC Payment Indicator	CY 2013 ASC Payment Indicator**
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg	R2*	G2
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*
0099T	Implantation of intrastromal corneal ring segments	R2*	R2*
0124T	Conjunctival incision with posterior extrascleral 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*	R2*
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed	R2*	G2
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*

* 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. At the time this final rule with comment period was being developed for publication, current law authorizes a negative update to the MPFS payment rates for CY 2013. For a discussion of those rates, we refer readers to the CY 2013 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 Covered Surgical Procedures Designated as Device-Intensive for CY 2013

In the CY 2013 OPPS/ASC proposed rule (77 FR 45164), we proposed for CY 2013 to update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with the proposed OPPS device-dependent APC update, reflecting the proposed APC assignments of procedures, designation of APCs as device-dependent, and APC device offset percentages based on the CY 2011 OPPS claims and cost report data available for the proposed rule. The OPPS device-dependent APCs are discussed further in section II.A.2.d.(1) of this final rule with comment period.

The ASC covered surgical procedures that we proposed to designate as device-intensive and that would be subject to the device-intensive procedure payment methodology for CY 2013 were listed in Table 42 of the CY 2013 OPPS/ASC proposed rule (77 FR 45165 through 45166). The CPT code, the CPT code short descriptor, the

proposed CY 2013 ASC payment indicator (PI), the proposed CY 2013 OPPS APC assignment, the proposed CY 2013 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 42 of the proposed rule. All of these procedures were included in Addendum AA to the proposed rule (which was available via the Internet on the CMS Web site). We invited public comments 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, regardless of whether the procedures are assigned to APCs that are designated as device-dependent under the OPPS. In a related suggestion, the 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 X 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 that the modified payment methodology for calculating ASC payment rates for device-intensive procedures shall apply to ASC covered surgical procedures that are assigned to device-dependent APCs under the OPPS for the same calendar year, where those APCs

have a device cost of greater than 50 percent of the APC cost (that is, the device offset percentage is greater than 50). We continue to believe these criteria ensure that ASC payment rates are adequate to provide packaged payment for high cost implantable devices and ensure Medicare beneficiaries have access to these procedures in all appropriate settings of care.

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, regardless of whether the procedure is assigned to a device-dependent APC under the OPPS. Nor do we agree with the commenters who suggest 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 less than 50 percent 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, and CY 2012 OPPS/ASC final rules with comment period (74 FR 60608 and 60609; 75 FR 72039; and 76 FR 74409, 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. Consistent with the OPPS, 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, and CY 2012 OPPS/ASC final rules with comment period (73 FR 68735; 74 FR 60608 through 60609; 75 FR 72039; and 76 FR 74409, respectively).

After consideration of the public comments we received, we are designating the ASC covered surgical procedures displayed in Table 54 below as device-intensive for CY 2013. The CPT code, the CPT code short descriptor, the final CY 2013 ASC payment indicator (PI), the final CY 2013 OPPS APC assignment, the final CY 2013 OPPS APC device offset percentage, and an indication if the full credit/partial credit (FB/FC) device adjustment policy will apply are also listed in Table 54 of this final rule with comment period. As we discuss in section XIII.B.3. of the CY 2013 OPPS/ASC proposed rule (77 FR 45161 through 45162) 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, 2012 and January 1, 2013 in this final rule with comment period. Because these codes were not available to us until after the CY 2013 OPPS/ASC proposed rule was published, these codes were not included in that rule. We have reviewed these new codes and have added six of these CPT codes to Table 54 because they are ASC covered surgical procedures and are assigned to device-dependent APCs that meet the ASC device-intensive criteria. Specifically, we added the following new codes to the list of ASC device-intensive procedures: CPT code 0316T (Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator); CPT code 0319T (Insertion or replacement of subcutaneous implantable defibrillator system with

subcutaneous electrode); CPT code 0321T (Insertion of subcutaneous implantable defibrillator pulse generator only with existing subcutaneous electrode); CPT code 0323T (Removal of subcutaneous implantable defibrillator pulse generator with replacement of subcutenous implantable defibrillator pulse generator only); CPT code 24370 (Revision of total elbow arthroplasty, including allograft when performed; humeral or ulnar component); and CPT code 24371 (Revision of total elbow arthroplasty, including allograft when performed; humeral and ulnar component). These new device-intensive procedures 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 2014 OPPS/ASC final rule with comment period. Each device-intensive procedure is assigned payment indicator "J8." 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). The OPPS device-dependent APCs are discussed further in section II.A.2.d.(1) of this final rule with comment period.

d. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

We generally discuss the no cost/full credit and partial credit devices under the heading entitled "ASC Payment for Covered Surgical Procedures." However, because the no cost/full credit and partial credit device policy applies to a subset of device-intensive procedures, we believe it would be clearer to discuss the device-intensive procedure policy and the no cost/full credit and partial credit device policy consecutively and to consolidate the tables that we usually publish separately. Our ASC policy with

regard to payment for costly devices implanted in ASCs at no cost/full credit or partial credit as set forth in § 416.179 is consistent with the OPPS policy. The proposed and final CY 2013 OPPS APCs and devices subject to the adjustment policy are discussed in section IV.B.2. of this final rule with comment period. 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 OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/ASC final rule with comment period for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices (73 FR 68742 through 68744).

Consistent with the OPPS, in the CY 2013 OPPS/ASC proposed rule (77 FR 45165), we proposed to update the list of ASC covered device-intensive procedures and devices that would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2013. Table 42 of the proposed rule (77 FR 45165 through 45166) displayed 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 2013. Specifically, we stated that when a procedure that is listed in Table 42 of the proposed rule is subject to the no cost/full credit or partial credit device adjustment policy and is performed to implant a device that is listed in Table 43 of the proposed rule (77 FR 45166 through 45167), where that device 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 would provide the same amount of payment reduction based on the device offset amount in ASCs that would apply under the OPPS under the same circumstances. 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 42 of the proposed rule that are subject to the no cost/full credit or partial credit device adjustment policy by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more 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 42 of the proposed rule 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 listed in Table 43 of the proposed rule. 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 comments on these proposals

We did not receive any comments on our CY 2013 proposal to continue the no cost/full credit and partial credit device adjustment policy for ASCs. For CY 2013, as we 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 for no cost/full credit cases. ASCs must append the modifier "FB" to the HCPCS procedure code when the device furnished without cost or with full credit is listed in Table 55, below, and the associated implantation procedure code is listed in Table 54. In addition, for CY 2013, we will reduce the payment for implantation procedures listed in Table 54 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. If the ASC receives a partial credit of 50 percent or more of the cost of a device listed in Table 55, the ASC must append the modifier "FC" to the associated implantation procedure code if the procedure is listed in Table 54.

TABLE 54.—ASC COVERED SURGICAL PROCEDURES DESIGNATED AS DEVICE-INTENSIVE FOR CY 2013, 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 2013 ASC PI	Final CY 2013 OPPS APC	Final CY 2013 Device-Dependent APC Offset Percent	FB/FC Policy Will Apply
0282T	Periph field stimul trial	J8	0040	56%	Yes
0283T	Periph field stimul perm	J8	0318	89%	Yes
0302T	Icar ischm mntrng sys compl	J8	0089	69%	Yes
0304T	Icar isch mntrng sys device	J8	0090	71%	Yes
0316T	Replc vagus nerve pls gen	J8	0039	87%	Yes
0319T	Insert subq defib w/eltrd	J8	0107	84%	Yes
0321T	Insert subq defib pls gen	J8	0107	84%	Yes
0323T	Rmvl & replc subq pls gen	J8	0107	84%	Yes
19296	Place po breast cath for rad	J8	0648	50%	Yes
19297	Place breast cath for rad	J8	0648	50%	Yes
19298	Place breast rad tube/caths	J8	0648	50%	Yes
19325	Enlarge breast with implant	J8	0648	50%	Yes
19342	Delayed breast prosthesis	J8	0648	50%	Yes
19357	Breast reconstruction	J8	0648	50%	Yes
24361	Reconstruct elbow joint	J8	0425	59%	Yes
24363	Replace elbow joint	J8	0425	59%	Yes
24366	Reconstruct head of radius	J8	0425	59%	Yes
24370	Revise reconst elbow joint	J8	0425	59%	Yes
24371	Revise reconst elbow joint	J8	0425	59%	Yes
25441	Reconstruct wrist joint	J8	0425	59%	Yes
25442	Reconstruct wrist joint	J8	0425	59%	Yes
25446	Wrist replacement	J8	0425	59%	Yes
27446	Revision of knee joint	J8	0425	59%	Yes
33206	Insertion of heart pacemaker	J8	0089	69%	Yes
33207	Insertion of heart pacemaker	J8	0089	69%	Yes
33208	Insertion of heart pacemaker	J8	0655	73%	Yes
33212	Insertion of pulse generator	J8	0090	71%	Yes
33213	Insertion of pulse generator	J8	0654	74%	Yes
33214	Upgrade of pacemaker system	J8	0655	73%	Yes

CPT Code	Short Descriptor	Final CY 2013 ASC PI	Final CY 2013 OPPS APC	Final CY 2013 Device-Dependent APC Offset Percent	FB/FC Policy Will Apply
33221	Insert pulse gen mult leads	J8	0654	74%	Yes
33224	Insert pacing lead & connect	J8	0655	73%	Yes
33225	Lventric pacing lead add-on	J8	0655	73%	Yes
33227	Remove&replace pm gen singl	J8	0090	71%	Yes
33228	Remv&replc pm gen dual lead	J8	0654	74%	Yes
33229	Remv&replc pm gen mult leads	J8	0654	74%	Yes
33230	Insrt pulse gen w/dual leads	J8	0107	84%	Yes
33231	Insrt pulse gen w/dual leads	J8	0107	84%	Yes
33240	Insert pulse generator	J8	0107	84%	Yes
33249	Eltrd/insert pace-defib	J8	0108	84%	Yes
33262	Remv&replc cvd gen sing lead	J8	0107	84%	Yes
33263	Remv&replc cvd gen dual lead	J8	0107	84%	Yes
33264	Remv&replc cvd gen mult lead	J8	0107	84%	Yes
33282	Implant pat-active ht record	J8	0680	74%	Yes
37227	Fem/popl revasc stnt & ather	J8	0319	53%	No
37231	Tib/per revasc stent & ather	J8	0319	53%	No
53440	Male sling procedure	J8	0385	62%	Yes
53444	Insert tandem cuff	J8	0385	62%	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	62%	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	55%	No
61885	Insrt/redo neurostim 1 array	J8	0039	87%	Yes
61886	Implant neurostim arrays	J8	0315	88%	Yes
62361	Implant spine infusion pump	J8	0227	82%	Yes
62362	Implant spine infusion pump	J8	0227	82%	Yes

CPT Code	Short Descriptor	Final CY 2013 ASC PI	Final CY 2013 OPPS APC	Final CY 2013 Device-Dependent APC Offset Percent	FB/FC Policy Will Apply
63650	Implant neuro-electrodes	J8	0040	56%	Yes
63655	Implant neuro-electrodes	J8	0061	69%	Yes
63663	Revise spine eltrd perq aray	J8	0040	56%	Yes
63664	Revise spine eltrd plate	J8	0040	56%	Yes
63685	Insrt/redo spine n generator	J8	0039	87%	Yes
64553	Implant neuro-electrodes	J8	0040	56%	Yes
64555	Implant neuro-electrodes	J8	0040	56%	Yes
64561	Implant neuro-electrodes	J8	0040	56%	Yes
64565	Implant neuro-electrodes	J8	0040	56%	Yes
64568	Implant neuro-electrodes	J8	0318	89%	Yes
64569	Revise/repl vagus n eltrd	J8	0040	56%	Yes
64575	Implant neuro-electrodes	J8	0061	69%	Yes
64580	Implant neuro-electrodes	J8	0061	69%	Yes
64581	Implant neuro-electrodes	J8	0061	69%	Yes
64590	Insrt/redo pn/gastr stimul	J8	0039	87%	Yes
65770	Revise cornea with implant	J8	0293	63%	No
69714	Implant temple bone w/stimul	J8	0425	59%	Yes
69715	Temple bne implnt w/stimulat	J8	0425	59%	Yes
69717	Temple bone implant revision	J8	0425	59%	Yes
69718	Revise temple bone implant	J8	0425	59%	Yes
69930	Implant cochlear device	J8	0259	84%	Yes
G0448	Place perm pacing cardiovert	J8	0108	84%	Yes

TABLE 55.—DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2013 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT

CY 2013 Device HCPCS Code	CY 2013 Short Descriptor
C1721	AICD, dual chamber
C1722	AICD, single chamber
C1728	Cath, brachytx seed adm
C1762	Conn tiss, human(inc fascia)
C1763	Conn tiss, non-human
C1764	Event recorder, cardiac
C1767	Generator, neurostim, imp
C1771	Rep dev, urinary, w/sling
C1772	Infusion pump, programmable
C1776	Joint device (implantable)
C1777	Stent, non-coat/cov w/o del
C1778	Lead, neurostimulator
C1779	Lead, pmkr, transvenous VDD
C1781	Mesh (implantable)
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
C1897	Lead, neurostim, test kit
C1898	Lead, pmkr, other than trans
C1900	Lead coronary venous
C2618	Probe, cryoablation
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
L8600	Implant breast silicone/eq

CY 2013 Device HCPCS Code	CY 2013 Short Descriptor
L8614	Cochlear device/system
L8680	Implt neurostim elctr each
L8685	Implt nrostm pls gen sng rec
L8686	Implt nrostm pls gen sng non
L8687	Implt nrostm pls gen dua rec
L8688	Implt nrostm pls gen dua non
L8690	Aud osseo dev, int/ext comp

e. ASC Treatment of Surgical Procedures Removed from the OPPS Inpatient List for CY 2013

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. As stated in the CY 2013 OPPS/ASC proposed rule (77 FR 45167), we evaluated each of the two procedures we proposed to remove from the OPPS inpatient list for CY 2013 based on the criteria for exclusion from the list of covered ASC surgical procedures. As stated in the proposed rule, we believe that these two procedures should continue to be excluded from the ASC list of covered surgical procedures for CY 2013 because they would be expected to pose a significant risk to beneficiary safety or to require an overnight stay in ASCs. The CPT codes for these two procedures and their long descriptors were listed in Table 44 of the proposed rule (77 FR 45167). We invited public comments on this proposal.

We did not receive any public comments regarding the procedures that we proposed to exclude from the list of ASC covered procedures for CY 2013 that were proposed for removal from the CY 2013 OPPS inpatient list. However, as detailed in section IX of this final rule with comment period, the proposal to remove the procedure described by CPT code 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)) from the OPPS inpatient list is not being finalized for CY 2013. Based on public comments received, CPT code 27447 will remain on the OPPS inpatient list for CY 2013. Therefore, we are finalizing our proposal to continue to exclude the procedure described by the CPT code 22856, which is listed in Table 56 below, from the list of ASC covered surgical procedures for CY 2013. In addition, we are excluding CPT code 27447 because it will remain on the OPPS inpatient list for CY 2013.

TABLE 56.—PROCEDURE EXCLUDED FROM THE ASC LIST OF COVERED PROCEDURES FOR CY 2013 THAT WAS REMOVED FROM THE CY 2013 OPPS INPATIENT LIST

CPT Code	Long Descriptor
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical

2. Covered Ancillary Services

Consistent with the established ASC payment system policy, in the CY 2013 OPPS/ASC proposed rule (77 FR 45167), we proposed to update the ASC list of covered ancillary services to reflect the proposed payment status for the services under the CY 2013 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 2013. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2012 may be proposed for packaged status under the CY 2013 OPPS and, therefore, also under the ASC payment system for CY 2013. Comment indicator "CH," discussed in section XIV.F. of the CY 2013 OPPS/ASC proposed rule (77 FR 45172), was used in Addendum BB to that proposed rule (which is available via the Internet on the CMS Web site) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2013.

Except for the Level II HCPCS codes listed in Table 37 of the CY 2013 OPPS/ASC proposed rule (77 FR 45161), all ASC covered ancillary services and their proposed payment indicators for CY 2013 were included in Addendum BB to that proposed rule.

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 2013 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. 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 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74451), we updated the CY 2011 ASC payment rates for ASC covered surgical procedures with payment indicators of "A2," "G2," and "J8" using CY 2010 data, consistent with the CY 2012 OPPS update. Payment rates for

device-intensive procedures also were updated to incorporate the CY 2012 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 2013 MPFS final rule with comment period) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2012 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 2012 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 2012 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 2013

In the CY 2013 OPPS/ASC proposed rule (77 FR 45168), we proposed to update ASC payment rates for CY 2013 using the established rate calculation methodologies under § 416.171. We note that, as discussed in section II.A.2.f. of that proposed rule (77 FR 45094 through 45098), because we proposed to base the OPPS relative payment weights on geometric mean costs for CY 2013, the ASC system would shift to the use of geometric means to determine relative payment weights under the ASC standard ratesetting 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 based on the CY 2013 OPPS proposal that reflects updated proposed OPPS device offset percentages, and to make payment for office-based procedures at the lesser of the proposed CY 2013 MPFS nonfacility PE RVU-based amount or the proposed CY 2013 ASC payment amount calculated according to the standard ratesetting methodology. We invited public comments on these proposals.

We did not receive any public comments on our proposal to calculate CY 2013 payment rates for ASC-covered surgical procedures according to our established methodologies. Therefore, we are finalizing our CY 2013 proposal, without modification, to calculate the CY 2013 final ASC payment rates for ASC-covered surgical procedures according to our established methodologies.

c. Waiver of Coinsurance and Deductible for Certain Preventive Services

As discussed in the CY 2013 OPPS/ASC proposed rule (77 FR 45168), 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 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 identified 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 in the CY 2013 OPPS/ASC proposed rule. We identify the specific services with a double asterisk in Addenda AA and BB to this CY 2013 OPPS/ASC final rule with comment period.

d. Payment for the Cardiac Resynchronization Therapy Composite

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 and 33249 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). We did not propose any changes to our current policy regarding ASC payment for CRT-D services for CY 2013.

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 services to the Medicare beneficiary being treated with LDR brachytherapy for prostate cancer.

As detailed in section II.A.2.e.(2) of the CY 2013 OPPS/ASC proposed rule (77 FR 45088 through 45089), in CY 2008 under the OPPS, 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 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 implemented this policy in the OPPS because reliance on single procedure claims to set payment rates for these services resulted in the use of mainly incorrectly coded claims for LDR prostate brachytherapy because a correctly coded claim should include, for the same date of service, CPT codes for both needle/catheter placement and application of radiation sources, as well as separately coded imaging and radiation therapy planning services (72 FR 66652 through 66655).

Currently under the ASC payment system, ASCs receive separate payment for the component services that comprise the LDR Prostate Brachytherapy Composite when the two services are provided on the same date of service. Specifically, ASCs that report CPT codes 55875 and 77778 on the same date of service receive a payment for CPT code 55875 where the payment rate is based on the OPPS relative payment weight for single procedure claims, and a separate payment for CPT code 77778 where payment is the lower of the rate based on the OPPS relative payment weight for single procedure claims or the MPFS nonfacility PE-RVU based amount.

A commenter to the CY 2012 OPPS/ASC proposed rule (76 FR 74429 through 74430) requested that CMS pay for LDR prostate brachytherapy services under the ASC payment system based on the composite OPPS payment rate rather than making two separate payments for the service reported by CPT codes 55875 and 77778. The commenter asserted that basing ASC payments for the services on the composite APC

methodology in which one payment is made for the combination of the two services would result in a more accurate payment than is currently being made to ASCs because ASC payment is based on costs from single-service claims that CMS has acknowledged are mostly incorrectly coded claims. We responded that we would take the commenter's request into consideration in future rulemaking, recognizing the lead time that is necessary for the creation of the associated G-code that would be used to identify when the procedures in the LDR prostate brachytherapy composite are performed on the same date of service in an ASC.

Because we agree that data from OPPS claims reporting both services required for LDR prostate brachytherapy provide the most accurate relative payment weight upon which to base ASC payment for the component services, in the CY 2013 OPPS/ASC proposed rule (77 FR 45169), we proposed to establish an ASC payment rate that is 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. We also proposed to create a HCPCS Level II G-code so that ASCs can properly report 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. We stated that the payment rate associated with the LDR prostate brachytherapy composite will be temporarily identified by HCPCS G-code "GXXX1" in Addendum AA to the CY 2013 OPPS/ASC proposed rule and the permanent HCPCS G-code that will identify this composite for ASCs will appear in this final rule with comment period. 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. We invited public comment on this proposal.

Comment: Several commenters supported CMS' proposal to establish an ASC payment rate that is 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.

Response: We appreciate commenters' support of our proposal. We are finalizing our proposal, without modification, 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 will 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.

2. Payment for Covered Ancillary Services

a. Background

Our final payment policies under the revised ASC payment system for covered ancillary services vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators "N," "Q1," and "Q2") under the OPPS. In the CY 2013 OPPS/ASC proposed rule (77 FR 45169), we further clarified our policy regarding the payment indicator assignment of codes that are conditionally packaged in the OPPS (status indicators "Q1" and "Q2"). Under the OPPS, a conditionally packaged code describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indictor "N1") under the ASC payment system. Thus, our final policy aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates, while we generally pay for

separately payable radiology services at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to "Z2" so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount, regardless of which is lower. This modification to the ASC payment methodology for ancillary services was finalized in response to a comment on the CY 2011 OPPS/ASC proposed rule that suggested it is inappropriate to use the MPFS-based payment methodology for nuclear medicine procedures because the associated diagnostic radiopharmaceutical, although packaged under the ASC payment system, is separately paid under the MPFS. We set the payment indicator to "Z2" for these nuclear medicine procedures in the ASC setting so that payment for these procedures would be based on the OPPS relative payment weight rather than the MPFS nonfacility PE RVU-based amount to ensure that the ASC will be compensated for the cost associated with the diagnostic radiopharmaceuticals.

In addition, because the same issue exists for radiology procedures that use contrast agents (the contrast agent is packaged under the ASC payment system but is separately paid under the MPFS), we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430) to set the payment indicator to "Z2" for

radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight and will, therefore, include the cost for the contrast agent.

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Other separately paid covered ancillary services in ASCs, specifically corneal tissue acquisition and device categories with OPPS 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 OPPS are separately paid under the ASC payment system. Currently, the four devices that are eligible for pass-through payment in the OPPS are described by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (Implantable)), HCPCS code C1830 (Powered bone marrow biopsy needle), HCPCS code C1840 (Lens, intraocular (telescopic)), and HCPCS code C1886 (Catheter, extravascular tissue ablation, any modality (insertable)). Payment amounts for HCPCS codes C1749, C1830, C1840, and C1886 under the ASC

payment system are contractor priced. In the CY 2012 OPPS/ASC final rule with comment period, we finalized the expiration of pass-through payment for HCPCS code C1749, which will expire after December 31, 2012 (76 FR 74278). Therefore, after December 31, 2012, the HCPCS code C1749 device costs 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 OPPS relative payment weights that will be used to establish ASC payment rates for CY 2013.

b. Payment for Covered Ancillary Services for CY 2013

For CY 2013, we proposed to update the ASC payment rates and make changes to ASC payment indicators as necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2013 OPPS and ASC payment rates (77 FR 45170). The proposed CY 2013 OPPS payment methodologies for brachytherapy sources and separately payable drugs and biologicals were discussed in section II.A. and section V.B. of that proposed rule, respectively, and we proposed to set the CY 2013 ASC payment rates for those services equal to the proposed CY 2013 OPPS rates.

Consistent with established ASC payment policy (72 FR 42497), the proposed CY 2013 payment for separately payable covered radiology services was based on a comparison of the CY 2013 proposed MPFS nonfacility PE RVU-based amounts (we referred readers to the CY 2013 MPFS proposed rule) and the proposed CY 2013 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 indicate whether the proposed payment rates for radiology services are based on the MPFS nonfacility PE RVU-based amount or the ASC standard ratesetting methodology, or whether payment for a radiology service is packaged into the payment for the covered surgical procedure (payment indicator "N1"). Radiology services that we proposed to pay based on the ASC standard ratesetting methodology are assigned payment indicator "Z2" (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 are 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 is made based on the OPPS relative payment weights rather than the MPFS nonfacility PE RVU-based amount, regardless of which is lower. 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. In the CY 2013 OPPS/ASC proposed rule (77 FR 45170), we proposed for CY 2013 to continue these modifications to the payment methodology and, therefore, set the payment indicator to "Z2" for these covered ancillary radiology services that involve nuclear medicine procedures or that use contrast agents.

Most covered ancillary services and their proposed payment indicators were listed in Addendum BB to the CY 2013 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site). We invited public comment on these proposals.

Comment: One commenter expressed appreciation to CMS for its responsiveness in the CY 2011 OPPS/ASC final rule with comment period to stakeholder concerns regarding ASC payment for nuclear medicine procedures. However, the commenter suggested that ASC payment policy for nuclear medicine procedures would be further improved by providing separate payment for the diagnostic radiopharmaceuticals that are used in nuclear medicine procedures.

Response: As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050) regarding separate payment for diagnostic radiopharmaceuticals used in ASCs, we do not agree with the commenter that we should establish separate payment for diagnostic radiopharmaceuticals under the ASC payment system because we follow the OPPS packaging policies which require that payment for these items is always packaged.

After consideration of the public comments we received, we are providing CY 2013 payment for covered ancillary services in accordance with the policies finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74430). Covered ancillary services and their final CY 2013 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 Cycle and Evaluation Criteria

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68176), we finalized our current process for reviewing applications to establish new classes of new technology intraocular lenses (NTIOLs), and for recognizing new candidate intraocular lenses (IOLs) inserted during or subsequent to cataract extraction as belonging to an NTIOL class that is qualified for a payment adjustment. Specifically, we established the following process:

- 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; and

○ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68227), we finalized our proposal to base our determinations on consideration of the following major criteria set out at 42 CFR 416.195:

- 42 CFR 416.195(a)(1): The IOL is approved by the FDA;
- 42 CFR 416.195(a)(2): Claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs are approved by the FDA for use in labeling and advertising;
- 42 CFR 416.195(a)(3): The IOL is not described by an active or expired NTIOL class; that is, it does not share the predominant, class-defining characteristic associated with the improved clinical outcome with designated members of an active or expired NTIOL class; and
- 42 CFR 416.195(a)(4): Evidence demonstrates that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. The statute requires us to consider the following improved outcomes:

○ Reduced risk of intraoperative or postoperative complication or trauma;

○ Accelerated postoperative recovery;

○ Reduced induced astigmatism;

- Improved postoperative visual acuity;
- More stable postoperative vision; or
- Other comparable clinical advantages.

Since implementation of the process for adjustment of payment amounts for NTIOLs that was established in the June 16, 1999 **Federal Register**, we have approved three classes of NTIOLs, as shown in the table with the associated qualifying IOL models, at the link entitled "NTIOL Application Determination Reference document Updated 01/06/2012," posted on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html.

2. NTIOL Application Process for Payment Adjustment

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 Lens (NTIOL)" posted on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html. For each completed request for a new class that is received by the established deadline, a determination is announced annually in the final rule updating the ASC and OPPS payment rates for the next calendar year.

We also summarize briefly in the final rule the evidence that we reviewed, the public comments we received timely, and the basis for our determinations in consideration of applications for establishment of a new NTIOL class. 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.

3. Requests to Establish New NTIOL Classes for CY 2013 and Deadline for Public Comments

As discussed in the CY 2013 OPPS/ASC proposed rule (77 FR 45171), we did not receive any requests for review to establish a new NTIOL class for CY 2013 by the March 2, 2012 due date (this due date was stated in the CY 2012 OPPS/ASC final rule with comment period at 76 FR 74443).

4. 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 in the CY 2013 OPPS/ASC proposed rule (77 FR 45171), we did not propose to revise the payment adjustment amount for CY 2013.

5. Revisions to the Major NTIOL Criteria Described in 42 CFR 416.195

The last significant revisions to the regulations containing the substantive NTIOL evaluation criteria under 42 CFR 416.195 occurred in 2007. In the CY 2013 OPPS/ASC proposed rule (77 FR 45171), we proposed significant revisions to § 416.195(a)(2) and § 416.195(a)(4). We stated our belief that revising § 416.195 is necessary in order to

improve the quality of the NTIOL applications. In recent years, we have received low quality NTIOL applications that may have been due in part to overly-broad evaluation criteria.

We proposed to revise § 416.195(a)(2) to require that the IOL's FDA-approved labeling contains a claim of a specific clinical benefit imparted by a new lens characteristic. The IOL would have to have a new lens characteristic in comparison to currently available IOLs. We also proposed to revise § 416.195(a)(4) to require that any specific clinical benefit referred to in § 416.195(a)(2) would have to be supported by evidence that demonstrated that the IOL results in a measurable, clinically meaningful, improved outcome. Improved outcomes include: (i) reduced risk of intraoperative or postoperative complication or trauma; (ii) accelerated postoperative recovery; (iii) reduced induced astigmatism; (iv) improved postoperative visual acuity; (v) more stable postoperative vision; and (vi) other comparable clinical advantages.

The proposed revision to § 416.195(a)(2) is necessary because recent NTIOL applications have not included FDA labeling claims of clinical benefit. Instead, the candidate IOLs have, in most cases, had some characteristic for which the applicant has tried to prove clinical relevance through various kinds of evidence that have not been evaluated by the FDA because the evidence is not associated with a labeling claim. The result has been the submission of low quality evidence that has been insufficient for NTIOL status. We believe that the quality of the evidence would improve if applicants were required to obtain a labeling claim for the NTIOL benefit and therefore have the evidence for such benefit evaluated by FDA. We believe that this proposed approach

would better serve CMS, FDA, and the applicants because any ultimate grant of NTIOL status would be supported by a labeling claim. The manufacturer could then advertise the NTIOL benefit without running afoul of FDA advertising limitations. We would have the benefit of an FDA review of the relevant evidence, which would be particularly valuable because the FDA has a dedicated team of scientists, physicians, and engineers who are experts in evaluating IOLs.

The proposed revision to § 416.195(a)(4) is necessary to insure that the claim is clinically relevant and represents an improved outcome for Medicare beneficiaries. We requested public comments on these proposed revisions to the NTIOL regulations.

Comment: Several commenters supported our proposed changes to the NTIOL regulations. These commenters believed that the proposed changes will better insure that any grants of NTIOL status will be supported by rigorous scientific evidence.

Response: We appreciate these comments and the commenters' support for our efforts to require rigor and accountability in the NTIOL program.

Comment: One commenter disagreed with the proposed revision to 416.195(a)(2), complaining that obtaining a label claim is difficult and time consuming. In addition, this commenter made the following main points:

- It is not the FDA's job to review evidence related to an NTIOL application;
- FDA does not typically evaluate claims of comparative clinical benefits, and is not obligated to do so;
- Clinical studies to support a label claim require substantial time and resources, and there is no guarantee that such efforts will be successful;

● Other new technology programs, such as transitional pass-through payments, do not require a claim of clinical benefit;

● Requiring a claim of clinical benefit would provide extended exclusivity to the first company to establish the NTIOL class;

● Requiring a claim of clinical benefit will limit patient access to new technology.

Response: We believe that this commenter's objections reflect at least a partial misunderstanding of the proposal. Our current regulations require that the FDA approved label contain information about the clinical benefit of a candidate IOL. They provide two options for satisfying this requirement; the candidate lens must have either: (1) claims of specific clinical benefits in comparison with currently available IOLs approved by the FDA for use in labeling and advertising; or (2) lens characteristics with established clinical relevance in comparison with currently available IOLs approved by the FDA for use in labeling and advertising. Both of these options require evaluation by the FDA. In recent years, lens manufacturers have used Option 2 to claim, for example, that the applicant lens had a specific lens characteristic (for example, blue filter, availability in .25 D increments, absence of glistenings, packaging in a disposable injector) listed somewhere in the FDA labeling; however, the manufacturer would provide no information about the clinical relevance of this characteristic in the FDA's labeling. The manufacturer would submit to CMS weak or nonexistent evidence of a clinical benefit that it claimed could be attributed to the characteristic described on the FDA-approved label. We believe that to remedy this problem and to clarify the intent of this regulation it

is necessary that the label contain a claim of a clinical benefit, which would be supported by evidence evaluated by the FDA.

Regarding this commenter's statement about the scope of FDA's duties, the evaluation of clinical evidence in support of a labeling claim is a core function of the FDA and is something that they do on a daily basis. There is nothing unusual about the FDA's proposed role as it relates to evaluating evidence in support of a labeling claim that could be used to satisfy the requirements for NTIOL status. This rule does not usurp or interfere with any functions currently carried out by the FDA.

Regarding this commenter's other points, the various new technology payment programs we administer have somewhat different requirements, depending on the statutory authority and the specific purposes of the various programs. We believe that Congress intended that NTIOL status function as an incentive for innovation. If requiring a claim of clinical benefit results in a longer period of a single manufacturer utilizing a new NTIOL class exclusively, we believe that such extended exclusivity would serve as an additional inducement for manufacturers to innovate and seek NTIOL status for their innovations. While we agree with the commenter that seeking a label claim requires time and effort, we believe that this process will better serve NTIOL applicants in that having a claim of a clinical benefit will substantially increase the likelihood of ultimate NTIOL approval.

Finally, this commenter predicted that if we finalize these proposed changes to the regulations, then Medicare beneficiaries will have reduced access to new IOL technology. We disagree that the proposed changes to the NTIOL regulations will affect

patient access to IOLs. For example, one of the 2012 NTIOL candidate IOLs had been on the market for 10 years and was the U.S. market leader at the time of NTIOL application. Lack of NTIOL status did not limit patient access to this IOL and we believe that it would also be unlikely to result in limited access to future IOLs. We also believe that having NTIOLs supported by a labeling claim of clinical benefit will increase patient confidence that they are receiving a medical device with a real evidence-based benefit versus existing technology.

After consideration of the public comments we received, we are finalizing the proposed changes to the NTIOL regulations.

6. Request for Public Comment on the "Other Comparable Clinical Advantages" Improved Outcome

Section 416.195(a)(4)), discussed above, lists the following improved outcomes: (i) reduced risk of intraoperative or postoperative complication or trauma; (ii) accelerated postoperative recovery; (iii) reduced induced astigmatism; (iv) improved postoperative visual acuity; (v) more stable postoperative vision; and (vi) other comparable clinical advantages.

This list is from the original 1994 NTIOL statutory provision. Because this provision is almost 20 years old, outcomes (i) through (v) have only limited relevance to modern cataract surgery. For example, regarding outcome (i), it is unclear what, if any, type of IOL could reduce the risk of complication or trauma associated with cataract surgery, or what, if any, contemporary cataract surgery complication could be affected by a new type of IOL. As for outcome (ii), postoperative recovery is already rapid in

uncomplicated cataract surgery; therefore, it is difficult to see how it could be significantly accelerated. Also, regarding outcome (iii), clinically significant induced astigmatism would be reflective of poor surgical technique and would not depend upon IOL design. Regarding outcome (iv), currently available IOLs provide such high quality postoperative visual acuity that it would be difficult to measure clinically significant improved postoperative visual acuity due to a new type of IOL. Finally, for outcome (v), postoperative vision is typically stable after uncomplicated cataract surgery, so again it would be difficult to improve upon this outcome.

The last of the listed improved outcomes is the nonspecific category described as "other comparable clinical advantages." Given that present-day cataract surgery is such a successful procedure that results in significantly improved vision for almost all patients who undergo the procedure and who are appropriate candidates for cataract surgery, in the CY 2013 OPPS/ASC proposed rule (77 FR 45172), we solicited comments on what potential benefits associated with a new IOL could be considered to be a "comparable clinical advantage" as compared to the list of the five improved outcomes from the statute and regulation described above.

Comment: Several commenters supported retaining the "comparable clinical advantage" outcome as an open-ended category as necessary to accommodate future innovations. One commenter offered the following examples of potential comparable clinical advantages:

- Reduced incidence of posterior capsular opacity;

- Improved delivery to reduce error and minimize changes to the wound from insertion'
- Reduced inflammation;
- Reduced astigmatism;
- Improved vision;
- Improved vision stability; and
- Improved quality of life.

Response: It is important that companies consider all of the various possibilities for new clinical advantages, and we appreciate the range of potential issues that could be addressed through new IOL technology. However, some significant questions remain. For example, it could be that the incidence of some of these complications so low such that it would be impossible to design a study to measure any improvement due to a new IOL. It also could be that some surgical complications could be the result of surgical technique that could not be easily compensated for with a new IOL design. We also remind stakeholders that innovations that provide greater surgeon convenience, but no direct patient benefit, would not qualify for NTIOL status. Also, vision improvements cannot be merely improved optical performance but must relate to a meaningful improved outcome in visual performance.

The list of improved outcomes in the regulation is statutory and therefore we are not modifying it. After consideration of the public comments we received, we are adopting, without modification, our NTIOL proposals.

7. Announcement of CY 2013 Deadline for Submitting Requests for CMS Review of Appropriateness of ASC Payment for Insertion of an NTIOL Following Cataract Surgery

In accordance with 42 CFR 416.185(a) of our regulations, CMS announces that in order to be considered for payment effective January 1, 2014, 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 1, 2013. 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 2013 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 2012 OPPS/ASC final rule with comment period. These addenda can be found in a file labeled "January 2012 ASC Approved HCPCS Code and Payment Rates" in the ASC Addenda Update section of the CMS Web site.

The "CH" comment indicator was used in Addenda AA and BB to the CY 2013 OPPS/ASC proposed rule (which were available via the Internet on the CMS Web site) to indicate that the payment indicator assignment has changed for an active HCPCS code; 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 2013 OPPS/ASC proposed rule (77 FR 45172), we did not propose any changes to the definitions of the ASC payment and comment indicators for CY 2013. We referred readers to Addenda DD1 and DD2 to the CY 2013 OPPS/ASC proposed rule (which were available via the Internet on the CMS Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2013 update.

We did not receive any public comments on the ASC payment and comment indicators. 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 commenter indicators for the CY 2013 update.

G. ASC Policy and Payment Recommendations

MedPAC was established under section 1805 of the Act to advise Congress on issues affecting the Medicare program. Subparagraphs (C) and (D) of section 1805(b)(1) of the Act require MedPAC to submit reports to Congress not later than March 15 and June 15 of each year that present its Medicare payment policy reviews and recommendations and its examination of issues affecting the Medicare program, respectively. The March 2012 MedPAC "Report to the Congress: Medicare Payment

Policy" included the following recommendations relating specifically to the ASC payment system for CY 2013:

Recommendation 5-1: "The Congress should update the payment rates for ambulatory surgical centers by 0.5 percent for calendar year 2013. The Congress should also require ambulatory surgical centers to submit cost data."

Regarding the ASC payment update for CY 2013, MedPAC further stated that: "On the basis of our payment adequacy indicators, the lack of ASC cost data, and our concerns about the potential effect of ASC growth on overall program spending, we believe a moderate update of 0.5 percent is warranted for CY 2013." With regard to the collection of cost data, MedPAC indicated that cost data are needed to fully assess ASC payment adequacy under the revised ASC payment system and to examine whether an alternative input price index would be an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed to annually update ASC payment rates.

CMS Response: We note that MedPAC's recommendation is for the Congress to increase ASC payment rates by 0.5 percent in CY 2013 and require ASCs to submit cost data. Congress has not yet acted on these recommendations. In the CY 2013 OPPS/ASC proposed rule (77 FR 45172), we proposed to continue our current policy to update the ASC conversion factor using the CPI-U, and we did not propose to require ASCs to submit cost data in the proposed rule. However, as discussed in section XIV.H.2.b. of the proposed rule (77 FR 45174), while we believe the CPI-U is appropriate to apply to update the ASC payment system, the CPI-U may not best reflect inflation for the goods and services provided by ASCs and, therefore, we sought public comment on the type of

cost information that would be feasible to collect from ASCs that would assist us in determining possible alternatives to using the CPI-U to update ASC payment rates for inflation. In section XIV.H.2.b. of this final rule with comment period, we summarize and respond to the public comments we received regarding the ASC update and the feasibility of collecting ASC cost data.

H. 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).

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 XIV.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. 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, and CBSA 22 Rural Massachusetts.

In CY 2011, we identified another area, specifically, CBSA 11340 Anderson, SC for which there is no IPPS hospital whose wage index data would be used to set the wage index for that area. Generally, we would use the methodology described above; however, in this situation, all of the areas contiguous to CBSA 11340 Anderson, SC are rural. Therefore, in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72058 through 72059), we finalized our proposal to set the ASC wage index by calculating the average of all wage indices for urban areas in the State when all contiguous areas to a CBSA are rural and there is no IPPS hospital whose wage index data could be used to set the wage index for that area. 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), and CY 2012 (76 FR 74446) 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. For CY 2013, 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 whose wage index data 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 2013 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). We note that, as discussed in section II.A.2.f. of the CY 2013 OPPS/ASC proposed rule (45094 through 45098) and in this final rule with comment period, because we proposed to base the OPPS relative payment weights on geometric mean costs for CY 2013, the ASC system would shift to the use of geometric means to determine relative payment weights under the ASC standard ratesetting methodology. Consistent with our established policy, in the CY 2013 OPPS/ASC proposed rule (77 FR 45173), we proposed to scale the CY 2013 relative payment weights for ASCs according to the following method. Holding ASC utilization and the mix of services constant from CY 2011, we proposed to compare the total payment using the CY 2012 ASC relative payment weights with the total payment using the CY 2013 relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2012 and CY 2013. We proposed to use the ratio of CY 2012 to CY 2013 total payment (the weight scaler) to scale the ASC relative payment weights for CY 2013. The proposed CY 2013 ASC scaler was 0.9331 (77 FR 45174) 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 2013 proposed rule, we had available 98 percent of CY 2011 ASC claims data. For this final rule with comment period, we have approximately 99 percent of all ASC claims data for CY 2011.

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 2011 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2011 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.

We did not receive any comments and, therefore, we are finalizing our CY 2013 ASC relative payment weight scaling methodology, without modification.

For this final rule with comment period, we used our proposed methodology described above to calculate the scaler adjustment using updated ASC claims data. The final CY 2013 scaler adjustment is 0.9324. This scaler adjustment is necessary to make the difference in aggregate ASC payments calculated using the CY 2012 ASC relative payment weights and the CY 2013 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 2011 ASC utilization from our claims data, and the CY 2012 wage index values. For this final CY 2013 calculation, we used the CY 2012 ASC conversion factor updated by the CY 2013 CPI–U, which is projected to be 1.4 percent, less the multifactor productivity adjustment of 0.8 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, for the CY 2013 ASC payment system, in the CY 2013 OPPS/ASC proposed rule (77 FR 45174), 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 2013, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2011 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2013 pre-floor and pre-reclassified hospital wage indices. Specifically, holding CY 2011 ASC utilization and service-mix and the proposed CY 2013 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2012 pre-floor and pre-reclassified hospital wage indices and the total adjusted payment using the proposed CY 2013 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 2012 pre-floor and pre-reclassified hospital wage indices to the total adjusted payment calculated with the proposed CY 2013 pre-floor and pre-reclassified hospital wage indices and applied the resulting ratio of 1.0002 (the proposed CY 2013 ASC wage index budget neutrality adjustment) to the CY 2012 ASC conversion factor to calculate the proposed CY 2013 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, "if the Secretary has not updated amounts established" under the revised ASC payment system in a calendar year, the payment amounts "shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved." The statute, therefore,

does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI-U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at 42 CFR 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI-U for CY 2010 and subsequent calendar years. Therefore, the annual update to the ASC payment system is the CPI-U (referred to as the CPI-U update factor).

Stakeholders, as well as MedPAC, have commented throughout the years that the CPI-U may not adequately measure inflation for the goods and services provided by ASCs (for example, 76 FR 74444, 74448 through 74450; 73 FR 68757; and 72 FR 66859). While we believe the CPI-U is appropriate to apply to update the ASC payment system, we are aware that the CPI-U is highly weighted for housing and transportation and may not best reflect inflation in the cost of providing ASC services. In developing the CY 2013 OPPS/ASC proposed rule, we considered possible alternatives to using the CPI-U to update ASC payment rates for inflation.

ASC stakeholders have urged us to adopt the hospital market basket to update ASC payment rates for inflation when commenting on each proposed rule since the beginning of the revised ASC payment system (72 FR 66859; 73 FR 68757; 74 FR 60628 through 60629; 75 FR 72063; and 76 FR 74449). We considered the hospital market basket as an alternative to the CPI-U and, while the items included in the hospital market basket seem reflective of the kinds of costs incurred by ASCs, as stated in the CY 2012 OPPS/ASC final rule with comment period, we believe that the hospital market basket does not align with the cost structures of ASCs. A much wider range of services, such as

room and board and emergency services, are provided by hospitals but are not reflective of costs associated with providing services in ASCs (76 FR 74450). As other possible alternatives to the CPI-U update, we considered using the physician's practice expense (PE) component of the Medicare Economic Index (MEI) update, as well as using an average of the hospital market basket update and the PE component of the MEI update. However, until we have more information regarding the cost inputs of ASCs, we are not confident that any of these alternatives are a better proxy for ASC costs than the CPI-U. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45174), we proposed a continuation of the established policy of basing the ASC update on the CPI-U. In addition, we requested public comment on the type of cost information that would be feasible to collect from ASCs in the future in order to determine if one of these alternative updates or an ASC-specific market basket would be a better proxy for ASC cost inflation than the CPI-U.

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. Section XVI.D. of the CY 2013 OPPS/ASC proposed rule (77 FR 45192 through 45193) provided a discussion of the proposed payment reduction to the annual update for ASCs that fail to meet the ASCQR Program requirements. In summary, we proposed 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. The reduced rates would apply beginning in CY 2014. We proposed that 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 proposed changes to §§ 416.160(a)(1) and 416.171 to reflect this proposal. Comments to this proposal are addressed in section XVI.D.2 of this final rule with comment period.

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 number. 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 payment determination 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 may reduce this percentage change below zero. 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 2013 OPPS/ASC proposed rule (77 FR 45175), for the 12-month period ending with the midpoint of CY 2013, the CPI-U update was projected to be 2.2 percent. Because the ASCQR Program does not affect payment rates until CY 2014, there would be no quality reporting reduction to the CPI-U for CY 2013. The MFP adjustment for the

period ending with the midpoint of CY 2013 was projected to be 0.9 percent based on the methodology for calculating the MFP adjustment 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). We proposed to reduce the CPI-U update of 2.2 percent by the MFP adjustment of 0.9 percent, resulting in an MFP-adjusted CPI-U update factor of 1.3 percent. Therefore, as stated in the CY 2013 OPPS/ASC proposed rule (77 FR 45175), we proposed to apply a 1.3 percent MFP-adjusted CPI-U update factor to the CY 2012 ASC conversion factor.

For CY 2013, we also proposed to adjust the CY 2012 ASC conversion factor ($42.627) by the wage adjustment for budget neutrality of 1.0002 in addition to the MFP-adjusted update factor of 1.3 percent discussed above, which resulted in a proposed CY 2013 ASC conversion factor of $43.190 (77 FR 45175). We invited public comments on these proposals.

Comment: Commenters expressed varied opinions regarding the feasibility of requiring ASCs to submit cost data to the Secretary. One commenter believes that CMS should require ASCs to submit cost data so that an appropriate market basket for ASC annual updates can be identified and so that analysts can determine the costs of an efficient provider of ASC services. The commenter believes that reporting such data is feasible because businesses such as ASCs typically keep record of their costs for filing taxes and other purposes. In addition, this commenter pointed out that other small providers, including home health agencies and hospices, submit cost data to CMS.

Other commenters (predominantly commenters who represent ASCs) opposed a requirement that ASCs submit cost data to CMS. The commenters believed that a requirement to submit cost data would be both unnecessary and administratively burdensome for ASCs.

Further, some commenters stated that requiring ASCs to submit cost data that would not be directly tied to receipt of payment would likely result in the submission of data that is unreliable. These commenters also maintained that using cost data to develop an ASC-specific market basket would not provide a more accurate reflection of ASC cost growth. Commenters believed that creating a single set of cost weights that are representative of the industry average would relate to few ASCs as most centers are specialized and would have a cost structure that is specific to the procedures they provide. These commenters also stated that, by CMS' own description, the hospital market basket itself is an imperfect measure of hospital outpatient costs but CMS has rationalized use of the hospital market basket as the best available measure of costs in the hospital outpatient setting. The commenters believe that, likewise, the best available proxy to measure costs in the ASC setting is the hospital market basket. Commenters expressed frustration that CMS has not adopted the hospital market basket to update ASC payment rates and urged the agency to not waste precious resources collecting ASC cost data when this reasonable measure of input prices is readily available.

Response: We thank all of the commenters for their thoughts regarding the type of cost information that would be feasible to collect from ASCs in the future in order to determine if an alternative update or an ASC-specific market basket would be a better

proxy for ASC cost inflation compared to the CPI-U. We will keep the commenters' perspectives about collecting cost information from ASCs in mind as we consider this issue further.

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 explained 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 2013 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. 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 OPPS 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 would appropriately reflect the cost structures of ASCs, and because we do not have cost data on ASCs, we are not able to recommend a more accurate update. Therefore, the CPI-U remains the most appropriate update. Regarding alignment of the MFP adjustment across payment systems, for 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 timeframes 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 2013 ASC conversion factor. Using more complete CY 2011 data for this final rule with comment period than was available for the proposed rule, we calculated a wage index budget neutrality adjustment of 1.0008. Based on updated data, the CPI-U for the 12-month period ending with the midpoint of CY 2013 is now projected to be 1.4 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) is 0.8 percent, resulting in an MFP-adjusted CPI-U update factor of 0.6 percent. The final ASC conversion factor of $42.917 is the product of the CY 2012 conversion factor of $42.627 multiplied by the wage index budget neutrality adjustment of 1.0008 and the MFP-adjusted CPI-U payment update of 0.6 percent. We also are finalizing proposed changes to §§ 416.160(a)(1) and 416.171, without modification, regarding the reduction to payment rates beginning in CY 2014 for ASCs that fail to meet the ASCQR Program requirements.

3. Display of CY 2013 ASC Payment Rates

Addenda AA and BB to this CY 2013 OPPS/ASC final rule with comment period (which are available via the Internet on the CMS Web site) display the final updated ASC payment rates for CY 2013 for covered surgical procedures and covered ancillary services, respectively. These addenda contain several types of information related to the CY 2013 payment rates. Specifically, in Addendum AA, a "Y" in the column titled "Subject to Multiple Procedure Discounting" indicates that the surgical procedure will be

subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session. Display of the comment indicator "CH" in the column titled "Comment Indicator" indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2013. 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 this final rule with comment period.

The values displayed in the column titled "CY 2013 Payment Weight" are the relative payment weights for each of the listed services for CY 2013. The payment weights for all covered surgical procedures and covered ancillary services whose ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. 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 2013 payment rate displayed in the "CY 2013 Payment" column, each ASC payment weight in the "CY 2013 Payment Weight" column was multiplied by the CY 2013 conversion factor of $42.917. 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 XIV.H.2.b. of this final rule with comment period).

In Addendum BB, there are no relative payment weights displayed in the "CY 2013 Payment Weight" column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The "CY 2013 Payment" column displays the CY 2013 national unadjusted ASC payment rates for all items and services. The CY 2013 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 2012.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are to be excluded from payment in ASCs for CY 2013.

We did not receive any public comments regarding the continuation of our policy to provide CY 2013 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 2013 for covered surgical procedures and covered ancillary services, respectively, and provide additional information related to the CY 2013 rates.

XV. 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 reporting programs for long term care hospitals, inpatient rehabilitation hospitals, the hospice program, ambulatory surgical centers (the Ambulatory Surgical Center Quality Reporting (ASCQR) Program), as well as a program for physicians and other eligible professionals, known as the Physician Quality Reporting System (PQRS) (formerly known as the Physician Quality Reporting Initiative (PQRI)). CMS has recently finalized quality reporting programs for inpatient psychiatric facilities and PPS-exempt cancer hospitals.

Finally, CMS has implemented a Hospital Value-Based Purchasing Program and an end-stage renal disease (ESRD) Quality Incentive Program (76 FR 628 through 646) 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. 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 electronic health records (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 generally applied the same principles for the development and the use of measures, with some differences:

- Our overarching goal is to support the National Quality Strategy's goal of better health care for individuals, better health for populations, and lower costs for health care. The Hospital OQR Program will help achieve these goals by creating transparency around the quality of care at hospital outpatient departments to support patient decision-making and quality improvement. Given the availability of well validated measures and the need to balance breadth with minimizing burden, measures should take into account and address, as fully as possible, the six domains of measurement that arise from the six priorities of the National Quality Strategy: Clinical care; Person- and caregiver-centered experience and outcomes; Safety; Efficiency and cost reduction; Care coordination; and Community/population health. More information regarding the National Quality Strategy can be found at: http://www.healthcare.gov/law/resources/reports/. HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act.

- Pay-for-reporting and public reporting should rely on a mix of standards, processes, outcomes, efficiency, and patient experience of care measures, including measures of care transitions and changes in patient functional status.

- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare and Medicaid public reporting and incentive payment systems to promote coordinated efforts to improve quality. The measure sets should evolve so that they include a focused set of

measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider category.

- We weigh the relevance and the utility of measures compared to the burden on hospitals in submitting data under the Hospital OQR Program. The collection of information burden on providers should be minimized to the extent possible. To this end, we are working toward the eventual adoption of electronically-specified measures so that data can be calculated and submitted via certified EHR technology with minimal burden. We also seek to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all-payer claims databases. In recent years we have adopted measures that do not require chart abstraction, including structural measures and claims-based measures that we can calculate using other data sources.

- To the extent practicable and feasible, and recognizing differences in statutory authorities, measures used by CMS should be endorsed by a national, multi-stakeholder organization. We take into account the views of the Measure Application Partnership (MAP). The MAP is a public-private partnership convened by the National Quality Forum (NQF) for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay for reporting programs. The MAP views patient safety as a high priority area and it strongly supports the use of NQF-endorsed safety measures. Accordingly, we consider the MAP's recommendations in selecting quality and efficiency measures. Information about the MAP can be found at

http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx

- Measures should be developed with the input of providers, purchasers/payers, consumers, and other stakeholders. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature.

- HHS Strategic Plan and Initiatives. HHS is the U.S. government's principal agency for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. Every 4 years HHS updates its Strategic Plan and measures its progress in addressing specific national problems, needs, or mission-related challenges. The goals of the HHS Strategic Plan for Fiscal Years 2010 through 2015 are to: Transform Health Care; Advance Scientific Knowledge and Innovation; Advance the Health, Safety, and Well-Being of the American People; Increase Efficiency, Transparency, and Accountability of HHS Programs; and Strengthen the Nation's Health and Human Services Infrastructure and Workforce (http://www.hhs.gov/about/FY2012budget/strategicplandetail.pdf). HHS prioritizes policy and program interventions to address the leading causes of death and disability in the United States, including heart disease, cancer, stroke, chronic lower respiratory diseases, unintentional injuries and preventable behaviors. Initiatives such as the HHS Action Plan to Reduce Healthcare-associated Infections (HAIs) in clinical settings and the Partnership for Patients exemplify these programs.

● CMS Strategic Plan. We strive to ensure that measures for different Medicare and Medicaid programs are aligned with priority quality goals, that measure specifications are aligned across settings, that outcome measures are used whenever possible, and that quality measures are collected from EHRs as appropriate

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74451 through 74452), we responded to public comment on many of these principles. In the CY 2013 OPPS/ASC proposed rulemaking, we generally applied the same principals for our considerations for future measures, with some differences.

Comment: Many commenters supported CMS' general principles of measure development, selection, and implementation, specifically, CMS' combined approach of using process and outcomes measures, as well as our intent to adopt NQF-endorsed measures whenever feasible, and to align measures across settings under different quality reporting programs. One commenter stated that CMS should only adopt measures that are useful for hospital outpatient departments to improve their quality performance.

A few commenters recommended that the Hospital OQR Program only adopt NQF-endorsed measures which undergo established sound, and timely measure maintenance and update procedures. Several commenters urged that CMS proceed cautiously when considering adopting non-NQF-endorsed measures, which in some cases may not have been rigorously field-tested and may end up in subsequent suspension or implementation deferral. Commenters requested that CMS delay adoption of measures in the future until specification problems are completely ironed out so that hospitals do not have to spend resources on preparing for incompletely specified or untested measures.

Response: As discussed, we usually focus on measures appropriate to the specific provider category that reflect the level of care and the most important areas of service and measures for that provider category. Section 1833(t)(17)(C)(i) of the Act requires the Secretary to ''develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.'' This provision does not require that the measures we adopt for the Hospital OQR Program be endorsed by any particular entity, and we believe that consensus among affected parties can be achieved by means other than endorsement by a national consensus building entity, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment.

Generally, we prefer to adopt NQF-endorsed measures. We rely on NQF to endorse only those measures that have met the rigorous field testing requirement and we do not re-test these measures prior to adoption. However, in some circumstances, as with OP-19, when we find the specifications require revision after the measure has been adopted, CMS chooses to suspend a measure rather than requiring continued data collection to alleviate burden on hospitals.

We strive to field test each measure we use in our programs. However, on rare occasions, we adopt measures that were developed and tested by other measure stewards. With respect to the commenters who recommended that, in the future, we delay adoption of measures until specification problems are completely resolved so that hospitals would

not have to spend resources on preparing for incompletely specified or untested measures, we believe the commenters may have been referring specifically to one measure-- OP-24: Cardiac Rehabilitation Patient Referral from an Outpatient Setting. For that measure, we are delaying data collection until January 1, 2014, and its application toward a payment determination will be for CY 2015 rather than CY 2014. If our interpretation of the comment was correct, we understand the commenter's concerns. However, we clarify that because we have not added any OP-24 measure specifications to the Specification Manual yet, it is highly unlikely that hospitals would have spent resources in preparing for this measure.

In instances where we develop our measures, we do proceed with caution, employing a rigorous consensus-based measure development and field testing process that incorporates broad stakeholder input. Therefore, we believe it is reasonable to adopt measures developed in this manner whether or not they achieve NQF endorsement. For those measures that we have not developed, we strive to obtain testing information on the technical aspects from the developer and to work with the developer to create specifications that enable standardized collection in national programs. In the case of measures we do not develop, the above specification process may occur after adoption of the measure in a reporting program, but prior to implementing data collection.

Comment: Some commenters supported CMS' goal to align measures in the Hospital IQR, Hospital OQR, and Medicare and Medicaid EHR Incentive Programs. Commenters also commended CMS for striving for quality reporting that is based upon meaningful and comparable measures.

Response: We thank the commenters for supporting our strategy to align measures across settings and programs whenever feasible and to move toward more meaningful measures in our programs.

2. Statutory History of the Hospital Outpatient Quality Reporting (Hospital OQR) Program

We refer readers to the CY 2011 OPPS/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%2FPage%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 OPPS/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. This process is necessary so that the Hospital OQR measures are calculated based on the most up-to-date scientific and consensus standards. Under this process, when a national consensus building entity updates the specifications for a measure that we have adopted for the Hospital OQR Program, we update our specifications for that measure accordingly. For measures that are not endorsed by a national consensus building entity, the subregulatory process is based on scientific advances as determined necessary by CMS, in part, through our measure maintenance process involving Technical Expert Panels (73 FR 68767). We provide notice of the updates via the QualityNet Web site, http://www.QualityNet.org, and in the Hospital OQR Specifications Manual.

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-9, CPT, NUBC, and HCPCS codes, and at least 6 months of advance notice for changes to data elements that would require significant systems changes.

Comment: One commenter believed that conversion of measures to use ICD-10-CM/PCS and eMeasure formats should be considered a substantial change and should warrant the proposed rulemaking process. One commenter asserted that there are shortcomings in the CMS subregulatory process. The commenter was concerned that this rapid subregulatory process may not include a field review of the measure. Secondly, the commenter stated that some measure changes affect data accuracy and completeness, such as change of diagnosis, procedure codes and changes to exclusions to the patient

population and extended application of the measure to other hospital locations. The commenter believed that these are substantive changes rather than non-substantive changes as noted by CMS.

Response: We will be transitioning all of our billing and measurement systems from ICD-9 to ICD-10. We intend to solicit public comment on the ICD-10 versions of our measure specifications through future rulemaking prior to implementation. 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. This is theoretically true of moving from ICD-9 to the ICD-10 coding system (or eMeasure format). However, we recognize that in moving to ICD-10 coding (or eMeasure format) there may be some nuances in the measures that when translated result in unanticipated differences in performance, rendering prior measure results untrendable with results for the same measures under the new coding system. We also intend to study this effect further once implementation has occurred and data are available to do so.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504), we indicated that examples of what we might generally regard as nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, or a broadening of age ranges. We believe that nonsubstantive changes may also include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. We note that the NQF process has already incorporated an opportunity for public comment and engagement in the measure maintenance process.

We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the Hospital OQR Program. 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, NQF expansion of endorsement of a previously endorsed measure to a new setting, procedure/process, or test administration). However, these and other changes would need to be evaluated on a case-by-case basis to determine whether or not a change to a measure is in fact substantive.

Comment: A few commenters expressed concern that the CMS procedures for notifying providers of significant changes to quality measures and general changes to the Hospital OQR Program may be problematic at times, as e-mail blasts, one of the CMS communication methods, do not always reach the appropriate quality measure personnel. The commenters requested consistency in transparency of CMS' communications to hospitals, vendors, and QIOs and requested sufficient notice be given to hospitals regarding the new start date of any measure changes.

Response: We thank these commenters for feedback on communication. We endeavor to communicate clearly to all Hospital OQR Program stakeholders. We offer e-mail blasts to subscribers who sign up to receive them, indicating they prefer to receive information by e-mail. The QualityNet Web site contains a full list of all e-mail blasts sent, and it is available for any stakeholder to review at any time. We do not intend the

listserv to replace QualityNet as the primary source for information and resources for the Hospital OQR Program.

We offer a helpline that is available weekdays to offer technical support and assistance to callers, in an effort to help any caller successfully comply with program requirements. Please find this helpline and program contact information by visiting the QualityNet Web site at https://www.qualitynet.org. From this page, choose "Hospitals-Outpatient" from the drop down menus across the top of the page, then click on "Support Contact."

Comment: A few commenters appreciated the 6-month advance notice of data elements and system changes but noted that the 6-month period for measure update and Specifications Manual release may not provide sufficient time for hospitals to make changes in data elements and system. Another commenter requested more detailed instructions on chart abstraction be provided because the training Qs and As posted on the QualityNet Web site are insufficient and appear to contradict the Specifications Manual at times.

Response: Our experience with this and other quality reporting programs indicates that 6 months' notice is sufficient for hospitals and their vendors to accommodate data element and system changes. We provide detailed abstraction instructions in our measure Specifications Manual, and provide additional guidance through Qs and As posted on the QualityNet Web site, and by offering periodic training.

We will take into consideration the recommendation to provide more detailed instructions on chart abstraction due to insufficient Qs and As posted on the QualityNet

Web site. We are aware of a specific situation we corrected earlier this year. Under the ED Throughput topic, we had two contradictory answers posted within our Qs and As for a brief period. We have corrected the situation and we apologize for the confusion it may have caused.

We will address this comment by having our primary support contractor review the current and incoming Qs and As to look for opportunities to incorporate answers into the Specifications Manual where appropriate. We strive to maintain high quality Qs and As that stakeholders can use as a reference for chart abstraction and measure specifications.

b. Publication of Hospital OQR Program Data

Section 1833(t)(17)(E) of the Act requires that the Secretary establish procedures to make data collected under the Hospital OQR Program available to the public. It also states that such procedures must ensure that a hospital has the opportunity to review the data that are to be made public, with respect to the hospital prior to such data being made public. To meet these requirements, data that a hospital has submitted for the Hospital OQR Program are typically provided to hospitals for a preview period via QualityNet, and then displayed on CMS Web sites such as the Hospital Compare Web site, http://www.hospitalcompare.hhs.gov following the preview period. The Hospital Compare Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care. We believe this information motivates beneficiaries to work with their doctors and hospitals to discuss the quality of care

hospitals provide to patients, thus providing additional incentives to hospitals to improve the quality of care that they furnish.

Under our current policy, we publish quality data by the corresponding hospital CMS Certification Number (CCN), and indicate instances where data from two or more hospitals are combined to form the publicly reported measures on the Hospital Compare Web site. That is, in a situation in which a larger hospital has taken over ownership of a smaller hospital, the smaller hospital's CCN will be replaced by the larger hospital's CCN (the principal CCN). For data display purposes, we will only display data received under the principal CCN. If both hospitals are submitting data, those data are not distinguishable in the warehouse; and the data is calculated together as one hospital.

Consistent with our current policy, we make Hospital IQR and Hospital OQR data publicly available whether or not the data have been validated for payment purposes. The Hospital Compare Web site currently displays information covering process of care, structural, ED throughput timing, health IT, and imaging efficiency measure data under the Hospital OQR Program.

In general, we strive to display hospital quality measures on the Hospital Compare Web site as soon as possible, after they have been adopted and have been reported to CMS. However, if there are unresolved display issues or pending design considerations, we may make the data available on other, non-interactive, CMS Web sites such as http://www.cms.hhs.gov/HospitalQualityInits/. Publicly reporting the information in this manner, though not on the interactive Hospital Compare Web site, allows us to meet the requirement under section 1833(t)(17)(E) of the Act for establishing

procedures to make quality data submitted available to the public following a preview period. When we display hospital quality information on non-interactive CMS Web sites, affected parties will be notified via CMS listservs, CMS e-mail blasts, memoranda, Hospital Open Door Forums, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than Hospital Compare.

We also require hospitals to complete and submit a registration form ("participation form") in order to participate in the Hospital OQR Program. With submission of this participation form, participating hospitals agree that they will allow CMS to publicly report the quality measure data submitted under the Hospital OQR Program, including measures that we calculate using Medicare claims.

Comment: One commenter urged CMS to continue to use both stakeholders and focus groups to develop and evaluate terminology to present user-friendly measurement data on Hospital Compare. The commenter believed this procedure would help to decrease misinformation and unnecessary alarm to patients. Another commenter questioned the value of the "old" data and the "outdated time-frame of data collection period" presented in Hospital Compare, in facilitating health care decisions by Medicare beneficiaries.

Response: On Hospital Compare, we strive to provide consumers with meaningful information that they can use to help make healthcare decisions. When warranted, we use formative consumer testing to assure the language and display of information makes sense to consumers before posting. Formative testing allows CMS to

adjust displays and language so that they are more meaningful to consumers based on consumer feedback. At the same time, we believe that it is critical to maintain the integrity of the measure intent, thereby not simplifying the data too much as to risk making the information so general that it is not meaningful.

The data we publicly report do not all have the same performance period. For example, the process-of-care measures are collected quarterly and are displayed as a rolling four quarters of data on Hospital Compare. We allow 4 to 4.5 months after the reporting quarter for hospitals to submit their complete data to the CMS clinical data warehouse. In contrast, the outcomes measures are calculated using 3 years of data from Medicare fee for service claims.

Comment: One commenter was concerned that the display of the acceptable quality range and benchmarks publicly reported for the Outpatient Imaging Efficiency (OIE) measures may cause unnecessary alarm to consumers.

Response: We appreciate the commenter's concerns. To provide meaningful performance benchmarks, we will emphasize the "within range" rates and facility outlier results in a facility's public reporting so as to minimize the potential for negatively affecting access to imaging services. In addition, we continue to use both stakeholder and focus groups for developing and evaluating terminology for presenting measurement data to the public, in order to avoid misleading or alarming patients unnecessarily.

B. Process for Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

In past rulemakings, we have proposed to retain previously adopted measures for each payment determination on a year-by-year basis and invited public comments on the proposal to retain such measures for all future payment determinations unless otherwise specified. In the CY 2013 OPPS/ASC proposed rule (77 FR 45178), for the purpose of streamlining the rulemaking process, beginning with this rulemaking, we proposed that when we adopt measures for the Hospital OQR Program beginning with a payment determination and subsequent years, these measures are automatically adopted for all subsequent year payment determinations unless we propose to remove, suspend, or replace the measures. We invited public comment on this proposal.

Comment: Some commenters recognized the importance of stability and consistency in the Hospital OQR Program set and supported the proposed automatic retention of Hospital OQR Program measures adopted in a previous year for subsequent payment year determinations. One commenter stated that proposed rulemakings should be devoted to address new changes rather than repeating discussions of continuing measures previously adopted. However, the commenter urged CMS to publish the full list of measures to be continued, in the OPPS/ASC proposed rule each year. The commenter believed publishing the list of measures would provide the public the opportunity to comment and to share experience on current measures.

Response: We appreciate the commenters' recognition of the importance of our goal to streamline the administrative process in rulemaking. As suggested by the

commenters, we will continue to publish the full list of measures to be continued in the OPPS proposed rules, for the public to provide input and share experience.

Comment: A few commenters urged that CMS continue to propose all Hospital OQR Program measures adopted, on an annual basis. Commenters were concerned that if measure retention occurs without going through the rulemaking process year by year, irrelevant and obsolete measures may not be removed timely, and the transparency of the rulemaking process will be compromised.

Response: We do not believe the proposed measure retention policy will compromise the transparency in rulemaking or slow down the removal or suspension of problematic measures. Rather, the measure retention policy would enhance administrative efficiency while providing clear expectations to hospital providers. Should we decide there is a need to remove or suspend a measure for concerns of patient safety, we will act expeditiously to remove or suspend the measure between rulemaking cycles. We will notify the public by using memoranda, e-mail blasts distributed through QualityNet, and news postings on the "Splash page" on QualityNet. We will thereafter confirm the removal or suspension of the measure through rulemaking.

In the FY 2010 IPPS/LTCH PPS rulemaking, we adopted a process for the Hospital IQR Program for immediate measure removal based on evidence that the continued use of the measure as specified raises patient safety concerns. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634), we adopted this same policy to be used in the Hospital OQR Program. Furthermore, should we determine that a measure is problematic based upon other criteria stated in the CY 2013 OPPS/ASC

proposed rule (77 FR 45178), we will utilize rulemaking to propose the removal or suspension of the measure and obtain public comment prior to determining whether to remove or suspend the measure.

After consideration of the public comments we received, we are finalizing the automatic retention of Hospital OQR Program measures adopted in previous payment determinations for subsequent year payment determinations.

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 of Hospital IQR Program measures based on evidence that the continued use of the measure as specified raises 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 OPPS/ASC final rule with comment period (74 FR 60634).

In previous Hospital IQR Program rulemakings, we have referred to the removal of measures from the Hospital IQR Program as "retirement." We have used this term to indicate that Hospital IQR Program measures are no longer included in the Hospital IQR Program measure set for one or more indicated reasons. However, we note that this term may imply that other payers/purchasers/programs should cease using these measures that are no longer required for the Hospital IQR Program. In order to clarify that this is not our intent, we stated in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28034) that

we will use the term "remove" rather than "retire" to refer to the action of no longer including a measure in the Hospital IQR Program. In the CY 2013 OPPS/ASC proposed rule (77 FR 45178), we proposed to adopt the same terminology of "removal" in the Hospital OQR Program to indicate our action of discontinuing a measure in the Hospital OQR Program.

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 Hospital OQR 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 OPPS/ASC proposed rule (77 FR 45178), we proposed to apply these measure removal criteria in the Hospital OQR Program as well, and we invited public comments on these proposals.

In addition to these criteria, we take into account the views of the Measure Application Partnership (MAP) in the evaluation of measure removal. The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for certain quality reporting programs and pay for performance programs. The MAP views patient safety as a high priority area and it strongly supports the use of NQF-endorsed measures. Furthermore, for efficiency and streamlining purposes, we strive to eliminate redundancy of similar measures.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45178), we did not propose to retire any measures from the Hospital OQR Program.

Comment: A few commenters agreed with CMS that the term "removal" is preferable to "retirement" as the measure at issue may still be relevant in other payers/purchasers/programs. The commenters supported all of the proposed measure removal criteria. One commenter noted that CMS should not always choose the availability of measures applicable to a broader patient population as a measure removal criterion, over focused measures targeted at subsets of patient population. The commenter asserted that in some instances, condition-specific measures are warranted.

Response: We thank the commenters for the support of the measure removal criteria. We are cognizant that some focused measures targeted at subsets of patient population are also relevant in the Hospital OQR Program. We want to clarify that before considering the removal of a measure in any given situation, we first assess whether the removal criteria are relevant. We would not be likely to propose the removal of a measure because there is a measure with broader applicability if what we seek to

measure requires a more targeted, condition or patient-specific assessment. We might, on the other hand, consider removal of a measure based on the availability of a measure that is more strongly associated with desired patient outcomes for a particular topic, since this might result in a focused measure that is targeted to subsets of patient populations. In any given situation, we will focus only on removal criteria that are relevant to a particular set of circumstances. If more than one of the measure removal criteria appears to be relevant, we intend to take a balanced approach in assessing the value of each of the different criteria in a given situation before removing any measure.

Comment: One commenter requested that besides using CMS program data, CMS should also solicit input from developers and analyze data from EHRs and registries to identify topped-out measures. To avoid the unintended consequence of hospitals not spending resources on specific interventions due to measure removal, one commenter urged CMS to suspend the measures at issue rather than removing measures whenever feasible. In addition, the commenter requested that CMS solicit public input before suspending or removing a measure.

Response: We expect hospitals to always follow appropriate standard of care and clinical guidelines in exercising positive interventions, regardless of whether a measure is being suspended or removed. Should we propose to remove measures using the rulemaking process, we seek input from the public, including measure developers and entities using EHRs to collect the measures. However, in the case of suspension or removal due to patient safety concerns, action would need to be taken quickly and may not coincide with rulemaking cycles. Should this occur, we would seek to suspend

measures in situations where we believe the measure can be re-specified in a manner that would not be overly prescriptive or overly burdensome to providers.

Comment: A few commenters urged CMS to closely align its measure removal with the MAP recommendations. The commenters cited as examples of measures that should be removed 7previously adopted Hospital OQR Program measures that are not NQF-endorsed and not recommended by the MAP.

Response: As we have already stated, we consider all of the MAP input we receive, including its recommendations for removal of measures, before making a decision about removing or keeping any particular measure. We did not include any proposals regarding the 7 measures that the commenters mentioned in the CY 2013 OPPS/ASC proposed rule. As such, we are not making any revisions to these measures in this rulemaking. However, we thank the commenters for these measure removal suggestions and will take them into consideration for future measure removal.

We note that section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures that the Secretary determines to be appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable to include measures set forth by one or more national consensus building entities. The Act does not require that the measures we adopt for the Hospital OQR Program be endorsed by any particular entity, such as the NQF. In addition, we believe that consensus among affected parties can be reflected by means other than endorsement by a national consensus building entity, including consensus achieved during the measure development process, consensus

shown through broad acceptance and use of measures, and consensus through public comment. Finally, the Act does not require us to do more than consider MAP input.

Comment: One commenter inquired about the criteria for resuming data collection for measures that are removed or temporarily suspended from the Hospital OQR Program.

Response: Measures that are removed must be proposed through rulemaking in order to be added back to the program prior to collecting data. For suspended measures, we will strive to align with the regular quarterly collection cycle that has been established for chart-abstracted measures, and we will provide sufficient notice (at least 3 months) prior to resuming collection of suspended measures. We will notify hospitals of resumed collection the same way we notify them of suspension - through QualityNet memoranda and e-mail blasts. We also intend to issue addenda to Specifications Manual releases. However, should we determine that the re-specified measure is substantively changed; that is, changes have been made that affect the underlying quality concepts being measured, we would use rulemaking to formally propose to replace the suspended measure with the modified measure. As we have noted in an earlier response, 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.

After consideration of the public comments we received, we are finalizing the term “removal” to indicate future action of discontinuing a measure in the Hospital OQR Program. Also, we are finalizing the adoption of the measure removal criteria used in the

Hospital IQR Program for the Hospital OQR Program. We also thank the commenters for the suggestions to keep, remove, or change the status of some of the measures we previously adopted. At this time, we intend to keep the measures as adopted.

2. Removal of One Chart-Abstracted Measure for the CY 2013 and Subsequent Years Payment Determinations

In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43863), we established a precedent to immediately remove a measure from a measure set using a subregulatory notification process followed by subsequent confirmation in rulemaking in situations when there is a reason to believe that continued collection of the measure raises patient safety concerns, and the measure cannot be reasonably revised in a manner that would alleviate the concern without being overly complex. For CY 2013 and subsequent year payment determinations, we are confirming what we stated in our August 13, 2012, memorandum "Removal of Hospital Outpatient Quality Reporting Measure (OQR) OP-16: Troponin results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of arrival" that we have removed measure OP-16. (To review this memorandum, visit http://www.qualitynet.org; from this page, choose "Hospitals-Outpatient" from the drop down menus across the top of the page, then click on "Email-Notifications." Memoranda are listed by date of publication.)

We adopted measure OP-16 for the Hospital OQR Program for the CY 2013 payment determination with data collection beginning with January 1, 2012 encounters. However, we are removing OP-16 from the Hospital OQR measure set based on patient

safety concerns. On July 11, 2012 the Food and Drug Administration (FDA) issued a Class I recall on several point of care (POC) testing kits, including those that provide Troponin results. The Class I recall was due to an increased frequency of false positive and false negative results. FDA defines a Class I recall as: "a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death." The FDA safety alert appears at the following Web site: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm311405.htm.

While OP-16 did not specify which type of laboratory equipment should be used to obtain Troponin results, hospitals may be using these POC tests in order to expedite results. We understand that the FDA considers the size of this recent Class I recall to be large. Due to the magnitude of this recall, we became concerned that continued collection of the measure may potentially impact patient safety because of the high probability of false results associated with the equipment. We chose to remove the measure from the program rather than suspend the measure because revision of the measure to address this issue would result in an overly prescriptive and complex measure. On August 13, 2012, we released a memorandum "Removal of Hospital Outpatient Quality Reporting Measure (OQR) OP-16: Troponin results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of arrival." This memorandum notified the Hospital OQR Program stakeholder community to cease chart abstraction for the OP-16 measure immediately,

and that CMS will not publically report, validate or use in the CY 2013 payment determination any data collected on this measure. The memorandum dated August 13, 2012 is available for review at the QualityNet Web site. To review this memorandum, access http://www.qualitynet.org; from this page, choose "Hospitals-Outpatient" from the drop down menus across the top of the page, then click on "Email-Notifications." Memoranda are listed by date of publication.) Since the memorandum was issued, we have received two Congressional inquiries from POC device manufacturers indicating that our decision to remove the measure will impact them negatively. One commenter also indicated that the measure has encouraged increased communication in the Emergency Department and expressed concern that removal of the measure would result in reduced communication.

We emphasize that despite the removal of OP-16 from the Hospital OQR Program, we expect hospitals to continue the timely triage, diagnosis and treatment of cardiac and other patients in the ED according to established clinical guidelines. We also expect that hospitals will continue their efforts to improve communication and throughput in the ED.

Although we have requested immediate discontinuation of chart abstraction for OP-16, CMS is unable to cease data collection in the system until January 1, 2013, when we have made certain system changes. In order to overcome CMS's system limitation, hospitals can choose to submit a meaningless value for this measure through December 31, 2012. We ask hospitals not to submit a blank value for OP-16, as a lack of a populated value for OP-16 will cause a case to be rejected. If a case is rejected due to

lack of data, this could impact a hospital's ability to meet the Hospital OQR requirements. Some vendors may have the capability to provide a default value for OP-16. Hospitals are encouraged to work with their vendors to determine options to populate the OP-16 data field at submission.

Comment: A few commenters supported the removal of OP-16 and believed that there was insufficient evidence to link this process measure to patient outcomes. However, some commenters were concerned that the removal of OP-16 may undermine the importance of Troponin testing or the need to receive the results of Troponin testing in a timely manner. Commenters asserted that clinical guidelines for the diagnostic evaluation of patients with AMI or presumed cardiac chest pain still recommend receiving results from cardiac marker testing, including Troponin, within 60 minutes. The commenters urged that CMS either reconsider the removal of OP-16 or provide guidance on when the measure will be reinstated. Commenters added that currently, there are new and improved Troponin testing technologies available that would meet the intent of OP-16.

Response: We thank the commenter for the support of the removal of this measure. We also clarify that hospitals should not cease testing Troponin and other cardiac markers, nor should they cease following clinical guidelines for diagnosis and treatment of cardiac patients based on our decision to remove OP-16 from the Hospital OQR Program. We are considering initiating a call for measures for this program, and will consider suggestions for measures on this and other topics that are submitted through such a process for future rulemaking.

Comment: A few commenters perceived the CMS' instruction to submit a blank value for OP-16 to be burdensome and stated that hospitals or their vendors should not have to bear the responsibility of submitting meaningless data. Commenters urged CMS to work with contractors to derive a technical solution that would not require hospitals to submit meaningless data.

Response: As we stated in our memorandum, we urge hospitals to work with their data submission vendors on low-burden ways to populate fields for measures that are suspended or removed until such time as our system changes can be made. In the case of OP-16, this will be January 1, 2013. We have asked our systems developers to add functionality to remove a measure from the data collection system without any delay and this feature will be incorporated into a future release of our hospital reporting data collection system. In addition, we have added a business requirement for our contractor to fix this as soon as possible and it has been prioritized as high as possible given all the competing demands on contract programmers.

We are confirming the removal of measure OP-16: Troponin Results for Emergency Department Acute Myocardial Infarction (AMI) Patients or Chest Pain Patients (with probable cardiac chest pain) Received Within 60 Minutes of Arrival from the Hospital OQR Program in this final rule with comment period.

3. Suspension of One Chart-Abstracted Measure for the CY 2014 and Subsequent Years Payment Determinations

In April of this year, we took immediate action to suspend OP-19 because of patient safety concerns. We chose to suspend this measure rather than to immediately

remove the measure from the program 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 believed that the measure could be quickly re-specified in a manner that would mitigate the concerns raised by hospitals and stakeholders.

For CY 2014 and subsequent year payment determinations, we are confirming that we have suspended the collection of measure OP-19: Transition Record with Specified Elements Received by Discharged ED Patients, which specifies patients or their caregivers (emphasis added) receive a transition record at the time of ED discharge. We adopted measure OP-19 for the Hospital OQR Program for the CY 2013 payment determination with data collection beginning with January 1, 2012 encounters. Since data collection for this measure began, concerns have been raised about the current measure specifications, including potential privacy concerns related to releasing certain elements of the transition record to a patient who is being discharged from an emergency department or the patient's caregiver. Some examples provided by hospitals of this were 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 regard to the issue of patient safety, there is evidence that, in some cases, following the measure as currently specified could lead to patient harm, especially when the medical results relate to pregnancy. During field testing of this measure, some women refused to accept transition records that documented pregnancy results. While it is unclear what motivated these particular women to decline to receive transition records,

literature supports a rationale for why pregnant women may be reluctant to receive documentation of pregnancy results; under certain circumstances, pregnancy is associated with increased risk of physical violence from a current or former male partner (Richardson, J. et al., 2002. Identifying domestic violence: cross sectional study in primary care, British Medical Journal).

After consideration of these issues and internal review of the measure specifications, we decided to suspend data collection for OP-19 effective with January 1, 2012 encounters until further notice. On April 2, 2012 we released a memorandum "Temporary Suspension of Hospital Outpatient Quality Reporting Measure OP-19: Transition Record with Specified Elements Received by Discharged Patients." This memorandum notified the Hospital OQR Program stakeholder community that we had suspended data collection for the OP-19 measure effective with January 1, 2012 encounters and until further notice.

On April 12, 2012, we released a memorandum, "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 in validation. The revised SDPS Memo is available for review at the QualityNet Web site (http://www.qualitynet.org) under the option "E-mail Notifications" within the "Hospitals – Outpatient" drop down menu found at the top of the page.

When NQF completes its maintenance review on this measure, and we have incorporated the necessary changes to the measure specifications in our measure manual,

we anticipate being able to resume data collection, and will notify hospitals of changes in the suspension status of the measure for Hospital OQR via e-mail blast.

Because CMS system constraints prevent immediate cessation of data collection, hospitals must continue to submit information for this measure during this temporary suspension. The data collection system currently requires a populated value for OP-19. During the period of time that the measure is suspended, hospitals may choose to populate their OP-19 submission field with a value that is not meaningful. Hospitals should not submit a null value because the lack of data for OP-19 will cause the submitted case to be rejected entirely from the data warehouse. In other words, failure to populate the OP-19 field could compromise reporting data for other measures for that same case because more than one measure can be reported within a single case.

Some vendors may have the capability to provide a default value for this measure to reduce data abstraction. Hospitals are encouraged to work with their vendors to determine options to reduce abstraction burden.

If a case is rejected from the data warehouse on the basis of a system error due to the current system's inability to accept a case without OP-19 data populated, in the event that the rejected case would have also fulfilled reporting requirements for one or more other measures, this rejection would could affect a hospital's ability to meet Hospital OQR Program requirements.

Therefore, we recommend continuing to submit a value for OP-19, although we will not use data submitted on OP-19 for payment determinations, will not publicly report

these data, and will not validate these data until all concerns are resolved and measure specifications are refined as necessary.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45178), because the developer is working to revise the measure specifications to address the concerns raised by affected parties, and the measure is undergoing NQF maintenance review this year, we did not propose to remove the measure from the program at this time. After completion of the NQF maintenance process, we anticipate that normal program operations for this measure could resume once we have updated the Hospital OQR Specifications Manual and made any necessary changes to our data collection infrastructure. However, should we determine that these concerns cannot be addressed, we would propose to remove this measure in a future OPPS/ASC rule. We invited public comment on the suspension of OP-19 until further notice. We also invited public comment on whether the measure should be removed from the program at this time.

Comment: A few commenters strongly urged CMS to retain the OP-19 measure, with the ongoing revision of the measure specifications to address privacy concerns.

Some commenters advocated the removal of this measure on grounds that are completely different from CMS's rationale for removing this measure. Some commenters were concerned that many patients may not be able to comprehend most of the data elements (for example, lab tests and results, and procedures performed in the ED) required by the measure, which would be in the transition record. Many commenters believed that the provision of transition records by EDs would not enhance coordination between sites of care. Rather, the commenters stated it will increase the likelihood of

confusion for the patients. Commenters were concerned that: (1) the transition records including instructions issued upon ED discharge are not final and may be changed subsequently by the observation unit staff, should the patient be put in the observation unit; and (2) the ED transition records may conflict with the subsequent transition record provided by the receiving provider, such as the home health care agency. In the commenters' view, the Emergency Medical Treatment and Labor Act (EMTALA) regulation already provides for the transfer of records that include communication between nurses and physicians. Some commenters suggested the provision of a simplified, user-friendly ED visit summary to patients would be a better alternative.

A few commenters requested clarification of the data elements specified in the Specifications Manual: major procedures and tests; patient instructions; follow up care; ED patient population; and medication types. Commenters stated that the data elements specified in the Specifications Manual are too vague and leave room for different interpretation. One commenter recommended creating individual measures to address each of the items that need to be included in the ED visit summary.

One commenter requested limiting the transition record information to include only diagnostic test procedures performed in the ED. One commenter did not view patients put on observation as ED patients and requested they be treated as exclusions in the measure specification. These commenters did not discuss their reasons for requesting these changes.

One commenter stated that currently, since hospitals are at different stages of implementing electronic health records technology, the time taken to generate electronic

transition records will vary greatly. For some hospitals, this may potentially delay the discharge of patients from the ED.

Response: We appreciate the support and the recommendations from the commenters. As for the comments on clarification of data elements in the Specifications Manual, we note that there are no specific requirements related to what constitutes appropriate documentation that must be transferred to the next site of care.

We are aware of the concerns expressed by the commenters. Since the suspension of OP-19 on April 2, 2012, we have been actively working with the American Medical Association Physician Consortium for Performance Improvement (AMA-PCPI) (the measure stewards) to clarify the specifications of this measure. The intent of OP-19 is to require a transition record to patients discharged directly to home or home health, not those patients who would otherwise be transferred to an acute care facility, regardless of EMTALA status. It is our hope that the revised specifications will address the commenters' concerns prior to reinstatement of the measure in the Hospital OQR Program.

Comment: Many commenters perceived the submission of a blank value for OP-19, as requested by CMS, to be burdensome and stated that hospitals or their vendors should not have to bear the responsibility of submitting meaningless data. Commenters requested that CMS refine specifications so that hospitals do not have to submit meaningless data.

Response: As we stated in our April 12, 2012 revised memorandum, we urge hospitals to work with their data submission vendors on low-burden ways to populate

fields for measures that are suspended or removed until such time as our system changes can be made.

We are confirming the suspension until further notice of measure OP-19: Transition Record with Specified Elements Received by Discharged ED Patients, effective with January 1, 2012 encounters. We are working with the measure steward, the AMA, to enhance OP-19 for future use. When the measure specifications have been updated and reviewed by the NQF, we will consider implementation of the revised measure.

4. Deferred Data Collection of OP-24: Cardiac Rehabilitation Measure: Patient Referral from an Outpatient Setting for the CY 2014 Payment Determination

In the CY 2012 OPPS/ASC final rule with comment period, we finalized OP-24: Cardiac Rehabilitation Measure: Patient Referral From an Outpatient Setting for the CY 2014 payment determination and indicated that the applicable quarters for data collection for this measure would be 1st quarter CY 2013 and 2nd quarter CY 2013 (76 FR 74464, 74481). In order for us to adhere to this data collection schedule, we would have needed to have published the measure specifications in the July 2012 release of the Hospital OQR Specifications Manual. While there are NQF-endorsed specifications for this measure, in order to implement standardized data collection on a national scale, we must include detailed abstraction instructions for chart-based measures in our Specifications Manual. These instructions were not completed and tested in time to include in the July 2012 release of the Specifications Manual, which includes collection instructions for measures beginning January 1, 2013. This was an

unanticipated delay in implementation that we do not expect to be a regularly occurring issue for the Hospital OQR Program.

Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45179), we proposed to defer the data collection for this measure to January 1, 2014 encounters. We also proposed that the measure would no longer be used for the CY 2014 payment determination, and that its first application would be for the CY 2015 payment determination. The data collection deferral for this measure is detailed in the "Form, Manner, and Timing" section of this final rule with comment period. We invited public comments on these proposals.

Comment: Many commenters supported the proposed deferred data collection of this measure until detailed instructions for data collection are completed. Commenters believed the measure is beneficial for patients with cardiovascular diseases and they were hopeful that the measure could be included into the Hospital OQR program for implementation beginning with January 1, 2014 encounters.

Response: With the inclusion of the abstraction instructions for this chart-abstracted measure in our July 2013 release of the Specifications Manual, we anticipate that data collection can begin with January 1, 2014 encounters.

Comment: One commenter asked if the data for this measure could be collected through claims instead of chart-abstraction. Also, the commenter viewed this measure as merely documentation of a referral being offered as the patient could have refused the referral to enroll in a cardiac rehabilitation program.

Response: This measure cannot be collected via claims because patient referral is not captured in claims data. We recognize that this measure does not focus on whether the patient actually enrolls in a cardiac rehabilitation program. Rather, the measure focuses on the process of referring a patient to a cardiac rehabilitation or secondary prevention program.

Comment: One commenter requested clarification on: (1) what setting will be included in the denominator for the measure population; (2) definition of an outpatient practice; and (3) definition of an outpatient clinic practice. The commenter interpreted the measure specification developed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American College of Cardiology Foundation, and the American Heart Association (AACVPR/AACF/AHA) Task Force to mean that the measure is intended for physicians providing follow-up care to patients after an acute event, and not for hospital outpatient department care. The commenter, therefore, suggested the removal of the current OP-24 measure and adoption of the measure "Cardiac Rehabilitation Patient Referral from an Inpatient Setting" for the Hospital OQR Program.

Response: We intend to operationalize the measure for patients seen for ongoing care at outpatient clinics affiliated with hospitals. The measure is designed for the outpatient setting and the denominator is intended to be the percentage of patients who had a qualifying event/diagnosis during the previous 12 months and have not participated in an outpatient cardiac rehabilitation program. Given the measure focus on the process of referring a hospital outpatient clinic patient to a cardiac rehabilitation program, we

expect it will incentivize Hospital Outpatient Departments (HOPDs) to better coordinate the care that their patients receive. We agree that the measure could also be appropriate as a measurement for physicians' follow-up care. We are currently working on the definitions the commenter has requested, outpatient practices and outpatient clinic practices, in the context of the HOPD.

After consideration of the public comments we received, we are finalizing the deferred data collection for OP-24 from January 1, 2013 to January 1, 2014 encounters for the CY 2015 payment determination.

D. Quality Measures for the CY 2015 Payment Determination

We previously finalized 26 measures for the CY 2015 Hospital OQR Program measure set in the 2012 OPPS/ASC rulemaking (76 FR 74472 through 74474).

In the CY 2013 OPPS/ASC proposed rule (77 FR 45179), taking into consideration the time and effort for CMS to develop, align, and implement the infrastructure necessary to collect data on the Hospital OQR Program measures and make payment determinations, as well as the time and effort on the part of hospital outpatient departments to plan and prepare for reporting additional measures, we did not propose any additional quality measures for CY 2015 and subsequent years payment determinations in this rulemaking.

As discussed above, we have removed OP-16 as of August 2012, we suspended measure OP-19 and deferred data collection for OP-24 until the measure specifications can be further refined.

In summary, in this final rule with comment period, we are not adopting additional measures for the CY 2015 payment determination, and we are retaining 25 of the 26 measures previously adopted for the CY 2014 payment determination for CY 2015 and subsequent year payment determinations.

Set out below are the previously adopted measures which we are retaining for the CY 2014, CY 2015, and subsequent years payment determinations under the Hospital OQR Program.

Hospital OQR Program Measures for the CY 2014, CY 2015 and Subsequent Year Payment Determinations
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-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-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data
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*
OP-17: Tracking Clinical Results between Visits
OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
OP-19: Transition Record with Specified Elements Received by 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

Hospital OQR Program Measures for the CY 2014, CY 2015 and Subsequent Year Payment Determinations	
OP-22: ED Patient Left Without Being Seen	
OP-23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival	
OP-24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting ***	
OP-25: Safe Surgery Checklist Use	
OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures	
Procedure Category	**Corresponding HCPCS Codes**
Gastrointestinal	40000 through 49999, G0104, G0105,G0121,C9716, C9724, C9725, 0170T
Eye	65000 through 68999, 0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, 0099T
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0062T
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, 0201T
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, C9727
Genitourinary	50000 through 58999, 0193T, 58805
Cardiovascular	33000 through 37999
Respiratory	30000 through 32999

*Information for OP-15 will not be reported in Hospital Compare in 2012. Public reporting for this measure would occur in July 2013 at the earliest.
**Data collection for OP-19 was suspended effective with January 1, 2012 encounters until further notice.
***Data collection for OP-24 would begin on January 1, 2014, and its first application toward a payment determination will be for CY 2015 rather than CY 2014.

Comment: Many commenters commended CMS' pausing in the expansion of the Hospital OQR Program by not proposing any new measures for the CY 2014 and CY 2015 payment determinations. Commenters appreciated CMS' recognition of burden from quality reporting on providers.

Response: We thank the commenters for supporting our decision not to add any new measures. We plan to continue to find ways to strike a balance between quality reporting and burden reduction for providers.

We received comments on some of the previously finalized measures that we have proposed to continue using under the Hospital OQR Program.

Comment: Commenters expressed support and opposition to the adopted measures from previous rulemakings. Commenters also provided suggestions on these measures, regarding measure implementation, adding exceptions, and revising measure specifications.

Response: We thank the commenters for their comments; those supporting our previously finalized proposals as well as those in opposition. We will consider all of these views for future rulemaking and Hospital OQR Program development.

E. Possible Quality Measures under Consideration for Future Inclusion in the Hospital OQR Program

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 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 work diligently toward this goal. We believe that this future progress at a future date, such as FY 2015, 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 e-specifications. This

includes completing electronic 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. In addition, we are considering initiating a call for input to assess the following measure domains: 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 and pay for performance programs such as the Hospital IQR Program.

We invited public comment on this approach and on our suggestions and rationale for possible quality measures for future inclusion in the Hospital OQR Program.

Comment: One commenter noted that it is important to address the priority areas in the National Quality Strategy; however, the commenter also suggested that measure selection should not be limited to only those that fall inside the six domains, as this would hinder improvement in other areas in HOPDs.

Response: We note that the six domains of measurement that arise from the six priorities of the National Quality Strategy are some of our considerations in measure

selection. We also weigh other aspects of measures as delineated in our measure selection criteria.

Comment: A few commenters strongly supported CMS in considering whether to initiate a call to get input to assess the measure domains. One commenter requested that CMS use the same process used in past rulemakings by providing a list of measures under consideration for future years for public input.

Response: In the past, we have solicited comments on a list of measures in the rule that are under consideration for future years of the program. Although we did not provide a list in this year's rulemaking, we will take this comment under consideration in future years.

In addition, we will consider hosting a call for measures for the Hospital OQR Program in the future.

Comment: Commenters suggested that CMS add the following measures to the Hospital OQR Program: a comprehensive "medication management" measure set; a system of care metric that looks at the overall median time to PCI in transferred patients to capture the entire process of care; a stroke measure set for outpatients; measures for diabetes care, congestive heart failure, heart attack, breast cancer detection rate, central-line associated blood stream infection, chronic obstructive pulmonary disease, coronary artery disease, and depression screening.

Response: We thank the commenters for the input on future measures and will take them into consideration in future measure selections.

Comment: One commenter strongly encouraged CMS to adopt registry-based measures for which providers submit quality data directly to a registry instead of to CMS.

Response: We thank the commenter for the recommendation for registry reporting. We intend to continue considering how registry reporting may be leveraged as a reporting mechanism for this and other quality programs.

Comment: A few commenters recommended that for burden reduction, CMS should harmonize measures in the Medicare and Medicaid EHR Incentive Programs and the Hospital OQR Program as well as limiting adopting future measures to e-specified measures only.

Response: As we stated previously, coordinated efforts to align measures in the Medicare and Medicaid public reporting programs and incentive payment systems have been ongoing, and we are working toward the eventual adoption of electronically-specified measures so that data can be calculated and submitted via certified EHR technology with minimal burden.

Comment: One commenter recommended that CMS refrain from adopting claims-based measures which the commenter believed are purely administrative in nature and yield little value in measuring quality of care.

Response: While we recognize the merits of chart-abstracted measures, we also believe that claims may still be needed to identify prior events and diagnosis for measures that require look-back periods, involving the matching of data for a single patient over a long period of time (for example, 1 year of prior history) across multiple settings.

Claims-based measurement facilitates the use of historical and longitudinal information on Medicare beneficiaries across providers.

Comment: Commenters also expressed views and provided suggestions regarding additional topics and previously finalized proposals including:

- Topped-out measures;
- ED measures;
- Outpatient imaging efficiency measures; and
- Removal of additional adopted measures.

Response: We appreciate the commenters' views on these additional topics or our previously finalized measures. However, these additional topics were not the subject of our proposed rule. It is our policy to retain previously adopted measures unless we specifically propose to remove or suspend measures, or take action outside of rulemaking to do so for patient safety reasons. We will consider these suggestions in future Hospital OQR Program development.

F. Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2013 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.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772), we discussed how the payment reduction for failure to meet the administrative, data collection, and data submission requirements of the Hospital OQR Program affected the CY 2009 payment update applicable to OPPS payments for HOPD services furnished by the hospitals defined under section 1886(d)(1)(B) of the Act to which the program applies. 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 requirements. All other hospitals paid under the OPPS that meet the reporting requirement receive the full OPPS payment update without the reduction.

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site): "P," "Q1," "Q2," "Q3," "R," "S," "T," "V," "U," or "X." In the CY 2009 OPPS/ASC

final rule with comment period (73 FR 68770), we adopted a policy that payment for all services assigned these status indicators would 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," and brachytherapy sources with assigned status indicator "U," which were paid at charges adjusted to cost in CY 2009. We excluded services assigned to New Technology APCs from the list of services subject to the reduced national unadjusted payment rates because the OPD fee schedule increase factor is not used to update the payment rates for these APCs.

In addition, section 1833(t)(16)(C) of the Act, as amended by section 142 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275), specifically required that brachytherapy sources be paid during CY 2009 on the basis of charges adjusted to cost, rather than under the standard OPPS methodology. Therefore, the reduced conversion factor also was not applicable to CY 2009 payment for brachytherapy sources because payment would not be based on the OPPS conversion factor and, consequently, the payment rates for these services were not updated by the OPD fee schedule increase factor. However, in accordance with section 1833(t)(16)(C) of the Act, as amended by section 142 of the MIPPA, payment for brachytherapy sources at charges adjusted to cost expired on January 1, 2010. Therefore, in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60641), we finalized our CY 2010 proposal, without modification, to apply the reduction to payment for brachytherapy sources to hospitals that fail to meet the quality data reporting

requirements of the Hospital OQR Program for brachytherapy services furnished on and after January 1, 2010.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS 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 OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative 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 OPPS, we multiply the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national

unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for 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 continued this policy in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642), in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72099), and in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74478). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this final rule with comment period.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2013

In the CY 2013 OPPS/ASC proposed rule (77 FR 45182), 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 2013 annual payment update factor. For the CY 2013 OPPS, the reporting ratio is 0.980, calculated by dividing the reduced conversion factor of $69.887 by the full conversion factor of $71.313. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2013 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,” “U,” and “X” (other than new technology APCs to which we have assigned status indicators “S” and “T”). 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 comments on these proposals. We did not receive any public comments on our CY 2013 proposal to apply the Hospital OQR Program reduction in the manner described above and, therefore, are finalizing our proposal, without modification.

Therefore, for the CY 2013 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.

G. Requirements for Reporting of Hospital OQR Data for the CY 2014 Payment Determination and Subsequent Years

1. Administrative Requirements for the CY 2014 Payment Determination and Subsequent Years

In order to participate 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 and subsequent years' payment updates in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74479 through 74487).

In the CY 2013 OPPS/ASC proposed rule (77 FR 45182), with respect to the payment determinations for CY 2014 and subsequent years, we proposed one modification to these requirements. Under current requirements, CMS deadlines for hospitals to submit notice of participation forms are based on the date identified as a hospital's Medicare acceptance date on the CMS Certification and Survey Provider Enhanced Reporting (CASPER) system. Deadlines are based on whether a hospital's Medicare acceptance date falls before January 1 of the year prior to the annual payment update, or on or after January 1 of the year prior to the annual payment update (for

example, 2013 would be the year prior to the affected CY 2014 annual payment update). Currently, for a hospital whose Medicare acceptance date is before January 1 of the year prior to the affected payment update affected, the notice of participation form is due by March 31 of the year prior to the affected annual payment update (76 FR 74479 through 74480). We proposed to extend this deadline for hospitals, as described below.

Hospitals with Medicare acceptance dates before January 1 of the year prior to the affected annual payment update: For the CY 2014 and subsequent years payment update, we proposed that any hospital that has 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) that is not currently participating in Hospital OQR and wishes to participate in the Hospital OQR Program must submit a participation form by July 31, rather than March 31, of the year prior to the affected annual payment update. We proposed a deadline of July 31 to give hospitals the maximum amount of time to decide whether they wish to participate in the Hospital OQR Program, as well as put into place the necessary staff and resources to timely report chart-abstracted data for the first quarter of the year's services which are due August 1.

We invited public comment on this proposed modification to Hospital OQR Program administrative requirements for the CY 2014 and subsequent years' payment determinations.

Comment: Several commenters supported the proposal to extend the deadline to submit a participation form for a hospital that is not currently participating in Hospital

OQR and wishes to participate in OQR to July 31, rather than March 31, of the year prior to the affected annual payment update.

Response: We thank these commenters for supporting our proposal to extend the deadline for submitting a participation form for a hospital that is not currently participating in Hospital OQR and wishes to participate.

After consideration of the public comments received, we are finalizing our proposal to extend the deadline for a hospital that is not currently participating in the Hospital OQR Program and wishes to participate in the Program to submit a participation form by July 31, rather than March 31, of the year prior to the affected annual payment update.

2. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program for the CY 2014 Payment Determination and Subsequent Years

a. Background

In the CY 2013 OPPS/ASC proposed rule (77 FR 45182), we did not propose any additional measures for the CY 2014 payment determination year. We refer readers to the following OPPS/ASC final rules with comment periods for a history of measures adopted for the Hospital OQR Program, including lists of: 11 measures finalized for the CY 2011 payment determination (74 FR 60637); 15 measures finalized for the CY 2012 payment determination (75 FR 72083 through 72084); 23 measures finalized for the CY 2013 payment determination (75 FR 72090); and 26 measures finalized for the CY 2014 and CY 2015 payment determinations (76 FR 74469 and 74473).

Because of the clarification in the measure table in section XV.D above that public reporting for OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache is not planned until July 2013 at the earliest, we confirm this measure will not be used in the CY 2014 payment determination. We will confirm our intent to include or exclude this measure in the CY 2015 payment determination in future rulemaking.

We refer readers to section XV.C.2 of this final rule with comment period for a discussion of measure OP-16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest pain) Received Within 60 minutes of Arrival. Due to a patient safety concern, this measure has been removed from the OQR Program measure set.

We refer readers to section XV.C.3. of this final rule with comment period for a discussion of measure OP-19: Transition Record with Specified Elements Received by Discharged ED Patients. Because the data collection for this measure is currently suspended, this measure will not be used in the CY 2014 payment determination. We will indicate whether data collection for this measure will resume in time for the CY 2015 payment determination in future rulemaking.

We refer readers to section XV.C.4. of this final rule with comment period for a discussion of measure OP-24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting. We proposed not to use this measure in the CY 2014 payment determination and deferred data collection for this measure until the CY 2015 payment determination.

b. General Requirements

In the CY 2013 OPPS/ASC proposed rule (77 FR 45183), we proposed to continue the policy that, to be eligible to receive the full OPD fee schedule increase factor for any payment determination, hospitals must comply with our submission requirements for chart-abstracted data, population and sampling data, claims-based measure data, and structural quality measure data, including all-patient volume data. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74480 through 74482) for a discussion of these requirements.

c. Chart-Abstracted Measure Requirements for CY 2014 and Subsequent Payment Determination Years

The table in section XV.D. of this final rule with comment period includes measures that are collected by abstracting the information from patient charts. In this final rule with comment period, we are confirming removal of one chart-abstracted measure from the program, OP-16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 30 minutes of Arrival. For a full discussion of this removal, please refer to section XV.C.2. of this final rule with comment period.

Comment: Several commenters supported the proposal not to collect data for measures that CMS proposed to exclude from the CY 2014 payment determination.

Response: We thank the commenters for supporting our proposal regarding collection of data for measures which are to be excluded from the CY 2014 payment

determination. A discussion of measures that are under review or have been removed from the program is found in section XV.C. above.

After consideration of the public comments received, we are finalizing our proposal to exclude chart abstracted measures OP-19 and OP-24, from the CY 2014 payment determination. In addition, in this final rule with comment period, we are confirming the removal of chart-abstracted measure OP-16. Thus, the following chart-abstracted measures remain in the Hospital OQR Program and data for these measures is required for the CY 2014 payment determination:

- 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

- 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

Of those measures for which we proposed to collect data for in CY 2014, the form and manner for submission of one of these measures, OP-22: ED Patient Left Without Being Seen, is unique, and the form and manner for this measure is detailed in section XV.G.2.f. of this final rule with comment period.

For the chart-abstracted measures for which we have finalized that we will collect data for the CY 2014 payment determination, we proposed that the applicable quarters for data collection would be as follows: 3rd quarter CY 2012, 4th quarter CY 2012, 1st quarter CY 2013, and 2nd quarter CY 2013 for hospitals that are continuing participants; newly participating hospitals would follow reporting requirements as outlined in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74480) and in section XV.G.1. of this final rule with comment period.

In general, submission deadlines would be approximately 4 months after the last day of each calendar quarter. Thus, for example, the submission deadline for data for services furnished during the first quarter of CY 2013 (January - March 2013) would be on or around August 1, 2013. We proposed to post actual submission deadlines on the http://www.QualityNet.org Web site.

Hospitals that did not participate in the CY 2013 Hospital OQR Program, but would like to participate in the CY 2014 Hospital OQR Program, and that have a Medicare acceptance date on the CASPER system before January 1, 2013, would begin data submission with respect to 1st quarter CY 2013 encounters using the previously

adopted measures which we are retaining for the CY 2014 payment determination, found in the table in section XV.D above. For those hospitals with Medicare acceptance dates on or after January 1, 2013, data submission must begin with the first full quarter following the submission of a completed online participation form.

For the CY 2015 payment determination, we proposed that the applicable quarters for previously finalized chart-abstracted measures would be as follows: 3rd quarter CY 2013, 4th quarter CY 2013, 1st quarter CY 2014, and 2nd quarter CY 2014.

Hospitals that did not participate in the CY 2014 Hospital OQR Program, but would like to participate in the CY 2015 Hospital OQR Program, and that have a Medicare acceptance date on the CASPER system before January 1, 2014, would begin data submission with respect to 1st quarter CY 2014 encounters using the previously adopted measures which we are retaining for the CY 2015 payment determination, found in the table in section XV.D above. For those hospitals with Medicare acceptance dates on or after January 1, 2014, data submission must begin with the first full quarter following the submission of a completed online participation form. We invited public comments on these proposals.

Comment: Some commenters encouraged CMS to improve alignment among CMS quality reporting programs; specifically, they would like to see alignment of data submission deadlines and encounter/discharge periods. These commenters urged CMS to review its programs for opportunities to harmonize program design. These commenters stated their belief that aligning program design and measures supports stakeholders in

fulfilling CMS' requirements, whereas lack of alignment results in stakeholders competing for resources to fulfill requirements.

Response: We thank these commenters for their suggestions. We agree that end users and stakeholders, especially those that fulfill reporting requirements for multiple programs, would benefit from standardized program requirements.

Besides the Hospital OQR Program, we have a significant number of quality data reporting or incentive programs. Currently, we are working on integrating the Hospital OQR, Hospital Inpatient Quality Reporting (IQR) Program, and the Hospital Value-Based Purchasing (VBP) Program more fully to meet the requirements of the Health Information Technology for Economic and Clinical Health Act. This statute promotes driving transformation through the adoption and use of health information technology (HIT), electronic health records (EHR) and health information organizations (HIOs)

We agree with commenters that alignment is important to reduce stakeholder burden, and we will also continue to consider opportunities to align program requirements for programs outside of the Hospital OQR, IQR, and VBP Programs.

Comment: Many commenters supported the proposed data submission deadlines for chart-abstracted measures.

Response: We thank these commenters for supporting the proposed deadlines.

After consideration of the public comments we received, we are finalizing our proposals for the applicable quarters for chart abstracted measures for the CY 2014 and CY 2015 payment determinations and for subsequent years. We are finalizing our

proposals for submission deadlines for chart abstracted data for the CY 2014 payment determination and for subsequent years, and for posting these deadlines on the QualityNet Web site. We are finalizing our proposals for hospitals who are newly participating or who are resuming participation in the OQR program to submit a notice of participation and begin submitting data to the OQR Program.

d. Claims-Based Measure Data Requirements for the CY 2014 and CY 2015 Payment Determinations

The table in section XV.D. of this final rule with comment period includes measures that the Hospital OQR Program collects by accessing electronic claims data submitted by hospitals for reimbursement.

OP-15 is a claims-based measure that has not been implemented for public reporting through rulemaking (76 FR 74456), and it is not required for the CY 2014 payment determination.

Therefore, the 6 remaining claims-based measures set out below will be included for the CY 2014 payment determination:

- 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

● OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)

We will continue our policy of calculating the measures using the hospital's Medicare claims data as specified in the Hospital OQR Specifications Manual; therefore, no additional data submission is required for hospitals. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74483), we stated that for the CY 2013 and CY 2014 payment updates, we will use paid Medicare FFS claims for services furnished from January 1, 2010 to December 31, 2010 and January 1, 2011 to December 31, 2011, respectively.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45184), for the CY 2015 Hospital OQR payment determination, we proposed to use paid Medicare FFS claims for services from a 12 month period from July 1, 2012 through June 30, 2013 for the calculation of the claims-based measures. While this would be a departure from the traditional 12 month calendar year period we have used for these measures, we proposed 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 the outpatient imaging efficiency on the Web site. We invited public comment on this proposal.

Comment: Some commenters supported the proposal to move away from the traditional 12 month data period 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 the outpatient imaging efficiency on the Web Site.

Response: We thank these commenters for supporting our efforts to align the data collection period for the Hospital OQR Program with that of the Hospital IQR Program.

Comment: One commenter questioned why CMS needs such a long delay in claims utilization. This commenter believed that CY 2011 claims are not appropriate to use in the CY 2014 payment determination.

Response: We have proposed to adjust the time period of when services are furnished; doing so moves the period away from the traditional January – December time period to make it six months more current. Regarding the data lag for claims based data, for the CY 2015 payment determination year, we proposed using paid, FFS claims for services during the time period from July 1, 2012 through June 30, 2013. Calculations based on this time period would be publicly reported on Hospital Compare in July 2014, and we would make actual payment determinations for the CY 2015 payment year on or around December 1, 2014.

For claims from the period July 1, 2012 through June 30, 2013, the data lag, or time elapsed until payment determination is made, is approximately 17 months at the longest (for data from July 1, 2012) to 5 months at shortest (for data from June 30, 2013). This is due to several factors. First, we allow three months after the last date of service to pass before pulling the data extract for claims based measures in order to ensure that we are capturing most of the final paid claims through the last date of service (in this example, the last date of service is June 30, 2012). Second, it takes three to six months to build our analytic files for the measures, generate calculations, and ensure their accuracy. For some claims-based measures, we generate and deliver detailed confidential reports

for hospitals. About two months prior to public reporting, we allow 30 days for hospitals to preview their data, after which we deliver final public reporting files for the Hospital Compare Web site.

With our proposal, we believe we have adequately balanced the need for current data with the need to have a stable set of FFS claims data for a payment determination and a preview process that takes into account the needs of hospital stakeholders.

Comment: One commenter believed that there is an inconsistency in the use of Medicare claims versus data from all patients. According to the commenter, CMS stated that it will use only Medicare FFS claims for structural measures, but proposes to use data from all patients (for example, including non-Medicare patients) for other measures.

Response: We do not use Medicare FFS claims for structural measures. For structural measures, hospitals currently review the time period covered in the reporting period to answer questions about registry use, safe surgery checklist use, etc. The structural measures in the Hospital OQR Program apply to the hospital outpatient department setting.

For clarification, the Hospital OQR chart-abstracted measures apply to all patients meeting the inclusion criteria for the measure regardless of payer, while the claims-based measures are calculated using only Medicare FFS claims. The structural measures apply to the hospital outpatient department.

We require hospitals to complete and submit a registration form (‘‘participation form’’) in order to participate in the Hospital OQR Program. With submission of this participation form, participating hospitals agree that they will allow us to publicly report

the quality measure data submitted under the Hospital OQR Program, including measures that we calculate using Medicare claims and all other submitted data, including non-Medicare data.

After consideration of the public comments we received, we are finalizing our proposals for the data periods we will use for claims-based measures for the CY 2014 and CY 2015 payment determinations.

e. Structural Measure Data Requirements for the CY 2014 Payment Determination and Subsequent Years

A summary of the previously finalized structural measures that we require for the CY 2014 and subsequent years payment determinations is set out 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 25: Safe Surgery Check List Use
- OP 26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures

We previously finalized that for the CY 2014 payment determination, hospitals will be required to submit data on all structural measures between July 1, 2013 and August 15, 2013 with respect to the time period from January 1, 2012 to December 31, 2012. In the CY 2013 OPPS/ASC proposed rule (77 FR 45184), we proposed to extend this submission deadline. Under this proposed change, for the

CY 2014 payment determination, hospitals would be required to submit data on all structural measures between July 1, 2013 and November 1, 2013 with respect to the time period from January 1, 2012 to December 31, 2012. In section XV.G.2.f. of this final rule with comment period, we describe how this proposal would likewise extend the deadline to submit data for OP-22: ED Patient Left Without Being Seen. We proposed to continue this schedule so that, for the CY 2015 payment determination, hospitals would be required to submit data on all structural measures between July 1, 2014 and November 1, 2014 with respect to the time period from January 1, 2013 to December 31, 2013. We invited public comments on these proposals.

Comment: Two commenters supported the change in the 12 month period because it better aligns the reporting period with that of other claims based measures displayed on Hospital Compare.

Response: We agree that this alignment is beneficial and we seek to align programs to the extent possible. We are finalizing this policy as proposed.

After consideration of the public comments we received, we are finalizing the proposal that, for the CY 2014 payment determination, hospitals would be required to submit data on all structural measures between July 1, 2013 and November 1, 2013 with respect to the time period from January 1, 2012 to December 31, 2012, and for the CY 2015 payment determination, hospitals would be required to submit data on all structural measures between July 1, 2014 and November 1, 2014 with respect to the time period from January 1, 2013 to December 31, 2013.

f. Data Submission Requirements for OP-22: ED Patient Left Without Being Seen for the CY 2015 Payment Determination

OP-22: ED Patient Left Without Being Seen is a chart-abstracted measure for which aggregate data is collected via a Web-based tool, as previously finalized. In other words, for purposes of data collection, this measure is treated like a structural measure. For this reason, it is collected on the same schedule as the structural measures described above, and, in the CY 2013 OPPS/ASC proposed rule (77 FR 45184) we proposed to extend the submission window for all structural measures, including OP-22. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), with respect to OP-22, we stated that hospitals would be required to submit data once for the CY 2014 payment determination via a Web-based tool located on the QualityNet Web site. For the CY 2014 payment determination, we proposed that hospitals would be required to submit data, including numerator and denominator counts, between July 1, 2013 and November 1, 2013 (comparable to the submission window that we proposed for the structural measures data collection in the section above) with respect to the time period of January 1, 2012 to December 31, 2012.

For the CY 2015 payment determination, we proposed to continue this policy. Hospitals would be required to submit data between July 1, 2014 and November 1, 2014 with respect to the time period of January 1, 2013 to December 31, 2013. We invited public comment on these proposals.

Comment: Some commenters opposed data collection for OP-22: ED Patient Left Without Being Seen. These commenters noted that OP-22 is not NQF-endorsed and

believed it is not a clear measure of quality of care for a variety of reasons: because there are credible reasons why a patient might choose to leave an ER prior to treatment; the measure disadvantages ED's in areas where an ED is used as a primary care facility; and there are no underlying patient records to validate this data.

Response: We thank the commenters for their feedback. Please refer to section XV.C.1 of this final rule with comment period for a discussion of measure OP-22.

After consideration of the public comments we received, we are finalizing our proposal to extend the data submission window for OP-22.

g. Population and Sampling Data Requirements for the CY 2014 Payment Determination and Subsequent Years

In the CY 2013 OPPS/ASC proposed rule (77 FR 45184), for the CY 2014 payment determination and subsequent years, we proposed to continue 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. We invited public comments on these proposals.

Comment: One commenter appreciated the policy that program participants can continue to submit population and sampling data voluntarily.

Response: We believe there is no need to require the submission of population and sampling data due to the high level of voluntary submission of these data.

After consideration of the public comments we received, we are finalizing our policies for population and sampling data requirements for the CY 2014 payment determination and subsequent years.

3. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2014 Payment Determination and Subsequent Years

a. Random Selection of Hospitals for Data Validation of Chart-Abstracted Measures for the CY 2014 Payment Determination and Subsequent Years

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74484 through 74485), similar to our approach for the CY 2012 payment determination (75 FR 72103 through 72106), we adopted a policy to validate chart-abstracted patient-level data submitted directly to CMS from randomly selected hospitals for the CY 2013 payment determination.

For the CY 2013 payment determination, we reduced the number of randomly selected hospitals from 800 to 450.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45184), we proposed to continue this policy for the CY 2014 payment determination and for subsequent years. We refer readers to the CY 2012 OPPS/ASC final rule with comment period

(76 FR 74484) for a discussion of sample size, eligibility for validation selection, and encounter minimums for chart abstracted data submitted directly to CMS from randomly selected hospitals. We invited public comment on this proposal.

Comment: One commenter was pleased that the number of hospitals selected dropped from 800 to 450 for the CY 2013 payment determination.

Response: We thank this commenter for supporting our proposal to maintain the sample size for hospitals selected for validation. We note that in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53552) the total base sample size of hospitals included in the annual validation random sample has recently been reduced from 800 to 400, to reduce overall burden. For both the Hospital IQR and Hospital OQR Programs, we believe we can reduce the annual random sample size without adversely affecting our ability to infer reliability of the chart-abstracted clinical data submitted to the programs.

After consideration of the public comments we received, we are finalizing our proposal to retain our sample size for hospitals randomly selected for data validation of chart-abstracted measures for the CY 2014 payment determination and subsequent years.

b. Targeting and Targeting Criteria for Data Validation Selection for the CY 2014 Payment Determination and Subsequent Years

In the CY 2011 OPPS/ASC proposed rule (75 FR 46380) we discussed applying, to CY 2013 and subsequent years' data submission, criteria to determine whether a hospital would be included in our validation selection based on abnormal data patterns or a specific situation. At that time we provided, for public comment, specific examples of what we thought could be appropriate criteria.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72106) we stated our belief that the targeting criteria we shared for comment were reasonable. We considered one commenter's concern that we should use targeting criteria to ensure we do not over-select a hospital for validation. We reiterated our intent to propose the specific targeting criteria in the upcoming CY 2012 OPPS/ASC proposed rule (76 FR 42332), in order to finalize and apply it to 2012 encounter data collected for the CY 2013 validation process year. We did so, and finalized our proposal without modification in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485).

In summary, we finalized our intent to select a random sample of hospitals for validation purposes, and to select an additional 50 hospitals based on specific criteria designed to measure whether the data these hospitals have reported raises a concern regarding data accuracy.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45185), for the CY 2014 payment determination and subsequent years, we proposed to continue these policies and to continue to use the targeting criteria finalized previously. Specifically, a hospital will be preliminarily selected for validation based on targeting criteria if it:

- Fails the validation requirement that applies to the previous year's payment determination. For example, if a hospital was selected for validation for the CY 2013 payment determination year, either on a random or targeted basis, and the hospital did not meet the 75 percent validation score for the designated time period, based upon our validation process, for the designated time period, the hospital would be included in the targeted sample pool for the CY 2014 payment determination); or

- Has an outlier value for a measure based on the data it submitted, based on finalized criteria from the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485).

In the CY 2012 OPPS/ASC proposed rule (76 FR 42333) and CY 2012 OPPS/ASC final rule with comment period (76 FR 74486) we describe additional data validation conditions under consideration for the CY 2014 payment determination and subsequent years. We thank those who commented on the CY 2012 proposed additional data validation targeting conditions and will take their views under consideration as we develop any future proposals on these issues. In the CY 2013 OPPS/ASC proposed rule (77 FR 45185), we did not propose any additional targeting criteria to use in selecting the additional 50 hospitals we include in the validation process for CY 2014 payment determination or in subsequent years. We invited public comment on this proposal.

Comment: One commenter believed that CMS quality measures should be based strictly on data derived either through claims or data abstracting on the Medicare population, not on all patients who are treated in the outpatient setting.

Response: Data submitted to the Hospital OQR Program are intended to provide the public with information on as many patients treated in the outpatient hospital setting as possible, including both Medicare and non-Medicare patients. As noted above, however, claims-based data collection is limited to Medicare FFS patients.

The Hospital OQR Program requires this data to be submitted under section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act. That provision states that subsection (d) hospitals that

do not report data required for the quality measures selected by the Secretary in the form and manner required by the Secretary will not receive the full payment rate update. We modeled the Hospital OQR Program after the Hospital IQR Program.

In order for us to evaluate the care of the Medicare population which is a subset of the entire population, we look at data of the whole population, to ensure Medicare beneficiaries are receiving the same level of care as non-Medicare beneficiaries receive. Because we collect chart-abstracted quality measure data on both Medicare and non-Medicare patients, we believe it is appropriate to establish sampling criteria that apply to the same populations, which include both Medicare and non-Medicare patients.

Comment: One commenter advocated selecting a valid sample based on local practice patterns, desiring inter-rater reliability. This commenter suggested that CMS select all 450 hospitals using criteria that measure whether the data hospitals have reported raises a concern regarding accuracy.

Response: We interpret the commenter to be suggesting that sampling criteria should be refined in order to reflect local practice patterns. Because we use quality measures reflecting national consensus, we do not believe that such further refinement is necessary. Regarding inter-rater reliability, this should not be affected by the criteria used for sample selection.

Comment: One commenter believed that our sample sizes would be acceptable if they were the only Federal data submission requirement. This commenter believed that the records requested by the Hospital OQR Program are in addition to those that are already established as part of the Federal integrity audit processes (for example, RAC,

Medicaid Integrity, ZPIC, and MAC). The commenter encourages CMS to review the validation process with respect to other CMS data requirements.

Response: We understand the commenter's concern regarding multiple Federal medical record requests. For Hospital OQR Program validation, we have worked to limit overall burden by reducing the number of hospitals participating annually in validation through our random sampling of hospitals. In addition, hospitals are reimbursed for photocopying and mailing costs. We agree that efforts should be made to keep record requests for validation purposes at the minimum necessary to ensure accuracy of submitted data.

We refer readers to section XV.J. Electronic Health Records (EHRs), below, for a discussion of how Hospital IQR and Hospital OQR Programs are transitioning to the use of certified EHR technology, for measures that otherwise require information from the clinical record. We look forward to the adoption of EHR technology as a means to reduce burden, allowing us to collect data for measures without the need for manual chart abstraction, and we will explore validating these data in ways that likewise reduce burden to providers.

Comment: One commenter would like CMS to clearly identify whether a record has been requested as a result of random selection or targeted selection.

Response: We interpret this commenter's suggestion to mean that we should indicate whether we selected a hospital for validation as a result of random or targeted selection.

For example, because all hospitals are eligible for random selection, a hospital that failed validation in one payment determination year would not know whether it was selected for validation in the subsequent payment determination year based on random or targeted selection. The hospital might have been selected in either of these categories.

We have refrained from noting on what basis a hospital is selected on public Web sites, since our targeting criteria are based on possible data quality issues.

However, we do have that information available. If a hospital would like to understand why it was selected for validation, the hospital may call the support contractor and request that information. Contact information for the Hospital OQR support contractor is available at https://qualitynet.org.

After consideration of the public comments we received, we are finalizing our proposal not to include any additional targeting criteria to use in selecting the additional 50 hospitals we include in the validation process for the CY 2014 payment determination or in subsequent years.

c. Methodology for Encounter Selection for the CY 2014 Payment Determination and Subsequent Years

In the CY 2013 OPPS/ASC proposed rule (77 FR 45185), for each selected hospital (random or targeted), we proposed to continue the approach we adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485 through 74486) for the CY 2014 payment determination and subsequent years. For the CY 2014 payment determination, for each selected hospital (random or targeted), we would continue to validate up to 48 randomly selected patient encounters (12 per quarter; 48 per year) from

the total number of encounters that the hospital successfully submitted to the OPPS Clinical Warehouse. If a selected hospital has submitted less than 12 encounters in one or more quarters, only those encounters available would be validated. For each selected encounter, a designated CMS contractor would request that the hospital submit the complete supporting medical record documentation that corresponds to the encounter. We refer readers to 42 CFR 482.24(c)(2) for a definition of what is expected in a medical record submitted for validation. The validation process requires full supporting medical documentation, including ECG tapes and/or other pieces of a medical record that may not be stored in a single location. The hospital must ensure a full medical record goes to the contractor for accurate validation.

We continue to believe that validating a larger number of encounters per hospital for fewer hospitals at the measure level has several benefits. We believe that this approach is suitable for the Hospital OQR Program because it will: (1) produce a more reliable estimate of whether a hospital's submitted data have been abstracted accurately; (2) provide more statistically reliable estimates of the quality of care delivered in each measured hospital as well as at a national level; and (3) reduce overall burden, for example, in submitting validation documentation, because hospitals most likely will not be selected to undergo validation each year, and a smaller number of hospitals per year will be selected.

For all selected hospitals, we would not be selecting cases stratified by measure or topic; our interest is whether the data submitted by hospitals accurately reflects the care delivered and documented in the medical record, not what the accuracy is by measure or

whether there are differences by measure or topic. We would be validating data from April 1 to March 31 of the year preceding the payment determination year. This provides validation results data in time to use to make the payment determination. For example, encounter data from April 1, 2012 to March 31, 2013 provides a full year of the most recent data possible to validate in time to make the CY 2014 payment determination. We invited public comment on our proposal to continue to use our established methodology for encounter selection and to continue to use our annual schedule for encounters to be validated and used in payment determinations.

We did not receive any public comments regarding our proposal to continue to use our established methodology for encounter selection and our annual schedule for encounters to be validated and used in payment determinations. As a result, we are finalizing our proposal to continue to use our established methodology for encounter selection and our annual schedule for encounters to be validated and used in payment determinations.

d. Validation Score Calculation for the CY 2014 Payment Determination and Subsequent Years

In the CY 2013 OPPS/ASC proposed rule (77 FR 45185) we proposed to retain the medical record return policy that we finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72104) for the CY 2014 payment determination and subsequent years. For the CY 2014 payment determination, we proposed to continue the validation score policies we adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74486), for the CY 2013 payment determination. We proposed to use the

validation calculation approach finalized for the CY 2012 and CY 2013 payment determinations with validation being done for each selected hospital. Specifically, we proposed to conduct a measures level validation by calculating each measure within a submitted record using the independently abstracted data and then comparing this to the measure reported by the hospital; a percent agreement would then be calculated. We would also compare the measure category for quality measures with continuous units of measurement, such as time, so that for these measures, both the category and the measure would need to match.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45185), for the CY 2014 payment determination and subsequent years, we proposed to use the medical record validation procedure we finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72105). A designated CMS contractor would, for each quarter that applies to the validation, ask each of the selected hospitals to submit medical documentation for up to 12 randomly selected cases submitted to and accepted by the OPPS Clinical Warehouse. The CMS contractor would request paper copies of medical documentation corresponding to selected cases from each hospital via certified mail or another trackable method that requires a hospital representative to sign for the request letter. A trackable method would be used so that we would be assured that the hospital received the request. The hospital would have 45 calendar days from the date of the request as documented in the request letter to submit the requested documentation and have the documentation received by the CMS contractor. If the hospital does not comply within 30 calendar days of receipt of the initial medical documentation request, the CMS contractor would send a

second letter by certified mail or other trackable method to the hospital, reminding the hospital that paper copies of the requested documentation must be submitted and received within 45 calendar days following the date of the initial CMS contractor request. If the hospital does not submit the requested documentation and the documentation is not received by the CMS contractor within the 45 calendar days, then the CMS contractor would assign a "zero" score to each data element for each selected case and the case would fail for all measures in the same topic (for example, OP–6 and OP–7 measures for a Surgical Care case).

We proposed that the letter from the designated CMS contractor would be addressed to the hospital's medical record staff identified by the hospital for the submission of records under the Hospital IQR Program (that is, the hospital's medical records staff identified by the hospital to its State QIO). If CMS has evidence that the hospital received both letters requesting medical records, the hospital would be deemed responsible for not returning the requested medical record documentation and the hospital would not be allowed to submit such medical documentation as part of its reconsideration request so that information not utilized in making a payment determination is not included in any reconsideration request.

Once the CMS contractor receives the requested medical documentation, the contractor would independently reabstract the same quality measure data elements that the hospital previously abstracted and submitted, and the CMS contractor would then compare the two sets of data to determine whether the two sets of data match. Specifically, the CMS contractor would conduct a measures level validation by

calculating each measure within a submitted case using the independently reabstracted data and then comparing this to the measure reported by the hospital; a percent agreement would then be calculated. The validation score for a hospital would equal the total number of measure matches divided by the total number of measures multiplied by 100 percent.

We invited public comment on our proposals regarding the medical record request policy for the CY 2014 payment determination and subsequent payment determination years.

Comment: Many commenters supported our proposal to continue the 45 day time period for medical record submission. These commenters noted that they appreciated the Hospital OQR Program's consistency with the RAC auditing.

Response: We thank these commenters for their support. We agree that the 45 day time period to submit medical record documentation for validation is reasonable and has the additional benefit of being consistent with RAC medical documentation requests.

To receive the full OPPS OPD fee schedule increase factor for CY 2014, we proposed that hospitals must attain at least a 75 percent reliability score, based upon the proposed validation process. We proposed to use the upper bound of a two-tailed 95 percent confidence interval to estimate the validation score. If the calculated upper limit is above the required 75 percent reliability threshold, we would consider a hospital's data to be "validated" for payment purposes. Because we are more interested in whether the measure has been accurately reported, we would continue to focus on whether the

measure data reported by the hospital matches the data documented in the medical record as determined by our reabstraction.

We proposed to calculate the validation score using the same methodology we finalized for the CY 2012 and CY 2013 payment determinations (75 FR 72105 and 76 FR 74486). We also proposed to use the same medical record documentation submission procedures that we also finalized for the CY 2012 and CY 2013 payment determinations (75 FR 72104 and 76 FR 74486). We invited public comments on these proposals.

Comment: One commenter expressed concerns regarding the strict validation of ED throughput measures, and recommended that CMS adopt the 5 minute allowance for the Hospital OQR Program, which was previously adopted for the Hospital IQR Program.

Response: We thank this commenter for expressing this concern. We believe the commenter is referring to our policy requiring validation of measures requiring time values. The commenter is referring to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53549).

We agree with the commenter that requiring time values to match exactly is not realistic based on our historical experience with clinical data abstraction, the recognition that hospital clocks may vary from system to system such that the same time may be recorded differently depending on the source, and the limited clinical significance of small deviations in time. We note that this particular concern affects the validation score for the CY 2014 payment determination as well as for future years.

Accordingly, we are finalizing that, for the CY 2014 payment determination and for subsequent years, we will not require, when scoring the following chart-abstracted measures, that these measures have matching numerator and denominator states:

- OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
- OP-19: Transition Record with Specified Elements Received by Discharged ED Patients (this measure is currently suspended and will not be used in the CY 2014 payment determination. We intend to confirm whether this measure will be included in future payment determinations in future rulemaking).
- 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
- OP-23: ED – Head CT Scan Results for Acute Ischemic Stroke

Instead, for scoring of these measures, we will allow a 5 minute variance between the time abstracted by the hospital and that abstracted by the Clinical Data Abstraction Center (CDAC).

After consideration of the public comments we received, we are finalizing our proposals as modified regarding the validation score calculation methodology and timeframe for submission of medical record documentation requested for validation.

H. Hospital OQR Reconsideration and Appeals Procedures for the CY 2014 Payment Determination and Subsequent Years

When the Hospital IQR Program was initially implemented, it did not include a reconsideration process for hospitals. Subsequently, we received many requests for reconsideration of those payment decisions and, as a result, established a process by which participating hospitals could submit requests for reconsideration. We anticipated similar concerns with the Hospital OQR Program and, therefore, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66875), we stated our intent to implement for the Hospital OQR Program a reconsideration process modeled after the reconsideration process we implemented for the Hospital IQR Program. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68779), we adopted a reconsideration process that applied to the CY 2010 payment decisions. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60654 through 60655), we continued this process for the CY 2011 payment update. This process required that a hospital's CEO sign any request for a reconsideration.

In the CY 2011 and CY 2012 OPPS/ASC final rules with comment periods (75 FR 72106 through 72108 and 76 FR 74486 through 75587), we continued this process for the CY 2012 and CY 2013 payment updates with some modification. In the CY 2011 OPPS/ASC final rule with comment period(75 FR 72107), we finalized that the CEO was not required to sign the reconsideration request form.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45186), we proposed to continue this process, with additional modifications, for the CY 2014 payment

determination and subsequent years' payment determinations. We have now realized that, in eliminating the requirement that a CEO sign a request form, we did not include any requirement for a signature on the reconsideration request form. To increase accountability, we proposed for the CY 2014 payment determination and subsequent years' payment determinations, that the hospital designate a contact on its reconsideration request form, who may or may not be the CEO. We would communicate with this designee. We also proposed that the hospital's designee must sign its reconsideration request form. This process is consistent with our recently adopted proposals for reconsideration requests under the ASCQR Program (77 FR 53643 through 53644).

Under this process, a hospital seeking reconsideration must--

- Submit to CMS, via QualityNet, a Reconsideration Request form that will be made available on the QualityNet Web site; this form must be submitted by February 3 of the affected payment year (for example, for the CY 2014 payment determination, the request must be submitted by February 3, 2014) and must contain the following information:
    - Hospital CCN.
    - Hospital Name.
    - 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.

○ Hospital basis for requesting reconsideration. This must identify the hospital's specific reason(s) for believing it met the affected year's Hospital OQR Program requirements and should receive the full OPD fee schedule increase factor.

○ Designated hospital personnel contact information, including name, e-mail address, telephone number, and mailing address (must include physical address, not just a post office box). We proposed that the designee, who may or may not be the hospital's CEO, must sign the form submitted to request reconsideration.

○ A copy of all materials that the hospital submitted to comply with the requirements of the affected year's Hospital OQR Program. Such material might include, but does not need to be limited to, the applicable Notice of Participation form or completed online registration form, and measure data that the hospital submitted via QualityNet.

● Paper copies of all the medical record documentation that it submitted for the initial validation (if applicable). Hospitals submit this documentation to a designated CMS contractor which has authority to review patient level information. We post the address where hospitals are to send this documentation on the QualityNet Web site.

● To the extent that the hospital is requesting reconsideration on the basis that CMS has determined it did not meet an affected 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 would be eligible to be reconsidered. We review the data elements that

were labeled as mismatched as well as the written justifications provided by the hospital, and make a decision on the reconsideration request.

We proposed these requirements for the CY 2014 payment determination year program and for subsequent years. We invited public comment on these proposed changes.

Comment: Many commenters supported the proposal that the CEO or designee be able to sign the reconsideration request form.

Response: We thank these commenters for their support.

Following receipt of a request for reconsideration, CMS --

- Provides an e-mail 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 that we finalized for the CY 2012 and CY 2013 payment determinations 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 would 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 the 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 the 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 proposed 45 calendar day timeframe (which we are finalizing in this final rule with comment period), 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 paper 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.

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).

We invited public comment on the modifications we proposed to the Hospital OQR Program reconsideration and appeals procedures.

Comment: One commenter thanked CMS for fully describing the process for making a reconsideration request.

Response: We thank the commenter and appreciate the support. We agree that the program process for reconsiderations should be clear and fully described.

After consideration of the public comments we received, we are finalizing our proposals to the Hospital OQR Program reconsideration and appeals procedures.

I. Extraordinary Circumstances Extension or Waiver for the CY 2013 Payment Determination and Subsequent Years

In our experience, there have been times when hospitals have been unable to submit required quality data due to extraordinary circumstances that are not within their control. It is our goal to not penalize hospitals for such circumstances and we do not want to unduly increase their burden during these times. Therefore, in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60046 through 600647), we adopted a

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. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72103), we retained these procedures with a modification to eliminate redundancy in the information a hospital must provide in the request. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74478 through 74479), for CY 2012 and subsequent years, we retained these procedures with one modification. The CY 2012 modification allowed that the original procedures for requesting an extension or waiver of quality data submission would thereafter also extend to include medical record documentation submission for purposes of complying with our validation requirement for the Hospital OQR Program. In the CY 2013 OPPS/ASC proposed rule (77 FR 45187), we proposed to retain these procedures with a modification for CY 2013 and subsequent years.

We proposed to modify one element of the information required on the CMS request form. Under the procedures set out in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74479), hospitals were required to submit "CEO and any other designated personnel contact information" (emphasis added), the CEO was required to sign the form, and CMS was required to respond to the CEO and additional designated hospital personnel. The information required in CY 2013 and subsequent years would include "CEO or other hospital-designated personnel contact information" (emphasis added). This proposed change would allow the hospital to designate an appropriate, non-CEO, contact at its discretion. This individual would be responsible for the submission,

and would be the one signing the form. Therefore, the hospital's designated-contact may or may not hold the title of CEO. We invited public comment on this proposed modification to the process for granting extraordinary circumstances extensions or waivers for the Hospital OQR Program.

Comment: Many commenters supported the proposal that the hospital should designate its own most appropriate contact for the signing and submission of the extraordinary circumstance extension and waiver form.

Response: We appreciate these commenters' support.

Thus, we proposed that, in the event of extraordinary circumstances, such as a natural disaster, not within the control of the hospital, for the hospital to receive 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 submit to CMS a request form that would be made available on the QualityNet Web site. The following information should be noted on the form:

- Hospital CCN;
- Hospital Name;
- CEO or other hospital-designated personnel contact information, including name, e-mail 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 would again be able to submit Hospital OQR data and/or medical record documentation, and a justification for the proposed date.

The request form would be signed by the hospital's designated contact, whether or not that individual is the CEO. A request form would be 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 e-mail acknowledgement using the contact information provided in the request notifying the designated contact that the hospital's request has been received;

(2) Provide a formal response to the hospital's designated contact using the contact information provided in the request notifying them of our decision; and

(3) Complete our review of any CY 2013 request and communicate our response within 90 days following our receipt of such a request.

We note that we might also decide to grant waivers or extensions to hospitals that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, hurricane) affects an entire region or locale. If we make the determination to grant a waiver or extension to hospitals in a region or locale, we would communicate this decision to hospitals and vendors through routine communication channels, including but not limited to e-mails and notices on the QualityNet Web site. We invited public comments on these proposals.

Comment: One commenter thanked CMS for fully describing the process for making a request for an extension or waiver of program requirements.

Response: We thank this commenter for supporting our efforts.

After consideration of the public comments we received, we are finalizing our proposed modifications to the procedures for requesting an extension or waiver of Hospital OQR Program requirements.

J. Electronic Health Records (EHRs)

Starting with the FY 2006 IPPS final rule, we have encouraged hospitals to take steps toward the adoption of EHRs (also referred to in previous rulemaking documents as electronic medical records) that will allow for reporting of clinical quality data from EHRs to a CMS data repository (70 FR 47420 through 47421). We sought to prepare for future EHR submission of electronic clinical quality measures (eCQMs), as they are referred to in the EHR Incentive Program), by sponsoring the creation of electronic specifications for eCQMs under consideration for the Hospital IQR Program. Through the Medicare and Medicaid EHR Incentive Programs, we expect that the submission of quality data through EHRs will provide a foundation for establishing the capacity of hospitals to send, and for CMS, in the future, to receive, eCQMs via hospital EHRs for Hospital IQR Program and Hospital OQR Program measures. We expect the Hospital IQR and Hospital OQR Programs to transition to the use of electronic specifications for eCQMs that otherwise require information from the clinical record. This would allow us to collect data for eCQMs without the need for manual chart abstraction.

In the FY 2012 IPPS/LTCH PPS proposed rule (75 FR 25894), we identified FY 2015 as a potential transition date to move to EHR-based submission and phase out manual chart abstraction for the Hospital IQR Program. We also anticipate such a

transition for hospital outpatient measures, although likely somewhat after the transition for hospital inpatient measures. This is because we hope to first align the eCQMs in the Medicare EHR Incentive Program with the Hospital IQR Program measures. Our goals are to align the hospital quality reporting programs, to seek to avoid redundant and duplicative reporting of quality measures for hospitals, and to rely largely on EHR submission for many eCQMs based on clinical record data.

As noted below, the Medicare and Medicaid EHR Incentive Programs – Stage 2 final rule (77 FR 54088) requires electronic reporting of eCQMs beginning in 2014 for eligible hospitals and CAHs that are beyond the first year of Stage 1 of meaningful use. Under our timeline for EHR-based submission under the Hospital OQR Program, some eligible hospitals would be in their second year of Stage 2 reporting and these eligible hospitals could be using two methods to report similar information for the Medicare and Medicaid EHR Incentive Programs and the Hospital OQR Program. In the CY 2013 OPPS/ASC proposed rule (77 FR 45188), we stated that we had considered allowing, but not requiring, EHR-based submission at the earliest possible date, so as to reduce the burden of hospitals. We did not propose this approach because we believe that it would not be consistent with our goal that measure results that must be publicly reported should be based on consistent, comparable results among reporting hospitals and because our first priority is the align EHR-based submissions under the Hospital IQR Program. We invited public comment on this issue.

Comment: A few commenters pointed out that the transition from manual to electronic submission is a huge task and could be very labor intensive. Another

commenter stated that the timeline to transition to electronic reporting is too aggressive. Some commenters urged CMS to immediately allow data submission via chart abstraction or electronically to ease the burden of quality reporting. Another commenter agreed with CMS's consideration for a full migration to electronic quality measurement and reporting. The commenter stated it is inappropriate to report data using chart-abstraction and electronic submission concurrently in the interim.

Response: We understand the transition to electronic submission is an immense undertaking that requires intense collaboration among stakeholders. As stated earlier, we still believe that public reporting should be consistent and comparable among reporting hospitals. We intend to move toward a full migration to electronic quality measurement and reporting. In addition, the EHR Incentive Program has incorporated eCQMs that are part of various hospital reporting programs, including the Hospital IQR and Hospital OQR Programs, in order to maximize financial incentives to help with this transition.

Comment: One commenter urged CMS to lay out its vision for electronic reporting, stating that it is overly burdensome for hospitals to collect and report data via chart abstraction and electronically.

Response: We have previously stated our vision, including in the Medicare and Medicaid EHR Incentive Programs – Stage 2 final rule (77 FR 54053). We noted that our alignment efforts focus on several fronts including using the same eCQMs for different programs, standardizing the measure development and electronic specification processes across our programs, coordinating quality measurement stakeholder involvement efforts, and identifying ways to minimize multiple submission requirements

and mechanisms. We gave the example that we are working toward allowing eCQM data submitted via certified EHR technology (CEHRT) by eligible professionals (EPs), eligible hospitals and CAHs to apply to other CMS quality reporting programs. A longer-term vision would be hospitals and clinicians reporting through a single, aligned mechanism for multiple CMS programs. For EPs, we have finalized such an alignment between the PQRS and the EHR Incentive Program, and we expect hospital reporting programs such as Hospital IQR and Hospital OQR Programs to follow.

In order to properly transition to electronic reporting, it is imperative that we take a staggered approach to electronic reporting in order to allow for careful review of the infrastructure and data integrity during the process. We have and will continue to look for ways to reduce reporting burden. We note that providers could collect data in EHRs even if the submission of the data is not done electronically for all quality reporting programs.

Comment: One commenter strongly recommended that all eCQMs should be field-tested and validated prior to implementation.

Response: We agree with the commenter that eCQMs should be tested and validated prior to implementation. We are collaborating with the NQF, measure stewards, and the ONC to develop accurate, and medical-record compatible electronic specifications while maintaining the integrity of the measures as endorsed.

We thank the commenters for submitting comments on the use of EHRs in the Hospital OQR Program and will take these comments into consideration as we develop future policies on this issue.

K. 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs

In the CY 2012 OPPS/ASC final rule with comment period, we finalized the voluntary 2012 Electronic Reporting Pilot for eligible hospitals and CAHs participating in the Medicare EHR Incentive Program for FY 2012 and also revised our regulations at § 495.8(b)(2) accordingly. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74489 through 74492) for detailed discussion of the 2012 Electronic Reporting Pilot.

We proposed to continue the Electronic Reporting Pilot for FY 2013 as finalized for FY 2012. We proposed to revise our regulations at § 495.8(b)(2)(vi) to reflect the continuation of the Electronic Reporting Pilot for FY 2013, and also to remove the reference to § 495.6(f)(9) in order to conform with the proposed changes to § 495.6(f) that were included in the Medicare and Medicaid EHR Incentive Programs - Stage 2 proposed rule (77 FR 13817). (We note we recently published the Medicare and Medicaid EHR Incentive Programs - Stage 2 final rule (77 FR 53968).)We invited public comments on these proposals.

We noted in the proposed rule that we finalized reporting clinical quality measures for the Medicare EHR Incentive Program by attestation of clinical quality measure results in the CY 2012 OPPS/ASC final rule with comment period for FY 2012 and subsequent years, such as FY 2013 (76 FR 74489). Thus, eligible hospitals and CAHs may continue to report clinical quality measure results as calculated by CEHRT by attestation for FY 2013, as they did for FYs 2011 and 2012. We also noted the intent of

CMS to move to electronic reporting. In the Medicare and Medicaid EHR Incentive Programs – Stage 2 final rule, we finalized that the Medicare EHR Incentive Program would require electronic reporting of clinical quality measures beginning in FY 2014 for eligible hospitals and CAHs that are beyond the first year of Stage 1 of meaningful use (77 FR 54088).

Comment: A few commenters stated that some eCQMs have not been sufficiently validated. One commenter also stated that not enough clinical quality measures in the Hospital IQR and Hospital OQR Programs are electronically specified, noting that some data elements are not always captured in CEHRT and still require manual review and input. A few commenters stated that electronic specifications have not undergone field testing.

Response: The clinical quality measures finalized in the Medicare and Medicaid EHR Incentive Programs – Stage 2 final rule (77 FR 53968) for reporting beginning with FY 2014 have either undergone feasibility testing in EHR systems and clinical settings or were finalized in the Stage 1 final rule for reporting in FYs 2011 and 2012, and specifications have been and will continue to be updated based on experiences with reporting those clinical quality measures in the EHR Incentive Program.

In addition, the Office of the National Coordinator for Health Information Technology's (ONC) 2014 Edition EHR certification criteria explicitly requires that EHR technology presented for certification must be able to capture the requisite data for each and every clinical quality measure to which the EHR technology is requested to be certified (see 45 CFR 170.314(c)(1) and 77 FR 54226 through 54232). Therefore EHR

technology that is certified to the 2014 Edition EHR certification criteria should include all of the data elements needed for each and every clinical quality measure to which an EHR technology is certified for the purposes of the EHR Incentive Program (for a list of these measures, including other quality measure programs that use the same measure, please refer to Table 10 of the Medicare and Medicaid EHR Incentive Programs-Stage 2 final rule at 77 FR 54083 through 54087). Finally, we do not believe that many of the issues experienced by providers with eCQMs in 2011 and 2012 of the EHR Incentive Program would continue.

We expect that eCQMs that will be electronically reported in hospital reporting programs such as the Hospital OQR Program would have undergone the same or similar processes as the eCQMs in the EHR Incentive Program (for more information, please refer to the Medicare and Medicaid EHR Incentive Programs – Stage 2 final rule 77 FR 54053 through 54056, section B.3. Criteria for Selecting CQMs and section B.4. CQM Specification). As the transition to electronic reporting becomes more ubiquitous in the hospital reporting programs, we expect that more eCQMs would be created de novo based on data that is readily available in EHR systems rather than retooled from paper-based specifications.

Comment: Several commenters stated that CMS should establish a process for updating specifications for eCQMs. These commenters also suggested that we establish a mechanism through which vendors and providers can offer feedback on problematic or unclear measures.

Response: The Electronic Reporting Pilot, which began in FY 2012 and is being finalized to continue in FY 2013, is used in part as a mechanism for testing the entire infrastructure for reporting eCQMs, including the ability to accurately abstract clinical quality data from EHRs, transmit them to CMS, and for CMS to receive the data. The EHR Incentive Program is currently the only CMS quality reporting program using electronic clinical quality measures for hospitals. The process of updating specifications regularly is expected to continue in order to maintain alignment with current clinical guidelines and ensure that the measure remains relevant and actionable within the clinical care setting.

In addition, we expect to make updates based on experiences of vendors, providers, and CMS during the process of reporting clinical quality data. We currently have various forums in which vendors and providers can provide feedback, such as the joint CMS and the Joint Commission ePilot vendor conference call, national partners' calls and open door forums. We continue to engage with the vendor and provider communities to keep an open dialogue for feedback and continuous improvement in electronic quality measurement.

Comment: One commenter did not support CMS having direct access to a facility's EHR for data abstraction.

Response: We have not proposed nor do we intend to directly access a facility's EHR for data abstraction. The Electronic Reporting Pilot for the Medicare EHR Incentive Program (established in the CY 2012 OPPS/ASC final rule with comment period and being finalized to continue in FY 2013 in this final rule with comment period)

is expected to be the basis for electronic reporting of clinical quality data in Hospital IQR and Hospital OQR Programs, as well as potentially in other hospital reporting programs.

Comment: Several commenters were concerned about participation levels in the Electronic Reporting Pilot and suggested flexibility with data transmission standards, such as using standards that EHR vendors already use. One commenter urged CMS to perform a comprehensive assessment of the pilot.

Response: The submission period for the first Electronic Reporting Pilot (that is, the pilot established for FY 2012) is October 1, 2012 through November 30, 2012. Therefore, when this final rule with comment period is published, the submission period for the first Electronic Reporting Pilot for hospitals would not yet be completed and a comprehensive assessment would not yet be possible. The data transmission standard used in the Electronic Reporting Pilot (Quality Reporting Data Architecture category I, or QRDA-I) has also been finalized in the Medicare and Medicaid EHR Incentive Programs – Stage 2 final rule as a standard that we will accept beginning with FY 2014 (77 FR 54088). ONC has also included QRDA-I in its 2014 Edition EHR certification criteria, which means that CEHRT should be capable of transmitting data using this standard if certified to the 2014 Edition EHR certification criteria. Therefore, it is a standard that we believe will continue to be used more widely for electronic reporting of clinical quality measures. As stated previously, we have and will continue to engage with the vendor community in order to continue to improve the ease and accuracy of electronic transmission of clinical quality data.

Comment: One commenter provided suggestions on development and selection of future electronic clinical quality measures, including considerations such as measure validity, quality improvement potential, reporting burden, and the National Quality Strategy described in the Medicare and Medicaid EHR Incentive Programs – Stage 2 final rule (77 FR 54054).

Response: We appreciate the suggestions on development and selection of future electronic clinical quality measures; however, this is outside the scope of this rulemaking. We will consider these suggestions when developing new electronic clinical quality measures and in future rulemaking when selecting new measures in our quality reporting programs.

Comment: One commenter stated that it is inconsistent for the Electronic Reporting Pilot to collect only Medicare data when reporting of all payer data is instrumental to meeting the goals of national initiatives as well as needed for Hospital Compare. This commenter was concerned that submission of patient-level data is inconsistent with the requirement in the EHR Incentive Program to report summary-level data and could have adverse consequences for patient privacy.

Response: In order to work towards the goal of transitioning our quality reporting programs to electronic reporting, we are piloting the electronic submission of patient-level data, which is the data level required in the hospital reporting programs, such as the Hospital IQR and Hospital OQR Programs. Whether the data are submitted to us through a manual process or electronically, all parties are expected to comply with HIPAA as applicable in order to maintain patient confidentiality and secure data

transmission. Since this is a pilot, we limited the data submission to Medicare patients only in order to limit the reporting burden on participating hospitals during the pilot phase.

Comment: One commenter suggested piloting both the QRDA-I (patient-level) and QRDA-III (aggregate-level) transmission formats in 2013.

Response: We proposed to continue the Electronic Reporting Pilot for FY 2013 exactly as adopted for FY 2012, which only included the QRDA-I transmission format. The QRDA-III format is currently being finalized and is not ready for full implementation in FY 2013.

Comment: Several commenters supported continuing the Electronic Reporting Pilot through the EHR Incentive Program. One of these commenters specifically supported the electronic reporting of clinical quality measures under the terms in the EHR Incentive Program.

Response: We thank the commenters for the support to continue the Electronic Reporting Pilot and for electronically-reported clinical quality measures.

After consideration of the public comments we received, we are finalizing our proposal to continue the Electronic Reporting Pilot for FY 2013, as finalized for FY 2012. We are revising our regulations as proposed at § 495.8(b)(2)(vi) to reflect the continuation of the Electronic Reporting Pilot for FY 2013 and to remove the reference to § 495.6(f)(9).

XVI. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XV.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 OPPS/ASC final rule with comment period (76 FR 74492 through 74493) for a detailed discussion of the statutory history of the ASCQR Program.

3. History of the ASCQR Program

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66875), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68780), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60656), and the CY 2011 OPPS/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 OPPS/ASC proposed rule (75 FR 46383), we solicited public comments on

10 measures. In addition to 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 as required by section 3006(f) of the Affordable Care Act, as added by section 10301(a) of the Affordable Care Act. We also submitted a report to Congress, as required by section 3006(f)(4) of the Affordable Care Act, entitled "Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan" that details this plan. This 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. If and when legislation is enacted that authorizes CMS to implement an ASC VBP program, we will develop the program and propose its implementation through notice-and-comment rulemaking.

In the CY 2012 OPPS/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 determination 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 updating of measures, publication of ASCQR Program data, and, for the CY 2014 payment determination, data collection and submission requirements for the claims-based measures. For a discussion of these final policies, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517).

In the CY 2012 OPPS/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 and appeals processes in the FY 2013 IPPS/LTCH PPS proposed rule, rather than in the CY 2013 OPPS/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 is 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.

Because we included proposals for the ASCQR Program in the FY 2013 IPPS/LTCH PPS proposed rule, we limited the number of proposals in the CY 2013 OPPS/ASC proposed rule. In addition, in an effort to prevent confusion regarding what we proposed in the CY 2013 OPPS/ASC proposed rule and what we proposed in the FY 2013 IPPS/LTCH PPS proposed rule, in the CY 2013 OPPS/ASC proposed rule, we limited our discussion of the proposals contained in the FY 2013 IPPS/LTCH PPS proposed rule primarily to background related to the proposals in the CY 2013 OPPS/ASC proposed rule.

Comment: Two commenters supported the implementation of a pay-for-performance program (that is, an ASC Value-Based Purchasing (VBP) Program) by

CY 2016 to reward high performing facilities and penalize low performing facilities. The commenters also recommended that the measure set for such a program focus not only on clinical outcomes and include clinical process, structural, and patient experience of care measures, but also minimize burden.

Response: Currently, we do not have the statutory authority to implement an ASC VBP Program. If legislation is enacted that authorizes CMS to implement such a program for ASCs, we will consider these recommendations.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

Section 1833(i)(7)(B) of the Act states that section 1833(t)(17)(C) of the Act shall apply with respect to ASC services in a similar manner in which they apply to hospitals for the Hospital OQR Program, "except as the Secretary may otherwise provide." The requirements under section 1833(t)(17)(C)(i) of the Act state that measures developed shall "be appropriate for the measurement of quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities."

In addition to following the statutory requirements, in selecting measures for the ASCQR Program and other quality reporting programs, we have focused on measures that have a high impact on and support HHS' and CMS' priorities for improved health care outcomes, quality, safety, efficiency, and satisfaction for patients. Our goal for the future is to expand any measure set adopted for the ASCQR Program to address these

priorities more fully and to align ASC quality measure requirements with those of other reporting programs as appropriate, including the Hospital OQR Program, so that the burden for reporting will be reduced.

In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to consensus development. However, as discussed above, the Hospital OQR Program statute only requires that we adopt measures that are appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings, reflect consensus among affected parties, and, to the extent feasible and practicable, include measures set forth by one or more national consensus building entities. Therefore, measures are not required to be endorsed by the NQF or any other national consensus building entity and, as we have noted in a previous rulemaking for the Hospital OQR Program (75 FR 72065), the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment. Further, the Secretary has broader authority under the ASCQR Program statute, as discussed above, to adopt non-endorsed measures or measures that do not reflect consensus for the ASCQR Program because, under the ASCQR Program statute, these Hospital OQR Program provisions apply "except as the Secretary may otherwise provide."

In developing the ASCQR Program, we applied the principles set forth in the CY 2011 OPPS/ASC proposed rule and final rule with comment period (76 FR 42337

through 42338 and 74494 through 74495, respectively). Although we did not propose any new measures for the ASCQR Program in the CY 2013 OPPS/ASC proposed rule as discussed below, we stated that we plan to apply the following principles in future measure selection and development for the ASCQR Program. These principles were applied in developing other quality reporting programs and many are the same principles applied in developing the ASCQR Program last year.

- Our overarching goal is to support the National Quality Strategy's goal of better health care for individuals, better health for populations, and lower costs for health care. The ASCQR Program will help achieve these goals by creating transparency around the quality of care provided by ASCs to support patient decision-making and quality improvement. More information regarding the National Quality Strategy can be found at: http://www.healthcare.gov/law/resources/reports/quality03212011a.html. HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act.

- Pay-for-reporting and public reporting programs should rely on a mix of standards, process, outcomes, and patient experience of care measures. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider/supplier characteristics.

- To the extent possible and recognizing the differences in payment system maturity and statutory authorities, measures should be aligned across public reporting and

payment systems under Medicare and Medicaid. The measure sets should evolve so that they include a focused core set of measures appropriate to the specific provider/supplier category that reflects the level of care and the most important areas of service and measures for that provider/supplier.

- We weigh the relevance and the utility of measures compared to the burden on ASCs for submitting data under the ASCQR Program. The collection of information burden on providers and suppliers should be minimized to the extent possible. To this end, we continuously seek to adopt electronic-specified measures so that data can be calculated and submitted via certified EHR technology with minimal burden. We also seek to use measures based on alternative sources of data that do not require chart abstraction or that use data already being reported by ASCs.

- We take into account the views of the Measure Application Partnership (MAP). The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay-for-reporting programs. The MAP views patient safety as a high priority area and it strongly supports the use of NQF-endorsed safety measures. Accordingly, we consider the MAP's recommendations in selecting quality and efficiency measures (we refer readers to the Web sites at: http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx, and http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885).

- Measures should be developed with the input of providers/suppliers, purchasers/payers and other stakeholders. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature.

- HHS' Strategic Plan and Initiatives. HHS is the U.S. Government's principal agency for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. Every 4 years, HHS updates its Strategic Plan and measures its progress in addressing specific national problems, needs, or mission-related challenges. The current goals of the HHS Strategic Plan can be located on the Web site at: http://www.hhs.gov/secretary/about/priorities/strategicplan2010-2015.pdf.

- CMS Strategic Plan. We strive to ensure that measures for different Medicare and Medicaid programs are aligned with priority quality goals, that measure specifications are aligned across settings, that outcome measures are used whenever possible, and that quality measures are collected from EHRs as appropriate.

We believe that ASCs are similar to HOPDs, insofar as the delivery of surgical and related nonsurgical services. Similar standards and guidelines can be applied between HOPDs and ASCs with respect to surgical care improvement because many of the same surgical procedures are provided in both settings. Measure harmonization assures that comparable care in these settings can be evaluated in similar ways, which further assures that quality measurement can focus more on the needs of a patient with a particular condition rather than on the specific program or policy attributes of the setting in which the care is provided.

We invited public comment on this approach for future measure selection and development for the ASCQR Program.

Comment: Some commenters supported CMS' efforts to establish the ASCQR Program. One commenter emphasized that ASCQR Program measures should reflect ASC facility-level accountability rather than physician-level accountability.

Response: We appreciate the commenters' support for the implementation of the ASCQR Program. The measures we adopted for the ASCQR Program are directly attributable to ASCs. The quality data are submitted by ASCs and are reported at a facility-level and not at a physician-level. We finalized a policy to publish ASC quality data by CMS Certification Number (CCN) in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), which is a facility-level identifier.

Comment: A few commenters asserted that ASCs are small entities and the utilization of EHR technology in the ASC industry is limited. Nonetheless, commenters requested that CMS consider electronic submission as an option for ASCs that have implemented EHR technology.

Response: We recognize that many ASCs are small entities and some may have limited EHR technology. We are still in the beginning stages of implementing the ASCQR Program, and we will need to assess the readiness of ASCs prior to considering an option of allowing electronic submission of measures for the ASCQR Program.

Comment: One commenter encouraged the adoption of NQF-endorsed measures to ensure that field testing and the consensus process are rigorous. Another commenter

urged CMS to facilitate direct representation from the ASC industry on either the National Priorities Partnership (NPP) or the MAP to formulate priorities for outpatient settings and coordinate efforts across inpatient and outpatient settings.

Response: In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to consensus development. However, sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, read together, require that the Secretary develop measures that the Secretary determines to be appropriate for the measurement of quality of care (including medication errors) furnished by ASCs and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities. Therefore, measures are not required to be endorsed by the NQF or any other national consensus building entity and, as we have noted in a previous rulemaking (75 FR 72065), the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment. Further, section 1833(i)(7)(B) of the Act states that these provisions shall apply to the ASCQR Program "except as the Secretary may otherwise provide." Thus, the Secretary has broad authority under the ASCQR Program statute to adopt non-endorsed measures or measures that do not reflect consensus.

As required by section 1890A of the Act, as added by section 3014 of the Affordable Care Act, we submit measures under consideration for this Program (and other programs utilizing quality measures) to the MAP by December 1 of each year, at

the same time that we make the list of measures available to the public. We consider the recommendations issued by the MAP prior to proposing measures for the ASCQR Program.

We encourage stakeholders interested in direct representation on either the NPP or the MAP to submit nominations to the NQF for consideration. The NQF holds open calls for membership nominations annually for both the NPP and the MAP, followed by a public comment period for vetting of balanced stakeholder groups.

Comment: A few commenters strongly supported CMS' measure selection criteria for ASCs. Commenters also commended CMS' effort to align some of the measures for the ASCQR Program with the Hospital OQR Program measures, and encouraged greater alignment of the measures so that Medicare beneficiaries can compare ASC and HOPD quality data.

Response: We appreciate the commenters' support for CMS' measure selection criteria. We believe that ASCs are similar to HOPDs, insofar as they deliver similar surgical and related nonsurgical services. Therefore, many of the measures may be applicable across these two settings. We agree with the commenters that greater harmonization of measures across these programs would allow beneficiaries to compare quality of care for similar services across these settings, and we will seek greater alignment in future program years.

After consideration of the public comments we received, we are finalizing our approach for future measure selection and development for the ASCQR Program.

2. ASCQR Program Quality Measures

In the CY 2012 OPPS/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. We also finalized our policy to retain measures from one calendar year payment determination to the next so that measures adopted for a previous payment determination year would be retained for subsequent payment determination years (76 FR 74504, 74509, and 74510).

We adopted the following five claims-based measures for the CY 2014 payment determination for services furnished between October 1, 2012 and December 31, 2012: (1) Patient Burns (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).

For the CY 2015 payment determination, we retained the five claims-based measures we adopted for the CY 2014 payment determination and adopted the following two structural measures: (1) Safe Surgery Checklist Use; and (2) ASC Facility Volume Data on Selected ASC Surgical Procedures. We specified that reporting for the structural measures would be between July 1, 2013 and August 15, 2013 for services furnished between January 1, 2012 and December 31, 2012, using an online measure submission Web page available at: https://www.QualityNet.org. We did not specify the data

collection period for the five claims-based measures for the CY 2015 payment determination.

For the CY 2016 payment determination, we finalized the retention of the seven measures from the CY 2015 payment determination (five claims-based measures and two structural measures) and adopted Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), a process of care, healthcare-associated infection measure (HAI). We specified that data collection for the influenza vaccination measure would be via the National Healthcare Safety Network (NHSN) from October 1, 2014 through March 31, 2015. We did not specify the data collection period for the claims-based or structural measures.

We stated that, to the extent we finalize some or all of the measures for future payment determination years, we would not be precluded from adopting additional measures or changing the list of measures for future payment determination years through annual rulemaking cycles so that we may address changes in program needs arising from new legislation or from changes in HHS' and CMS' priorities.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45191), considering the time and effort required for us to develop, align, and implement the infrastructure necessary to collect data on the ASCQR Program quality measures and make payment determinations, and likewise the time and effort required on the part of ASCs to plan and prepare for quality reporting, we did not propose to delete or add any quality measures for the ASCQR Program for the CY 2014, CY 2015, and CY 2016 payment determination years, or to adopt quality measures for subsequent payment determination years. For readers'

reference, the following table lists the ASCQR Program quality measures that were previously finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74504 through 74511).

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 Category	**Corresponding HCPCS Codes**
Gastrointestinal	40000 through 49999, G0104, G0105,G0121,C9716, C9724, C9725, and 0170T
Eye	65000 through 68999, G0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, and 0099T
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, and 0062T
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, and 0201T
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, and C9727
Genitourinary	50000 through 58999, 0193T, and 58805
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.

Comment: Many commenters applauded CMS' plan of not adding new measures to the ASCQR Program at this time because it would allow ASCs adequate time to adapt

to reporting requirements for the initial measure set for the CY 2014 payment determination.

Response: We appreciate the commenters' support.

3. ASC 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. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45191), we stated that, through future rulemaking, we intend to propose new measures consistent with the principles discussed in section XVI.B.1. of the proposed rule, in order to select quality measures that address clinical quality of care, patient safety, and patient and caregiver experience of care. We invited public comment specifically on the inclusion of procedure-specific measures for cataract surgery, colonoscopy, endoscopy, and for anesthesia-related complications in the ASCQR Program measure set.

Comment: Commenters either supported or suggested the inclusion of the following measure topics under the ASCQR Program:

- Patient Experience of Care
- Surgical Site Infection
- Surgical Complications
- Anesthesia-Related Complications
- Otolaryngology
- Gastroenterology
- Equipment Reprocessing

- Adverse Events after Discharge

Response: We appreciate the commenters' suggestions for future measure topics for the ASCQR Program.

4. Clarification Regarding the Process for Updating ASCQR Program Quality Measures

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's measures (76 FR 74513 through 74514). This process includes the same subregulatory process for the ASCQR Program as used for the Hospital OQR Program for updating measures, including issuing regular manual releases at 6-month intervals, providing addenda as necessary, and providing at least 3 months of advance notice for nonsubstantive changes such as changes to ICD-9-CM, CPT, NUBC, and HCPCS codes, and at least 6 months' notice for substantive changes to data elements that would require significant systems changes. We provided a citation to the CY 2009 OPPS/ASC final rule with comment period where the final Hospital OQR Program policies are discussed (73 FR 68766 through 68767).

In examining last year's finalized policy for the ASCQR Program, we recognize that we may need to provide additional clarification of the ASCQR Program policy in the context of the previously finalized Hospital OQR Program policy in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767). Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45191), we sought to more clearly articulate the policy that we adopted for the ASCQR Program, which is the same policy that has been adopted for the Hospital OQR Program.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established a subregulatory process for making updates to the measures we have adopted for the Hospital OQR Program. This process is necessary so that the Hospital OQR measures are calculated based on the most up-to-date scientific evidence and consensus standards. Under this process, when a national consensus building entity updates the specifications for a measure that we have adopted for the Hospital OQR Program, we update our specifications for that measure accordingly and provide notice as described above and in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514). An example of such an entity is the NQF. For measures that are not endorsed by a national consensus building entity, the subregulatory process is based on scientific advances as determined necessary by CMS, in part, through our measure maintenance process involving Technical Expert Panels (73 FR 68767). We invited public comment on this clarification of the finalized ASCQR Program policy of using a subregulatory process to update measures.

Comment: A few commenters requested that CMS consider the measure changes made by measure developers and stewards of measures, as these can occur at any time based on a change in evidence, consensus standards, or other factors that merit an update. With respect to measures that are not endorsed by a national entity, the commenters recommended that CMS consult with ASC clinical and operational experts. Further, the commenters suggested that the Technical Expert Panels (TEPs), which are charged with maintenance of the ASCQR Program measures, include substantial representation from the ASC community and relevant surgical specialty societies.

Response: We regularly monitor changes to measures adopted for the ASCQR Program and other quality programs that are made by measure stewards, as well as the evidence upon which the measures are based. The current ASCQR Program measure set has been implemented with input by ASC stakeholders, including the measure stewards, as well as other affected parties.

For NQF-endorsed measures, measure developers and stewards are expected to present these changes to the NQF for review annually. We would incorporate these changes based upon the NQF's acceptance. For non-NQF-endorsed measures, we evaluate changes to measures recommended by our contractors' surgical TEP, which includes outpatient ASC surgical representatives.

In summary, we clarified that we adopted the Hospital OQR Program's process for updating the ASCQR Program measures that was finalized in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), which is explained above.

C. Requirements for Reporting of ASC Quality Data

1. Form, Manner, and Timing for Claims-Based Measures for the CY 2014 Payment Determination and Subsequent Payment Determination Years

a. Background

In the CY 2012 OPPS/ASC final rule with comment period, we adopted claims-based measures for the CY 2014, CY 2015, and CY 2016 payment determination years (76 FR 74504 through 74511). We also finalized that, to be eligible for the full CY 2014 ASC annual payment update, 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). As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), ASCs will add the appropriate QDCs on their Medicare Part B claims forms, the Form CMS-1500s 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 ASCQR Program Specifications Manual located on the QualityNet Web site (https://www.QualityNet.org). We also 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. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53640), we adopted a policy that claims for services furnished between October 1, 2012 and December 31, 2012, would have to be paid by the Medicare administrative contractor (MAC) by April 30, 2013, to be included in the data used for the CY 2014 payment determination. We believe that this claim paid date will allow ASCs sufficient time to submit claims while allowing CMS sufficient time to complete required data analysis and processing to make payment determinations and to supply this information to administrative contractors.

b. Form, Manner, and Timing for Claims-Based Measures for the CY 2015 Payment Determination and Subsequent Payment Determination Years

In the CY 2013 OPPS/ASC proposed rule (77 FR 45192) we proposed that, for the CY 2015 payment determination and subsequent payment determination 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. We proposed that the data collection period for the claims-based quality measures would be for the calendar year 2 years prior to a payment determination. We also proposed that the claims for services furnished in each calendar year would have to be paid by the MAC by April 30 of the following year of the ending data collection time period to be included in the data used for the payment determination. Thus, for example, for the CY 2015 payment determination, we proposed the data collection period to be claims for services furnished in CY 2013 (January 1, 2013 through December 31, 2013) which are paid by the MAC by April 30, 2014. We believe that this claim paid date would allow ASCs sufficient time to submit claims while allowing CMS sufficient time to complete required data analysis and processing to make payment determinations and to supply this information to administrative contractors. We invited public comment on these proposals.

Comment: Some commenters agreed with CMS' proposals to begin the data collection period for claims-based measures in the calendar year 2 years prior to a payment determination, and to establish the policy that the claims for services furnished in each calendar year would have to be paid by the MAC by April 30 of the following year of the ending data collection time period to be included in the data used for the

payment determination. The commenters stated that they believed the April 30 deadline would allow sufficient time for claims processing.

However, other commenters believed the proposed period for the collection of claims data may be too abbreviated to capture all pertinent data. Because ASCs have up to 1 year to submit claims for services furnished, some commenters suggested that the period for the collection of claims data be as close to 1 year from the date the service was furnished to be included in a payment determination. Some commenters suggested that CMS establish a longer time period for the claims payment deadline in order to include all available claims data in the data used for payment determinations; one commenter suggested a June 30 deadline rather than April 30 deadline.

Response: We appreciate the commenters' support of our proposals regarding the period for the collection of claims data and the time allowed for data processing to be included in payment determinations. We agree that sufficient time should be allowed for claims processing to obtain complete data. We have conducted an internal analysis of claims submission by ASCs and have found that over 90 percent of the ASC claims are submitted and paid within the proposed timeframe. Therefore, we believe at this time that the proposed April 30 claims paid date is the latest date that would allow CMS to acquire and analyze the claims data, make payment determinations, and importantly, provide sufficient time for the MACs to program their systems. However, as we gain more experience and our systems become established, we will explore whether allowing more time for claims processing may be possible; if so, we will propose such changes through notice-and-comment rulemaking.

Comment: One commenter expressed concern with the lag between the quality data reporting period and the payment reductions under the ASCQR Program by basing payment adjustments on participation a full 2 years before the results of a payment determination take effect.

Response: We understand the commenter's concern with the lag between when data are reported and when payment is affected, and we will strive to reduce this lag without significant adverse effects on data completeness and quality. However, we note that with the data collection period ending December 31 for the payment determinations becoming effective beginning January 1, the lag basically is 1 year past the end of the data collection period. Based upon our current experience, we believe the timeline we are finalizing provides a balance between data completeness and expediency.

Comment: One commenter stated that the ASCQR Program's use of the term "claims-based" is not consistent with the Hospital IQR Program's use and does generate additional costs to the organization. The commenter stated that claims-based measures under the Hospital IQR Program truly means that CMS can obtain the data solely based on coding data without the organization taking additional steps of manually applying quality coding and having a clinician review the record for inclusion/exclusion criteria. The commenter further stated that for process measures, it is not accurate to label them as "claims-based" and state that this process is not time consuming and costly.

Response: We understand the commenter's concerns. However, we are clarifying that we have used the term "claims-based" to indicate the data source and mechanism for data submission as well as to differentiate claims-based measures from

measures based on manual chart-abstracted data. We believe that a claims-based mechanism for data collection is less time consuming and less costly than such chart-abstracted quality measures. In addition, the use of the term "claims-based" for the claims-based ASCQR Program quality measures is consistent with the Physician Quality Reporting Program (PQRS), which also uses QDCs for the reporting of quality data via claims.

After consideration of the public comments we received, we are finalizing our proposals without modification that, for the CY 2015 payment determination and subsequent payment determination 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. We also are finalizing that the data collection period for such claims-based quality measures will be for the calendar year 2 years prior to a payment determination and that the claims for services furnished in each calendar year will have to be paid by the MAC by April 30 of the following year of the ending data collection time period to be included in the data used for the payment determination.

2. Data Completeness and Minimum Threshold for Claims-Based Measures Using QDCs

a. Background

In the CY 2012 OPPS/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 based upon the considerations discussed above for the initial implementation years of the ASCQR Program. We stated in that final rule that we intend to propose to increase this percentage for subsequent payment determination years as ASCs become more familiar with reporting requirements for the ASCQR Program.

Comment: One commenter asked what method CMS would use to assess when to raise the required threshold for the level of completeness.

Response: We plan to monitor the level of completeness for submitting QDCs and to monitor the ASCQR Program for issues as they arise. Based upon program experience, we will assess what level of completeness should be required. Any changes in the threshold level for completeness of reporting for ASCQR Program claims-based measures will be proposed through notice-and-comment rulemaking.

b. Data Completeness Requirements for the CY 2015 Payment Determination and Subsequent Payment Determination Years

After publication of the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28101 through 28105), we realized that we did not propose a methodology for determining data completeness for the CY 2015 payment determination and subsequent payment determination years. Therefore, in the CY 2013 OPPS/ASC proposed rule

(77 FR 45192), we proposed that data completeness for claims-based measures for the CY 2015 payment determination and subsequent payment determination years 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 payment determination years. We stated that this method is the same method for determining data completeness for claims-based measures that was finalized in the CY 2012 OPPS/ASC final rule with comment period for the CY 2014 payment determination (76 FR 74516).

However, 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 invited public comment on this proposal.

Comment: One commenter asked how ASCs would be notified of their claim completeness percentages and encouraged CMS to post claim completeness percentages on the QualityNet Web site (http://www.QualityNet.org).

Response: We appreciate the commenter's suggestion. We intend to supply preliminary completeness percentages and other data submission information to ASCs prior to the closing of the data submission deadline in April 2013 either electronically or by the mailing of a facility-specific report so ASCs can assess their data completeness levels. In addition, ASCs can use their remittance information to assess if QDCs have been successfully processed by MACs.

We did not receive any public comments regarding our proposal that data completeness for claims-based quality measures for the CY 2015 payment determination and subsequent payment determination years 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 payment determination years. Therefore, we are finalizing this proposal without modification.

3. Other Comments on the ASCQR Program

Comment: Commenters expressed views and provided suggestions regarding additional topics and previously finalized policies for which we did not make proposals in the CY 2013 OPPS/ASC proposed rule, including comments and suggestions on the following:

- The NHSN infrastructure;
- Retention of quality measures from one calendar year to the next;

- Case thresholds for determining completeness of reporting;
- Alternative methods of data collection for certain finalized measures;
- The utility of certain finalized measures;
- Public reporting of data, including previewing data prior to public display;
- Patient exclusions for specific measures;
- Data collection and submission time periods for finalized measures;
- Validation;
- Mechanisms for opting out of reporting due to lack of cases meeting measure specifications;
- The use of alternatives to claims-based reporting such as registries and EHRs;
- The use of administrative claims data for the identification of HAIs;
- ASCQR Program implementation date; and
- Educational outreach to ASCs regarding the ASCQR Program.

Response: We greatly appreciate the commenters' views on these new topics and our previously finalized policies. Although we did not make proposals in the CY 2013 OPPS/ASC proposed rule on these topics or finalized policies, we will consider all of these views for future rulemaking and program development. For information on the ASCQR program, we refer readers to the information posted on the QualityNet Web site (http://www.QualityNet.org) and the CMS Web site (http://www.cms.hhs.gov) under the Quality Initiatives and ASC sections.

D. 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 the CY 2014 Payment Determination and Subsequent Payment Determination Years

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 XIV.H. of this final rule with comment period.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45193), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we proposed that we would calculate two conversion factors: a full update conversion factor and an ASCQR Program reduced update conversion factor.

We proposed 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 proposed 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 proposed that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor.

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators "A2," "G2," "J8," "P2," "R2," and "Z2." These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures and radiology services where payment is based on the MPFS PE RVU amount and a few other specific services that receive cost-based payment. As a result, we also proposed 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 XIV.D.2.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 proposed 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 proposed 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 proposed 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.

We invited public comment on these proposals but did not receive any public comments. Therefore, we are finalizing our proposals without modification regarding the process for reducing ASC payment rates for ASCs that fail to meet the ASCQR Program requirements for the CY 2014 payment determination and subsequent payment determination years.

XVII. Inpatient Rehabilitation Facility (IRF) Quality Reporting Program Updates

A. Overview

In accordance with section 1886(j)(7) of the Act, as added by section 3004 of the Affordable Care Act, the Secretary established a quality reporting program (QRP) for Inpatient Rehabilitation Facilities (IRFs). The IRF Quality Reporting Program (IRF QRP) was implemented in the FY 2012 IRF PPS final rule (76 FR 47836). We refer readers to the FY 2012 IRF PPS final rule (76 FR 47873 through 47883) for a detailed discussion on the background and statutory authority for the IRF QRP.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45193 through 45196), we proposed to: (1) adopt updates to a previously adopted measure for the IRF QRP that will affect the annual prospective payment amounts in FY 2014; (2) adopt a policy that would provide that any measure that has been adopted for use in the IRF QRP will remain in effect until the measure is actively removed, suspended, or replaced; and (3) adopt policies regarding when rulemaking will be used to update existing IRF QRP measures.

While we generally would expect to publish IRF QRP proposals in the annual IRF PPS rule, there are no proposals for substantive changes to the IRF PPS this year; therefore, we published only an IRF PPS payment update notice for FY 2013.[2] Because full notice-and-comment rulemaking is required for the proposals mentioned above in regard to the IRF QRP, we needed to identify an appropriate rulemaking vehicle in which

[2] The FY 2013 IRF PPS Payment Update Notice was published in the Federal Register on July 30, 2012 (77 FR 44618). We refer readers to: http://www.gpo.gov/fdsys/pkg/FR-2012-07-30/pdf/2012-18433.pdf

we could insert our IRF QRP proposals. Because the CY 2013 OPPS/ASC proposed rule was already scheduled to include additional pay-for-reporting proposals for the Hospital OQR Program and quality reporting requirements for the ASCQR Program, it offered an opportunity to allow the public to review all three quality programs' proposals in concert with one another in a timeframe that would be appropriate for implementing the IRF QRP proposals in time for the FY 2014 IRF PPS payment cycle. Therefore, we elected to include the IRF QRP proposals in the CY 2013 OPPS/ASC proposed rule.

B. Updates to IRF QRP Measures Which Are Made as a Result of Review by the National Quality Forum (NQF) Process

Section 1886(j)(7) of the Act generally requires the Secretary to adopt measures that have been endorsed by the entity with a contract under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF). The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process.[3]

The NQF's responsibilities include: (1) reviewing new quality measures and national consensus standards for measuring and publicly reporting on performance; (2) providing annual measure maintenance updates to be submitted by the measure steward for endorsed quality measures; (3) providing measure maintenance endorsement on a 3-year cycle; (4) conducting required follow-up reviews of measures with time-limited

[3]For more information about the NQF Consensus Development Process, we refer readers to the Web site at: http://www.qualityforum.org/Measuring_Performance/Maintenance_of_NQF-Endorsed%C2%AE_Performance_Measures.aspx).

endorsement for consideration of full endorsement; and (5) conducting ad hoc reviews of endorsed quality measures, practices, consensus standards, or events when there is adequate justification for a review.[4] In the normal course of measure maintenance, the NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle. In this measure maintenance process, the measure steward is responsible for updating and maintaining the currency and relevance of the measure and for confirming existing specifications to the NQF on an annual basis.[5] As part of the ad hoc review process, the ad hoc review requester and the measure steward are responsible for submitting evidence to be reviewed by a NQF technical expert panel (TEP) which, in turn, provides input to the Consensus Standards Approval Committee (CSAC). This committee then makes a recommendation to the NQF Board on endorsement status and/or specification changes for the measure, practice, or event.

Through the NQF's measure maintenance process, the NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes that we gave in the CY 2013 OPPS/ASC proposed rule (77 FR 45194) included updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure's endorsement to apply to other settings. We stated in the proposed rule that we believed

---

[4] For more information about the NFQ Ad Hoc Review process, we refer readers to the Web site at: http://www.qualityforum.org/Projects/ab/Ad_Hoc_Reviews/CMS/Ad_Hoc_Reviews-CMS.aspx).

[5] For more information about the NQF Measure Maintenance process, we refer readers to the NQF Web site at: http://www.qualityforum.org/Measuring_Performance/Improving_NQF_Process/Process_Assessment__Measure_Maintenance.aspx.

these types of maintenance changes are distinct from more substantive changes to measures that result in what can be considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

In the CY 2013 OPPS/ASC proposed rule, we proposed that if the NQF updates an endorsed measure that we have adopted for the IRF QRP in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the information that is posted on the CMS IRF QRP Web site at: http://www.cms.gov/IRF-Quality-Reporting/ so that it clearly identifies the updates and provides links to where additional information on the updates can be found. In addition, we would refer IRFs to the NQF Web site for the most up-to-date information about the quality measures (http://www.qualityforum.org/). We would provide sufficient lead time for IRFs to implement the changes where changes to the data collection systems would be necessary.

We proposed to continue to use the rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. We believe that our proposal adequately balances our need to incorporate NQF updates to NQF-endorsed IRF QRP measures in the most expeditious manner possible, while preserving the public's ability to comment on updates to measures that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We noted that, in the FY 2013 IPPS/LTCH PPS proposed rule, we proposed a similar policy for the Long-Term Care Hospital Quality Reporting (LTCHQR) Program (77 FR 53652

through 53653). CMS finalized a modified version of this policy for the LTCHQR Program, as discussed below.

Comment: Many of the commenters supported the use of the subregulatory process to incorporate NQF updates to measures that do not substantially change the nature of the measure. One commenter believed that this approach would be reasonable, as long as the use of the subregulatory process does not create any additional burden for IRFs. Another commenter stated that not all NQF updates need to be subject to a formal rulemaking process before the update can be implemented.

Response: We appreciate the commenters' support of our proposal. However, in response to some of the concerns expressed by other commenters below, and to be consistent with the policy that we have adopted for other quality reporting programs, we are finalizing this proposal with the modifications discussed below.

Comment: Several commenters supported the proposal to use the subregulatory process to incorporate non-substantial NQF updates to quality measures that are made between rulemaking cycles. However, the commenters expressed concern regarding how CMS would define substantial and non-substantial changes. The commenters were concerned that even slight changes to a measure's specifications will cause them to incur significant burden. The commenters urged CMS to use great caution in making decisions about what should be classified as a substantial change and a non-substantial change. One commenter expressed concern regarding the lack of specificity in the definition of a substantial change to a measure. One commenter suggested that the decision on whether a change to a measure rises to the level of substantial should be made by giving

consideration not only to the measure itself, but also to what data the provider is required to report on the changed measure and how it would impact providers. Another commenter expressed concern that there was a lack of specificity by both CMS and the NQF regarding the definition of a substantive change in a measure. Several commenters disagreed with the examples of substantial and non-substantial changes to a measure that were presented in the CY 2013 OPPS/ASC proposed rule. Another commenter urged CMS to consider any update to a measure that requires any additional data collection as a substantial change and thus subject to the more formal rulemaking process.

Response: The NQF regularly maintains its endorsed measures through annual and triennial reviews, which may result in the NQF making updates to the NQF-endorsed measures. We believe that it is important to have a subregulatory process in place, which we can use to incorporate non-substantive changes made by the NQF to measures we have adopted for use in the IRF QRP. Such a policy would allow for IRF QRP measures to be updated quickly and with a minimum amount of burden to IRF providers. However, we do recognize that some changes the NQF might make to its endorsed measures are substantive in nature and, therefore, it might not be appropriate for CMS to adopt these changes to the measures used in the IRF QRP using a subregulatory process.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45194), we proposed a policy to use a subregulatory process to adopt changes made to quality measures by the NQF that we consider to be non-substantial in nature. We further proposed to continue using the rulemaking process to adopt changes made by the NQF if we consider them to substantially change the nature of a measure. We have recently reconsidered these

proposals in light of modified policies that were finalized in other quality reporting programs, such as the LTCHQR Program and the Hospital IQR Program. We have also reconsidered our proposals regarding this policy in light of the public comments we received. We believe that consistency and harmonization among the Medicare quality reporting programs is vitally important and helps to reduce provider burden.

In the FY 2013 IPPS/LTCH final rule (77 FR 53504) we indicated examples of what we might generally regard as non-substantive changes to measures might include, but are not limited to, updated diagnosis or procedure codes, medication updates for categories of medications, or a broadening of age ranges. We believe that non-substantive changes may also include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. We noted that the NQF process has already incorporated an opportunity for public comment and engagement in the measure maintenance process.

We stated that we will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the IRF Quality Reporting Program. Examples of changes that we might generally consider to be substantive would include, but are not limited to, those circumstances 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, NQF expansion of endorsement of a previously endorsed measure to a new setting, procedure/process, or test administration). However, these and other changes would need to be evaluated on a case-by-case basis to

determine whether or not a change to a measure is in fact substantive. We intend to follow this modified policy when making changes to all IRF QRP measures.

Comment: One commenter recommended that CMS clearly identify subregulatory updates, provide links to where additional information about the updates can be found, and provide sufficient lead time for IRFs to implement any changes related to the NQF's updates. Another commenter recommended that CMS confer with a sufficient number of stakeholders in the rehabilitation hospital community to apprise them of the impending change and to seek informal feedback and input prior to adopting the measure's change. Further, the commenter recommended that CMS conduct testing of the change to determine its effectiveness before implementation.

Response: In the event that any measure that has been previously adopted for use in the IRF QRP is updated in a manner that we deem to be non-substantive in nature, we will use the subregulatory process to incorporate those changes. We will ensure that stakeholders are fully informed about these changes and that they have been afforded adequate lead time to make any necessary changes. Some of the methods that we will use to keep our stakeholders informed include: posting of information on the IRF QRP Web page[6]; holding special open door forums, posting information in the CMS weekly E-News publication, and responding to provider questions that we receive through the IRF QRP helpdesk[7]. While we expect to provide notice to stakeholders when we intend to

[6] http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html?redirect=/IRF-Quality-Reporting/

[7] IRF.questions@cms.hhs.gov

seek NQF's review of measures, the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process.[8]

After consideration of the public comments we received, we are adopting as final a policy to: (a) utilize a subregulatory process to incorporate updates to the IRF QRP quality measures that are not substantive in nature; and (b) continue use of the rulemaking process to adopt changes to measures that we consider to be substantive in nature.

C. Process for Retention of IRF Quality Measures Adopted in Previous Fiscal Year Rulemaking Cycles

We expect that the measures that we adopt for purposes of the IRF QRP will remain current and useful for a number of years after their initial adoption. While we could elect to adopt measures for each fiscal year's payment determinations, we believe that it would be easier for all parties concerned if we adopt the measures in perpetuity with an expectation that we will propose to remove, suspend or replace measures through future rulemaking, if necessary. Therefore, for the purpose of streamlining the rulemaking process, in the CY 2013 OPPS/ASC proposed rule (77 FR 45194), we proposed that when we initially adopt a measure for the IRF QRP for a payment determination, that measure will be automatically adopted for all subsequent fiscal year's payment determinations or until such time as we might propose and finalize the measure's removal, suspension, or replacement.

[8] For information about the NQF consensus development process, we refer readers to the NQF Web site at: http://www.qualityforum.org/Measuring_Performance/Consensus_Development_Process%e2%80%99s_Principle/Public_and_Member_Comment.aspx

Quality measures may be considered for removal by CMS if: (1) measure performance among IRFs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made; (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) a more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic is available; (6) a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; or (7) collection or public reporting of a measure leads to negative unintended consequences.

For any such removal, the public will be given an opportunity to comment through the next annual rulemaking process. However, if there is reason to believe that continued data collection of a measure raises potential safety concerns, we will take immediate action to remove the measure from the IRF QRP and not wait for the annual rulemaking cycle. Such measures will be promptly removed with IRFs and the public being immediately notified of such a decision through the usual IRF QRP communication channels, including listening sessions, memos, email notifications, and Web site postings. In such instances, the immediate removal of a measure will also be formally confirmed in the next annual rulemaking cycle. We invited public comment on our proposal that once a quality measure is adopted, it is retained for use in the subsequent fiscal year's payment determinations unless otherwise stated.

Comment: One commenter suggested that CMS should be required to re-propose quality measures each year so that stakeholders have the opportunity to submit comments before measures are finalized for use. The commenter stated that there needs to be a continuing opportunity for the public to comment each year on not only measures that are being proposed, but also on measures that were previously adopted. Further, the commenter expressed concern that this policy would result in a scenario in which stakeholder comments about previously adopted measures would not be given proper consideration.

Response: Our proposal to retain previously finalized IRF QRP measures for future years aligns with our policy to retain measures for future years in other Medicare quality reporting programs such as the LTCHQR Program and the Hospital IQR Program. We plan to review quality measures that have been adopted for use in the IRF QRP on at least an annual basis to make sure that each measure remains relevant, valid and reliable. The optimum time to perform this review would be at the time when we review and analyze the quality measure data received from IRFs for any given reporting period or data reporting cycle. Some of the IRF QRP measures may be reviewed more often, depending upon the frequency with which we receive data for these measures or whether other circumstances prompt review. We will perform ad hoc reviews of IRF QRP quality measures if we find any indication that a measure is no longer valid, reliable or that continued collection of data for this measure leads to negative unintended consequences. Regardless of the type of review performed, if our analysis of these data reveals that a quality measure meets any of the above-stated enumerated criteria for

removal (for reasons other than patient safety) we will propose to remove that measure in the next rulemaking cycle. If, at any time, we discover that an IRF quality measure poses a potential safety concern, we will take immediate action to remove that measure from the IRF QRP.

We have provided IRFs with a mechanism by which to submit comments regarding quality measures that have previously been adopted for use in the IRF QRP. IRFs may submit comments regarding quality measures that are already being used in the IRF QRP through the IRF QRP helpdesk email box.[9] We will give full consideration to any comments that we receive.

Finally, we also plan to solicit input in regard to the quality measures that are already being used in the IRF QRP from technical experts, as well as the public, through venues such as listening sessions, special open door forums, and national provider calls. These venues will provide IRFs with several ways to provide us with input on quality measures that are currently in use under the IRF QRP. We will give equal consideration to comments that we receive in regard to measures, whether they are being proposed or have previously been finalized for use under the IRF QRP. This will help to ensure that each of the adopted measures remains appropriate for continued inclusion in the IRF QRP.

After consideration of the public comments we received, we are finalizing our proposal to retain adopted quality measures for subsequent reporting periods (and the associated annual payment determinations) unless we propose to remove, suspend, or replace these measures.

---

[9] IRF.questions@cms.hhs.gov

We proposed to apply this principle to the two measures that were selected for use in the IRF QRP beginning on October 1, 2012. These adopted measures are: (1)) An application of the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome measure (NQF #0138)[10], and (2) An application of the Percent of Residents with Pressure Ulcers that Are New or Worsened measure (NQF #0678). We also invited public comment on our proposal to apply the principle of retention to the two above-stated quality measures that were adopted for use under the IRF QRP in the FY 2012 IRF PPS final rule (76 FR 47874 through 47878) for the second and all subsequent reporting periods (and associated payment determinations).

Likewise, we invited public comment on our proposed use of the process, as stated above, for retention of any additional future quality measures that may be adopted for use in the IRF QRP.

Comment: Two commenters supported CMS' proposal for retention of the two quality measures that were previously finalized for use under the IRF QRP.

Response: We appreciate the commenters' support of our proposed approach for retention of the two quality measures adopted for use under the IRF QRP.

After consideration of the public comments we received, for the reasons set forth above, we are finalizing our proposal to apply this policy of retention of IRF QRP quality

[10] The CAUTI measure that was adopted in the FY 2012 IRF PPS final rule (76 FR 47836 through 47915) was titled "Urinary Catheter-Associated Urinary Tract Infection [CAUTI] Rate Per 1,000 Urinary Catheter Days for ICU patients." However, this measure was submitted by the CDC (measure steward) to the NQF for a measure maintenance review. As part of their NQF submission, the CDC asked for changes to the measure, including expansion of the scope of the measure to non-ICU settings, including IRFs. The NQF approved the CDC's request on January 12, 2012. Due to the changes that were made to the measure, the CDC believed that it was appropriate that the measure title be changed. This measure is now titled "National Health Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure."

measures to the two measures that were finalized in the FY 2012 IRF PPS final rule. These measures are (1) An application of the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) (previously titled "CAUTI rate per 1,000 urinary catheter days, for Intensive Care Unit Patients"); and (2) An application of the Percent of Residents with Pressure Ulcers that Are New or Worsened measure (NQF #0678).[11] Although we are retaining these measures for the IRF QRP, we discuss below certain updates that we are making with respect to each of them.

D. Measures for the FY 2014 Payment Determination

We have previously identified the measurement of pressure ulcers and the prevalence of urinary tract infections (UTI) as two critical areas for quality measurement under the IRF QRP. While section 1886(j)(7) of the Act generally requires the adoption of endorsed measures, there were no NQF-endorsed measures for the two desired areas in the IRF context at the time CMS was conducting its rulemaking. As section 1886(j)(7)(D)(ii) of the Act authorizes the use of measures that are not endorsed when there are no feasible and practicable endorsed options, in the FY 2012 IRF PPS final rule (76 FR 47874 through 47878), we adopted applications of an NQF-endorsed pressure ulcer measure that had been endorsed for use in skilled nursing facilities (NQF #0678) and a CDC measure, the CDC's Urinary Catheter Associated Urinary Tract Infection [CAUTI] rate per 1, 000 urinary catheter days, for Intensive Care Unit [ICU]

[11] This measure was recently reviewed by the NQF and the scope of the measure was expanded to include post-acute care settings such as IRFs. Patients in post-acute care settings are referred to as "patients" as opposed to "residents", which is a term used in the nursing home setting. To reflect the expansion in the scope of this measure, the title was changed to "Percent of ***Patients/Residents*** with Pressure Ulcers that Are New or Worsened (NQF #0678)" (emphasis added).

Patients (NQF #0138), that had NQF endorsement for use in intensive care settings of hospitals.

1. Clarification Regarding Existing IRF Quality Measures That Have Undergone Changes During NQF Measure Maintenance Processes

In the FY 2012 IRF PPS final rule (76 FR 47874 through 47876), we used the endorsement exception authority under section 1886(j)(7)(D)(ii) of the Act. This authority permitted us to adopt the Urinary Catheter-Associated Urinary Tract Infection [CAUTI] rate per 1,000 urinary catheter days, for Intensive Care Unit [ICU] Patients measure (NQF #0138). We chose to adopt this measure because there was no NQF-endorsed CAUTI measure available to assess the prevalence of urinary CAUTI rates in the IRF setting.

As stated in section XVII.C. of this final rule with comment period, the CAUTI measure steward, the CDC, submitted the CAUTI measure to the NQF for a scheduled measure maintenance review in late 2011. At that time, the CDC also filed a request to expand the CAUTI measure to non-ICU settings, including IRFs. The NQF granted the CDC's request for an expansion of the scope of endorsement of the CAUTI measure to additional non-ICU care settings, including "rehabilitation hospitals." The NQF defined the term "rehabilitation hospitals" as including both freestanding IRFs, as well as IRF units that are located within an acute care facility. Despite the expansion in the scope of endorsement of the CAUTI measure, the original NQF endorsement number (NQF #0138) was retained. However, the measure was re-titled "National Health Safety

Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure."[12]

As amended, the expanded CAUTI measure includes a different data calculation method, which is referred to as the standardized infection ratio (SIR).[13] The change in the data calculation method does not, however, change the way in which IRFs will submit CAUTI data to the CDC. IRFs will still be required to submit their CAUTI data to the CDC via the National Healthcare Safety Network (NHSN) online system.

Under the originally endorsed version of the CAUTI measure, the CDC calculated an infection rate per 1,000 urinary catheter days. Under the new method, CDC will use a SIR calculation method, which is comprised of the observed number of infections over the expected number of infections.[14] The SIR calculation consists of an "observed" rate of CAUTI infections over the "expected rate" of CAUTI infections for that particular healthcare location. The CDC calculates the "expected rate" of CAUTI infections from CAUTI data that is reported to them by healthcare facilities. According to the epidemiologists at the CDC, they will need to analyze approximately 12 months of CAUTI data in order to calculate the "expected rate" of CAUTI infections for any given healthcare facility.

We believe that the SIR calculation method is a more accurate way to calculate the CAUTI measure results for comparative purposes because it takes into account an IRF's case mix. In addition, use of the SIR calculation does not require any change to the

---

[12] http://www.qualityforum.org/MeasureDetails.aspx?actid=0&SubmissionId=1121#k=0138&e=0&st=&sd=&s=n&so=a&p=1&mt=&cs=&ss=

[13] Centers for Disease Control and Prevention (2012, January), Catheter Associated Urinary Tract Infection Event. Retrieved from: http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf.

[14] http://www.cdc.gov/nhsn/pdfs/pscmanual/7psccauticurrent.pdf.

type of data required to be submitted by IRFs or the method of data submission that IRFs must use in order to comply with the CAUTI measure reporting requirements.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45196), we made the following proposals in regards to the CAUTI measure: (1) we proposed to adopt the changes made to the NQF #0138 CAUTI measure, which will apply to the FY 2014 annual payment update determination; (2) we proposed to adopt the CAUTI measure, as revised by the NQF on January 12, 2012, for the FY 2015 payment determination and all subsequent fiscal year's payment determinations; and (3) we proposed to incorporate, for use under the IRF QRP, any future changes to the CAUTI measure to the extent these changes are consistent with our proposal in section XVII.B. of the CY 2013 OPPS/ASC proposed rule to update measures.

Comment: Several commenters supported our proposal to adopt the changes made by the NQF to the CAUTI measure. Several commenters also supported use of the SIR calculation. The commenters also supported the delay in the implementation of the SIR calculation by the CDC. One commenter agreed that CMS should delay public reporting of the CAUTI measure data until after the CDC has collected enough data to calculate the expected CAUTI infection rate that will be used in the SIR calculations.

Response: We agree that use of the SIR calculation will be a more accurate method for risk stratified calculation of the CAUTI measure data. We also agree that public reporting of the CAUTI measure data should not take place until sufficient baseline data has been collected by the CDC.

Comment: One commenter expressed concern regarding CMS being able to properly risk adjust the CAUTI data results using the SIR calculation. The commenter was concerned that IRFs caring for more complicated patients will appear to have worse quality outcomes than other IRFs that care for less specialized patients, unless CMS can make the proper type of risk adjustments. The commenter further expressed concern that the SIR calculation method will be unable to provide adequate risk adjustment when comparing IRFs that have a specialized patient population to other IRFs that tend to have a more general patient population.

Response: After the IRF QRP begins, the CDC will take time to collect and analyze the CAUTI measure data in an amount that is sufficient to calculate an "expected rate" of CAUTI infection for IRF locations/units. The CDC needs up to 12 months of CAUTI data from various IRF's in order to calculate the "expected" CAUTI rates for the IRFs locations and units. These expected CAUTI infection rates can then be used to calculate a SIR for each IRF that includes adjustment for the patient population mix. The CDC and their subject matter experts, will make a determination with regard to how the patient population mix will be used in the risk adjustment for the SIR.

Comment: One commenter expressed concern regarding IRFs being held accountable for CAUTI infections that a patient acquired prior to an admission or transfer into that IRF.

Response: To help determine where the CAUTI infection may have developed, the CAUTI measure specifications incorporate a "transfer rule." The "transfer rule" provides that if a patient develops a CAUTI within 48 hours of transfer from another

location, the CAUTI is attributed back to the transferring location (http://www.cdc.gov/nhsn/pdfs/pscmanual/7psccauticurrent.pdf). We believe that the use of the transfer rule to the CAUTI measure calculations will help ensure that CAUTI infections are properly attributed to the facility where they originated.

Comment: One commenter suggested that pediatric patients should be excluded from the CAUTI measure because it has not been NQF-endorsed for the pediatric population due to low frequency of catheter use and difficulty in attributing UTIs.

Response: We disagree with the commenter's suggestion that pediatric patients should be excluded from this measure for the reasons stated below. The measure specifications for the NQF #0138 CAUTI measure exclude patients in a neonatal ICU, but otherwise have no other age based exclusions. The target population age range for the NQF #0138 CAUTI measure is described in the measure specifications as follows: "***Patients of all ages*** are eligible except patients in Levels I, II, II/III and III nurseries, and in locations where patients do not reside overnight." (Emphasis added)

Second, we believe that it is important to gather and analyze CAUTI measure data from patients of all age groups so that we can study the rate of CAUTI infections in not only adults and the elderly, but also in children. There are several IRFs that specialize in the rehabilitation of pediatric patients. Many other IRFs also treat pediatric patients. We would be remiss in our duty to measure the quality of care in the IRF setting if we did not gather CAUTI measure data from these IRFs on their pediatric patients.

After consideration of the public comments we received, we are finalizing our proposals to: (1) adopt the changes made to the NHSN Catheter-Associated Urinary Tract

Infection (CAUTI) Outcome Measure (NQF #0138) as applicable to the FY 2014 annual payment update determination; and (2) adopt the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) measure for the FY 2015 payment determination and all subsequent fiscal year payment determinations thereafter.

2. Updates to the "Percent of Residents Who Have Pressure Ulcers That Are New or Worsened" Measure

In the FY 2012 IRF PPS final rule (76 FR 47876 through 47878), we again used the endorsement exception authority under section 1886(j)(7)(D)(ii) of the Act to adopt an application of the "Percent of Residents with Pressure Ulcers that Are New or Worsened" measure (NQF #0678). We selected this measure because there was no other NQF-endorsed measure available to assess the percentage of patients with pressure ulcers that are new or worsened in the IRF setting at that time. We recognized that the NQF endorsement of this measure was, at that time, limited to short-stay nursing home patients, but we noted our belief that this measure was highly relevant to patients in any setting who are at risk of pressure ulcer development and a high priority quality issue in the care of IRF patients. Therefore, in the FY 2012 IRF PPS final rule, we finalized the adoption of an application of the NQF-endorsed #0678 pressure ulcer measure. We also stated that we would request that the NQF extend its endorsement of this short-stay nursing home pressure ulcer measure to the IRF setting (76 FR 47876 through 47878).

In April 2012, CMS filed an ad hoc request for review of the NQF #0678 short-stay pressure ulcer measure with the NQF. As part of that request, we asked the NQF to expand its endorsement of the measure to several other care settings, including

IRFs. As we noted in the FY 2012 IRF PPS final rule, we believe this measure is highly applicable to all post acute care settings, including IRFs (76 FR 47876). We stated in the proposed rule that if the pressure ulcer measure was revised by the NQF, we anticipated that it would be re-titled "Percent of ***Patients or Residents*** with Pressure Ulcers That Are New or Worsened" (NQF #0678) (emphasis added) so as to reflect the expansion in the scope of the applicable patient population.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45196), we noted that, as of the publication of that proposed rule, the NQF review process for the NQF #0678 pressure ulcer measure expansion request was still in progress. We proposed that if the NQF expands the scope of endorsement for this measure to the IRF setting, without any substantive changes, we would adopt and use the NQF-endorsed pressure ulcer measure in the IRF QRP, in accordance with the policy set forth above in section XVII.B. of that proposed rule. We believed that, in this anticipated scenario, the pressure ulcer measure, as revised, would be substantively the same measure, although broader in scope, than the current NQF-endorsed #0678 pressure ulcer measure. We invited public comments on our proposed use of this policy. For the reasons stated below, we have decided not to finalize this proposal.

In the meantime, in the CY 2013 OPPS/ASC proposed rule (77 FR 45196), we proposed to proceed with our plan, as finalized in the FY 2012 IRF PPS final rule, to use an application of the Percent of Residents With Pressure Ulcers that Are New or Worsened (NQF #0678) measure for the FY 2014 payment determination and all subsequent fiscal year payment determinations. For the reasons stated below, we will

collect only part of the pressure ulcer measure data as part of the pressure ulcer measure that we adopted last year. We have decided to adopt a non-risk-adjusted version of the NQF #0678 short-stay pressure ulcer measure, and will not publicly report the measure data until such time that we are able to collect data on the IRF-PAI necessary to calculate risk-adjusted measure rates.

Comment: Many commenters supported the use of the "Percent of Residents with Pressure Ulcers That Are New or Worsened" (NQF #0678) measure in the IRF QRP. The commenters also supported CMS' request to expand this measure to the IRF setting. One commenter expressed support for the use of the updated pressure ulcer measure, but recommended adding the term "patients" to the title of this measure.

Response: We appreciate the commenters' support and agree that adding the word "patients" to the title of the revised pressure ulcer measure will help to distinguish the IRF population from patients in nursing homes who are typically referred to as "residents." However, for the reasons discussed below, at this time, we are adopting a non-risk-adjusted version of the NQF-endorsed pressure ulcer measure (NQF #0678).

Comment: One commenter expressed doubt regarding the applicability of the pressure ulcer measure to the IRF setting.

Response: We believe that pressure ulcer development and worsening is an issue that is highly relevant to the IRF setting. Pressure ulcers are high-volume and high-cost adverse events across the spectrum of health care settings from acute hospitals to home health. Patients in the IRF setting may have medically complex conditions and severe functional limitations, and are, therefore, at high risk for the development, or worsening,

of pressure ulcers. Pressure ulcers are serious medical conditions and an important measure of quality. Pressure ulcers can lead to serious, life threatening infections, which substantially increase the total cost of care. Even if the proportion of patients in IRFs with new or worsening pressure ulcers is small, any such cases are particularly troubling.

Comment: One commenter urged CMS to remove this measure from the IRF QRP until such time as the issues that have been raised in stakeholder calls regarding the measure specifications and definitions can be resolved. The commenter stated that CMS has given conflicting guidance on how to stage pressure ulcers and document pressure ulcer data on the Inpatient Rehabilitation Facility – Patient Assessment Instrument (IRF-PAI) during several different provider outreach activities. The commenter opposed "back-staging" of pressure ulcers, and suggested that the IRF-PAI does not allow for the documentation of unstageable pressure ulcers that develop after the patient is admitted. Another commenter expressed concern that the modifications to the "Quality Indicator" section of the IRF-PAI are confusing. The commenter stated that the pressure ulcer questions that were added to the IRF-PAI do not account for all categories of pressure ulcers, such as unstageable pressure ulcers and suspected deep tissue injuries. Two commenters suggested that CMS delay implementation of the pressure ulcer measure and take time to work with IRFs and the National Pressure Ulcer Advisory Panel (NPUAP) to develop a standardized approach to reporting pressure ulcers.

Response: We have made several different types of training opportunities available to the IRF provider community. We held special open door forums on November, 29, 2011, and April 19, 2012. We also provided a full day in-person provider

training on May 2, 2012. Most recently, we initiated a four-part series of special open door forums held on July 26, 2012; August 16, 2012; September 20, 2012; and October 18, 2012. PowerPoint slides used at the IRF Open Door Forums are available on the IRF QRP Web page. (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html?redirect=/IRF-Quality-Reporting/). Documentation of the collection of pressure ulcer data is contained in Section 4 of the IRF-PAI training manual. This manual is available on the CMS Web site (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRFPAI-manual-2012.pdf).

During each of these training/outreach activities, we provided individuals with information regarding the IRF quality reporting program, including information about CAUTI and pressure ulcer data reporting. The information that we have offered to providers at each of the outreach activities noted above has been consistent.

We have also engaged the help of two widely known experts in the area of skin conditions and wound care. These experts have served as consultants to CMS and have taught our outreach activities. These experts have given presentations on how to stage and report pressure ulcer data. One of these experts was a guest lecturer at our provider training, which took place on May 2, 2012. Our pressure ulcer experts also attended the open door forums held on July 26, 2011, August 16, 2012, and October 18, 2012. At three of the open door forums held, these experts were available to answer questions from providers.

In addition, we held an open door forum on September 20, 2012, that dealt exclusively with the issue of pressure ulcer staging and documentation on the IRF-PAI. We also presented answers to questions that had been previously raised as well as a copy of a properly completed "Quality Indicator" section (questions 48A to 50C) of the IRF-PAI, which corresponded to the scenarios presented in each question. We believed that showing examples of a properly completed IRF-PAI for each question would help to reduce the confusion that IRFs were experiencing regarding the coding of pressure ulcer data on the IRF-PAI. We also discussed during this open door forum the issue of "back-staging" pressure ulcers, and explained that we do not, nor have we ever recommended, "back-staging" pressure ulcers in the IRF QRP.

We have provided IRFs with written guidance related to the staging of pressure ulcers, collection of pressure ulcer data, and documentation of pressure ulcer data in the "Quality Indicator" section of the IRF-PAI. This written guidance is contained in Section 4 of the IRF-PAI training manual. This manual is available on the CMS Web site (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRFPAI-manual-2012.pdf).

We recognize that the format and structure of the pressure ulcer questions, which are located in the "Quality Indicator" section of the revised IRF-PAI has resulted in some unintended limitations in the type and amount of pressure ulcer data that can be collected. We will continue to work with stakeholders to address their concerns and make the appropriate modifications to the data collection instrument over time. In the meantime,

we will continue with the collection of the pressure ulcer measure data using the questions contained in the "Quality Indicator" section of the IRF-PAI.

We do not believe that it would be in the best interest of many of the IRF providers if we were to delay the use of the pressure ulcer measure in the IRF QRP until such time as the IRF-PAI is modified. . We recognize that IRFs have incurred a significant financial burden preparing their EHR systems and staff to report pressure ulcer measure data beginning on October 1, 2012.[15].

Comment: One commenter expressed concern that revisions to the IRF-PAI do not allow IRFs to adequately document suspected deep tissue injury (DTI) that is present when the patient is admitted to the IRF. The commenter stated that DTIs are "wounds" that are evolving or in the process of "declaring" their final stage. The commenter stated that if the suspected DTI cannot be adequately recorded upon admission, and the wound later progresses to its final stage (stage 3 or 4), it will appear that the IRF was responsible for the pressure ulcer, instead of the location where the DTI occurred.

Response: We believe that it is important to do a thorough admission assessment on each patient who is admitted to an IRF at the soonest possible time after admission. This admission assessment should include a through skin assessment and should include the documentation of the presence of any pressure ulcers as well as any unstageable pressure ulcers, including suspected deep tissue injury. The IRF-PAI admission

[15] For quality reporting purposes, only those patients that are admitted on after 10/01/2012 will be included in the measure. Data obtained from partient that are admitted before 10/01/2012 but discharged after 10/01/2012 will not be used in the measure calculations.. For more information about this policy, we refer readers to the IRF-PAI training manual.

assessments must be performed within 3 days after admission. However, the IRF staff would also document the admission assessment findings in their medical records as well.

We also agree with the commenter that it is not possible to directly document suspected DTIs on the revised IRF-PAI (which became effective on October 1, 2012) immediately when doing the IRF-PAI admission assessment. However, an IRF provider can and certainly should, as part of its normal patient assessment and good care, perform the skin assessment and note any finding of suspected DTI or pressure ulcers at any stage in the patient's medical record. Documentation of pressure ulcer data on the IRF-PAI is not a replacement for proper clinical documentation in a patient's medical record.

A suspected DTI is one of three types of unstageable pressure ulcers, which can be documented on the IRF-PAI after it becomes stageable and "declares" its final stage. We believe that we have given IRF providers instructions about how to document unstageable pressure ulcers on the IRF-PAI on several different occasions. This issue was discussed during a question and answer session that took place during the IRF QRP special open door forum held on July 26, 2012, and at another IRF QRP special open door forum held on August 16, 2012. In addition, this issue was discussed again at another IRF QRP special open door forum held on September 20, 2012. The September 20, 2012 open door forum was devoted solely to the discussion of staging and documentation of pressure ulcers on the IRF-PAI. PowerPoint slides used during the September 20, 2012 special open door forum included scenarios in the form of questions and answers, as well as examples of the IRF-PAI with the correct coding to correspond to the scenario presented in each question. As noted above, the PowerPoint slides used at

any of the IRF QRP open door forums are available to IRFs on the IRF QRP Web page (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html?redirect=/IRF-Quality-Reporting/).

Also, we have provided written guidance on how to document unstageable pressure ulcers that have become stageable on the IRF-PAI in Section 4 of the IRF-PAI training manual. On page IV-3 of Section 4 of the IRF-PAI training manual, suspected deep tissue injury is defined as one of the three types of unstageable pressure ulcers. Section 4 of the IRF-PAI training manual further states that unstageable pressure ulcers that are present at the time of admission are not documented on the IRF-PAI.

As documented in Section 4 of the IRF-PAI training manual , if a pressure ulcer is unstageable upon admission, but becomes stageable later during the patient's IRF stay, this pressure ulcer should be considered as present on admission, at the stage at which it first becomes stageable. The admission assessment should be modified to reflect this. For example, if the IRF had documented on the patient's admission assessment that there were no pressure ulcers on admission, and then a suspected DTI progressed to a Stage 2 or higher pressure ulcer, the IRF would change the admission assessment to document the final stage of that pressure ulcer. Doing so will help to ensure that the IRF-PAI reflects that this pressure ulcer was present on admission, and what stage the ulcer was when it first became stageable. We believe that this effectively prevents the finding that an unstageable pressure ulcer that became stageable during the IRF stay developed during the patient's IRF stay and/or is attributed to the IRF.

Comment: One commenter expressed concern about making comparisons in pressure ulcer rates between IRFs because of the differences in patient populations that are served by each IRF. The commenter suggested that CMS develop a mechanism whereby these IRFs are not unfairly compared against peers that do not care for like populations of patients in any public reporting of the pressure ulcer measure data or other quality measures.

Response: The specifications for both the application of the pressure ulcer measure that we adopted in the FY 2012 IRF PPS final rule, as well as the specifications for the updated NQF-endorsed version of the measure (NQF #0678), include data elements that allow the measure to be risk adjusted when calculated in the IRF setting. These risk adjustment specifications take into consideration items such as the patient's height, weight, and co-morbid conditions. When we were revising the "Quality Indicator" section of the IRF-PAI by replacing the old voluntary quality items with the mandatory pressure ulcer questions, we worked within the existing format and framework of the IRF-PAI. We recognize that placement of quality measurement data items within the format of the IRF-PAI has resulted in some unintended limitations in the type and amount of pressure ulcer data that can be collected.

We will continue to work with stakeholders to address their concerns and make the appropriate modifications to the "Quality Indicator" section of the IRF-PAI. However, we do not believe that it would benefit IRFs to delay the start of the pressure ulcer measure data reporting during the time that we are working to make the necessary revision to the IRF-PAI. We say this for several reasons. First, evaluating the pressure

ulcer data that is reported to us during the first several reporting periods is one of the best ways for us to see what changes and modifications are needed to the IRF-PAI to ensure that it properly collects all of the data elements needed to calculate risk-adjusted rates. Second, many IRFs have incurred a significant amount of time and money to prepare themselves to report pressure ulcer data. Also, use of a non-risk adjusted version of the NQF-endorsed pressure ulcer measure will not cause IRF providers any increased burden because it will not require any change in the way that IRFs are required to collect and report pressure ulcer data.

After giving full consideration to the public comments we have received, we have decided to: (1) adopt a non-risk-adjusted version (numerator and denominator data only) of the NQF #0678 pressure ulcer measure; (2) collect the pressure ulcer measure data using the current version of the IRF-PAI; and (3) not begin public reporting of pressure ulcer measure data until we have: (a) thoroughly reviewed and researched this matter and consulted technical experts; (b) made appropriate modifications to the "Quality Indicator" section of the IRF-PAI to add the risk adjustment items; and (c) adopted the NQF-endorsed pressure ulcer measure (#0678) and notified stakeholders of our intentions through the rulemaking process.

Comment: MedPAC made suggestions related to additional quality measures that it believed CMS should add to the IRF QRP. MedPAC suggested that CMS develop a risk-adjusted readmission measure. Further, MedPAC requested that CMS comment, in this final rule with comment period, on the progress of the development of this type of readmission measure. MedPAC also urged CMS to consider adding a measure of

functional improvement. MedPAC pointed out that regaining functional status represents a central goal of IRF care.

Response: We appreciate MedPAC's input. We agree that both a risk-adjusted readmission measure and a measure of functional improvement would be extremely valuable measures of quality in the IRF setting. We are working to develop and implement these measures in the IRF QRP at the soonest possible time. We invite MedPAC to meet with the CMS IRF QRP team for further discussion of these quality measures.

Comment: One commenter made reference to the IRF quality measures that CMS included on a list made publicly available in late 2012 in accordance with section 1890A(a)(2) of the Act. The commenter noted that none of these measures were proposed for adoption into the IRF QRP in the proposed rule. This commenter offered their opinion and rationale as to whether some of measures should, or should not be added to the IRF QRP. The measures are as follows:

- **Incidence of potentially preventable venous thromboembolism (VTE) -** The commenter stated that this measure requires considerable clarification because, many, if not most, rehabilitation patients are at very high risk for VTE. The commenter further pointed out that many IRF patients are on VTE prophylaxis, yet, some of the IRF patients still get VTEs..

- **Health care worker influenza immunization –** This commenter supported adoption of this measure as long as data is reported by IRFs to NHSN;

- **The percent of patients/residents on a scheduled pain medication regimen on admission who self-repor**t – The commenter stated that in intensive rehabilitation, providers need to strike a balance between relieving pain completely, and avoiding overmedication so that the patient can safely participate in an intensive rehabilitation program;

- **Percent of nursing home residents who were assessed and appropriately given the seasonal influenza vaccine** - Because most patients that enter IRFs were previously hospitalized, it is likely that their influenza vaccination status already was established in the hospital during the flu season. The commenter further stated that, in some cases, with repeat questioning, some patients may elect vaccination after they have left the acute care facility or had a change of mind within the facility;

- **Percent of nursing home residents who were assessed and appropriately given the pneumococcal vaccine.** - This commenter stated that the same problems that may occur with the patient influenza vaccination measure may also occur with this measure;

- **Functional improvement measure** - Of particular note is that the commenter expressed opposition to the use of a functional measure that is based upon the FIM™ scale. The commenter stated that data related to FIM™ change are impacted dramatically by high rates of discharges back to acute care hospitals from rehabilitation facilities caring for the most complex and unstable rehabilitation patients. The commenter further stated that if quality measures for rehabilitation emphasize FIM™ change during rehabilitation, it is quite possible that IRFs will be incentivized to deny

admission to the most complex patients who, in fact, have the greatest need for rehabilitation.

Response: We appreciate the commenter's thoughts and suggestions offered regarding the above-stated quality measures. All of these measures remain under active consideration for future adoption into the IRF QRP, and we will consider this information during future rulemaking cycles when we are selecting quality measures for inclusion under the IRF QRP.

XVIII. Revisions to the Quality Improvement Organization (QIO) Regulations (42 CFR Parts 476, 478, and 480)

A. Summary of Changes

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 previously changed from "Peer Review Organizations" to "Quality Improvement Organizations" through rulemaking (67 FR 36539). In the CY 2013 OPPS/ASC proposed rule (77 FR 45196 through 45205), we identified several changes that we proposed because they are essential to remedying longstanding problematic aspects of the QIOs' review activities. These proposed changes would enable us to improve the QIO program by ensuring that QIOs are better able to meet the needs of Medicare beneficiaries.

Several of the proposed changes are specific to the QIOs' processing of quality of care reviews, which includes beneficiary complaint reviews. Although references are made to QIO sanction activities, the proposed changes did not impact QIO sanction activities or the regulations located in 42 CFR Part 1004.

In addition, as part of our review of our regulations in light of the President's Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011), we have identified several technical corrections that would improve the readability and use of the QIO regulations.

B. Quality of Care Reviews

Section 9353(c) of Pub. L. 99-509 amended section 1154(a) of the Act (adding a new paragraph (14)) to require that QIOs (then PROs), effective August 1, 1987, conduct an appropriate review of all written complaints from beneficiaries or their representatives about the quality of services (for which payment may otherwise be made under Medicare) not meeting professionally recognized standards of health care. This authority was in addition to the QIOs' already existing authority under section 1154(a)(1)(B) of the Act to perform quality of care reviews. In order to provide more clarity regarding the QIOs' roles, in the CY 2013 OPPS/ASC proposed rule (77 FR 45196), we proposed to add a definition of "quality of care review" under § 476.1 to make clear that this review type refers to both beneficiary complaint reviews (written or oral) and general quality of care reviews. We also proposed to add under § 476.1 definitions for "beneficiary complaint" to mean a complaint by a beneficiary or a beneficiary's representative alleging that the quality of services received by the beneficiary did not meet professionally recognized standards of care and may consist of one or more quality of care concerns; "beneficiary complaint review" to mean a review conducted by a QIO in response to the receipt of a written beneficiary complaint to determine whether the quality of Medicare covered services provided to beneficiaries was consistent with professionally recognized standards of health care; and "general quality of care review" to mean a review conducted by a QIO to determine whether the quality of services provided to a beneficiary(s) was consistent with professionally recognized standards of health care. We proposed that a general quality of care review may be carried out as a

result of a referral to the QIO or a QIO's identification of a potential concern during the course of another review activity or through the analysis of data. In addition, we proposed to revise the language under § 476.71(a)(2) to make clear that the scope of a QIO's review includes the right to conduct quality of care reviews, including beneficiary complaint reviews and general quality of care reviews, as well as a new review process that QIOs can offer Medicare beneficiaries called "immediate advocacy," which is described more fully in section XVIII.B.1. of this final rule with comment period.

We proposed additional changes to the QIO regulations related to the following issues:

1. Beneficiary Complaint Reviews

At the time QIOs assumed the authority under section 9353(c) of Pub. L. 99-509 to conduct reviews of written beneficiary complaints, we made a decision to rely upon the existing regulations for certain requirements (for example, the timeframes for requesting medical records and the practitioner's right to consent to the release of specific findings to beneficiaries), and to subsequently establish other remaining procedural requirements through manual instructions. While this approach has provided QIOs with a basic framework for completing the reviews, we have become aware of other issues that need to be addressed through the promulgation of new regulations as well as revisions to existing regulations.

In 2003, the United States Court of Appeals for the District of Columbia Circuit issued a decision in the case of Public Citizen, Inc. v. U.S. Department of Health and Human Services (332 F.3d 654, June 20, 2003) (referred to below as Public Citizen) in

which the court determined that QIOs must, at a minimum, notify a complainant of the results of its review. We recently completed a comprehensive revision to the manual instructions governing both beneficiary complaints and quality of care reviews, which, in part, was designed to ensure compliance with this court decision (Transmittal 17, April 6, 2012, CMS Manual System, Pub. 100-10 Medicare Quality Improvement Organizations, Chapter 5, Quality of Care Review) (available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R17QIO.pdf). These new instructions were effective May 7, 2012. While these manual revisions were necessary, we believe that additional regulatory changes are needed in order to improve QIO operations. In order to subject these additional changes to the processing of beneficiary complaint reviews and general quality of care reviews to notice-and-comment rulemaking, in the proposed rule, we proposed to add new §§ 476.110, 476.120, 476.130, 476.140, 476.150, 476.160, and 476.170 as described below in this section. We also proposed to add new definitions of "authorized representative", "appointed representative; "beneficiary representative" and "quality improvement initiative," and revise the definition of "preadmission certification" in § 476.1. In addition, to ensure consistency with the proposed revisions to or additional sections under Part 476, we proposed to revise §§ 480.107, 480.132, and 480.133, as discussed more fully below.

The proposed revisions to the regulations under Part 476 include several changes that would improve the beneficiary's experience when contacting a QIO about the quality of health care he or she has received and also shorten key timeframes so that beneficiaries

can achieve resolution of their health care concerns in less time. We proposed regulations under new proposed § 476.110 regarding a new alternative dispute resolution process called "immediate advocacy." We proposed to add a definition of "immediate advocacy" under § 476.1, and to make clear that this process is specific to oral complaints. We proposed to define "immediate advocacy" as an informal alternative dispute resolution process used to quickly resolve an oral complaint that a beneficiary or his or her representative has regarding the quality of health care received, and that this process involves a QIO representative's direct contact with the provider and/or practitioner.

Comment: Several commenters expressed support for the proposed definitions and stated that the availability of clear definitions would help ensure consistent interpretation and application of rules and processes, as well as prevent confusion and dissatisfaction for beneficiaries, providers, practitioners, and QIOs. Other commenters, although supportive of the definitions, raised concerns with specific definitions such as the inclusion of "oral beneficiary complaints" in the definition of quality of care reviews, because, in the opinion of the commenters, beneficiary complaints must be written. In addition, other commenters suggested that the wording of a beneficiary complaint should be modified to denote that a complaint must contain at least one quality of care concern because nonmedical, ancillary issues, including perceptions that staff are impolite, it is too hot or cold in the facility, or complaints about the reception process in the waiting room, are not considered to be quality of care issues. Moreover, some commenters suggested that the definition of beneficiary complaint should be modified so that the

focus is not on whether the care met professionally recognized standards because care, even when meeting professionally recognized standards of care, could raise quality issues that a QIO should address.

One commenter believed that a definition of professionally recognized standards of health care should be included because it is not clear what this entails. Another commenter requested further clarification regarding what is considered as an episode of care and asked if it relates to one setting, one continuous course of treatment across multiple settings, or something else.

Response: We appreciate the commenters' support of our proposed definitions. With regard to the inclusion of oral beneficiary complaints in the definition of quality of care reviews, we recognize that, under section 1154(a)(14) of the Act, QIOs are required to review written complaints submitted by Medicare beneficiaries. However, section 1154(a)(1)(B) of the Act also gives QIOs general authority to conduct quality of care reviews based on concerns conveyed from a variety of different sources, regardless of the manner in which these concerns have been conveyed. Therefore, a QIO can review concerns that have been expressed orally by any parties, including beneficiaries. Moreover, with regard to the comment that all beneficiary complaints include at least one quality of care concern and that nonmedical, ancillary issues should be excluded, we do not believe that the statute limits the concept of a beneficiary complaint in this way. Beneficiaries have the right to lodge complaints under section 1154 (a)(14) of the Act based on their perception that the quality of services they received did not meet recognized standards of care. This concept of a complaint does not require that the

complaint allege a concern that the QIO believes could actually relate to a violation of a standard of care, only that the complaint be about the quality of services not meeting the standard. Many beneficiaries are not in the position of being able to determine whether or not some aspect of their care actually violated a medical standard—nor should beneficiaries be discouraged from filing complaints because they must first make a judgment about standards of care. Additionally, we believe that the examples provided, such as impolite staff, the facility being too hot or too cold, or the reception process in the waiting room, can potentially contribute to the QIO's overall assessment of whether particular services met standards of care. The specific facets that impact the quality of care are not always readily quantifiable, and the QIO must consider various factors before determining whether an issue does or does not relate to the standard of care received. As such, we are not making any change to the definition at this time.

While we considered the concern that quality of care issues could be evident even where professionally recognized standards of care are met, we believe that QIOs must fulfill their statutory obligation to focus their efforts on determining, in any given situation, whether professionally recognized standards of care have been met. At this time, we also have determined that a definition of professionally recognized standards of care is not something we can define for all QIOs in all States. Section 1154(a)(6) of the Act specifically requires that each QIO apply professionally developed norms of care based upon typical patterns of practice within the QIO's own geographic area as principal points of evaluation and review, taking into consideration national norms where appropriate. The norms of care must be based on a list of specific elements that each

QIO must consider. The intricacies on what must go into a standard of care are further discussed in the QIO regulations at 42 CFR 476.1 (definitions of norms; standards; and regional norms, criteria, and standards), and 42 CFR 476.100, which includes details on establishing these elements of review for a QIO's particular locale. Moreover, the QIOs have extensive experience in identifying and implementing their own standards of care. Regarding the questions about an "episode of care," this term is designed to incorporate flexibility so that QIOs can identify the best approach to assessing complaints. As such, we believe that defining the term could unintentionally restrict QIOs' flexibility to link different settings and/or services when the QIO believes that a particular complaint spans a beneficiary's experience with medical care across different settings and/or services. An "episode" in one case might therefore be different for different beneficiaries.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45197 through 45199), we proposed an informal review process for beneficiary complaints. Historically, the only option available to beneficiaries, regardless of the severity or type of issue, has been the right to file a written complaint. Once a written complaint is received, the QIO is then obligated to conduct a formal peer review of the complaint, which includes a review of the beneficiary's medical information. Although this peer review process is effective, it can be quite lengthy and burdensome on providers and practitioners, given the various steps that must be completed by the QIO prior to the QIO rendering its final decision, with providers and practitioners cooperating with the QIO throughout this process. These steps include the time needed by the QIO to follow up with beneficiaries to ensure receipt of the complaint in writing, request and receive the medical information from the

provider and/or practitioner, discuss the QIO's interim decision with the practitioner and/or provider, respond to a practitioner's and/or provider's request that a QIO conduct a re-review of the initial peer reviewer's decision, and obtain the practitioner's consent to the release of specific findings in the final letter to the beneficiary. By regulation, QIOs must disclose to patients or their representatives information they have requested within 30 calendar days (42 CFR 480.132); it is possible that obtaining a practitioner's consent alone could take 30 calendar days. Even if there are no delays at any point in the current peer review process, it can take over 150 calendar days for a QIO to complete its review of a beneficiary's written complaint.

At times, the length of the current peer review process can render the beneficiary's original concern moot, particularly where the beneficiary's concern relates to a communication issue between his or her providers and/or practitioners, the prescribing of medications, or the failure to receive a necessary medical item, such as a wheelchair. For these types of concerns, we believe that requiring a beneficiary to submit the complaint in writing and waiting more than 150 calendar days so that the QIO can complete its review does not provide prompt and customer friendly service to Medicare beneficiaries. Moreover, at times, certain issues raised by a Medicare beneficiary in a complaint may not even be documented in the beneficiary's medical information. This is particularly true for complaints related to communication or coordination issues surrounding the beneficiary's care. Thus, a QIO may actually know at the outset of a review that the peer review process will not divulge any information related to the beneficiary's complaint.

We believe that, under an informal process such as "immediate advocacy," the QIO would be able to offer an alternative to a Medicare beneficiary in those situations where a resolution is needed more quickly than the current traditional peer review process. We believe that the proposed new informal process would also be beneficial in those instances where information relevant to a complaint would most likely not be contained in the medical information or where the Medicare beneficiary may simply be put off by the formality of the traditional peer review process. We specified in proposed § 476.110(a) that this new informal process would be available for oral complaints so that there is a clear distinction from the process requiring a written complaint under section 1154(a)(14) of the Act. Again, the proposed definition of "immediate advocacy" under § 476.1 also would make this clear.

We also proposed that the use of "immediate advocacy" would not be available if the QIO makes a preliminary determination that the complaint includes concerns that could be deemed significant, substantial, or gross and flagrant violations of the standard of care to which a beneficiary is entitled (proposed § 476.110(a)(2)(ii)). In addition, we proposed to add definitions of "quality of care concern" and "significant quality of care concern" under § 476.1, and to incorporate the definitions of "gross and flagrant violation" and "substantial violation in a substantial number of cases" as these two terms are used in 42 CFR 1004.1. Section 1004.1 covers definitions that apply to a QIO's sanction authority under 42 CFR Part 1004. We proposed to define "quality of care concern" to mean a concern that care provided did not meet a professionally recognized standard of health care, and that a general quality of care review or a beneficiary

complaint review may cover a single concern or multiple concerns. "Significant quality of care concern" would mean a determination by the QIO that the quality of care provided to a beneficiary(s) did not meet the standard of care and while not a gross and flagrant or substantial violation of the standard, represents a noticeable departure from the standard that could reasonably be expected to have a negative impact on the health of a beneficiary. "Gross and flagrant violation" would mean that a violation of an obligation specified in section 1156(a) of the Act has occurred in one or more instances which presents an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations (as specified in 42 CFR 1004.1). "Substantial violation in a substantial number of cases" would mean a pattern of providing care that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the QIO (as specified in 42 CFR 1004.1).

We stated that we believe that the proposed definitions would give improved clarity to the distinctions made among concerns that do not meet the standard of care and demonstrate that QIOs are responsible for reviewing all quality-related cases to determine whether care provided to a beneficiary could have violated a standard, and to address any violation, not just the most significant or flagrant failures to meet a standard of care. With regard to "immediate advocacy," we believe that this informal process is not appropriate for those situations where a QIO preliminarily determines that a complaint could involve a "gross and flagrant" or "substantial" concern. In these circumstances, the QIO would not offer the immediate advocacy process, but instead would inform the

beneficiary of the right to file a written complaint. Moreover, while we proposed to exclude the use of the immediate advocacy process for those instances where "significant quality of care concerns" might be present, we requested public comments regarding whether the immediate advocacy process should be made available for these concerns as well. In addition, while we proposed to restrict the use of the immediate advocacy process to a period of 6 months after a beneficiary has received the care at issue (proposed § 476.110(a)(1)), we also requested public comments on whether this time period should be extended beyond 6 months, whether based on the proposed structure or in order to accommodate the potential broadening of its use for "significant quality of care concerns." The public comments that we received are discussed later in this section.

We proposed, under proposed § 476.110(a)(2), to specify that the immediate advocacy process can be used for issues that are not directly related to the clinical quality of health care itself or that accompany or are incidental to the medical care received, but might, as a general matter, contribute to a standard of care not being met. This includes, but is not limited to, issues such as delays in obtaining much needed medical items (for example, wheelchairs). In addition, under § 476.110(a)(3), we proposed that the Medicare beneficiary must agree to the disclosure of his or her name in order for the immediate advocacy process to be used. We believe that it is important for the Medicare beneficiary to disclose his or her name because the immediate advocacy process is based on the need for open discussions to quickly resolve a beneficiary's concerns. Moreover, we also proposed that all parties orally consent to the use of immediate advocacy (proposed § 476.110(a)(4)). Because our goal is to work with the providers and

practitioners to resolve a beneficiary's concerns, we believe that consent is necessary. The use of oral consent, and not written consent, is in keeping with the cost-saving attributes of alternative dispute resolution processes.

Although we believe that the immediate advocacy process will be of great value to Medicare beneficiaries, providers, practitioners, and the QIOs, we recognize that, for some, the process may not provide the desired resolution. In addition, there could be situations where a QIO determines, after the immediate advocacy process has begun, that more serious concerns are evident. Therefore, we proposed under § 476.110(b) that the QIO and either party can discontinue participation in immediate advocacy at any time and the steps a QIO will take when this occurs. This includes informing the beneficiary of his or her right to submit a written complaint.

Under proposed § 476.110(c), we proposed to convey the need to maintain the confidentiality of the immediate advocacy proceedings by specifically referencing the redisclosure restrictions under § 480.107. We proposed to make a corresponding change to § 480.107 by adding new paragraph (l), to specify that the redisclosure of confidential information related to immediate advocacy proceedings can occur when there is consent by all parties. Under proposed § 476.110(d), we proposed to include procedures that QIOs would follow in those instances where a party fails to participate or otherwise comply with the immediate advocacy procedures. This includes making a beneficiary aware of his or her right to submit a written complaint.

We believe that the use of the immediate advocacy process will greatly reduce the burden on practitioners and providers by avoiding the formality of the traditional peer

review process in appropriate situations and quickly identifying resolutions and improvements in the provision of health care. In fact, the immediate advocacy process has already been introduced through the recently completed manual instructions, and preliminary feedback indicates that it is being received positively by providers, practitioners, and Medicare beneficiaries. Medicare beneficiaries have indicated their appreciation of the quicker and more appropriate resolution of their concerns. Many times, Medicare beneficiaries would wait months for the resolution of a formal written complaint, only to be disappointed in what the QIO actually found or frustrated that the concern initially raised was rendered obsolete by more recent events. Under the immediate advocacy process, the QIO has a mechanism to resolve beneficiaries' concerns, sometimes the same day the beneficiary calls. Moreover, providers and practitioners have responded positively to being given the opportunity to immediately address beneficiary's concerns and improve care, particularly where communication is one of the beneficiary's primary concerns. In addition, the provider's or practitioner's ability to avoid receiving and processing a formal complaint letter from the QIO and the related time and costs related to forwarding medical records and engaging in the lengthy review process also have been positively received. The decreased burden on Medicare beneficiaries, providers, and practitioners and the time and cost savings are cornerstones of alternative dispute resolution processes. We are confident the positive responses to this new option will continue.

Comment: Commenters supported the establishment of the immediate advocacy process. The commenters noted the efficiencies of immediate advocacy and the ability to

identify and achieve quality improvements much more quickly in a less formal environment. Many commenters noted that immediate advocacy will enable providers and practitioners to avoid the costly and time-consuming written beneficiary complaint process and, thus, dedicate already scarce resources to delivering high-quality care. Some commenters noted that swift and effective resolutions should be the goal, whether the complaint is oral or written, and that immediate advocacy is best for nonsignificant concerns related to the experience of care or issues that stem from a breakdown in communication that likely would not be documented in a medical record. One commenter suggested that CMS ensure the general public is aware of the availability of immediate advocacy.

Some commenters suggested that immediate advocacy be used for all complaints unrelated to quality of care or patient safety issues, and that the formal beneficiary complaint process be restricted to complaints involving patient safety issues or quality of care issues. One commenter asked whether immediate advocacy could tie up hospital and QIO resources in the long run, leading to slower response times and more administrative burden and whether it could increase "busy work" for providers. The same commenter then suggested that immediate advocacy be used only on a trial basis until the benefits are clear. Another commenter was similarly concerned that the immediate advocacy process would place a greater burden on the providers and practitioners because the QIOs would be contacting them directly.

Other commenters indicated that CMS should consider not implementing immediate advocacy because other avenues already exist for addressing complaints about

the quality of care, such as reporting the concerns directly to the provider or to State-based agencies, and that having multiple complaint processes impacts the resources of providers because they are sometimes forced to respond multiple times to the same issues. One commenter suggested that, because the QIOs would be documenting the complaint in its own words and it does not require a proper investigation of the patient's experience and the staff's actions, the QIO will lose neutrality and thus become an agent of the patient.

Response: We appreciate the commenters' support of the use of immediate advocacy, and we have already taken steps to ensure that beneficiaries, providers, and practitioners are aware that this new alternative dispute resolution process is available. We acknowledge the commenters' suggestion that the division of precise categories or types of concerns for which immediate advocacy should be used be distinct from those covered by the formal beneficiary complaint process. However, we believe that the proposed structure, which considers the severity of the concern and not the type of concern, represents the best approach to the design of both the immediate advocacy process and the beneficiary complaint review process. This approach gives beneficiaries as well as providers and practitioners options in achieving resolutions of complaints. Moreover, the immediate advocacy process is designed using the principles of the well-established alternative dispute resolution process, which focuses on achieving results in less time with lower costs. This is certainly true when compared to the traditional beneficiary complaint review process, which can take months and necessitates multiple reviews by physician reviewers, along with ongoing repetitive involvement of

the pertinent practitioners and/or providers. While we appreciate the suggestion that immediate advocacy only be used on a trial basis, we indicated in the proposed rule that immediate advocacy is already being used and that initial results are positive in that there is improved satisfaction with results, with less time and resources being expended to achieve the results. This initial feedback from practitioners and providers indicates that the process is, in fact, less burdensome and directly attributable to the complaint being resolved within hours or a couple of days versus several months, the avoidance of responding to a request for medical records, and a provider's and/or practitioner's limited involvement in the immediate advocacy process compared to the repeated back and forth communication necessitated throughout the lengthy formal beneficiary complaint review process. However, if any provider or practitioner believes that immediate advocacy is more burdensome and costly in any given situation, the provider or practitioner has the option to decline to participate in the immediate advocacy process. Although reference was made to the impact on providers and practitioners resulting from the availability of multiple options for filing a complaint, Federal law has specifically provided Medicare beneficiaries with the right to file written complaints with the QIOs. Thus, QIOs are obligated to appropriately review these complaints. We believe that the QIOs' substantial experience in resolving beneficiary complaints will enable them to determine what is necessary to conduct an appropriate review of a patient's experiences and staff reactions. Moreover, because immediate advocacy will only be used for less severe quality of care concerns, we believe the QIOs are well equipped to determine the appropriate and necessary level of their review efforts. We also believe the QIOs'

substantial experience in resolving complaints will enable them to effectively fulfill their roles in immediate advocacy without becoming agents of the beneficiaries, providers, or practitioners.

Comment: Numerous commenters opposed the expansion of immediate advocacy for use with significant quality of care concerns. Many commenters indicated that the immediate advocacy approach is not appropriate for these significant concerns because the roots of these concerns do not lend themselves to rapid resolution, and there is a risk that the cursory analysis may not sufficiently address the concerns in light of the short timeframe (8 hours to 2 days) within which immediate advocacy is intended to be completed. These commenters believed that this could ultimately be a disservice to beneficiaries and that, for these significant concerns, the medical record should be reviewed. Some commenters suggested that the review of medical records offers the best protection for providers, practitioners, and beneficiaries. Others commenters stated that the use of oral consent is not sufficient if significant quality of care concerns are present.

Response: We appreciate the commenters' responses on this issue. In light of these comments, we are not expanding the use of immediate advocacy for significant quality of care concerns at this time. As the QIOs continue to use immediate advocacy, we will continue to evaluate its use to determine if the future expansion to include significant quality of care concerns is warranted.

Comment: Several commenters agreed with the proposed 6 month timeframe regarding complaints that are eligible for immediate advocacy because they believed that this time seemed reasonable. Others commenters stated that, while the 6 month

timeframe is reasonable, exceptions should be granted for extenuating circumstances. However, other commenters believed that 6 months is too long because frequently these cases involve issues happening at the time of the call and, as such, 3 months is more appropriate. They believed that the shorter timeframe also would facilitate using these issues as "teaching tools" for practitioners and providers.

Commenters noted that the longer window could result in staff involved in the complaint no longer being with the provider, which is significant because the medical record is not being reviewed. Other commenters believed that immediate advocacy could be effective for complaints received up to a year after the date of care.

Response: In considering the exact period of time applicable to the use of immediate advocacy, we believe we must balance the cost-saving aspects, the desire to timely resolve the complaints, and the level of involvement required by practitioner and provider staff. We continue to believe that 6 months represents the best balance of these factors. We appreciate the comments provided and will consider making additional adjustments as the QIOs gain experience in using immediate advocacy.

While we believe that the immediate advocacy process represents a significant step forward in ensuring the timely, appropriate, and cost-efficient resolution of Medicare beneficiaries' concerns, we recognize that additional changes are needed to improve the QIOs' review process in general. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45198 through 45202), we proposed regulations governing written beneficiary complaint reviews as well as general quality of care reviews. We proposed to add a new § 476.120 that would govern a Medicare beneficiary's submission of a written complaint

and proposed, under proposed § 476.120(a), language limiting the time period for submitting a written complaint to 3 years from the date on which the care giving rise to the complaint occurred. We believe this is necessary because the ability of a QIO to thoroughly review a complaint becomes more problematic the longer the period of time is between the circumstances giving rise to a complaint and the actual filing of the complaint. An individual's memory can fade, and we are aware of some instances where Medicare beneficiaries have submitted complaints about issues that have occurred decades ago. In these situations, the QIOs' ability to obtain the necessary information, let alone render a valid decision, has been severely compromised. As such, we believe that a 3-year look back period should be sufficient to ensure that a QIO can effectively complete its review.

Under proposed § 476.120(a)(1), we proposed that a complaint submitted electronically to the QIO would meet the requirement for the submission of a written complaint. We proposed, under proposed § 476.120(a)(2), that if a beneficiary contacts a QIO about a potential complaint but decides not to submit it in writing (and the QIO did not believe it was appropriate to offer immediate advocacy), the QIO may use its authority under section 1154(a)(1)(B) of the Act to complete a general quality of care review in accordance with new proposed procedures at proposed § 476.160. We noted that, in these situations, the beneficiary would not receive any results of the QIO's review. We also proposed to limit the QIO's authority to conduct a general quality of care review in response to an oral complaint to those situations where the QIO makes a

preliminary determination that the complaint contains a potential gross and flagrant, substantial, or significant quality of care concern.

Under proposed § 476.120(b), we proposed instructions for QIOs when a beneficiary submits additional concerns after the initial submission of a written complaint. We believe that the focus on an episode of care, which we proposed in § 476.130(a)(1), gives the QIO adequate flexibility to consider all related concerns surrounding a complaint, but for those rare instances where a beneficiary does convey a new concern, the QIO would now have specific instructions regarding the right to consider the additional concerns either during the same complaint review or as a separate complaint.

Under proposed § 476.130(a), we proposed to convey the QIO's obligation to consider any information submitted by the beneficiary or his/her representative and by the provider and/or practitioner, along with the QIO's obligation to maintain the information received as confidential information, if that information falls within the definition of "confidential information" under existing § 480.101. Moreover, proposed § 476.130(a)(1) also would convey that the focus of the QIO's review will be on the episode of care from which the complaint arose and that in completing its review, the QIO will respond to the specific concerns raised by the beneficiary along with any additional concerns the QIO identifies while processing the complaint. We believe that the focus on the episode of care could potentially reduce the burden on providers and practitioners and reduce timeframes for completing individual reviews. Historically, QIOs would closely track the complaint as originally conveyed by a Medicare

beneficiary. However, often Medicare beneficiaries would become dissatisfied with the focus and/or results of the QIO's review, and the QIO would be forced to reexamine the same complaint in light of these entirely new issues, either in addition to or replacing the original issues. On occasion, this could result in the beneficiary raising concerns that should have been filed as an entirely new complaint, based on issues that might be related to, but were not reviewed as part of, the original complaint. This situation could slow the progress of the complaint indefinitely because there were no limits on what beneficiaries could add to existing complaints and the time span in which they could do this. These situations also could add to the burden on providers and practitioners because they would be required to participate in the review of the additional concerns and even provide additional medical documentation related to a complaint that might have changed course multiple times.

In conjunction with limiting complaints to an episode of care, we proposed, under proposed § 476.130(a)(1),to specify the details of the QIO's authority to separate a beneficiary's concerns into separate complaints if the QIO determines that the concerns relate to different episodes of care. We believe that focusing on the episode of care will put QIOs in a better position to identify all potential concerns at the onset and help alleviate any potential back and forth based on the specter of new or different concerns arising after the review has begun.

Under proposed § 476.130(a)(2), we proposed to set forth the QIO's use of evidence-based standards of care to the maximum extent practicable, and specify the method that the QIO must use to establish standards if no standard exists. Moreover, this

paragraph (a)(2) also conveys the finality of a QIO's determination regarding the standard to be used for a particular concern, in that the QIO's determination regarding the standard used is not subject to appeal. We believe that the focus on evidence-based standards of care is vital to the improvement of health care nationally.

Under proposed § 476.130(b), we proposed to specify the timeframes that practitioners and providers must follow when a QIO requests medical information in response to a written beneficiary complaint. We proposed a 10 calendar day timeframe for responding to these requests and believed providers and practitioners would also benefit from the faster resolution of complaints. We also noted that QIOs have historically employed a different, shorter timeframe for reviews where a Medicare beneficiary is still receiving care (concurrent review), compared to those situations where a Medicare beneficiary has already been discharged (retrospective review). For concurrent reviews, QIOs request that medical information be received within 1 calendar day, and typically this timeframe has been adhered to by providers and practitioners. Although we did not propose the continued use of the concurrent and retrospective review framework for responding to written complaints, we recognize that there could be circumstances in which an even shorter timeframe for receiving medical information is warranted, and we proposed to include language detailing a QIO's right to earlier receipt of medical information. We proposed that this right to earlier receipt of medical information be related to potential gross and flagrant or substantial quality of care concerns. However, we requested public comments on whether there are other

circumstances, involving less serious kinds of concerns, for which this authority to employ a shorter timeframe should be used.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53664 through 53665), we finalized proposed changes to § 476.78 to add references to "practitioners" in parts of this section, which referred only to "providers," in order to equalize the 30-day and 21-day timeframes for submitting records. In that final rule, we also made changes to § 476.90 to equalize the ramifications for not submitting records on time, including denying payment, because we saw no reason to differentiate between a provider's and a practitioner's records. We note that these changes had not been finalized when we issued the CY 2013 OPPS/ASC proposed rule, and in anticipation of the changes proposed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28119 through 28120), we requested public comment in the CY 2013 OPPS/ASC proposed rule on whether changes similar to those we proposed for beneficiary complaints, including shortening of the 30-day and 21-day timeframes, should be incorporated into § 476.78(b) for requests for medical information in general, for any kind of QIO reviews, including nonquality related reviews. In the CY 2013 OPPS/ASC proposed rule, we also proposed to apply a shorter timeframe for all of a QIO's requests for records, without limiting this application to quality reviews in just one instance: where secure transmissions of electronic versions of medical information are available, we proposed a shorter timeframe. Our proposal regarding secure transmissions of electronic versions of medical information is discussed more fully later in this section.

In the CY 2013 OPPS/ASC proposed rule (77 FR 45200), under proposed § 476.130(c), we proposed to include a requirement for beneficiary complaints that the QIO issue its interim initial determination within 7 calendar days after receiving all medical information. We stated that we believe that this timeframe is sufficient to evaluate a complaint and identify the key aspects of the care provided. Under proposed § 476.130(c)(1), we proposed to specify the provider's and/or practitioner's right to discuss the QIO's determination before it is finalized, and to specify that the QIO's initial notification will be made by telephone. We proposed a 7-calendar day timeframe for completion of the discussion. In addition, we proposed that the QIO's interim initial determination would become the QIO's final determination if the discussion is not completed timely because the provider and/or practitioner has failed to respond (proposed § 476.130(c)(2)). Again, our focus is on obtaining resolutions to complaints within reasonable timeframes, and the completion of the discussion is an area where improved instructions may benefit the timeliness of complaint processing because we have experienced significant delays in completing this particular step. The term "final initial determination" should not be confused with the term used in 42 CFR Part 405, because Part 405 relates to whether a beneficiary is entitled to services or the amount of those services, while this regulation covers only the quality of services as specified in the QIO statute. At the same time, we proposed, under proposed § 476.130(c)(3), the provider's or practitioner's right to submit a written statement in lieu of a discussion, with the requirement that the written statement be received within the same 7-calendar day timeframe from the date of the initial offer. We believed that allowing the submission of

a written statement would benefit practitioners or providers that may have trouble being available at a specific time within the 7-calendar day timeframe. Moreover, under proposed § 476.130(c)(4), we proposed to include the QIO's right to extend the timeframe for holding the discussion or submission of a written statement in lieu of a discussion in those rare instances where a practitioner or provider is unavailable, whether because of military tours of duty, travel or other unforeseen circumstances.

In addition, we noted in the CY 2013 OPPS/ASC proposed rule that we were considering restricting a provider's or practitioner's right to submit new or additional medical evidence in the form of test results, X-rays, and other evidence, as part of this discussion. We stated that we believe that doing so would emphasize the need for providers and practitioners to supply all relevant evidence when first requested by the QIO and also would maintain the focus on the discussion a physician or provider is due in accordance with section 1154(a)(14) of the Act. Allowing the submission of additional or new evidence could also substantially raise the possibility that the discussion will become, in effect, an entirely new review by the QIO. Moreover, providers and practitioners will still be able to submit information as part of a request for a reconsideration review. We requested public comments on whether providers and/or practitioners should be prohibited from submitting new or additional medical evidence in response to the offer of a discussion.

Under proposed § 476.130(d), we proposed to specify the QIO's obligation to issue a written final initial determination, regardless of whether care did or did not meet standards for all concerns, and that this determination must be issued within 72 hours

after completion of the QIO's review or, in cases where the standard was not met, the QIO's discussion or receipt of the provider's and/or practitioner's written statement. In addition, we proposed, under proposed § 476.130(d)(1), to specify that the notice of the final initial determination will be forwarded to all parties, and paragraph (d)(2) lists the actual content of the notice. We also proposed to specify that the QIO would not forward the notice if either party requests a reconsideration of the final initial determination.

These proposed changes represent significant departures from the process QIOs have historically used when resolving beneficiary complaints and are necessary to improve the fairness of the review process and increase the transparency of the QIO review process. When the process was originally established, CMS determined that physicians, providers, or Medicare beneficiaries would not be afforded the right to request a reconsideration of these determinations under section 1155 of the Act. However, providers and practitioners were afforded an administratively created option, referred to as a "re-review," if the provider or practitioner disagreed with the QIO's initial decision. Medicare beneficiaries were not provided this re-review opportunity and, in fact, were not given any response until after completion of the re-review. Moreover, the actual information a beneficiary received in response to the submission of a complaint was further limited by certain provisions in the existing regulations. Section 480.132 covers the general requirements that a QIO must meet in disclosing information to a beneficiary when that beneficiary has requested information about him or herself. Section 480.132(a)(1)(iii) states that this information cannot include any practitioner-specific information. We have read this provision in conjunction with

§ 480.133(a)(2)(iii), which authorizes a QIO to disclose practitioner-specific information when the practitioner has consented to the disclosure. In the past, we have interpreted these provisions as applying in the context of beneficiary complaints. This limitation greatly reduced a beneficiary's access to information related to the QIO's specific findings. In fact, § 480.132 also gave attending practitioners the authority to direct that a QIO not provide results directly to a Medicare beneficiary should that practitioner determine that the released information could "harm the patient." This same provision gave QIOs a full 30 calendar days before they had to respond to a beneficiary's request for information, which would apply even in the context of a complaint. Thus, the QIO was required to obtain a practitioner's consent to disclose information within this 30-calendar day timeframe before the QIO could disclose the specific results of its complaint review to the beneficiary.

As a result of the provisions in the existing regulation, the QIO was often delayed in its ability to respond to the beneficiary, and was sometimes forced to identify a representative and then give the results to the representative even if the Medicare beneficiary believed he or she was able to represent himself or herself and legally had not been deemed otherwise. This scenario has frustrated Medicare beneficiaries over time and placed QIOs in difficult situations. Furthermore, if a practitioner did not consent to any disclosures or to limited disclosures of information that would identify the practitioner, a QIO's decision typically contained a conclusory statement about the results of the QIO's review but no information about the standards of care the QIO used, the evidence the QIO considered, or the rationale for how the QIO arrived at its conclusion.

The limitations on what information Medicare beneficiaries received and broad authority given to attending practitioners have been particularly troubling in those instances in which the beneficiary's complaint relates to care that the attending physician provided. In fact, the lack of information given to Medicare beneficiaries in response to a complaint was the precise issue addressed in the Public Citizen decision.

We stated in the proposed rule that we believe that the proposed changes to § 476.130(d), including paragraphs (d)(1) and (d)(2), are necessary to ensure beneficiaries are given the same information and rights as practitioners and providers. The proposed changes make clear that the timeframe given to QIOs for issuing the final initial determination in response to a complaint is separate and distinct from the timeframe given to QIOs when responding to a beneficiary's request for information. Any requests for information, including requests for information pertaining to beneficiary complaint reviews that are unrelated to a QIO's issuance of its final initial determination, would continue to be governed by § 480.132. Moreover, while the proposed 72-hour timeframe in § 476.130 appears short in comparison to the 30-calendar day timeframe in § 480.132 that has historically been used, we believe that the 72-hour timeframe represents a more appropriate and reasonable period of time in which to issue these decisions. In most cases, the QIO's final initial determination may not change significantly from the interim initial determination. Thus, QIOs would be able to rely heavily upon the interim initial determination in most instances, with only minor adjustments being made in light of information received in response to the opportunity for discussion. In addition, in paragraph (d)(2), we proposed the content of the written

decision to be given to the beneficiary, provider, and/or practitioner. We proposed that the content include a statement for each concern that the care did or did not meet the standard of care, the standard identified by the QIO for each of the concerns, and a summary of the specific facts that the QIO determines are pertinent to its findings. This list makes clear that § 480.132 will no longer govern what information a QIO may provide to a beneficiary in resolving a complaint. We believe this approach more fully supports the court's decision in the Public Citizen case.

In addition, we believe that the language under section 1155 of the Act supports the decision to give all parties the right to request that the QIO reconsider its initial decision, and we proposed to offer providers, practitioners, and beneficiaries the right to request a reconsideration in proposed § 476.140(a) for complaints filed after July 31, 2014. This includes proposed specific requirements regarding the manner in which these requests are to be submitted and the obligations of beneficiaries, providers, and practitioners to participate in the reconsideration process in proposed § 476.140(a)(1) through (a)(3). We proposed to delay implementation of this new proposed right to ensure all processing requirements are fully developed for QIOs to follow in reviewing these reconsideration requests.

In addition to the proposed specific content of the notice at proposed § 476.130(d)(2) when a final initial determination is issued and under proposed § 476.140(b) when a reconsideration final decision is issued, we proposed to make corresponding changes to existing §§ 480.132(a) and (b) and 480.133(a) (proposed new paragraph (a)(2)(iv)). In order to make clear that § 480.132 relates solely to a

beneficiary's request for information, but not to a beneficiary's receipt of information from a QIO in resolution of a complaint review, we proposed the inclusion of a cross-reference to §§ 476.130(d) and 476.140(b) in paragraph (a). Similarly, we proposed to include language in § 480.132 (a)(1)(iii) to denote that the removal of all other patient and practitioner identifiers does not apply to disclosures described in § 480.132(b). We also proposed clarifications to § 480.132(b) to improve the link between paragraph (b) and the provisions of § 478.24 regarding requests for information relied upon in rendering initial denial determinations, which are cross-referenced in paragraph (b). We note that § 478.24 does not require seeking the advice or consent of the practitioner that treated the patient, nor does it prohibit the QIO from disclosing practitioner identifiers. We have made this clear by the proposed deletion of paragraph (b)(1)(i) and added language to the end of current paragraph (b)(1)(ii) to indicate that the information provided under § 478.24 includes relevant practitioner identifiers. With the deletion of paragraph (b)(1)(i), there is no longer a need for multiple paragraphs in (b)(1). Therefore, we proposed to eliminate the current designation for paragraph (b)(1)(ii), with the provision being included as part of paragraph (b)(1). We also proposed a corresponding change to § 480.133(a)(2)(iv) that makes clear a practitioner's or provider's consent is not required prior to releasing information to a beneficiary in connection with an initial denial determination or in providing a beneficiary with the results of the QIO's findings related to a beneficiary complaint review as described in §§ 476.130(d) and 476.140(b).

We also proposed to remove from existing § 480.132(a)(2) and (c)(1) the right of an attending practitioner to direct a QIO to withhold information based on a "harm" determination. This included the proposed removal of the requirement from existing § 480.132(c)(2) that a QIO release results to a beneficiary's representative if a "harm" determination has been made by the attending practitioner. This also included our proposed decrease in the timeframe that QIOs must follow in responding to a beneficiary's request for information (in any situation, as well as in the context of a beneficiary complaint) in § 480.132(a)(2) from 30 calendar days to 14 calendar days. This timeframe is strictly related to those situations where a beneficiary is making a request for information and will no longer be associated with obtaining responses to beneficiary complaints in the form of the QIO's final initial determination and the QIO's issuance of a final decision after a reconsideration, which are detailed in proposed §§ 476.130(d) and 476.140(b). We believe the decrease from 30 calendar days to 14 calendar days is warranted in light of the improved ability to maintain data, including in electronic formats, so that less time is needed when responding to requests. The proposed changes would ensure that Medicare beneficiaries have more control over the designation of their representatives and also give a QIO more appropriate steps to follow in identifying a representative when one is actually needed. As an example, the existing regulations at § 480.132(c)(3) direct a QIO to "first" look to the medical record to identify a representative but then direct the QIO to "rely on the attending practitioner" if no information is contained in the medical record. The changes we proposed to § 480.132(c) place more emphasis on the obligation of the QIO to follow the

requirements under State law regarding the designation of health care representatives or agents, rather than focusing on "where" the information might be contained.

Lastly, under proposed § 476.140(b), we proposed to specify that the QIO must notify the beneficiary and the practitioner and/or provider of its final, reconsidered, decision within 72 hours after receipt of the request for a reconsideration or, if later, 72 hours after receipt of any medical or other records needed for such a reconsideration. The QIO may do so orally, by telephone, in order to meet this timeframe. Proposed § 476.140(b)(1) also would specify that a written notice must be mailed by noon of the next calendar day and specifies the content of the notice. In addition, under proposed § 476.140(b)(2), we proposed to describe the QIO's authority to provide information in its final decision to beneficiaries, providers and/or practitioners regarding improvement opportunities. The information QIOs provide regarding potential improvements could include specific opportunities related to the practitioner's or the provider's delivery of care and/or even broader improvements focusing on the community served by the practitioners and/or the providers. Some QIOs have, in fact, been providing this information to beneficiaries since it can offer the beneficiaries assurance that their complaints and any underlying problems are being addressed.

We proposed to include, under proposed new § 476.150, specific requirements for QIOs to follow in response to abandoned complaints. We believe that these instructions are necessary in light of a QIO's experience when handling complaints where a Medicare beneficiary initially submits a complaint but then all attempts by the QIO to contact the beneficiary are unsuccessful. Historically, QIOs have been responsible for continual

follow-up with beneficiaries, even if months later the beneficiary still had not responded. We believe that giving QIOs the discretion to close these cases will eliminate this unnecessary follow-up and reduce costs. Moreover, it will alleviate provider's and/or practitioner's concerns in those situations where the QIO may have already reached out to them about a potential complaint. We also proposed to add, under proposed § 476.150(b), instructions for QIOs to follow in those situations, which we believe will be rare, where a QIO must reopen a beneficiary complaint review. We would have QIOs apply the same procedures that appear in the already existing regulations at § 476.96 for the reopening of cases involving initial denial determinations and changes as a result of DRG validation, simply using those same procedures for a different purpose. We proposed to do this by placing a reference in § 476.150(b) to the procedures in § 476.96.

Comment: Numerous commenters supported the establishment of regulatory provisions addressing beneficiary complaint reviews, including the streamlining of the overall process. Several commenters supported a beneficiary's right to submit additional concerns after the initial submission of a written complaint, a QIO's right to determine whether concerns should be processed as a single complaint or separated into multiple complaints, as well as the procedures for handling abandoned complaints. In addition, one commenter supported the provision allowing payment denials for practitioners and providers.

However, several commenters noted that a strong operational infrastructure must be developed to ensure the stricter timeframes in the beneficiary complaint review process can be effectively implemented, particularly in light of the QIO's budget limits

and the aggressive system-wide changes being attempted. Other commenters supported the provision allowing the submission of complaints electronically, although one commenter stated that CMS does not allow QIOs to accept electronic beneficiary complaints. One commenter also suggested that QIOs should not be communicating directly with physicians in resolving beneficiary complaints since this undercuts quality management of physician practices and instead the QIOs should communicate directly with the quality offices of the practices' system so that more orderly systematic approach to quality control can be maintained. Another commenter recommended that all communications exchanged between QIOs and beneficiaries be written at a 6th grade level and that, due to disabilities, visual impairments and non-English speaking Medicare beneficiaries, communications must be available in alternative formats.

Response: We appreciate the support for these regulatory provisions. With regard to the need for a strong operational infrastructure, the QIOs have been performing beneficiary complaint reviews for over 25 years and already have a strong operational infrastructure in place. While some adjustments could be necessary to the content of letters, any changes to the infrastructure will most likely be related to the new reconsideration right to be given to beneficiaries. In recognition of this, we proposed delaying the implementation of this new right until August 2014. In addition, we appreciate the commenters' support for the submission of complaints electronically. However, we are concerned by the comment that QIOs have been advised by CMS that complaints cannot be accepted electronically. This is incorrect, and we have communicated this to QIOs on several occasions. As these regulations will make clear,

beneficiaries have the right to submit complaints electronically, including by email, if they desire. Although we appreciate the concern that QIOs communicate with the provider's system quality office in resolving beneficiary complaints, we believe that communication must ensure the involved practitioner is also involved and nothing in these regulations limit the QIOs' ability to communicate directly with the provider's quality improvement staff. We appreciate the recommendations regarding the QIOs communications and availability of alternative formats and have already taken steps to ensure that communications are written in plain language and offered in other languages so that the needs of Medicare beneficiaries are met.

Comment: Some commenters suggested that CMS also require that, when QIOs investigate a complaint, all parties are informed as to who else has received the complaint, such as State survey agencies and the Joint Commission. Commenters suggested that this level of coordination is necessary because resources are being expended by all of the various entities, including the involved providers and/or practitioners, and coordinating the initial investigation or interview would be a cost-effective method that could also lead to an earlier resolution of the complaint. Moreover, the commenters believed that this would also ensure that information is better shared between oversight entities. They believed that doing so could alleviate duplicative efforts.

Response: While we recognize that, at times, several agencies could be investigating the same or similar concerns, our concern at this time is ensuring that beneficiaries, providers, practitioners, and QIOs have clear instructions regarding the

processing of beneficiary complaints. As such, we are not recommending specific changes designed to improve the coordination among various entities as a direct result of these regulations.

Comment: Several commenters expressed concern regarding the impact of the proposed regulations on the recently effectuated manual instructions included in Transmittal 17 (issued on April 6, 2012, CMS Manual System, Pub. 100-10 Medicare Quality Improvement Organizations, Chapter 5, Quality of Care Review). Specifically, commenters raised concerns regarding the extent to which beneficiaries can rely on the additional protections included in Transmittal 17 because the notice-and-comment rulemaking process may take a different and conflicting turn, leaving the beneficiary who relied on the transmittal in an insecure and vulnerable position.

Response: While we recognize that the timing of Transmittal 17 could cause confusion in light of the proposed regulations, this rule does not remove any of the additional protections conveyed through Transmittal 17. Rather, the regulatory provisions are designed to bring about additional changes that will improve the processing of beneficiary complaint reviews for all parties and provide beneficiaries with even more access to information. We anticipate making additional changes to the manual instructions to comply with the new regulatory provisions once the regulations are in effect.

Comment: Many commenters supported the 3-year period for submitting beneficiary complaints, while other commenters believed that 3 years is too long. Many commenters urged CMS to consider a 1- or 2-year timeframe, with the potential to allow

for additional time in rare circumstances. Many of the commenters' concerns about the 3-year time period were based on the ability of providers to reasonably defend against allegations of inappropriate care after three years, since memories fade. Moreover, the commenters believed that the time lapse could result in the standards of care being different in light of clinical advances that have occurred. Other commenters believed that the timeframe should be shortened because the proposed time practitioners and/or providers are being given to provide medical evidence is much shorter.

Response: While we recognize that a variety of factors could impact the success of the QIO's review process, we believe that because these reviews are primarily conducted by reviewing medical information supplied by the practitioner and/or provider, the longer time period is appropriate. Moreover, QIOs are experienced at identifying the appropriate standard of care, including any changes or updates to the standard of care since the time the actual care was provided. Therefore, we believe that 3 years represents a reasonable period of time for submitting complaints.

Comment: Numerous commenters opposed giving QIOs the authority to identify the standard of care, including the right to determine a standard of care where a clear standard does not exist. Commenters noted that standards of care are complex and can be reliably developed only with clinical experts assessing the available medical information, and there is no reason to believe that QIOs will have more relevant medical expertise available to make such determinations for all medical care issues. Some commenters also noted that there are numerous areas of medical practice for which insufficient evidence exists to guide the conclusion of what should be the standard of practice and that the

QIOs should not be expected to make up a standard where evidence to support it does not exist. One commenter noted that allowing QIOs to determine the standards of care will actually create more variation in the standards. In addition, some commenters believed that it was cause for concern that the QIO would make a determination as to whether the care provided met professionally recognized standards of care but the provider's/practitioner's perspective, including the provider's/practitioner's intimate knowledge of the patient's care, was secondary. Many commenters were troubled that a QIO's decision regarding the standard of care is not subject to appeal and believed that an independent third party entity should be established to review QIOs' decisions regarding the standard of care. One commenter also suggested that giving beneficiaries results of reviews could be more problematic in light of these concerns over the standards of care.

Response: QIOs were specifically established to make available a cadre of peer reviewers, including both physician and nonphysician practitioners, with expertise who could review complaints and other quality of care concerns in order to make determinations as to whether the care provided met professionally recognized standards of care. As part of this process, QIOs take care in matching the clinical background of their peer reviewers with the specific care at issue in the complaint and ensure that the peer reviewer's knowledge of existing practices in the relevant health care setting and the particular geographic area is current. Moreover, the identification of the standard of care is based on a robust review of current literature and available evidence pertaining to the standard in addition to the peer reviewer's own clinical judgment. QIOs have been reviewing quality of care concerns and making decisions regarding the standards of care

to be used when conducting these reviews for over 30 years. The regulations merely continue a process that has been in place since the program was initially established, and we see no reason to change the process at this time. In particular, we believe the suggestion that a third party be created to review the QIOs' decisions is unnecessarily duplicative because this is the precise reason QIOs were created, and a QIO is specifically tasked with applying the standards of care as described in section 1154(a)(6)(A) of the Act based on its evaluation of the typical patterns of practice within the geographic area it serves. This responsibility is also detailed in 42 CFR 476.100.

Comment: Numerous commenters supported the regulatory changes giving beneficiaries more detailed results of review findings, the removal of a physician's right to consent to the release of specific findings, and the provision of information to beneficiaries regarding quality improvement activities in the final decision letters. Many commenters believed that it is imperative that beneficiaries have the same access to information about complaints as practitioners and providers and that this right should not be defeated by the objection of a practitioner or provider. Many commenters also agreed that the elimination of the consent requirement would improve beneficiary satisfaction and that it aligns with the value of patient centered care in addition to reducing the processing timeframe by 30 days.

Other commenters supported the providing of information regarding quality improvement activities, but believed that the QIOs will need to take care that the information is presented in an easily understandable manner because it can be difficult at times for a beneficiary to discern how particular quality improvement activities relate to

the quality of care the beneficiary received. One commenter supported the proposal to reduce the time that a QIO is given in responding to requests for information from beneficiaries from 30 to 14 calendar days. However, another commenter noted that giving beneficiaries more information could be contrary to State law, and provided an example that, under Florida law, psychiatrists may redact notes or provide a summary statement to patients in lieu of providing them clinical notes, which may be harmful to the patient. Another commenter suggested that the failure to obtain a practitioner's consent could expose the QIO to legal activity, which would result in the need for increased liability insurance, additional costs for the QIO and for CMS and potentially peer reviewers refusing to participate in the process because of concerns over potential litigation.

Response: We regard the provision of more detailed information to beneficiaries to be a direct, logical, and reasonable outgrowth of the Public Citizen decision and recognize the benefits of providing this more detailed information to beneficiaries. We appreciate the support for providing this information and agree that quality improvement activities must be conveyed in an easy and understandable way to beneficiaries. We believe that the QIOs are already well-equipped to effectively communicate this information. With regard to the provision being contrary to State law, we do not agree that this provision will place a QIO in jeopardy of violating State law requirements. QIOs would be effectuating the procedures of a Federal program that is mandated by a Federal statute and interpreted under Federal regulations. As such, a QIO's obligations to provide information under a Federal statute and regulations would preempt any State law

requirements that conflict with the QIO's obligations. The information conveyed by the QIO will be limited because it will be specific to the care a beneficiary has received, and relate only to the facts that are essential to determining whether a provider or practitioner met professionally recognized standards of care. Lastly, with regard to a QIO or a peer reviewer being exposed to legal action, the liability protections afforded under section 1157 of the Act would apply to the QIO and its staff. Section 1157(b) of the Act states that any QIO or person employed by or who provides professional services to the QIO, or who has a fiduciary relationship with a QIO, cannot be held to have violated any criminal law or to be civilly liable under any Federal or State law as a result of his or her performance of any duties, functions, or activities required under or authorized by the QIO statute or under the QIO's contract with CMS.

Comment: Several commenters supported the reduction in timeframes related to requests for medical information. One commenter noted that, because providers have already demonstrated the ability to respond to requests for medical information related to expedited appeals within 4 hours, 10 days should be ample time. One commenter also supported the removal of the retrospective and concurrent distinction in processing complaints, as well as the authority to request medical information in less time when circumstances warranted. Other commenters believed that the shorter timeframes were necessary in order to give beneficiaries results in a reasonable period of time in response to a complaint.

Some commenters supported the efforts to shorten the timeframes associated with completing quality of care reviews, but believed that the 10-day timeframe was

insufficient because navigating a hospital's complex medical records system is time-consuming. Moreover, some commenters expressed concerns that the shorter timeframes would disrupt the providers' and practitioners' daily work in order to comply with the decreased timeframe and will ultimately lead to additional costs, including for providers and/or practitioners using vendors. Other commenters noted that a 10-day timeframe could not be met until providers and practitioners have established electronic health record systems that would easily facilitate the collection of medical information and that the current 21-day and 30-day timeframes should be maintained. Many of these commenters noted that a significant number of providers and practitioners either still rely entirely on paper records or are in a hybrid state with some paper records and some electronic records. Several commenters suggested that the 3-year "look back" period for complaints affected the ability to comply with this requirement because the providers and practitioners may have to retrieve medical information from offsite facilities. Other commenters noted that providers and practitioners receive numerous requests for medical information from various entities and that frequently the timeframes for responding are different for each entity, and these issues impact the ability of providers and practitioners to respond in a timely fashion. Several commenters also questioned whether the shorter timeframes will have any material benefit for beneficiaries that have submitted complaints. One commenter noted that, for one QIO, approximately 75 percent of providers are already complying with the 10-day timeframe, and that the other 25 percent are taking up to 25 days to respond, with the non-hospital providers and practitioners taking the longest to respond.

In addition, many commenters supported a similar shortening of the timeframes for replying to requests for medical information in response to other review activities. However, several commenters believed that the 21-day and 30-day timeframes should be maintained for other review activities for the same reasons they supported maintaining the current timeframes associated with completing quality of care reviews.

Response: In determining the precise number of days for responding to requests for medical information, we must consider the impact on the QIOs' ability to make timely decisions, the beneficiaries' right to have complaints or other review activities decided in a timely fashion, as well as the burden on practitioners and providers in responding to medical record requests. While we recognize that the shorter timeframes could cause concerns for some practitioners and providers, particularly nonhospital providers, we also considered the additional flexibilities we have proposed regarding the ability to securely transmit electronic versions of medical information.

In light of the concerns raised, we are modifying the proposed regulations to require that medical information be obtained within 14 calendar days when requested in response to a quality of care review. In addition, we are adopting this same 14 calendar day timeframe for all QIO review activities. We believe that having a single timeframe will facilitate provider's and practitioner's response times. This same timeframe will be applicable whether the provider or practitioner is forwarding paper copies of medical records or electronic versions. We believe that the ability to timely comply with these requests will be further enhanced by additional infrastructure changes we are working towards implementing in the near future, including electronic facsimile capabilities and

secure file-sharing capabilities. We will continue evaluating additional changes to this timeframe as providers and practitioners increasingly move towards electronic health records. However, we are finalizing the proposed regulatory language that gives QIOs authority to request medical information in less time if circumstances warrant the earlier receipt.

Comment: Several commenters supported the proposed decrease in timeframes for completing various steps of the review process, and several commenters commended CMS for streamlining the process. Some commenters noted that the prior lengthy timeframes were not patient-centered and have historically been a point of beneficiary dissatisfaction. Other commenters believed that the reduced timeframes were necessary so that providers and practitioners obtain results more quickly, and this is particularly helpful where the concerns are unfounded.

However, numerous commenters expressed concerns regarding the decreased timeframes. In particular, commenters raised concerns regarding the ability to meet the 7-day timeframe for completing the interim initial determinations and that, in order to do so, the more aggressive process improvements for expedited appeals would need to be adopted. Some commenters alleged that CMS is attempting to make the beneficiary complaint process similar to the expedited appeals process, and that this is not appropriate because these are not payment determinations in need of rapid resolution. Some commenters mentioned that the need of a QIO to complete a Quality Review Decision form for each concern and need to identify evidence-based standards of care

will impact the ability of QIOs to meet the reduced timeframes for making the interim initial determination.

Some commenters also noted that the 72-hour timeframe for rendering the final initial determination and the 72-hour timeframe for rendering the reconsideration decision are too short in consideration of the scope of the review necessary and need to thoroughly evaluate the medical information. Other commenters also believed that the requirement that reconsideration requests be submitted by noon the day after the notification of the final initial determination is too short because the beneficiary and the providers and/or practitioners need adequate time to consider the essence of the QIO's decision. Moreover, the commenters stated that the fact that the interim and final initial determinations are conveyed orally could impact the ability to fully evaluate whether a reconsideration request should be filed and may even violate confidentiality and privacy rights of the individual. Some commenters alleged that the provider, practitioner, or beneficiary could question the identity of the caller. Still other commenters noted that it is critical not to rush the QIOs' investigations of these issues, particularly because, when final, the determinations could be used by plaintiffs' attorneys to pursue additional actions against providers and practitioners. Another commenter noted that shortening the timeframes too extensively could have unintentional negative consequences resulting in the value of the review process being compromised for the beneficiaries who would prefer that their concerns are properly addressed. One commenter noted that there are already shorter processing timeframes currently in place through the concurrent review process and, thus, it is not clear why there is a need for decreased timeframes when

responding to retrospective reviews. Another commenter expressed concern regarding the sequence of the reconsideration right, for example, should the review of a beneficiary's reconsideration request occur before or after the practitioner's or provider's request, and believed that a beneficiary could be upset should a concern be confirmed at the conclusion of the final initial determination only to have it overturned as a result of a practitioner's or provider's reconsideration request. Other commenters believed that the shorter timeframes would increase costs, including the compensation costs for physician reviewers. Several commenters noted that the new Chapter 5 instructions already include shorter timeframes for completing various steps of the review process and that these timeframes should be maintained until medical information can be received electronically from providers and practitioners and also conveyed electronically to peer reviewers. Some commenters questioned why a beneficiary's right to request a reconsideration cannot be implemented sooner than August 2014.

Response: In considering the reduced timeframes for various steps, we attempted to identify timeframes that would balance the interests of beneficiaries, providers, and practitioners in obtaining timely resolution of complaints with the time necessary for the QIOs to effectively and thoroughly complete the various tasks involved in the review process. We have routinely heard from beneficiaries that the time necessary to complete reviews is a point of dissatisfaction, and clearly a process that requires more than 150 days to complete a review can be frustrating to all involved. Moreover, we disagree with the suggestion that our goal is to make the beneficiary complaint review process similar to the expedited appeals process. Because the expedited appeal decisions are typically

made within 24 to 48 hours of the filing of the appeal, the expedited appeal process is quite different from the proposed complaint process, which allows 7 days to make the interim initial determination, offers providers and practitioners the opportunity to discuss the results, and then permits several more days before the final initial determination is made.

We are concerned by the statement of the commenter who noted the need to create a Quality Review Decision form for each concern identified during the review. That is inaccurate. Only one Quality Review Decision form needs to be created to track the QIO's review of a beneficiary complaint or completion of a general quality of care review. Moreover, with regard to the comment that these shorter timeframes appear unnecessary in light of the already existing authority to conduct concurrent beneficiary complaint reviews, we advised in the proposed rule that the retrospective and concurrent distinction in reviews would no longer be used. Our goal is to move away from having a distinction in processing requirements that is determined by the beneficiary's inpatient (concurrent) or discharge (retrospective) status and instead consider the severity of the issues in order to determine how quickly to process the complaints. We have already addressed that QIOs have the authority to request medical information within shorter periods of time if circumstances warranted. Moreover, the timeframes for completing the interim initial determination and final initial determination convey that the QIO must complete its review "within" the prescribed period of time. We believe that our timeframe should be sufficient, even for complaints that are unexpectedly complex, and that QIOs have the flexibility to use the full time allotted for the interim and final initial

determinations or to complete these steps in less time if circumstances warrant it, such as when circumstances surrounding the complaint have a severe impact on the quality of care received.

With regard to the sequence, all parties will be offered the right to request a reconsideration at the same time, and each party must understand that the review will be an independent review that could result in the final initial determination being overturned. In addition, while it is accurate that the new Chapter 5 manual instructions contain processing timeframes that are shorter than those historically used, we undertook the task of writing these new regulatory provisions because we believed that additional improvements, including the potential incorporation of even shorter timeframes, could be made and that any additional and more comprehensive timeframes should be accomplished through notice-and-comment rulemaking.

However, we recognize that some of the timeframes are considerably more aggressive than those followed by the QIOs as recently as 6 months ago. After considering the public comments we received, we have decided to extend the timeframe for the QIO to make the interim initial determination from 7 calendar days to 10 calendar days. Although we do not agree that QIOs will be unable to meet the proposed 7-day timeframe based on the need to identify evidence-based standards of care because QIOs have always been responsible for identifying standards of care and will have a readily available repository of up-to-date standards of care for most concerns, we nonetheless choose to extend the timeframe to 10 days based on the concerns that peer reviewers be

given adequate time to review the medical information, particularly if the medical information is somewhat voluminous.

In addition, in this final rule with comment period, we have modified the timeframe for making the final initial determination from 72 hours to 3 business days. We also have extended the timeframe for filing reconsideration requests from noon the calendar day following the initial notification to 3 calendar days. In addition, to ensure that all parties can properly evaluate the need to file a reconsideration request, we have modified the regulatory requirements to require that QIOs issue the final initial determination in writing. Lastly, we have extended the timeframe for QIOs to render the reconsideration decision from 72 hours to 5 calendar days. Although it was suggested that the right to request reconsiderations could be implemented sooner than August 2014, we continue to believe that this period of time is necessary to ensure all process and system requirements can be effectively implemented. This includes ensuring that beneficiaries, providers, and practitioners are aware of this new right.

Comment: Several commenters believed that the reduction of time for completing the opportunity for discussion could impact the accuracy and thoroughness of the review process and that because the results of the interim initial determination and right to an opportunity for discussion are initially conveyed orally, this will require a physician with quality improvement experience to ensure that the issues are accurately conveyed to the practitioner or provider and to ensure that any response from the practitioner is correctly transcribed. Several commenters believed that it would be better for the response to be in writing in all circumstances. Other commenters believed that the

timeframe for completing the opportunity should be extended to 10 days with exceptions built in for certain events. One commenter noted that more time was necessary because it is hard to reach practitioners and/or providers and leaving messages is not appropriate. The commenter believed that this timeframe is even more problematic where multiple practitioners and/or providers are involved in a single complaint and that should the practitioners and providers be reached on different days, the QIOs would be forced to separately track the response time period applicable to each practitioner and/or provider.

Several commenters suggested that practitioners and providers be allowed to submit new or additional medical information during the opportunity for discussion. Some commenters suggested that refusing to allow the submission of additional medical information is grossly unfair if the amount of time provided for submitting medical information is reduced. Moreover, commenters noted that providers and practitioners could find additional medical documentation in researching the results of the interim initial determination. Other commenters believed that not allowing the submission of additional evidence during the opportunity for discussion would result in the unnecessary filing of additional reconsideration requests. In addition, commenters noted that, frequently, when a physician or provider receives a call regarding the opportunity to discuss the QIOs findings, this is the first time the provider and/or practitioner learns that a complaint has been filed. Thus, the commenters added, the discussion can be helpful to explain the content of the discussion, particularly because the content of the medical information may not be readily available.

Response: While we recognize that any shortening of timeframes creates concerns, our objective is to identify a period of time that ensures beneficiaries obtain resolution of complaints in a timely fashion, while also giving a practitioner or provider an adequate period of time to discuss the QIO's initial findings. In considering the comments, we noted that, while some concerns were related to the ability to reach the physician and/or provider, the primary concerns related to the impact on the QIO's initial decision and request for medical information and not the discussion itself. In fact, QIOs have noted that, rather than focus being given to the discussion of a QIO's findings, the "discussion" instead frequently becomes an additional period of time during which the provider or practitioner attempts to convey additional medical information that was not provided when the request was first made. In shortening the timeframe and restricting the submission of additional medical information, we intend that more focus be given to the discussion with emphasis on improving the quality of care provided. Moreover, many QIOs already conduct the opportunity for discussion based solely on oral communications with the providers and/or practitioners, and we see no need to restrict the process to written exchanges of information in light of the QIOs' historical experience in effectively completing the discussions orally. At the time of the discussion, the QIO has made its interim initial determination, with the specific problematic care and pertinent standard of care being identified. Thus, the discussions can be narrowly focused to the QIO's findings. As such, in considering the public comments provided regarding the opportunity for discussion, we have determined that the 7-day time period is an appropriate period of time to complete this step. However, we recognized that the offer

of the opportunity to discuss the QIO's interim initial determination findings can be the first time the provider and/or practitioner is made aware that a complaint has been filed. Therefore, we have modified the regulations at § 476.130(b) to add new language at paragraph (2) that when requesting medical information in response to a complaint, the QIO must advise that the information is being requested as the result of a complaint and convey to the provider and/or practitioner that they will be given the right to discuss the QIO's interim initial determination. The QIO also must request, at that time, a contact name to ensure the opportunity for discussion can be completed in a timely fashion.

We are not persuaded that an opportunity to submit additional medical information is necessary as part of the opportunity for a discussion. While we appreciate the fact that the ability to submit additional medical information could facilitate the resolution of concerns and avoid the submission of reconsideration requests, we believe that there is sufficient time to ensure QIOs receive the correct medical information to resolve the complaint correctly the first time such that the discussion does not routinely result in the QIO learning that its review was completed without all the medical information. Making providers and practitioners aware that the initial request for medical information is the result of a beneficiary complaint will facilitate the QIOs' receipt of thorough and complete medical information. This will also ensure that the discussions are focused more on ways to improve the quality of care rather than the continued pursuit of obtaining all pertinent medical records.

After consideration of the public comments we received, we are adopting our proposals regarding the beneficiary complaint review process, except for those

modifications to the proposed timeframes related to the issuance of the interim initial determination, the issuance of the final initial determination, the time period provided for requesting a reconsideration, the time given to QIOs for issuing the reconsideration decision, the new notification requirement for medical information requests in response to beneficiary complaints, and the change requiring that written notice of the final initial determination be forwarded in all situations.

2. Completion of General Quality of Care Reviews

As we noted in the proposed rule, although the QIO's responsibility for completing quality of care reviews is already set forth in the QIO program regulations at existing § 476.71(a)(2), the procedures that QIOs use in completing these reviews are not. As we previously noted, many process improvements were incorporated into the new manual instructions mentioned previously (Transmittal 17, April 6, 2012, CMS Manual System, Pub. 100-10 Medicare Quality Improvement Organizations, Chapter 5, Quality of Care Review) (available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R17QIO.pdf). These new instructions were effective May 7, 2012. However, we believe that it was also necessary to propose these regulations to attain additional improvements and to ensure transparency of the QIO program operations.

First, in the CY 2013 OPPS/ASC proposed rule (77 FR 45202), under new § 476.160(a)(1), we proposed to specify those circumstances in which a QIO may conduct a general quality of care review. These circumstances would include those situations where a potential quality of care issue is referred to the QIO by another source,

such as by another CMS contractor, an individual submitting a request anonymously, or another Federal or State entity. In addition, we recognize that more frequently the QIOs are working to use the substantial data available to them to identify potential areas where improvements in the quality of health care could be attained, and we believe these instances should be accounted for as we move forward. We also are aware that QIOs frequently identify potential quality of care issues when conducting other case review activities, including medical necessity reviews, expedited discharge appeals, among others; therefore, we have included this as an instance where a general quality of care review can be initiated.

Under proposed new § 476.160(a)(2), we proposed to specify that the QIO's review will focus on all concerns raised by the source of a referral or report and/or identified by the QIO. While the episode of care should still be considered, it may be less significant for these reviews than those in response to a complaint submitted by a beneficiary, because the main goal of complaint reviews is to address a beneficiary's particular experiences with receiving certain services at a particular time. However, we again proposed under proposed § 476.160(a)(3) that the QIO will use evidence-based standards of care to the maximum extent practicable in completing these reviews, and that the QIO's determination regarding the standard used in completing the review is not subject to appeal.

Under proposed new § 476.160(b), we proposed to specify the responsibility of providers and practitioners to supply requested medical information. This language is identical to the language in proposed new § 476.130(b) applicable to written beneficiary

complaints, including the proposed 10-calendar day timeframe for practitioners and providers to respond to requests for medical information and the QIO's right to request even earlier receipt when the QIO preliminarily determines that a concern may be serious enough to qualify as a gross and flagrant or substantial quality of care concern. Although the decreased timeframe is not related to the goal of providing beneficiaries with more timely resolution of their complaints (because beneficiaries will not be getting results of these reviews), we still believe there is ample justification to warrant the reduced timeframe. Providers and practitioners will benefit from the faster resolution of these reviews and the increased focus on identifying and resolving impediments to improved health care (particularly in cases involving potential serious concerns). These improvements will ultimately benefit patients. Additionally, as with written beneficiary complaints, the timeframes are comparable to models typically used by vendors. We also considered that, as with written beneficiary complaints, the QIOs currently use shorter timeframes where the beneficiaries impacted by the general quality of care review are still receiving care (concurrent review), compared to those situations where a beneficiary has already been discharged (retrospective review). Again, while we did not propose the continued use of the concurrent and retrospective designations, we recognize that there are circumstances, even with general quality of care reviews, where even shorter timeframes may be warranted.

As mentioned previously, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53664 through 53665), we finalized proposed changes to § 476.78 to add references to "practitioners" in parts of this section, which previously referred only to

"providers," in order to equalize the 30-day and 21-day timeframes for submitting records. We also made changes to § 476.90 to equalize the ramifications for not submitting records on time because we see no reason to differentiate between a provider's and a practitioner's records. While these changes in the FY 2013 IPPS/LTCH PPS final rule had not been finalized when we issued the CY 2013 OPPS/ASC proposed rule, in the CY 2013 OPPS/ASC proposed rule, we proposed to modify the current general 30-day and 21-day timeframes in § 476.78(b) to reflect the new timeframes in §§ 476.130(b) and 476.160(b), which apply only to records submitted for purposes of beneficiary complaint and general quality reviews. We also requested public comment on whether changes similar to those we proposed for beneficiary complaints and general quality of care reviews, including shortening of the 30-day and 21-day timeframes, should be incorporated more broadly into § 476.78(b) for requests for medical information in general, for any kind of QIO reviews, including nonquality-related reviews. We proposed to apply a shorter timeframe for all of a QIO's requests for records, without limiting this application to beneficiary complaints or general quality reviews in just one instance; where secure transmissions of electronic versions of medical information are available, we proposed a shorter timeframe. Our proposal regarding secure transmissions of electronic versions of medical information is discussed more fully later in this section.

We also proposed new § 476.160(c), which would specify that the QIO peer reviewer will render the initial determination within 7 calendar days of the receipt of all medical information; this paragraph is substantially different from the proposed

beneficiary complaint review procedures in proposed new § 476.130 in two areas. First, beneficiaries would not be provided any information regarding these reviews. Although we recognize that, at times, potential quality concerns a QIO identifies could impact a specific beneficiary, we believe that this type of review does not warrant any communication directly to the beneficiary. In fact, we believe that giving feedback of potentially poor care to an unknowing beneficiary could cause more anxiety than is warranted by the circumstances, and that is not our goal. We also recognize that, in many situations, the reviews could relate to or involve numerous beneficiaries. However, those beneficiaries may only be a sample of the beneficiaries potentially impacted. This is particularly true in those circumstances where the QIO is reviewing system-related aspects of care, and it will be incumbent upon the QIO to determine what medical information--and by extension the sample of beneficiaries receiving care--to be analyzed in completing these reviews.

Second, we proposed that practitioners and providers not be given an opportunity to discuss the QIO's initial determination before it becomes final. We believe that giving such an opportunity is not necessary, particularly because these discussions frequently become, in effect, an entirely new review by the QIO and not merely a discussion, and because we already proposed at proposed new § 476.170(a) that the practitioner and/or provider be given the right to request a reconsideration of the QIO's initial determination. As with beneficiary complaint reviews, we proposed that this right not be available until after July 31, 2014, to give us time to fully establish the process requirements and ensure

that this right is meaningful for providers and practitioners, although they continue to have the right to request a re-review.

In addition, under proposed new § 476.170(a)(1) through (a)(3), we proposed requirements similar to those in § 476.140 regarding the timeframe for submitting a request for a reconsideration (by noon of the calendar day following initial notification), the obligation of a practitioner and/or provider to be available to answer questions or supply information, as well as the QIO's obligation to offer the provider the opportunity to provide information as part of the reconsideration request. We also proposed provisions under proposed new § 476.170(b) concerning the QIO's issuance of its final decision. This includes the requirement that the QIO's decision be issued within 72 hours after receipt of the request for a reconsideration, or, if later, 72 hours after receiving any medical information or other records needed for such a reconsideration, the specific content of the final decision, and the right of the QIO to provide information to the provider or practitioner regarding opportunities for improving care given to beneficiaries based on the specific findings of its review. The information QIOs provide regarding potential improvements could include specific opportunities related to the practitioner's or provider's delivery of care and/or even broader improvements focusing on the community served by the practitioners and/or providers.

Comment: Commenters conveyed the same concerns regarding several aspects of general quality of care reviews as were raised with beneficiary complaint reviews, including the authority to establish the standards of care and lack of an appeal mechanism for these standards, shorter timeframes for medical information requests, decreased

timeframes for various steps, including the timeframe for rendering the initial determination, the time given to submit reconsideration requests, and the timeframe given to QIOs to render reconsideration decisions.

Response: For the same reasons we discussed regarding beneficiary complaint reviews, we are not making any changes to the proposed regulations regarding the QIOs' authority to establish standards of care, but we are modifying several key timeframes as discussed below. As previously mentioned, we are extending the time period for responding to medical record requests from 10 calendar days to 14 calendar days for all review types, including general quality of care reviews. We are extending the period of time given to the QIO peer reviewer in rendering the initial determination from 7 calendar days to 10 calendar days, and we believe this additional time is warranted to ensure the peer reviewer has adequate time to render a thorough decision. In addition, as with reconsideration requests submitted in response to beneficiary complaints, we are increasing the time to file a reconsideration request from noon of the calendar day following the initial notification to 3 calendar days. We also are increasing the time given to a QIO to complete the reconsideration decision from 72 hours to 5 calendar days. Moreover, we are modifying § 476.160(c) to make clear that the initial determination must be issued in writing and also are adding a corresponding change to § 476.170(a) denoting that a reconsideration request be received within 3 calendar days of the receipt of the written determination.

Comment: Some commenters expressed support for the QIOs' authority to pursue quality of care concerns when a beneficiary decides not to file a complaint.

However, some commenters noted that using the "imminent danger" criterion embedded within the definition of "gross and flagrant" violations was too limiting and QIOs should have more authority to pursue these issues. One commenter questioned why CMS was creating this "new authority" – and a second oversight body - when States already have oversight over hospital quality. This commenter also suggested that the QIOs' efforts are duplicative and thus the overlap of State efforts is problematic.

Response: We appreciate the commenters' support and agree that having QIOs pursue certain quality of care issues, even when a beneficiary chooses not to file a complaint, can be helpful in identifying improvements to the quality of care. However, we believe that some limits should be placed on the type or severity of concerns that QIOs should pursue in order to maximize the use of QIO resources. Thus, we are maintaining the limit on the QIOs' authority to pursue these as conveyed in the proposed regulation.

With regard to the concern that we are creating a "new authority," this is inaccurate. QIOs have actually had and used this authority for more than 30 years, although this is the first time the process requirements have been detailed in regulations. We are obligated to ensure the effective implementation of the QIO program in light of the statutory authority granted the QIOs, regardless of whether certain State programs have been established to address similar issues.

Comment: Several commenters expressed concern regarding the proposed removal of the right to request an opportunity for discussion. The commenters expressed concern that the QIO could make decisions on these concerns without an opportunity for

a counter argument from the involved practitioner and/or provider. Several commenters suggested that the change would merely result in the receipt of more reconsideration requests being filed based on initial determinations being made without input from the involved practitioner and/or provider or the ability to obtain additional medical information. Other commenters suggested that providers and practitioners should have the same rights to due process here as with beneficiary complaint reviews and that the discussion can often clarify the concerns so that the provider or practitioner is better able to respond. Some commenters suggested that the opportunity for discussion was necessary because, in comparison to beneficiary complaints, these concerns are often the most serious cases because they include issues identified by the QIO through evaluation of other QIO review activities or from referrals from other agencies.

Response: Although we appreciate the concerns raised regarding the removal of this step, we believe that it is not necessary for purposes of general quality of care reviews because, as many commenters acknowledged, the discussion has become little more than an opportunity to convey additional medical information to the QIO with no actual discussion occurring about ways to improve the quality of care. We believe that there are modifications that can be made to the manner in which medical information is initially requested by the QIO to ensure that all medical information is obtained prior to the QIO's review, and we will work to ensure that these modifications are incorporated into the QIO's processing requirements. This will then eliminate what many commenters suggested was the primary purpose of the opportunity for discussion.

Moreover, there is a statutory distinction between situations in which discussions have been specifically required and those in which they are not. In those circumstances where Congress believed that such an opportunity to discuss a particular type of issue was warranted, the right was specifically added to the statute, as in section 1154(a)(3)(B)(ii) of the Act regarding those situations where an item or service furnished or to be furnished is disapproved and section 1154(a)(14) of the Act regarding written beneficiary complaints.

In terms of the commenters' other concerns—that providers and practitioners will not have an opportunity to make counter arguments, that decisions would be made without input from the involved practitioners or providers, that providers and practitioners will not have the same rights to due process as in beneficiary complaint reviews, and that providers' and practitioners' concerns in general quality reviews often involve the most serious cases--we would note that these parties continue to have the opportunity to make counter arguments and give input on the QIO's decisions by requesting a re-review until the reconsideration right becomes available. A provider's or practitioner's right to request a re-review is, in fact, a due process right that beneficiaries are not given. Providers and practitioners also will have an opportunity to present their point of view in the context of a reconsideration when that right is implemented, and beneficiaries will be afforded the same right.

After consideration of the public comments we received, we are adopting as final our proposals regarding general quality of care reviews, except that we have extended the timeframes for submitting medical records to 14 calendar days, rendering the initial

determination to 10 calendar days, filing a reconsideration request to 3 calendar days, and issuing the reconsideration decision to 5 calendar days.

C. Use of Confidential Information That Explicitly or Implicitly Identifies Patients

The QIO regulations at § 480.101(b) define any information that explicitly or implicitly identifies an individual patient as confidential information. Although provisions are included in 42 CFR Part 480 governing a practitioner's and/or provider's right to allow a QIO to use or disclose confidential information about the named practitioner or provider (§§ 480.105(b), 480.133(a)(2)(iii), and 480.140(d)), a similar right is not conveyed for beneficiaries. Thus, QIOs are prohibited from obtaining a beneficiary's authorization to use or disclose the beneficiary's confidential information, even in situations where a use or disclosure could be helpful to the beneficiary and his or her health care or even where the beneficiary specifically asks the QIO to disclose the information.

One of the key challenges for the QIOs is identifying improvements in health care delivery systems. In fact, the "patient-centeredness" aim of the QIO's current scope of work requires more patient involvement, and the goal of many patient and family engagement efforts is to incorporate a "real-world person's" experiences to demonstrate the compelling and urgent need for healthcare delivery reform. Additionally, beneficiaries have asked to participate in the QIO's work in a meaningful way. Unfortunately, we are often unable to accommodate these requests in light of the current regulatory restriction. We believe that this restriction, which was developed may years

ago, is outdated, and that beneficiaries should be given the right to make choices regarding the use and disclosure of their confidential information.

Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45204), we proposed new § 480.145 that will govern a beneficiary's right to authorize a QIO's use or disclosure of the beneficiary's confidential information. Under proposed § 480.145(a), we proposed that, except as otherwise authorized by the QIO confidentiality regulations, a QIO may not use or disclose a beneficiary's confidential information without an authorization from the beneficiary and that the QIO's use or disclosure must be consistent with the authorization. Under proposed § 480.145(b)(1) through (b)(6), we listed those aspects of an authorization necessary to make the authorization valid. This includes the requirements that a specific and meaningful description of the confidential information be included, and that the authorization also include the name(s) of the QIO(s) and QIO point(s) of contact making the request to use or disclose the information, the name or other specific identification of the person, or class of persons to whom the QIO may allow the requested use or make the requested disclosure, a description of the purpose(s) of the use or disclosure, the date or event upon which the authorization will expire, and the signature and date of the beneficiary authorizing the use and/or disclosure of the information. We also proposed under § 480.145(c)(1) and (c)(2) that the authorization must contain a statement that the beneficiary maintains the right to revoke his or her authorization in writing and that the QIO must specify any exceptions to the right to revoke, as well as the process a beneficiary must use to revoke the authorization. In addition, under § 480.145(c)(3), we proposed the requirement that the QIO convey to the

beneficiary its inability to condition the review or other activities it is responsible for (such as beneficiary complaint reviews, medical necessity of a beneficiary's services, or discharge appeals) on whether or not the beneficiary provides authorization. We also proposed under § 480.145(c)(4) to make clear the consequences of authorizing the use or disclosure of information, and the fact that the QIO may be unable to protect the information from redisclosure. Under § 480.145(d), we proposed that an authorization must be written in plain language, and under § 480.145(e) that a QIO must provide the beneficiary with a copy of the signed authorization. Lastly, although we make reference to a beneficiary's right to revoke authorization under proposed § 480.145(c)(1), in paragraph (f) we proposed a specific provision that will make clear that a beneficiary may revoke, in writing, an authorization at any time, except when the QIO has taken action in reliance upon the authorization.

We believe that these proposed changes appropriately relax some of the historical restraints on the QIO's use of a beneficiary's confidential information, enable QIOs to better meet the needs of Medicare beneficiaries, and give beneficiaries the opportunity to participate in efforts to improve the quality of their health care.

Comment: Several commenters supported this new authority. One commenter requested that the regulations should also be changed to allow for the use of video as well as social media, while another commenter requested that whatever authorization form CMS develops should be in plain, understandable language and as short as possible.

Response: We appreciate the support for this new regulatory authority. We believe that the regulatory provisions as proposed already give the flexibility to use video

and social media. The proposed regulations specify the beneficiary's right to authorize the use of his or her confidential information and the mechanism through which QIO's can obtain this authorization. However, the provisions do not, in any way, restrict the use of the confidential information to one specific mechanism, such as print advertisements. In terms of the development of an authorization form, at this time we do not intend to develop such a form. Each QIO will be responsible for developing an authorization form that meets the requirements of the new regulatory provisions.

After consideration of the public comments we received, we are adopting, without modification, our proposals regarding the use of confidential information that implicitly or explicitly identifies patients.

D. Secure Transmissions of Electronic Versions of Medical Information

When the QIO program regulations were first written in 1985, computers, along with digitally or electronically stored information, were still in their infancy. Thus, the QIO program regulations were written based on the perspective that most information sharing would be through the exchange of paper copies of medical records and other information. Since that time, we have seen great advances in the ability to electronically share data, whether through the use of mass storage devices (flash drives), the sending and receipt of electronic facsimiles, and even the use of e-mail. At the same time, several laws, including HIPAA and the Federal Information Security and Management Act (FISMA), have been established to protect sensitive information. However, because the QIO program regulations have not undergone significant modification since they were originally adopted, the regulations do not account for electronic sharing of information

and the QIOs' work is carried out within the context of exchanging paper copies of documents and information. At times, this creates additional work and costs because those providers and practitioners who have the ability to securely share electronic versions of medical records must actually print out the records and pay to have the paper copies mailed to the QIOs.

To address these issues, in the CY 2013 OPPS/ASC proposed rule (77 FR 45204) we proposed to revise existing § 476.78(b)(2) to add a new paragraph (iii) to make clear the QIOs' right to exchange secure transmissions of electronic versions of medical information, subject to a QIO's ability to support the exchange of the electronic version. We believe that this proposal would enable QIOs to receive and send medical information in a variety of formats, including through secure electronic faxes, and would reduce costs for providers and practitioners because they would no longer have to print and mail paper copies. In addition, to fully take advantage of the ability to receive and send electronic versions of medical information, we believe that a reduced timeframe is warranted for those instances where electronic versions are to be forwarded in response to requests from a QIO. Therefore, we proposed under proposed § 476.78 (b)(2)(iii) to require providers and practitioners to deliver electronic versions of medical information within 10 calendar days of the request from the QIO. As we noted previously, changes to existing § 476.78(b) have already been adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53664 through 53665). As discussed earlier in this preamble, we proposed in the CY 2013 OPPS/ASC proposed rule additional changes to § 476.78 to take into account the different, more expedited timeframes we proposed for medical records

related to beneficiary complaint and general quality of care reviews. In the CY 2013 OPPS/ASC proposed rule (77 FR 45204), we also requested public comments on whether additional changes should be made to § 476.78(b) to expand the different timeframes to cover medical records for all kinds of reviews. We also requested public comments on whether any modifications should be made to the reimbursement methodologies for paper copies described in § 476.78(c). We note that we carried forth in the proposed rule the proposed change to the section heading for § 476.78 that was included in the FY 2013 IPPS/LTCH PPS proposed rule, that is, the proposed change from "Responsibilities of health care facilities" to "Responsibilities of providers and practitioners" (which has now been finalized).

Comment: Several commenters supported the proposed regulation that would enable QIOs to securely transmit electronic versions of medical information. Some commenters noted that the ability to transmit information electronically is a long overdue process change and the QIOs have been "severely hampered" by not being allowed to incorporate more electronic exchanges of information into their activities. These commenters also urged CMS to consider how QIOs can more effectively accept electronic records. Other commenters, while supportive of the proposal to allow QIOs to securely transmit electronic versions of medical information, cautioned CMS that QIOs will need instructions, equipment and electronic exchange infrastructure to be in place before these changes are implemented. Some commenters noted that ensuring remote access to CMS information systems for QIO staff and access to medical information is necessary to achieve the full benefits of this proposed regulation because peer reviewers

frequently are not located onsite at the QIOs' place of business. Some commenters noted that the ability to securely transmit electronic versions of information is particularly significant in light of the proposed tighter timeframes for completing review activities, while other commenters expressed concerns surrounding the ability to correctly track the differences in timeframes for responding to different types of requests. In addition, some commenters suggested that the proposed provision could help reduce costs related to the shipping of paper copies of medical information from providers and practitioners to the QIO, as well as from the QIOs to their physician reviewers and then back to the QIOs.

Response: We appreciate the commenters' support and agree that instructions, equipment, and electronic exchange infrastructure must be put in place in order to take full advantage of this new flexibility. We are currently initiating efforts to allow QIOs to receive electronic versions of medical information in multiple ways, as well as exchange these electronic versions with staff, including peer reviewers, remotely. We agree that this new flexibility can only facilitate providers' and practitioners' ability to comply with requests for medical information and also anticipate that the opportunity to use electronic exchanges will enable QIOs to complete their activities more quickly at reduced costs compared to the use of paper copies of medical records. Moreover, we appreciate that providers and practitioners receive a variety of requests for medical records and that these requests are not just from QIOs. Thus, tracking the different timeframes can be problematic. As we previously noted, we are adopting a uniform 14 calendar day timeframe for responding to requests for medical information for all requests, except that

QIOs will maintain the authority to request medical information more quickly if circumstances warrant earlier receipt.

Comment: Some commenters stated that the amounts of reimbursement for photocopies do not adequately cover the cost of what it takes to generate the requested records and that the methodology for determining reimbursement rates needs to be routinely updated to keep pace with inflation.

Response: We thank the commenters for their input. At this time we are continuing to examine ways to possibly accommodate changes in reimbursement rates. We plan to consider various factors, such as how the new flexibility to securely transmit electronic versions of medical information might affect the payments we will be able to make for the submission of paper records. We are not making specific changes at this time, but will consider the commenters' input as we pursue possible changes to these regulations in future rulemaking.

After consideration of the public comments we received, we are adopting, as final, our proposals regarding secure transmissions of electronic versions of medical information, except that we are extending the timeframe for submission of medical information to 14 calendar days.

E. Active Staff Privileges

In our efforts to ensure the QIO program is able to meet the needs of Medicare beneficiaries and improve the quality of health care moving forward, we have identified an aspect of the QIO program regulations that has become increasingly problematic for the QIOs. Under existing § 476.98(a)(1), QIOs are required to use an individual with

"active staff privileges in one or more hospitals" in making initial denial determinations. However, there is an accelerating trend toward primary care physicians (family physicians/internists) who provide care solely in the outpatient care settings and a corresponding decline in the number of family practice physicians who provide any care in hospitals. In fact, many of these individuals do not provide any inpatient care and either have no hospital privileges or only "courtesy" privileges, which do not meet the definition in existing § 476.1 of "active staff privileges." While we believe that the continued use of peer reviewers is necessary and vital to the success of the QIO program, the need to use physicians with "active staff privileges" is not. We believe that the proposed removal of this requirement would increase the number of peer reviewers available for use by the QIOs, which, at times, has become particularly problematic for the QIOs. Therefore, in the CY 2013 OPPS/ASC proposed rule (77 FR 45204 through 45205), we proposed to remove the definition of "active staff privileges" under § 476.1 and to remove the phrase referring to using individuals "with active staff privileges in one or more hospitals in the QIO area" in making initial denial determinations under § 476.98(a)(1).

Comment: Several commenters opposed the proposal to remove "active staff privileges" as a requirement for peer reviewers making an initial denial determination and indicated that having active staff privileges is necessary because there is a need to ensure peer reviewers are cognizant of "emerging clinical evidence and practices," particularly because clinical practice can change so rapidly. Others commenters noted that CMS should at least require active staff privileges in the State where the care was provided,

while some commenters may have misunderstood the terminology and believed that the change would enable QIOs to use physicians who are not actively practicing. Some commenters also noted that requiring QIOs to use physicians with active staff privileges made assessing the care provided by potential reviewers easier because it supplemented the information QIOs could glean from State licensure, National Practitioner Data Bank, and self-reported information, and that the use of physicians with active staff privileges added to the credibility of the QIOs' peer review activities in the medical community.

Several commenters supported the removal of this requirement and believed it would allow for the inclusion of more specialized physician reviewers, provide more flexibility to QIOs in hiring peer reviewers by increasing the pool of eligible reviewers, and more closely mirror the current practicing medical environment. In particular, one commenter noted that, by removing this language, QIOs would be able to rely more on "setting-based" expertise (such as a nursing home or clinic), than is currently allowed by the more narrow active staff privilege requirement. Another commenter supported the change but not the removal of the phrase "in the QIO area" because of a concern that it could be interpreted to mean that a physician from outside the QIO's review area could conduct the review.

Response: We appreciate the comments and agree that having physicians with current, relevant knowledge of medical care is imperative to the operations of the QIOs and its cadre of physician reviewers. However, it appears that some commenters erroneously equated the removal of the active staff privileges requirement to the QIOs' use of physicians who were not actively practicing medicine. This is inaccurate and

QIOs are obligated to use physicians who are actively practicing. Other commenters believed that physicians with active staff privileges would be those with the most current and relevant knowledge of medical care that is the subject of the QIO's review. However, we are unaware of any studies or research supporting this claim. In identifying physicians for use as reviewers, the QIOs would still be able to procure the services of actively practicing physicians with knowledge of the most current, relevant medical care. We believe that the removal of the active staff privileges requirement, however, would enable QIOs to better match and utilize the expertise of physicians to the actual settings in which the care in question is provided. That is because, historically, the requirement to use a physician with active staff privileges could prevent the use of a physician who practiced in, and was more intimately familiar with, the care provided in a particular setting (for example, a nursing home setting) if that physician lacked active staff privileges in a hospital.

While it is possible that the removal of this requirement might result in a QIO being obligated to take some additional steps in evaluating the performance or effectiveness of a potential peer reviewer, we see no reason why having QIOs assume these extra steps should amount to a significant addition to their workload. We regard these steps as an essential part of the process a QIO should follow in finding the best match, including by specialty and setting, for any particular review activity. Lastly, while we appreciate the concern that removal of the language "in the QIO area" could cause confusion surrounding the QIO's obligation to use a physician within the QIO's area, we note that, in fact, this obligation continues to be clearly laid out in provisions of

the statute, including in section 1154(a)(7) of the Act, and in other references within the regulations at 42 CFR Part 476. However, in order to minimize any possible confusion, we are modifying the proposal to maintain the "in the QIO area" language within § 476.98(a)(1).

After consideration of the public comments we received, we are adopting as final our proposal to remove the language regarding active staff privileges, except that we are maintaining the language "in the QIO area."

F. Technical Corrections

In addition to the proposed changes discussed above, in the CY 2013 OPPS/ASC proposed rule (77 FR 45205), we proposed to make the following technical corrections to the QIO regulations:

- In 1989, several sections in 42 CFR Part 405 were redesignated to 42 CFR Part 411 (54 FR 41746), but the cross-references to these sections in the QIO regulations was never made. Therefore, we proposed to make the following reference changes:

+- Changing the reference "§ 405.330(b)" in existing § 476.71(b) to "§ 411.400(b)";

+- Changing the reference "§ 405.332" in § 476.74 to "§ 411.402";

+ Changing the references "§ 405.310(g) or § 405.310(k)" in § 476.86 to "§ 411.15(g) or § 411.15(k)".

● In 1999, 42 CFR Parts 466, 473, and 476 were redesignated as 42 CFR Parts 476, 478, and 480, respectively (64 FR 66236). Therefore, we proposed to make changes to correct several cross-references to sections in these Parts:

+ Changing the reference "§ 466.73(b)(3)" in § 476.73 to "§ 476.78(b)(3)".

+ Changing the reference "part 473" in § 476.78(f) to "part 478".

+ Changing the reference "part 473" in § 476.94(c)(3) to "part 478".

+ Changing the reference "§ 473.24" in §§ 480.132 and 480.133 to "§ 478.24".

+ Changing the reference "§ 466.98" in § 478.28 to "§ 476.98".

+ Changing the reference to "Part 478" in §§ 478.15, 478.16, 478.20, 478.38, 478.42, and 478.48 to "Part 473".

+ Changing the reference "§ 473.24" in § 480.132 to "§ 478.24".

+ Changing the references "Part 466" and "§ 473.24" in § 480.133(b) to "Part 476" and "§ 478.24", respectively.

● We proposed the deletion of several provisions in Part 476 regarding risk-basis contracts because risk-basis contracts previously under section 1876 of the Act no longer exist. As such, these provisions are obsolete and no longer used under the QIO program. Specifically, we are deleting the following sentence from § 476.70(a): "Section 1154(a)(4) of the Act requires QIOs, or, in certain circumstances, non-QIO entities, to perform quality of care reviews of services furnished under risk-basis contracts by health maintenance organizations (HMOs) and competitive medical plans (CMPs) that are covered under subpart C of part 417 of this chapter." We proposed to delete the following sentence from § 476.70(b): "Section 466.72 of this part also applies, for

purposes of quality of care review under section 1154(a)(4) of the Act, to non-QIO entities that enter into contracts to perform reviews of services furnished under risk basis contracts by HMOs and CMPs under subpart C of part 417 of this chapter." We proposed to delete § 476.72 - Review of the quality of care of risk-basis health maintenance organizations and competitive medical plans, in its entirety for the same reason.

- In § 476.70(a), we proposed to change the word "basis" to "bases" to match the title of this section and to correctly denote that there is more than one statutory basis described in paragraph (a).

- We proposed technical corrections to sections in Part 476 and 480 to accurately reflect the transition to Medicare administrative contractors (MACs) to process Medicare claims and conduct other actions. This transition is ongoing, and fiscal intermediaries and carriers still exist. However, we believe that the presence of MACs should be accounted for to accurately reflect current contractual relationships. As such, we proposed to incorporate references to "Medicare administrator contractors" in the following sections, where appropriate:

+ § 476.1, in the definition of "Preadmission Certification";

+ § 476.71(c)(1);

+ § 476.73(a);

+ § 476.74(b) and (c)(1);

+ § 476.80 section heading, and §§ 476.80(a), (a)(1), (a)(2), (b)(1), (c), (c)(3)(ii), (d)(1), (d)(2), (e) paragraph heading, (e)(1), and (e)(2);

+ § 476.86(a)(2), (c) introductory text, (c)(1), and (d);

+ § 476.94(a)(1)(iv) and (d);

+ § 476.104(a); and

+ § 480.105(a).

● We proposed a technical correction to § 480.139 by adding a paragraph "(a)" in front of "(1)" to the beginning of the text of the section to correct a recent inadvertent coding error which had removed the "(a)".

● We proposed to correct the statutory citation in § 480.132(b) by changing "section 1154(a)(3)" to "section 1154(a)(2)".

Comment: Commenters agreed with the proposed technical changes.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are adopting, without modification, our proposals regarding the technical changes.

XIX. Files Available to the Public via the Internet

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 the CY 2013 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 "1589-FC" from the list of regulations. All Addenda for this final rule with comment period are contained in the zipped folder entitled "2013 OPPS 1589-FC Addenda" at the bottom of the page.

To view the Addenda of this final rule with comment period pertaining to the CY 2013 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 "1589-FC" from the list of regulations. All Addenda for this final rule with comment period are contained in the zipped folder entitled "Addenda AA, BB, DD1 and DD2", and "Addendum EE" at the bottom of the page.

XX. 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 estimated 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 2013 OPPS/ASC proposed rule (77 FR 45206), we solicited public comments on each of the issues outlined above as discussed below that contained information collection requirements.

B. Requirements in Regulation Text

1. 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs (§ 495.8)

Under the definition of "meaningful EHR user" in 42 CFR 495.4, we require eligible hospitals and CAHs participating in the Medicare EHR Incentive Program (which would include those participating in the 2013 Medicare EHR Incentive Program Electronic Reporting Pilot) to successfully report the hospital clinical quality measures (CQMs) selected by CMS to CMS in the form and manner specified by CMS. Although eligible hospitals and CAHs may continue to report CQM results as calculated by certified EHR technology by attestation for 2013, they also may choose to participate in

the 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs. Eligible hospitals and CAHs participating in the 2013 Medicare EHR Incentive Program Electronic Reporting Pilot must submit CQM data on all 15 CQMs (listed in Table 10 of the Stage 1 final rule (75 FR 44418 through 44420) for the Medicare and Medicaid EHR Incentive Program) to CMS, via a secure transmission based on data obtained from the eligible hospital or CAH's certified EHR technology.

Eligible hospitals and CAHs are required to report on core and menu set criteria for Stage 1 of meaningful use. We estimated that it would take an eligible hospital or CAH 0.5 hour to submit the required CQM information via the proposed 2013 Medicare EHR Incentive Program Electronic Reporting Pilot. Therefore, the estimated total burden for all 4,922 Medicare eligible hospitals and CAHs participating in the Pilot (3,620 acute care hospitals and 1,302 CAHs) is 2,461 hours.

We believe that an eligible hospital or CAH might assign a computer and information systems manager to submit the CQM information on its behalf. We estimated the cost burden for an eligible hospital or CAH to submit the CQMs and hospital quality requirements is $30.21 (0.5 hour x $60.41 (mean hourly rate for a computer and information systems manager based on the 2011 Bureau of Labor Statistics)) and the total estimated annual cost burden for all eligible hospitals and CAHs to submit the required CQMs is $148,694 ($30.21 x 4,922 hospitals and CAHs). We solicited public comments on the estimated numbers of eligible hospitals and CAHs that may register for the Medicare EHR Incentive Program Electronic Reporting Pilot that would submit the CQM information via the proposed Electronic Reporting Pilot in 2013.

We also invited comments on the type of personnel or staff that would mostly likely submit on behalf of eligible hospitals and CAHs.

We did not receive any public comments on these information collection requirements. Therefore, we are finalizing the proposed burden estimates.

C. Associated Information Collections Not Specified in Regulatory Text

In the CY 2013 OPPS/ASC proposed rule, we made reference to proposed associated information collection requirements that are not discussed in the regulation text contained in the proposed rule. The following is a discussion of those requirements.

1. Hospital OQR Program

As previously 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 72064 through 72110 and 72111 through 72114) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74549 through 74554) for detailed discussions of the Hospital OQR Program information collection requirements we have previously finalized.

2. Hospital OQR Program Measures for the CY 2012, CY 2013, CY 2014, and CY 2015 Payment Determinations

a. Previously Adopted Hospital OQR Program Measures for the CY 2012, CY 2013, and CY 2014 Payment Determinations

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766), we retained the 7 chart-abstracted measures we used in CY 2009 and adopted 4 new

claims-based imaging measures for the CY 2010 payment determination, bringing the total number of quality measures for which hospitals had to submit data to 11 measures. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60637), we required hospitals to continue to submit data on the same 11 measures for the CY 2011 payment determination. The burden associated with the aforementioned data submission requirements is currently approved under OCN: 0938-1109. This approval expires on October 31, 2013.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72071 through 72094), we adopted measures for the CY 2012, CY 2013, and CY 2014 payment determinations.

For the CY 2012 payment determination, we retained the 7 chart-abstracted measures and the 4 claims-based imaging measures we used for the CY 2011 payment determination. We also adopted 1 structural HIT measure that tracks HOPDs' ability to receive laboratory results electronically, and 3 claims-based imaging efficiency measures. These actions bring the total number of measures for the CY 2012 payment determination for which hospitals must submit data to 15 measures. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72112 through 72113), we discussed the burden associated with these information collection requirements.

For the CY 2013 payment determination, we required that hospitals continue to submit data for all of the quality measures that we adopted for the CY 2012 payment determination. We also adopted 1 structural HIT measure assessing the ability to track clinical results between visits, 6 new chart-abstracted measures on the topics of HOPD

care transitions and ED efficiency, as well as 1 chart-abstracted ED-AMI measure that we proposed for the CY 2012 payment determination but which we decided to finalize for the CY 2013 payment determination. These actions bring the total number of quality measures for the CY 2013 payment determination for which hospitals must submit data to 23 measures.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72071 through 72094), for the CY 2014 payment determination, we retained the CY 2013 payment determination measures, but did not adopt any additional measures. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72112 through 72113), we discussed the burden associated with these information collection requirements.

b. Hospital OQR Program Measures for the CY 2014 Payment Determination

In the CY 2011 OPPS/ASC final rule with comment period, we did not adopt any new measures for the CY 2014 payment determination. In the CY 2012 OPPS/ASC final rule with comment period, we added, for the CY 2014 payment determination, 1 chart-abstracted measure and 2 structural measures (including hospital outpatient volume data for selected outpatient surgical procedures). However, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74456), we did not implement public reporting of the claims-based OP: 15 Use of Brain Computed Tomography (CT) in the ED for Atraumatic Headache. Because this is a claims-based measure, hospitals continue to submit relevant claims to be paid, but these administrative data and any measure calculations from them are not being made publicly available as

specified for required hospital outpatient hospital quality of care measure data under section 1833(t)(17)(E) of the Act.

In addition, in section XV.C. of the proposed rule, we stated that we were confirming that, using a subregulatory process, we have suspended indefinitely data collection for one measure, OP-19: Transition Record with Specified Elements Received by Discharged Patients, and have deferred data collection for another measure, OP-24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting. (We note that, in this final rule with comment period, we are confirming the removal of the measure, OP-16: Troponin results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with probable cardiac chest pain) received within 60 minutes of arrival, and we will cease data collection in the system for this measure effective January 1, 2013.) Thus, for the CY 2014 and subsequent years payment determinations, as proposed, we are finalizing in this final rule with comment period a total of 25 measures (rather than 26 measures as we indicated in the proposed rule (77 FR 45207), with hospitals reporting data on only 22 of them (rather than 23 measures as we indicated in the proposed rule (77 FR 45207)). The required measure set for the CY 2014 and subsequent years' payment determinations includes the measures shown below; all measures were previously adopted.

Hospital OQR Program Measures for the CY 2014, CY 2015 and Subsequent Years Payment Determinations
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

Hospital OQR Program Measures for the CY 2014, CY 2015 and Subsequent Years Payment Determinations	
OP-6: Timing of Antibiotic Prophylaxis	
OP-7: Prophylactic Antibiotic Selection for Surgical Patients	
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-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data	
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*	
OP-17: Tracking Clinical Results between Visits	
OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	
OP-19: Transition Record with Specified Elements Received by 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	
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	
OP-24: Cardiac Rehabilitation Patient Referral from an Outpatient Setting***	
OP-25: Safety Surgery Checklist	
OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures	
Procedure Category	**Corresponding HCPCS Codes**
Gastrointestinal	40000 through 49999, G0104, G0105, G0121, C9716, C9724, C9725, and 0170T
Eye	65000 through 68999, G0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, and 0099T
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, and 0062T
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, and 0201T

Hospital OQR Program Measures for the CY 2014, CY 2015 and Subsequent Years Payment Determinations	
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, and C9727
Genitourinary	50000 through 58999, 0193T, and 58805
Cardiovascular	33000 through 37999
Respiratory	30000 through 32999

*Information for OP-15 will not be reported in Hospital Compare in 2012. Public reporting for this measure would occur in July 2013 at the earliest.
**Data collection for OP-19 was suspended effective with January 1, 2012 encounters until further notice.
***Data collection for OP-24 is deferred from January 1, 2013 to January 1, 2014, and its first application toward a payment determination would be for CY 2015 rather than CY 2014.

We will calculate the six claims-based measures (rather than seven claims-based measures as indicated in the proposed rule (77 FR 45207) using Medicare FFS claims data and do not require additional hospital data submissions. With the exception of OP-22, we are using the same data submission requirements related to the chart-abstracted quality measures that are submitted directly to CMS that we used for the CY 2011 and CY 2012 payment determinations. For the four structural measures, including the collection of data for all-patient volume for selected outpatient procedures, hospitals will enter data into a Web-based collection tool during a specified collection period once annually. Under the Hospital OQR Program requirements, hospitals must complete and submit a notice of participation form for the Hospital OQR Program if they have not already done so or have withdrawn from participation. By submitting this document, hospitals agree that they will allow CMS to publicly report the measures for which they have submitted data under the Hospital OQR Program.

For the CY 2014 payment determination, the burden associated with these requirements is the time and effort associated with completing the notice of participation

form, and collecting and submitting the data on the required measures. For the chart-abstracted measures (including those measures for which data are submitted directly to CMS, as well as the OP-22 measure for which data will be submitted via a Web-based tool rather than via an electronic file), we estimated that there will be approximately 3,200 respondents per year. For hospitals to collect and submit the information on the chart-abstracted measures (excluding the chart-abstracted OP-22 measure), we estimated it will take 35 minutes per sampled case. Based upon the data submitted for the CY 2011 and CY 2012 payment determinations, we estimated there will be a total of 1,628,800 cases per year, approximately 509 cases per year per respondent. The estimated annual burden associated with the submission requirements for these chart-abstracted measures is 949,590 hours (1,628,800 cases per year x 0.583 hours per case).

For the chart-abstracted OP-22 measure plus the 3 structural measures (excluding the all-patient volume for selected surgical procedures measure), we estimated that each participating hospital will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with these measures 2,138 hours (3,200 hospitals x 0.167 hours per hospital x 4 measures per hospital). For the proposed rule (77 FR 45208), we inadvertently stated the burden to be 1,603 hours because we excluded the OP-22 measure in our burden computation.

For the collection of all-patient volume for selected outpatient surgical procedures (OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures), because hospitals must determine their populations for data reporting purposes and most hospitals are voluntarily reporting population and sampling data for Hospital OQR

Program purposes, we believe the only additional burden associated with this requirement is the reporting of the data using the Web-based tool. We estimated that each participating hospital will spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with this measure 534 hours (3,200 hospitals x 0.167 hours per measure x 1 all-patient volume measure per hospital). We note that we inadvertently indicated that the total of this computation was 53 hours in the proposed rule (77 FR 45208).

We did not receive any public comments on these information collection requirements and, therefore, are finalizing our proposed burden estimates with the modifications we have described above.

c. Hospital OQR Program Measures for CY 2015

In the CY 2012 OPPS/ASC final rule with comment period, for the CY 2015 payment determination, we retained the requirement that hospitals must complete and submit a notice of participation form in order to participate in the Hospital OQR Program. For the CY 2015 payment determination, we also retained the measures used for CY 2014 payment determination (including the measures adopted in the CY 2012 final rule with comment period) and did not add any additional measures.

For the CY 2015 payment determination, the burden associated with these requirements is the time and effort associated with completing the notice of participation form, collecting and submitting the data on the measures, and collecting and submitting all-patient volume data for selected outpatient surgical procedures. For the chart-abstracted measures, we estimated that there will be approximately 3,200

respondents per year. For hospitals to collect and submit the information on the chart-abstracted measures where data are submitted directly to CMS (excluding the chart-abstracted OP-22 measure), we estimated it will take 35 minutes per sampled case. Based upon the data submitted for the CY 2011 and CY 2012 payment determinations, we estimated there will be a total of 1,628,800 cases per year, approximately 509 cases per year per respondent. The estimated annual burden associated with the aforementioned submission requirements for the chart-abstracted data is 949,590 hours (1,628,800 cases per year x 0.583 hours per case).

For the chart-abstracted OP-22 measure plus the 3 structural measures (excluding the all-patient volume for selected surgical procedures measure), we estimated that each participating hospital will spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with these measures 2,138 hours (3,200 hospitals x 0.167 hours per hospital x 4 measures per hospital). In the proposed rule (77 FR 45208), we inadvertently excluded the OP-22 measure in our burden computation.

For the collection of all-patient volume data for selected outpatient surgical procedures, because hospitals must determine their populations for data reporting purposes and most hospitals are voluntarily reporting population and sampling data for Hospital OQR purposes, we believe the only additional burden associated with this requirement will be the reporting of the data using the Web-based tool. We estimated that each participating hospital will spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with this measure 534 hours (3,200

hospitals x 0.167 hours per hospital). We note that we inadvertently indicated that the total of this computation was 53 hours in the proposed rule (77 FR 45208).

We invited public comment on the burden associated with the information collection requirements.

We did not receive any public comments on these information collection requirements and, therefore, are finalizing our proposed burden estimates with the modifications we have described above.

3. Hospital OQR Program Validation Requirements for CY 2014

In the CY 2013 OPPS/ASC proposed rule, we proposed to retain the requirements related to data validation for CY 2014 that we adopted in the CY 2011 OPPS/ASC final rule with comment period (76 FR 74486) for CY 2013, and that we revised in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74553). While these requirements are subject to the PRA, they are currently approved under OCN: 0938-1109. This approval expires on October 31, 2013.

Similar to our approach for the CY 2013 Hospital OQR Program payment determination (76 FR 74484 through 74485), we proposed to continue to validate data from randomly selected hospitals for the CY 2014 payment determination, selecting 450 hospitals. We note that, because hospitals would be selected randomly, every hospital participating in the Hospital OQR Program would be eligible each year for validation selection.

In the CY 2011 OPPS/ASC proposed rule and final rule with comment period (75 FR 46381 and 75 FR 72106, respectively), we discussed additional data validation

conditions under consideration for CY 2013 and subsequent years. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485 and 76 FR 74553), we finalized a policy under which we will select for validation up to 50 additional hospitals based upon targeting criteria.

For each selected hospital (random or targeted), generally we will randomly select up to 48 patient encounters per year (12 per quarter) for validation purposes from the total number of cases that the hospital successfully submitted to the OPPS Clinical Warehouse during the applicable time period. However, if a selected hospital submitted less than 12 cases in one or more quarters, only those cases available would be validated.

The burden associated with the CY 2014 requirement is the time and effort necessary to submit validation data to a CMS contractor. We estimated that it would take each of the sampled hospitals approximately 12 hours to comply with these data submission requirements. To comply with the requirements, we estimated each hospital must 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 CY 2014 is approximately 6,000 hours.

We proposed to maintain the deadline of 45 days for hospitals to submit requested medical record documentation to a CMS contractor to support our validation process.

We invited public comment on the burden associated with these information collection requirements.

We did not receive any public comments on these information collection requirements. Therefore, we are finalizing our burden estimates as proposed.

4. Hospital OQR Program Reconsideration and Appeals Procedures

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68779), we adopted a mandatory reconsideration process that applied to the CY 2010 payment decisions. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60654 through 60655), we continued this process for the CY 2011 payment update. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72106 through 72108), we continued this process for the CY 2012 payment update with some modifications. We eliminated the requirement that the reconsideration request form be signed by the hospital CEO to facilitate electronic submission of the form and reduce hospital burden. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74487 and 74488 and 76 FR 74553 and 74554), we specified that we were continuing this process for the CY 2013 and subsequent years' payment determinations.

In this CY 2013 OPPS/ASC final rule with comment period, we are making one change to this process--to modify a requirement that the CEO must sign the reconsideration request to allow the CEO or other designated personnel to sign the required form.

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.

We did not receive any public comments on our proposed burden statement and therefore are finalizing it with modification in this final rule with comment period.

5. ASCQR Program Requirements

a. Claims-Based Outcome Measures for the CY 2014 Payment Determination

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74496 through 74504), we adopted five claims-based measures (four outcome and one process) to be used for the CY 2014 payment determination. We will collect quality measure data for the five claims-based measures by using QDCs placed on submitted claims beginning with services furnished from October 1, 2012 through December 31, 2012. The five outcome measures are:

- Patient Burns (NQF #0263)
- Patient Falls (NQF #0266)
- Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)
- Hospital Transfer/Admission (NQF #0265)
- Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264)

The first four measures listed above are outcome measures and the fifth measure is a process measure.

Approximately 71 percent of ASCs participate in Medical Event Reporting, which includes reporting on the first four claims-based measures listed above. 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 Surgery Center Environmental Scan (July 2008) (Contract No. GS-10F-0096T)). Thus, we estimated the burden to report QDCs on this number of claims per year for the first four claims-based measures to be nominal due to the small number of cases (less than 1 case per month per ASC, or about 11.8 events per year).

For the remaining claims-based measure, Prophylactic IV Antibiotic Timing, we estimated the burden associated with submitting QDCs to be nominal, as few procedures performed by ASCs will require prophylactic antibiotic administration.

b. Claims-Based Process, Structural, and Volume Measures 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 measures: Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures (76 FR 74504 through 74509). For the CY 2015 payment determination, we proposed (and are finalizing in this final rule with comment period) that the data collection period for claims-based measures would be for services furnished from January 1, 2013, through December 31, 2013, that are paid by the administrative contractor by April 30, 2014.

For the CY 2016 payment determination, we finalized the retention of the seven measures for the CY 2015 payment determination and added Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) (76 FR 74509). For the CY 2016 payment determination, we proposed (and are finalizing in this final rule with comment period) that the data collection period for claims-based measures would be for services

furnished from January 1, 2014, through December 31, 2014, that are paid by the administrative contractor by April 30, 2015.

Based on our data for CY 2014 payment determinations above, extrapolating to 100 percent of ASCs reporting, there would be an average of 11.8 events per year. Thus, we estimated the burden to report QDCs on this number of claims per year for the first four claims-based measures to be nominal due to the small number of cases (approximately one case per month per ASC) for the CYs 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 structural 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 structural 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 864 hours (5,175 ASCs x 1 measure x 0.167 hours per ASC).

For the ASC Facility Volume Data on Selected ASC Surgical Procedures structural 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, 864 hours (5,175 ASCs x 1 measure 0.167 hours per ASC).

We have not yet proposed reporting requirements for the Safe Surgery Checklist or the ASC Volume Data on Selected ASC Surgical Procedures nor have we proposed

details on submission of the NHSN HAI measure: Influenza Vaccination Coverage Among Healthcare Personnel for the CY 2016 payment determination.

Public comments in reference to the use of the term “claims-based” on these information collection requirements are discussed in section XVI.C.1.b. of this final rule with comment period. We did not receive any other public comments on these information collection requirements and, therefore, are finalizing our burden estimates as proposed.

c. Program Administrative Requirements and QualityNet Accounts; Extraordinary Circumstance and Extension Requests; Reconsideration Requests

In the CY 2012 OPPS/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 payment determination 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 payment determination 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, we finalized for the CY 2015 payment determination the requirement that ASCs to 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 51,750 hours (10 hours x 5,175 ASCs).

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 hospitals that have submitted a request for an extension or waiver from the Hospital OQR Program over the past 4 years, we estimated that 1 ASC 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 2 hours per year.

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 such as redeterminations, reconsiderations, or appeals or all of these actions.

We did not receive any public comments on our burden discussion in the proposed rule.

6. IRF QRP

In the FY 2012 IRF PPS final rule (76 FR 47873 through 47883), we finalized the initial reporting requirements of the IRF QRP, including two quality measures for CY 2012 reporting. These two quality measures are: (1) Percent of Residents with Pressure Ulcers that are New or Worsened (NQF #0678); and (2) Urinary Catheter Associated Urinary Tract Infection (CAUTI) rate per 1,000 urinary catheter days, for Intensive Care Unit (ICU) Patients (NQF #0138).

We also established reporting mechanisms for these two measures in the FY 2012 IRF PPS final rule. IRFs were instructed to use the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) (approved under OCN: 0938-0842) to collect pressure ulcer measure data on Medicare Part A, Part B, and Medicare Advantage beneficiaries, and they were to collect CAUTI measure data on all patients and report that

data to CDC's National Healthcare Safety Network (NHSN). The burden associated with this collection of information for IRFs was included in the FY 2012 IRF PPS final rule (76 FR 47884 through 47885).

In section XVII. of the proposed rule, we proposed to adopt three proposals for the IRF QRP, which are: (1) a proposal to implement updates made by the NQF to the CAUTI measure which will affect the annual payment update in FY 2014; (2) a proposal that any measure selected for use in the IRF QRP would remain in effect until actively removed, suspended, or replaced; and (3) a proposal to implement policies regarding when rulemaking will be used to update existing IRF QRP measures.

We stated that the first proposal would allow us to incorporate recent updates that were made to the CAUTI measure (NQF#0138) by the NQF. However, we stated that these changes would not affect the type or amount of data that IRFs will be required to collect and submit.

The second proposal involves the implementation of a policy that IRF quality measures will remain in effect until a measure is actively removed, suspended, or replaced. We stated that this policy would not add any additional information collection requirements for CY 2013 and beyond as discussed below.

The third proposal involves implementing a policy regarding when rulemaking would be used to update existing IRF QRP measures that have been updated by the NQF. We stated that this proposal would likewise not create any increased information collection burden on IRFs.

a. Pressure Ulcer Measure

In the CY 2013 OPPS/ASC proposed rule, we did not propose to make any changes in the way the pressure ulcer data are to be collected and submitted to CMS using the current version of the IRF-PAI. As discussed in section XVII.D.2. of this final rule with comment period, we have decided to adopt a nonrisk-adjusted version of the NQF #0678 pressure ulcer measure. We will collect pressure ulcer data using the current version of the IRF-PAI, which became effective on October 1, 2012.

We have decided to use a nonrisk-adjusted application of the NQF #0678 pressure ulcer measure as opposed to the NQF-endorsed version of this measure. However, this change in the nature of the measure will not change the information collection burden that IRFs will incur for the reporting of pressure ulcer data. Nor will the burden differ from that which was stated in the FY 2012 IRF PPS final rule (76 FR 47884 through 47885). Likewise, the information collection burden will not differ from the burden estimated that is currently approved for the IRF-PAI under OCN: 0938-0842. It is important to note that, while the FY 2012 IRF PPS final rule mainly discusses the reporting requirement that will be incurred by IRFs for the FY 2014 payment determination, we do not anticipate that the policies we are finalizing in this final rule with comment will create an increase in the information collection burden for subsequent fiscal years.

b. CAUTI Measure

As discussed above, the FY 2012 IRF PPS final rule adopted the "Urinary Catheter Associated Urinary Tract Infection (CAUTI) rate per 1,000 urinary catheter

days, for Intensive Care Unit (ICU) Patients" (NQF# 0138) measure for the IRF QRP. However, subsequent to the publication of the FY 2012 IRF PPS final rule, this measure was expanded to several non-ICU settings, including IRFs. The CDC also changed the way the CAUTI measure is calculated from an infection rate per 1,000 days to a standardized infection ratio ("SIR"). The SIR calculation is comprised of the actual rate of infection over the expected rate of infection.

These changes will not impact the type or amount of data that IRFs will be required to collect and submit. Therefore, the information collection estimates that are stated in the FY 2012 IRF PPS final rule (76 FR 47884 through 47885) for reporting CAUTI data remain unchanged for the FY 2014 payment determination as well as for subsequent years payment determinations.

Summaries of the public comments we received on the proposed policies and the burden associated with these proposed information collection requirements and our responses are discussed in section XVII. of this final rule with comment period.

If you comment on these information collection and recordkeeping requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS-1589-FC; Fax: (202) 395-6974; or Email: OIRAsubmittions_@omb.eop.gov

XXI. Waiver of Proposed Rulemaking and Response to Comments

A. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking

includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We utilize HCPCS codes for Medicare payment purposes. The HCPCS is a national coding system comprised of Level I codes (CPT codes) and Level II codes that are intended to provide uniformity to coding procedures, services, and supplies across all types of medical providers and suppliers. CPT codes are copyrighted by the AMA and consist of several categories, including Category I codes which are 5-digit numeric codes, and Category III codes which are temporary codes to track emerging technology, services, and procedures. The AMA issues an annual update of the CPT code set each Fall, with January 1 as the effective date for implementing the updated CPT codes. The HCPCS, including both CPT codes and Level II codes, is similarly updated annually on a calendar year basis. Annual coding changes are not available to the public until the Fall immediately preceding the annual January update of the OPPS and the ASC payment system. Because of the timing of the release of these new codes, it is impracticable for us to provide prior notice and solicit comment on these codes and the payments assigned to them in advance of publication of the final rule that implements the OPPS and the ASC payment system. However, it is imperative that these coding changes be accounted for and recognized timely under the OPPS and the ASC payment system for payment because services represented by these codes will be provided to Medicare beneficiaries in

hospital outpatient departments and ASCs during the calendar year in which they become effective. Moreover, regulations implementing HIPAA (42 CFR Parts 160 and 162) require that the HCPCS be used to report health care services, including services paid under the OPPS and the ASC payment system. We assign interim payment amounts and status indicators to any new codes according to our assessment of the most appropriate APC based on clinical and resource homogeneity with other procedures and services in the APC. If we did not assign payment amounts to new codes on an interim basis, the alternative would be to not pay for these services during the initial calendar year in which the codes become effective. We believe it would be contrary to the public interest to delay establishment of payment amounts for these codes.

Therefore, we find good cause to waive the notice of proposed rulemaking for the establishment of payment amounts for selected HCPCS codes identified with comment indicator "NI" in Addendum B and Addendum BB to this final rule with comment period. We are providing a 60-day public comment period.

B. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this final rule with comment period, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XXII. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this final rule with comment period as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Contract with America Advancement Act of 1996 (Pub. L. 104-121) (5 U.S.C. 804(2)). This section of the final rule with comment period contains the impact and other economic analyses for the provisions that we are finalizing.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated as an "economically" significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Contract with America Advancement Act of 1996 (Pub. L. 104-121). Accordingly, the rule has been reviewed by the Office of

Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this final rule with comment period. In the proposed rule (77 FR 45210), we solicited public comments on the regulatory impact analysis provided.

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 2013. 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 revised the APC relative payment weights using claims data for services furnished on and after January 1, 2011, through and including December 31, 2011, and updated cost report information.

For CY 2013, 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. Also, we list the 23 drugs and biologicals in Table 32 that we are removing from pass-through payment status for CY 2013.

This final rule with comment period is also necessary to update the ASC payment rates for CY 2013, 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 2013. 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 2013, there will be no impacts associated with this payment reduction because it will not be applied until CY 2014.

3. Overall Impacts for OPPS and ASC Payment Provisions

We estimate that the effects of the 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 expenditures under the OPPS for CY 2013 compared to CY 2012 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 2013 will be approximately $4.571 billion higher, relative to expenditures in CY 2012. 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 57 displays the redistributional impact of the CY 2013 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 2013) will increase total OPPS payments by 1.8 percent in CY 2013. 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 will be 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 2012 and CY 2013, 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 1.9 percent.

We estimate that the effects of the ASC provisions in this final rule with comment period for the ASC payment system would result in expenditures exceeding $100 million in any 1 year. We estimate the total increase (from changes in this final rule with comment period as well as enrollment, utilization, and case-mix changes) in expenditures under the ASC payment system for CY 2013 compared to CY 2012 to be approximately $189 million. Because this final rule with comment period for the ASC payment system 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 final rule with comment period. Tables 58 and Table 59 of this final rule with comment period display the redistributional impact of the CY 2013 changes on ASC payment, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Detailed Economic Analyses

a. Estimated Effects of OPPS Changes in this Final Rule with Comment Period

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2013 policy changes on various hospital groups. We post on the CMS Web site our hospital-specific estimated payments for CY 2013 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-1589-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 57 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. 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 proposed rule, we solicited public comment and information about the anticipated effects of our changes on providers and our methodology for estimating them. Any public comments that we receive are addressed in the applicable sections of this final rule with comment period that discuss the specific policies.

(2) Estimated Effects of OPPS Changes on Hospitals

Table 57 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 scalar 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 57 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 2012, we are paying 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). For CY 2013, we are finalizing our proposal to continue this APC payment structure and are basing payment fully on the geometric mean costs calculated using data for the type of provider for which rates are being set, that is, hospital or CMHC. We display separately the impact of this policy 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 IPPS market basket percentage increase for FY 2013 is 2.6 percent (77 FR 53258). Section 1833(t)(3)(F)(i) of the Act reduces that 2.6 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.7 percentage points (which is also the MFP adjustment for FY 2013 in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53258); and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act further reduce the market basket percentage increase by 0.1 percentage point, resulting in the OPD fee schedule increase factor of 1.8 percent, which we are using in the calculation of the CY 2013 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 2013 estimates in Table 57.

To illustrate the impact of the CY 2013 changes, our analysis begins with a baseline simulation model that uses the CY 2012 relative payment weights, the FY 2012 final IPPS wage indices that include reclassifications, and the final CY 2012 conversion factor. Table 57 shows the estimated redistribution of the increase in payments for CY 2013 over CY 2012 payments to hospitals and CMHCs as a result of the following factors: APC reconfiguration and recalibration based on our historical methodology

using median costs (Column 2); the marginal impact of basing the APC relative payment weights on geometric mean costs over basing them on median costs (Column 3); APC recalibration based on geometric mean costs (Column 4, the combined effect of Columns 2 and 3); the wage indices and the rural adjustment (Column 5); the combined impact of APC recalibration based on geometric mean costs, the wage indices and rural adjustment, and the OPD fee schedule increase factor update to the conversion factor (Column 6); the combined impact of APC recalibration based on geometric mean costs, the wage indices and rural adjustment, the conversion factor update, and the CY 2013 frontier State wage index adjustment (Column 7); and the estimated impact taking into account all payments for CY 2013 relative to all payments for CY 2012 (Column 8), including the impact of changes in estimated outlier payments and changes to the pass-through payment estimate.

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we did not make any changes to the policy for CY 2013. 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 2012 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 2012 and CY 2013 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the OPPS rates for CY 2013 will have a positive effect for providers paid under the OPPS, resulting in a 1.9 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 still 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 57 shows the total number of facilities (4,127), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2011 hospital outpatient and CMHC claims data to model CY 2012 and CY 2013 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not accurately estimate CY 2012 or CY 2013 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 (3,905) of OPPS hospitals, 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 159 CMHCs at the bottom of the impact table and discuss that impact separately below.

Columns 2, 3, and 4: APC Recalibration

These columns show the combined effects of the reconfiguration, recalibration, and other policies (such as setting payment for separately payable drugs and biologicals at ASP+6 under our CY 2013 decision to apply the statutory default). Column 2 shows the reclassification effects if we were to base the relative payment weights on the median costs of services. Column 3 shows the marginal effects of using the geometric mean costs compared to the effects if we were to base the relative payment weights on the median costs of services, in other words the effects of our policy change from medians to geometric means. We are providing this column comparing the additional impact of developing the CY 2013 OPPS relative payment weights using geometric mean costs only in the CY 2013 OPPS/ASC proposed and final rules because the CY 2013 OPPS will establish geometric mean costs as a baseline configuration for the OPPS. Column 4 shows the combined effect of Columns 2 and 3, in other words the effect of our decision to base the relative payment weights on geometric mean costs. It reflects the impacts of

the reclassification of services among APC groups and the recalibration of APC relative payment weights, based on 12 months of CY 2011 OPPS hospital claims data and the most recent cost report data, and determining relative payment weights using the geometric mean costs of services. We modeled the effect of the APC recalibration changes by varying only the relative payment weights (the final CY 2012 relative weights versus the CY 2013 relative weights calculated using the service-mix and volume in the CY 2011 claims used for this final rule with comment period) and calculating the percent difference in the relative weight. 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.

Overall, we estimate that changes in APC reassignment and recalibration across all services paid under the OPPS will slightly decrease payments to urban hospitals by 0.1 percent. However, the smallest urban hospitals will receive slight payment increases of 0.6 percent (hospitals with 0-99 beds), attributable to increased payments for partial hospitalization, group psychotherapy and cardiac rehabilitation monitoring services furnished in the hospital. Due to recalibration, we estimate that low volume urban hospitals billing fewer than 21,000 lines for OPPS services will experience increases ranging from 1.0 percent to 4.9 percent. The increase of 4.9 percent for urban hospitals billing fewer than 5,000 lines per year is similarly attributable to an increase in payment for partial hospitalization and group psychotherapy services furnished in the hospital.

Overall, we estimate that rural hospitals will experience a small increase of 0.5 percent as a result of changes to the APC structure, with the largest increases going to

the smallest hospitals both by number of beds (1.2 percent to those with less than 50 beds) and volume (3.1 percent to those with fewer than 5,000 lines). As a result of the recalibration, we estimate that rural hospitals that report 5,000 or more lines for OPPS services will experience payment increases ranging from 0.3 percent to 1.5 percent.

Classifying hospitals according to teaching status, we estimate that the APC recalibration will lead to small payment decreases of 0.1 to 0.2 percent for major and minor teaching hospitals, respectively. We estimate that nonteaching hospitals will experience an increase of 0.2 percent. Classifying hospitals by type of ownership suggests that voluntary, proprietary, and governmental hospitals will experience changes ranging from a decrease of 0.1 percent to an increase of 0.3 percent as a result of the APC recalibration.

For most hospitals, we estimate insignificant impacts of our final policy of using geometric mean-based relative payment weights. Most hospitals will receive small increases in payments of up to 6.5 percent. We estimate that hospitals for which DSH payments are not available (mostly urban hospitals) will experience an increase of 6.5 percent. Hospitals for which DSH data are not available (non-IPPS hospitals) furnish a large number of psychiatric services and we believe that the increase in payment is due to increased payment for partial hospitalization and group psychotherapy services, as well as for hemodialysis services furnished in the hospital.

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 using geometric means; the wage index update; the rural adjustment; and the cancer hospital 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 2012 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indices.

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 did not make any changes to the policy for CY 2013. Similarly, the differential impact between the CY 2012 cancer hospital payment adjustment and the CY 2013 cancer hospital payment adjustment had no effect on the budget neutral adjustment to the conversion factor. 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 2013 scaled weights and a CY 2012 conversion factor that included a budget neutrality adjustment for the effect of changing the wage indices between CY 2012 and CY 2013. This column estimates the impact of applying the FY 2013 IPPS wage indices for the CY 2013 OPPS without the influence of the frontier State wage index adjustment, which is not budget neutral. The frontier State wage index adjustment

is reflected in the combined impact shown in Column 7. We are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2013, as described in section II.E.2. of this final rule with comment period. We estimate that the combination of updated wage data and nationwide application of rural floor budget neutrality will redistribute payment among regions. We also updated the list of counties qualifying for the section 505 out-migration adjustments.

Overall, we estimate that as a result of the updated wage indices and the rural adjustment, urban hospitals will experience no change from CY 2012 to CY 2013. Rural sole community hospitals will not be affected, but other rural hospitals will experience decreases of 0.4 percent. Urban hospitals in the East South Central and Pacific regions will experience the most significant payment changes with a decrease of 0.7 percent in the East South Central region and an increase of 1.4 percent in the Pacific region. Overall, we estimate that rural hospitals will experience a decrease of 0.2 percent as a result of changes to the wage index for CY 2013. Regionally, the changes will range from a decrease of 0.9 percent in the rural Pacific region to an increase of 0.7 percent in the rural Mountain region.

Column 6: All Budget Neutrality Changes Combined with the OPD Fee Schedule Increase

Column 6 demonstrates the cumulative impact of the budget neutral adjustments from Column 5 and the OPD fee schedule increase factor of 1.8 percent. We estimate that for most hospitals, the addition of the OPD fee schedule increase factor of

1.8 percent will mitigate the negative impacts created by the budget neutrality adjustments made in Column 5.

While most classes of hospitals will receive an increase that is more in line with the 1.8 percent overall increase after the update is applied to the budget neutrality adjustments, urban hospitals that bill fewer than 5,000 lines, rural hospitals that bill fewer than 5,000 lines, and hospitals for which DSH information is not available will experience larger increases ranging from 4.5 percent to 8.2 percent. In particular, urban hospitals that report fewer than 5,000 lines will experience a cumulative increase, after application of the OPD fee schedule increase factor and the budget neutrality adjustments, of 6.7 percent, largely as a result of increases in payments to partial hospitalization and group psychotherapy services furnished in the hospital. Similarly, urban hospitals for which DSH data are not available will experience an increase of 8.0 percent, also largely as a result of increases in payment for partial hospitalization, group psychotherapy and hemodialysis services furnished in hospitals.

Overall, we estimate that these changes will increase payments to urban hospitals by 1.8 percent. We estimate that large urban hospitals and "other" urban hospitals will also experience increases of 1.9 and 1.6 percent, respectively. Urban hospitals in the Pacific region will experience an increase of 3.3 percent, largely as a result of the change in wage index shown under column 3 and discussed above. We estimate that rural hospitals will experience a 2.1 percent increase as a result of the OPD fee schedule increase factor and other budget neutrality adjustments.

Classifying hospitals by teaching status suggests that the OPD fee schedule increase factor and the budget neutrality adjustments will result in an increase of 1.7 percent for major teaching hospitals, 1.5 percent for minor teaching hospitals and 2.0 percent for nonteaching hospitals.

Classifying hospitals by type of ownership suggests that proprietary hospitals will experience an estimated increase of 2.3 percent, while voluntary hospitals will experience an estimated increase of 2.0 percent and government hospitals will experience an estimated increase of 1.8 percent.

Column 7: All Adjustments with the Frontier State Wage Index Adjustment

This column shows the impact of all budget neutrality adjustments, application of the 1.8 percent OPD fee schedule increase factor, and the nonbudget neutral impact of applying the 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 non-budget neutral frontier State wage index adjustment.

In general, we estimate that all facilities and all hospitals will experience a combined increase of 0.1 percent due to the nonbudget neutral frontier State wage index adjustment. The index will only affect urban hospitals in the West North Central and Mountain regions. Urban hospital in those regions will experience increases of 1.0 percent (West North Central) and 0.4 percent (Mountain) that are attributable to the frontier State wage index, and rural hospitals will experience increases of 1.2 percent

(West North Central) and 2.1 percent (Mountain) that are attributable to the frontier State wage index.

Column 8: All Changes for CY 2013

Column 8 depicts the full impact of the CY 2013 policies on each hospital group by including the effect of all the changes for CY 2013 and comparing them to all estimated payments in CY 2012. Column 8 shows the combined budget neutral effects of Columns 2 through 5; the OPD fee schedule increase; the impact of the frontier State wage index adjustment; the impact of estimated OPPS outlier payments as discussed in section II.G. of this final rule with comment period; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XV. of this final rule with comment period); and the impact of increasing the estimate of the percentage of total OPPS payments dedicated to transitional pass-through payments. Of the 101 hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2012 update (and assumed, for modeling purposes, to be the same number for CY 2013), we included 30 hospitals in our model because they had both CY 2011 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2013 will increase payments to all providers by 1.9 percent for CY 2013. We modeled the independent effect of all changes in Column 8 using the final relative payment weights for CY 2012 and the relative payment weights for CY 2013. We used the final conversion factor for CY 2012 of $70.016 and the CY 2013 conversion factor of $71.313 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 2013 IPPS/LTCH PPS final rule of 4.24 percent (1.0424) to increase individual costs on the CY 2011 claims, and we used the most recent overall CCR in the July 2012 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2012. Using the CY 2011 claims and a 4.24 percent charge inflation factor, we currently estimate that outlier payments for CY 2012, using a multiple threshold of 1.75 and a fixed-dollar threshold of $2,025 should be approximately 0.9 percent of total payments. The estimated current outlier payments of 0.9 percent are incorporated in the CY 2013 comparison in Column 8. We used the same set of claims and a charge inflation factor of 8.66 percent (1.0866) and the CCRs in the July 2012 OPSF, with an adjustment of 0.9880, to reflect relative changes in cost and charge inflation between CY 2011 and CY 2013, to model the CY 2013 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $2,025.

We estimate that the anticipated change in payment between CY 2012 and CY 2013 for the hospitals failing to meet the Hospital OQR Program requirements will be negligible. Overall, we estimate that facilities will experience an increase of 1.9 percent under this final rule with comment period in CY 2013 relative to total spending in CY 2012. This projected increase (shown in Column 8) of Table 57 reflects the 1.8 percent OPD fee schedule increase factor, with 0.07 percent for the change in the pass-through estimate between CY 2012 and CY 2013, with an additional 0.1 percent for the difference in estimated outlier payments between CY 2012 (0.9 percent) and CY 2013

(1.0 percent), less 0.04 percent due to the expiration of the section 508 wage adjustment, less 0.1 percent due to the frontier adjustment in CY 2012, plus 0.1 percent due to the frontier State wage index adjustment in CY 2013. When we exclude cancer and children's hospitals (which are held harmless to their pre-BBA amount) and CMHCs, the estimated increase continues to be 1.9 percent after rounding. We estimate that the combined effect of all changes for CY 2013 will increase payments to urban hospitals by 1.9 percent, with large urban hospitals experiencing an estimated 2.0 percent increase and "other" urban hospitals experiencing an estimated 1.7 percent increase. We estimate that urban hospitals that bill less than 5,000 lines of OPPS services will experience an increase of 6.8 percent, largely attributable to the increase in payment for partial hospitalization and group psychotherapy services furnished in the hospital. We estimate that urban hospitals that bill 11,000 or more lines of OPPS services will experience increases between 1.8 percent and 3.1 percent, while urban hospitals that report between 5,000 and 10,999 lines will experience an increase of 4.4 percent.

Overall, we estimate that rural hospitals will experience a 2.2 percent increase as a result of the combined effects of all changes for CY 2013. We estimate that rural hospitals that bill less than 5,000 lines of OPPS services will experience an increase of 4.6 percent and that rural hospitals that bill 5,000 or more lines of OPPS services will experience increases ranging from 2.1 to 2.8 percent.

Among teaching hospitals, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 1.8 percent for major teaching

hospitals and 2.1 percent for nonteaching hospitals. Minor teaching hospitals will experience an increase of 1.7 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 1.9 percent, proprietary hospitals will experience an increase of 2.2 percent, and governmental hospitals will experience an increase of 1.9 percent.

TABLE 57.—ESTIMATED IMPACT OF THE CY 2013 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	**APC Recalibration (Median) (%)**	**Impact of Basing Weights Using Geo Mean(%)**	**APC Recalibration (Geo Mean) (%)**	**New Wage Index and Provider Adjustments (%)**	**Comb-ination of Cols 4, 5 with Market Basket Update (%)**	**Column 6 with Frontier Wage Index Adjustment (%)**	**All Changes (%)**
ALL FACILITIES *	4,127	0.0	0.0	0.0	0.0	1.8	1.9	1.9
ALL HOSPITALS	3,905	0.0	0.0	0.0	0.0	1.8	1.9	1.9
(excludes hospitals permanently held harmless and CMHCs)								
URBAN HOSPITALS	2,957	-0.1	0.0	-0.1	0.0	1.8	1.8	1.9
LARGE URBAN	1,611	-0.1	0.0	-0.1	0.2	1.9	1.9	2.0
(GT 1 MILL.)								
OTHER URBAN	1,346	-0.1	0.0	-0.1	-0.1	1.6	1.8	1.7
(LE 1 MILL.)								
RURAL HOSPITALS	948	0.3	0.1	0.5	-0.2	2.1	2.3	2.2
SOLE COMMUNITY	385	0.4	0.1	0.5	0.0	2.3	2.8	2.4
OTHER RURAL	563	0.3	0.1	0.4	-0.4	1.9	1.9	2.0

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	**APC Recalibration (Median) (%)**	**Impact of Basing Weights Using Geo Mean(%)**	**APC Recalibration (Geo Mean) (%)**	**New Wage Index and Provider Adjustments (%)**	**Comb-ination of Cols 4, 5 with Market Basket Update (%)**	**Column 6 with Frontier Wage Index Adjustment (%)**	**All Changes (%)**
BEDS (URBAN)								
0 - 99 BEDS	1,047	0.4	0.2	0.6	0.0	2.5	2.6	2.7
100-199 BEDS	833	0.1	0.1	0.2	0.2	2.2	2.3	2.3
200-299 BEDS	458	-0.1	0.0	-0.1	0.1	1.7	1.9	1.9
300-499 BEDS	415	-0.2	0.0	-0.2	0.1	1.7	1.8	1.9
500 + BEDS	204	-0.2	-0.1	-0.3	-0.2	1.3	1.3	1.5
BEDS (RURAL)								
0 - 49 BEDS	356	0.8	0.4	1.2	-0.3	2.8	3.0	2.8
50- 100 BEDS	352	0.5	0.1	0.7	0.0	2.4	2.7	2.6
101- 149 BEDS	137	0.2	0.1	0.2	-0.6	1.5	1.7	1.6
150- 199 BEDS	55	0.3	0.1	0.4	-0.3	1.8	2.4	2.0
200 + BEDS	48	-0.2	0.0	-0.2	0.1	1.7	1.7	1.8
VOLUME (URBAN)								
LT 5,000 Lines	597	2.4	2.5	4.9	-0.1	6.7	6.8	6.8
5,000 - 10,999 Lines	126	1.3	1.3	2.6	-0.3	4.1	4.5	4.4
11,000 - 20,999 Lines	197	0.7	0.3	1.0	0.1	2.9	3.0	3.1

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	**APC Recalibration (Median) (%)**	**Impact of Basing Weights Using Geo Mean(%)**	**APC Recalibration (Geo Mean) (%)**	**New Wage Index and Provider Adjustments (%)**	**Comb-ination of Cols 4, 5 with Market Basket Update (%)**	**Column 6 with Frontier Wage Index Adjustment (%)**	**All Changes (%)**
21,000 - 42,999 Lines	429	0.3	0.1	0.4	0.1	2.3	2.4	2.5
42,999 - 89,999 Lines	688	0.0	0.0	0.0	0.1	1.9	1.9	2.0
GT 89,999 Lines	920	-0.2	0.0	-0.2	0.0	1.6	1.7	1.8
VOLUME (RURAL)								
LT 5,000 Lines	59	1.8	1.3	3.1	-0.3	4.5	7.6	4.6
5,000 - 10,999 Lines	61	0.5	0.9	1.5	-0.9	2.3	2.3	2.5
11,000 - 20,999 Lines	146	0.6	0.6	1.2	-0.3	2.7	3.1	2.8
21,000 - 42,999 Lines	282	0.7	0.2	0.9	-0.3	2.4	2.7	2.5
GT 42,999 Lines	400	0.2	0.1	0.3	-0.2	1.9	2.2	2.1
REGION (URBAN)								
NEW ENGLAND	149	0.3	0.0	0.3	-0.6	1.5	1.5	1.5
MIDDLE ATLANTIC	349	-0.1	-0.1	-0.1	-0.3	1.4	1.4	1.5
SOUTH ATLANTIC	453	-0.1	-0.1	-0.2	-0.5	1.1	1.1	1.3
EAST NORTH CENT.	474	-0.2	0.0	-0.2	0.3	1.9	1.9	1.9
EAST SOUTH CENT.	179	-0.3	-0.1	-0.4	-0.7	0.7	0.7	0.8
WEST NORTH CENT.	188	0.0	0.0	0.0	0.3	2.1	3.1	2.5

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	**APC Recalibration (Median) (%)**	**Impact of Basing Weights Using Geo Mean(%)**	**APC Recalibration (Geo Mean) (%)**	**New Wage Index and Provider Adjustments (%)**	**Comb-ination of Cols 4, 5 with Market Basket Update (%)**	**Column 6 with Frontier Wage Index Adjustment (%)**	**All Changes (%)**
WEST SOUTH CENT.	515	-0.1	0.1	-0.1	-0.4	1.4	1.4	1.6
MOUNTAIN	208	0.2	0.0	0.2	0.6	2.7	3.1	2.8
PACIFIC	395	-0.1	0.1	0.0	1.4	3.3	3.3	3.4
PUERTO RICO	47	-0.1	0.0	-0.1	0.1	1.8	1.8	2.0
REGION (RURAL)								
NEW ENGLAND	25	0.7	0.0	0.7	0.4	3.0	3.0	3.1
MIDDLE ATLANTIC	67	0.4	0.0	0.4	0.0	2.2	2.2	2.3
SOUTH ATLANTIC	161	0.2	0.1	0.3	-0.4	1.6	1.6	1.7
EAST NORTH CENT.	127	0.2	0.1	0.3	0.4	2.5	2.5	2.5
EAST SOUTH CENT.	175	0.0	0.1	0.1	-0.5	1.4	1.4	1.5
WEST NORTH CENT.	98	0.5	0.1	0.7	-0.5	2.0	3.2	2.1
WEST SOUTH CENT.	201	0.5	0.4	0.9	-0.4	2.3	2.3	2.4
MOUNTAIN	65	0.6	0.0	0.6	0.7	3.1	5.2	3.5
PACIFIC	29	0.7	0.1	0.8	-0.9	1.7	1.7	1.8
TEACHING STATUS								
NON-TEACHING	2,930	0.1	0.1	0.2	0.0	2.0	2.1	2.1

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	**APC Recalibration (Median) (%)**	**Impact of Basing Weights Using Geo Mean(%)**	**APC Recalibration (Geo Mean) (%)**	**New Wage Index and Provider Adjustments (%)**	**Comb-ination of Cols 4, 5 with Market Basket Update (%)**	**Column 6 with Frontier Wage Index Adjustment (%)**	**All Changes (%)**
MINOR	687	-0.1	0.0	-0.2	-0.1	1.5	1.8	1.7
MAJOR	288	-0.1	-0.1	-0.1	0.1	1.7	1.7	1.8
DSH PATIENT PERCENT								
0	14	1.4	0.0	1.4	-0.1	3.1	3.1	3.2
GT 0 - 0.10	343	0.1	-0.1	0.0	0.0	1.8	1.9	2.0
0.10 - 0.16	327	0.1	0.0	0.0	0.1	1.9	2.0	2.0
0.16 - 0.23	686	0.0	0.0	0.0	0.0	1.7	1.9	1.8
0.23 - 0.35	1,064	0.0	0.0	0.0	-0.1	1.7	1.9	1.9
GE 0.35	832	-0.2	0.0	-0.1	0.1	1.8	1.8	2.0
DSH NOT AVAILABLE **	639	2.1	4.3	6.5	-0.1	8.2	8.2	8.3
URBAN TEACHING/DSH								
TEACHING & DSH	885	-0.1	-0.1	-0.2	0.0	1.6	1.7	1.7
NO TEACHING/DSH	1,458	0.0	0.0	0.0	0.1	1.9	2.0	2.0
NO TEACHING/NO DSH	14	1.4	0.0	1.4	-0.1	3.1	3.1	3.2
DSH NOT AVAILABLE**	600	2.1	4.1	6.2	0.0	8.0	8.0	8.0

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Number of Hospitals	**APC Recalibration (Median) (%)**	**Impact of Basing Weights Using Geo Mean(%)**	**APC Recalibration (Geo Mean) (%)**	**New Wage Index and Provider Adjustments (%)**	**Comb-ination of Cols 4, 5 with Market Basket Update (%)**	**Column 6 with Frontier Wage Index Adjustment (%)**	**All Changes (%)**
TYPE OF OWNERSHIP								
VOLUNTARY	2,053	-0.1	0.0	-0.1	0.0	1.8	1.9	1.9
PROPRIETARY	1,294	0.1	0.2	0.3	-0.1	2.0	2.1	2.2
GOVERNMENT	558	0.1	0.0	0.1	-0.1	1.8	1.8	1.9
CMHCs	159	-1.8	-3.9	-5.7	-0.6	-4.5	-4.5	-4.4

Column (1) shows total hospitals and/or CMHCs.

Column (2) shows the impact of changes resulting from the reclassification of HCPCS codes among APC groups, the use of median costs in developing relative payment weights, and the final recalibration of APC weights based on CY 2011 hospital claims data.

Column (3) shows the estimated impact of basing the CY 2013 OPPS final payments on geometric mean costs, by comparing estimated CY 2013 payments under the policy for a geometric mean cost based system to those under a median based OPPS.

Column (4) shows the impact of changes resulting from the reclassification of HCPCS codes among APC groups, the use of geometric mean costs in developing the CY 2013 final OPPS relative payment weights, and the recalibration of APC weights based on CY 2011 hospital claims data.

Column (5) shows the budget neutral impact of updating the wage index by applying the FY 2013 hospital inpatient wage index. The rural adjustment is 7.1 percent in both years so its budget neutrality factor is 1. Similarly, the differential in estimated cancer hospital payments for the final adjustment is minimal and thus results in a budget neutrality factor of 1.

Column (6) shows the impact of all budget neutrality adjustments and the final addition of the 1.8 percent OPD fee schedule increase factor (2.6 percent reduced by 0.7 percentage points for the multifactor productivity adjustment and further reduced by 0.1 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).

Column (7) shows the non-budget neutral impact of applying the frontier State wage adjustment in CY 2013, after application of the CY 2013 final OPD fee schedule increase factor.

Column (8) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adds estimated outlier payments. This column also shows the expiration of section 508 wages on March 30, 2012, and the application of the frontier State wage adjustment for CY 2012 and 2013.

*These 4,127 facilities include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

(3) Estimated Effects of OPPS Changes on CMHCs

The last line of Table 57 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization (PHP) services under the OPPS. In CY 2012, 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 first implemented these four APCs for CY 2011 and adopted 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 but provided a transition to CMHC rates based solely on CMHC data for the two CMHC PHP per diem rates. For CY 2013, we are continuing the provider-specific APC structure that we adopted for CY 2011 and are basing payment fully on the data for the type of provider furnishing the service. 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 2011 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. Because the relative payment weights for APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs) decline in CY 2013 using geometric mean-based relative payment weights as opposed to median-based relative payment weights (shown

in Columns 3 and 4), we estimate that there will be an overall 4.4 percent decrease in payments to CMHCs (shown in Column 8).

Column 5 shows that the estimated impact of adopting the CY 2013 wage index values will result in a small decrease of 0.6 percent to CMHCs. We note that all providers paid under the OPPS, including CMHCs, will receive a 1.8 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 2013 and the CY 2013 wage index updates, results in an estimated decrease of 4.5 percent. Column 7 shows that adding the frontier State wage adjustment will result in no change to the cumulative 4.5 percent decrease. Column 8 shows that adding the changes in outlier and pass-though payments will result in a 0.1 percent decrease in payment for CMHCs. This reflects all changes to CMHCs for CY 2013.

(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 example, for a service assigned to Level IV Needle Biopsy/Aspiration Except Bone Marrow (APC 0037) in the CY 2012 OPPS, the national unadjusted copayment is $227.35, and the minimum unadjusted copayment is $215.00, 20 percent of the national unadjusted payment rate of $1,074.99. For CY 2013, the national unadjusted copayment for APC 0037 is $227.35, the same amount as the national unadjusted copayment in effect for CY 2012. The minimum unadjusted copayment for APC 0037 is

$223.71 or 20 percent of the CY 2013 national unadjusted payment rate for APC 0037 of $1,118.54. The minimum unadjusted copayment will increase for CY 2013 compared to CY 2012 because the payment rate for APC 0037 will increase for CY 2013. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.H. 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 2012 hospital inpatient deductible is $1,156. The amount of the CY 2013 hospital inpatient deductible is not available at the time of publication of this final rule with comment period.

In order to better understand the impact of changes in copayment on beneficiaries, we modeled the percent change in total copayment liability using CY 2011 claims. We estimate, using the claims of the 4,127 hospitals and CMHCs on which our modeling is based, that total beneficiary liability for copayments will decrease as an overall percentage of total payments, from 22.0 percent in CY 2012 to 21.5 percent in CY 2013 due largely to changes in service-mix.

(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 XIV. 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 2013. 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 XXII.A. of this final rule with comment period.

(7) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we 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 Basing the APC Relative Payment Weights on Geometric Mean Costs Rather than Median Costs

As described in section II.A.2.f. of this final rule with comment period, we are basing the CY 2013 relative payment weights on which OPPS payments are calculated using geometric mean costs rather than median costs. We established this policy based on stakeholder public comments, the improvements we have made to the data process to obtain more data and additional accuracy in estimating cost, and the other reasons described in the geometric mean based relative payment weights section.

In developing this policy, we considered another alternative, which was to continue basing the relative payment weights based on median costs. As discussed in the geometric mean based weights section, medians have historically served as a good measure of central tendency and continue to do so. In the initial establishment of the

OPPS, we selected medians as the measure of central tendency on which to base the weights for a number of reasons. Those included statistical bases such as medians' resistance to outlier observations and their impact as well as reasons surrounding the practical implementation of the OPPS as a new payment system. While some of those reasons for selecting medians continue to apply, others are now less relevant because of changes we have made in our data process, or no longer apply because of factors such as actual development of a working payment system. We have made a number of changes to the OPPS to address some of the challenges in arriving at better estimates of service cost, including trims, more specific application of cost to charge ratios in estimating cost, modeling changes to better simulate payment mechanisms, and methods of obtaining additional claims data through what is already available such as the bypass list.

We believe that those changes have helped to improve the relative costs on which the payment system is based. We also believe that geometric mean costs better incorporate the range of costs associated with providing a service, and thus will represent one such additional improvement. Therefore, in order to improve the accuracy at which we arrive at service costs used to set relative payment weights, to be responsive to stakeholder concerns regarding the degree to which OPPS payment appropriately reflects service cost, and the other reasons described in section II.A.2.f. of this final rule with comment period, we will establish the CY 2013 OPPS relative payment weights based on geometric means rather than continuing our historical practice of modeling costs using median costs.

● Alternatives Considered for Payment of Drugs and Biologicals That Do Not Have Pass-Through Status

We are paying for separately payable drugs and biologicals at ASP+6 percent, based on section 1833(t)(14)(A)(iii)(II) of the Act, also referred to as the statutory default. As detailed in greater depth in section V.B.3 of this final rule with comment period, this payment will represent the combined payment for both the acquisition and pharmacy overhead costs of separately payable drugs and biologicals.

We considered three alternatives for payment for drugs and biologicals that do not have pass-through status for CY 2013 (separately payable drugs and biologicals). The first alternative we considered was to propose to use the standard methodology, as described in the CY 2006 OPPS/ASC final rule with comment period (70 FR 68642). We compared 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, to calculate the estimated percent of ASP that would serve as the best proxy for the combined acquisition and pharmacy overhead costs of separately payable drugs and biologicals, but without redistribution of estimated pharmacy overhead costs. Under this methodology, without a redistribution of overhead costs from packaged drugs to separately payable drugs, using April 2012 ASP information and costs derived from CY 2011 OPPS claims data, we estimated the combined acquisition and overhead costs of separately payable drugs and biologicals to be ASP+0 percent. We also determined that the combined acquisition and overhead costs of packaged drugs are 311 percent of ASP.

We did not choose this alternative because we believe that this analysis indicates that hospital charging practices reflected in our standard drug payment methodology have the potential to "compress" the calculated costs of separately payable drugs and biologicals to some degree when there is no redistribution of estimated pharmacy overhead costs. Further, we recognize that the attribution of pharmacy overhead costs to packaged or separately payable drugs and biologicals through our standard drug payment methodology of a combined payment for acquisition and pharmacy overhead costs depends, in part, on the treatment of all drugs and biologicals each year under our annual drug packaging threshold. Changes to the packaging threshold may result in changes to payment for the overhead cost of drugs and biologicals that do not reflect actual changes in hospital pharmacy overhead cost for those products.

The second alternative we considered was to propose to continue our overhead adjustment methodology for CY 2013 and redistribute $270 million in overhead costs from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals. Using this approach, we adjusted the CY 2011 pharmacy overhead redistribution amount of $200 million using the PPI for Pharmaceuticals for Human Use, resulting in a redistribution amount of $270 million and a payment rate for separately payable drugs of ASP+6 percent. We did not choose this alternative because of the reasons discussed below and in further detail in section V.B.3 of this final rule with comment period.

The third option that we considered, and the one that we are adopting for CY 2013, is to pay for separately payable drugs and biologicals administered in the

hospital outpatient department, at ASP+6 percent based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act, which 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. We determined that this ASP+6 percent payment amount for separately payable drugs and biologicals represents the combined acquisition and pharmacy overhead payment for drugs and biologicals for CY 2013.

As described in further detail in section V.B.3 of this final rule with comment period, we chose this alternative because we are uncertain about the full cost of pharmacy overhead and acquisition cost, due to the limitations of the submitted hospital charge and claims data for drugs. We believe that the continued use of our current drug payment methodologies may not appropriately account for average acquisition and pharmacy overhead cost and therefore could result in future payment rates that are not appropriate.

Therefore, we finalized our proposal to pay for separately payable drugs and biologicals based on the statutory default at the physician's office Part B payment rates, as established in sections 1842(o) and 1847A of the Act, at ASP+6 percent. We believe that paying for separately payable drugs and biologicals at ASP+6 percent based on the statutory default is appropriate at this time as it yields increased predictability in payment for drugs and biologicals under the OPPS while appropriately paying for drugs at a level consistent with payment amounts yielded by our methodology of the past 7 years.

b. Estimated Effects of ASC Payment System Final Policies

On August 2, 2007, we published in the Federal Register the final rule for the revised ASC payment system, effective January 1, 2008 (72 FR 42470). In that final rule, we adopted the methodologies to set payment rates for covered ASC services to implement the revised payment system so that it would be designed to result in budget neutrality as required by section 626 of Pub. L. 108-173; established that the OPPS relative payment weights would be the basis for payment and that we would update the system annually as part of the OPPS rulemaking cycle; and provided that the revised ASC payment rates would be phased in over 4 years.

ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIV. of this final rule with comment period, we set the CY 2013 ASC relative payment weights by scaling the CY 2013 OPPS relative payment weights by the ASC scaler of 0.9324. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 58 and 59 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).

Because the ASCQR Program will not affect payment rates until CY 2014, there will be no reduction to the CPI-U for failure to meet the requirements of the ASCQR Program for CY 2013. We calculated the CY 2013 ASC conversion factor by adjusting the CY 2012 ASC conversion factor by 1.0008 to account for changes in the pre-floor and pre-reclassified hospital wage indices between CY 2012 and CY 2013 and by applying the CY 2013 MFP-adjusted CPI-U update factor of 0.6 percent (projected CPI-U update of 1.4 percent minus a projected productivity adjustment of 0.8 percent). The CY 2013 ASC conversion factor is $42.917.

(1) Limitations of Our Analysis

Presented here are the projected effects of the changes for CY 2013 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2011 and CY 2013 with precision. We believe that the net effect on Medicare expenditures resulting from the CY 2013 changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

(2) Estimated Effects of ASC Payment System Final 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 2013 payments would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the CY 2013 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2011 claims data. Table 58 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2012 payments to estimated CY 2013 payments, and Table 59 shows a comparison of estimated CY 2012 payments to estimated CY 2013 payments for procedures that we estimate would receive the most Medicare payment in CY 2012.

Table 58 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 58.

● 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 2012 ASC Payments were calculated using CY 2011 ASC utilization (the most recent full year of ASC utilization) and CY 2012 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2012 ASC payments.

● Column 3—Estimated CY 2013 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 would be attributable to updates to ASC payment rates for CY 2013 compared to CY 2012.

As seen in Table 58, we estimate that the update to ASC rates for CY 2013 would result in a zero percent change in aggregate payment amounts for eye and ocular adnexa procedures, a 2-percent increase in aggregate payment amounts for digestive system procedures, and a 3-percent increase 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 2013 update are variable.

For instance, we estimate that, in the aggregate, payment for integumentary system procedures, respiratory system procedures, and cardiovascular systems procedures would decrease by 3 percent, whereas auditory system procedures would increase by 1 percent under the CY 2013 rates.

An estimated increase in aggregate payment for the specialty group does not mean that all procedures in the group would experience increased payment rates. For example, the estimated increase for CY 2013 for nervous system procedures is likely due to an increase in the ASC payment weight for some of the high volume procedures, such as CPT code 63685 (Insrt/redo spine n generator) where estimated payment would increase by 8 percent for CY 2013.

Also displayed in Table 58 is a separate estimate of Medicare ASC payments for the group of separately payable covered ancillary items and services. The payment estimates for the covered surgical procedures include the costs of packaged ancillary items and services. We estimate that aggregate payments for these items and services would remain unchanged for CY 2013.

TABLE 58.—ESTIMATED IMPACT OF THE FINAL CY 2013 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2013 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2012 ASC Payments (in Millions) (2)	Estimated CY 2013 Percent Change (3)
Total	$3,480	1%
Eye and ocular adnexa	$1,453	0%

Surgical Specialty Group (1)	Estimated CY 2012 ASC Payments (in Millions) (2)	Estimated CY 2013 Percent Change (3)
Digestive system	$719	2%
Nervous system	$471	3%
Musculoskeletal system	$433	-2%
Genitourinary system	$160	0%
Integumentary system	$131	-3%
Respiratory system	$45	-3%
Cardiovascular system	$31	-3%
Ancillary items and services	$21	0%
Auditory system	$11	1%
Hematologic & lymphatic systems	$5	0%

Table 59 below shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2013. The table displays 30 of the procedures receiving the greatest estimated CY 2012 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2012 program payment.

- Column 1–CPT/HCPCS code.
- Column 2–Short Descriptor of the HCPCS code.
- Column 3–Estimated CY 2012 ASC Payments were calculated using CY 2011 ASC utilization (the most recent full year of ASC utilization) and the CY 2012 ASC payment rates. The estimated CY 2012 payments are expressed in millions of dollars.
- Column 4–Estimated CY 2013 Percent Change reflects the percent differences between the estimated ASC payment for CY 2012 and the estimated payment for CY 2013 based on the update.

TABLE 59.--ESTIMATED IMPACT OF THE FINAL CY 2013 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code* (1)	Short Descriptor (2)	Estimated CY 2012 ASC Payments (in millions) (3)	Estimated CY 2013 Percent Change (4)
66984	Cataract surg w/iol, 1 stage	$1,079	1%
43239	Upper GI endoscopy, biopsy	$157	2%
45380	Colonoscopy and biopsy	$144	2%
45385	Lesion removal colonoscopy	$92	2%
45378	Diagnostic colonoscopy	$89	2%
66982	Cataract surgery, complex	$83	1%
64483	Inj foramen epidural l/s	$73	5%
62311	Inject spine l/s (cd)	$68	5%
66821	After cataract laser surgery	$55	5%
63650	Implant neuroelectrodes	$40	-2%
15823	Revision of upper eyelid	$39	-2%
G0105	Colorectal scrn; hi risk ind	$38	2%
64493	Inj paravert f jnt l/s 1 lev	$36	5%
29827	Arthroscop rotator cuff repr	$36	-6%
64721	Carpal tunnel surgery	$31	-1%
G0121	Colon ca scrn not hi rsk ind	$30	2%
29881	Knee arthroscopy/surgery	$30	-1%
63685	Insrt/redo spine n generator	$28	8%
64590	Insrt/redo pn/gastr stimul	$25	8%
29880	Knee arthroscopy/surgery	$25	-1%
45384	Lesion remove colonoscopy	$23	2%
43235	Uppr gi endoscopy diagnosis	$23	2%
52000	Cystoscopy	$20	4%
28285	Repair of hammertoe	$19	-1%
62310	Inject spine c/t	$18	5%
26055	Incise finger tendon sheath	$17	-4%
67042	Vit for macular hole	$17	-1%
29826	Shoulder arthroscopy/surgery	$17	-1%
67904	Repair eyelid defect	$17	-3%
50590	Fragmenting of kidney stone	$17	-4%

*Note that HCPCS codes we are deleting for CY 2013 are not displayed in this table.

(3) Estimated Effects of ASC Payment System Final Policies on Beneficiaries

We estimate that the CY 2013 update to the ASC payment system would 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 2013. 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.) Furthermore, the additions to the ASC list of covered surgical procedures will provide beneficiaries access to more surgical procedures in ASCs. 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 2013, the beneficiary coinsurance amount would 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 changes 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. Some of the major ASC issues discussed in this final rule with comment period and the options considered are discussed below.

- Alternatives Considered for the Annual Update to ASC Payments for Inflation

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 under the revised payment system, we are not compelled to increase the ASC payment amounts by the CPI-U. Nonetheless, we adopted a policy, which we codified at § 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI-U for CY 2010 and subsequent calendar years. While we believe the CPI-U is appropriate to apply to update the ASC payment system, we are aware that the CPI-U is highly weighted for housing and transportation and may not best reflect inflation in the cost of providing ASC services. Therefore, as alternatives to using the CPI-U to update ASC payment rates for inflation, in developing this final rule with comment period, we considered using: (1) the hospital market basket, which is

used to update OPPS rates for inflation; (2) the PE component of the MEI update, which is used to update the MPFS payment rates for inflation; or (3) the average of the hospital market basket update and the PE component of the MEI update.

However, until we have more information regarding the cost inputs of ASCs, we are not confident that any of the alternatives are a better proxy for ASC cost inputs than the CPI-U. Therefore, we proposed and are finalizing our established policy to continue to base the ASC update on the CPI-U.

- Alternatives Considered for Office-Based Procedures

According to our existing policy for the ASC payment system, we designate as office-based those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years and that we determine are predominantly performed in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure HCPCS code and/or, if appropriate, the clinical characteristics, utilization, and volume of related HCPCS codes. We establish payment for procedures designated as office-based at the lesser of the MPFS nonfacility practice expense payment amount or the ASC rate developed according to the standard methodology of the ASC payment system.

In developing this final rule with comment period, we reviewed CY 2011 utilization data for all surgical procedures added to the ASC list of covered surgical procedures in CY 2008 or later years and for those procedures for which the office-based designation is temporary in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74406 through 74408). Based on that review and as discussed in section

XIV.C.1.b. of this final rule with comment period, we are newly designating 6 surgical procedures as permanently office-based, are making temporary office-based designations for 6 procedures in CY 2013 of the 8 procedures that were designated as temporarily office-based for CY 2012, and are making temporary office-based designations for 2 procedures that are new ASC covered surgical procedures for CY 2013. We considered two alternatives in developing this policy.

The first alternative we considered was to make no change to the procedure payment designations. This would mean that we would pay for the 6 procedures we proposed to designate as permanently office-based and the 8 procedures we proposed to designate as temporarily office-based at an ASC payment rate calculated according to the standard ratesetting methodology of the ASC payment system. We did not select this alternative because our analysis of the data and our clinical review indicated that all 6 procedures we proposed to designate as permanently office-based, as well as the 8 procedures that we proposed to designate temporarily as office-based, are considered to be predominantly performed in physicians' offices. Consistent with our final policy adopted in the August 2, 2007 final rule (72 FR 42509 through 42513), we were concerned that making payments at the standard ASC payment rate for the 6 procedures we proposed to designate as permanently office-based and the 8 procedures we proposed to designate as temporarily office-based could create financial incentives for the procedures to shift from physicians' offices to ASCs for reasons unrelated to clinical decisions regarding the most appropriate setting for surgical care. Further, consistent with our policy, we believe that when adequate data become available to make permanent

determinations about procedures with temporary office-based designations, maintaining the temporary designation is no longer appropriate.

The second alternative we considered and the one we selected for CY 2013 is to designate 6 additional procedures as permanently office-based for CY 2013 and to designate 8 procedures as temporarily office-based in CY 2013. We chose this alternative because our claims data and clinical review indicate that these procedures would be considered to be predominantly performed in physicians' offices. We believe that designating these procedures as office-based, which results in the CY 2013 ASC payment rate for these procedures potentially being capped at the CY 2013 physicians' office rate (that is, the MPFS nonfacility practice expense payment amount), if applicable, is an appropriate step to ensure that Medicare payment policy does not create financial incentives for such procedures to shift unnecessarily from physicians' offices to ASCs, consistent with our final policy adopted in the August 2, 2007 final rule.

c. Effects of the Revisions to the QIO Regulations

In section XVIII. of this final rule with comment period, we discuss our changes to the QIO program regulations, including: adding provisions for processing beneficiary complaints that will give beneficiaries more information about the QIO's review process, which includes a new alternative dispute resolution option (immediate advocacy); giving QIOs the authority to send and receive secure transmissions of electronic versions of health information; conveying beneficiaries the right to authorize the QIOs' use and disclosure of confidential information; and removing outdated regulatory provisions that will enable QIOs to give more information regarding the results of reviews. We believe

the changes will improve the QIO program, give beneficiaries better information regarding review activities and reduce burden for both providers and practitioners.

The QIO program requests approximately 62,400 medical records each year for the Hospital IQR and Hospital OQR Programs combined (38,400 for inpatient and 24,000 for outpatient). For the Hospital IQR Program, the average number of pages per medical record is 289 pages, and for the Hospital OQR Program, the average number of pages is 74. Reimbursement is made at a rate of $0.12 per page for PPS hospitals, which includes the costs of toner, paper, and labor associated with the copying of paper medical records. We also note that the labor associated with copying the medical records can be considerable. In fact, many providers and practitioners store health information electronically, and these same providers and practitioners are forced to print hard copies of the information for shipment to the QIOs. Sometimes this may entail using the "print screen" function to create the record to be shipped. On average, the cost of shipping the records is approximately $32.35 per shipment, with approximately 5,200 shipments being made. The shipping amount takes into consideration that, for some QIO review activities, multiple records are shipped at one time, which can involve the use of several boxes.

Under our proposal, by example, assuming all hospitals operate under a PPS, should all hospitals transfer health information on a digital versatile device (DVD), the costs associated with the toner and paper would be replaced by the costs of a DVD. In fact, numerous medical records could be copied to a single DVD. Moreover, the labor in copying the records would be substantially reduced because, for example, rather than

copying the average 289 pages related to a Hospital IQR Program review, the file could be electronically transferred to a DVD for shipping. We estimate that the $0.12 per page rate could be reduced by as much as $0.07 per page. Based on the overall average number of pages for the Hospital IQR Program and Hospital OQR Program, respectively, reducing the per page rate to $0.05 per page would save $901,152 ((11,097,600 pages x $0.12 = $1,331,712) + (1,776,000 pages x $0.12 = $213,120) – (11,097,600 pages x $0.05 = $554,880) – (1,776,000 pages x $0.05 = $88,800)).

The changes also would reduce the costs associated with mailing the records. For the Hospital IQR Program, hospitals sometimes need to ship as many as four or five large boxes of medical records. By comparison, a single DVD can house multiple medical records and even if multiple DVDs were required, all the DVDs could be mailed in a single envelope at a significantly lower cost. Potentially, the per envelope mailing cost could be as low as $5 compared to the per shipment average cost of $32.35. Thus, if all records were shipped on DVDs, the program would save $142,220 ($168,220 – $26,000).

The changes allowing the sending and receiving of electronic versions of health information also would reduce costs for other QIO review activities. QIOs request approximately 100,000 medical records in completing other review activities, including but not limited to requests related to the processing of general quality of care reviews, written beneficiary complaint reviews, medical necessity reviews, and expedited discharge appeal reviews. The average number of pages associated with each of these reviews varies greatly, and we have estimated an overall average of approximately 175 pages per request. The reimbursement rate for requests associated with these

activities is $0.12 per page for PPS providers and $0.15 per page for practitioners and non-PPS providers. Assuming an overall average number of 175 pages for each record, we estimate that the total number of pages requested is approximately 17,500,000. Assuming that approximately 75 percent (13,125,000) of the pages are from practitioners and non-PPS providers, with the remaining 25 percent (4,375,000) from PPS providers, based on the $0.12 or $0.15 per page reimbursement rate, we estimate that the total costs would be approximately $1,968,750 and $525,000, respectively. If all these requests were fulfilled using a DVD or other electronic means, we estimate that the cost per page could be reduced to approximately $0.05 per page for PPS providers and $0.06 per page for practitioners and non-PPS providers. Thus, the estimated savings related to PPS providers would be approximately $306,250 ($525,000 - $218,750) and the estimated savings related to practitioners and non-PPS providers would be approximately $1,181,250 ($1,968,750 – $787,500).

With regard to mailing, we also believe the changes would significantly reduce the costs for other QIO review activities. Moreover, unlike the Hospital IQR and Hospital OQR Programs, the number of medical records requested for these other QIO review activities more closely mirrors the actual number of shipments made. For example, on average, the QIOs request 100,000 medical records related to these other activities, and we estimate that this equates to approximately 82,000 shipments. We estimate that there is a corresponding decrease in the cost per shipment ($7 per shipment compared to $32.35 per shipment for the Hospital IQR and OQR Programs). If DVDs

were used instead of paper copies of the medical records, we estimate saving of $164,000 (82,000 x $7 – 82,000 x $5).

Beginning with the QIOs' most recent scope of work, which began August 1, 2011, QIOs began offering immediate advocacy to Medicare beneficiaries for the resolution of certain types of oral complaints. We believe that cost savings will be realized as a result. In developing this new process, we had several goals. One of these goals was to create a way for Medicare beneficiaries to obtain resolutions of complaints much faster than the traditional peer review process, which usually take over 158 days to complete because, inevitably, various timeframes throughout the review process are not met (for example, providers and practitioners sometimes take more time that allowed to respond to medical record requests or the opportunity for discussion). By comparison, we believe that immediate advocacy normally can be completed within 2 calendar days. However, this process could result in reductions of more than merely a reduction in days. Because immediate advocacy is completed without reviewing a beneficiary's medical record, QIOs would save the costs associated with requesting the records, which includes the labor, supplies (toner and paper), and mailing of the records. Moreover, although there may be some variation among QIOs, immediate advocacy would typically be carried out by a nurse or social worker, and, thus, the QIO can avoid the more expensive costs associated with the use of a physician reviewer.

In addition, for a traditional complaint review, the QIO's peer reviewer completes three separate and distinct reviews (the interim initial determination, the final initial determination, and the reconsideration determination), each time reviewing the medical

information and providing his/her conclusion about the quality of care provided. Moreover, the provider and/or practitioner who is the subject of the complaint will be brought into the complaint process each time to respond to the conclusions. With immediate advocacy, the nurse or social work would be involved once, early in the process, with the primary role being to listen to the beneficiary's concerns and then coordinate a resolution with the provider or practitioner, instead of merely reviewing information contained in the beneficiary's medical information. Not only would this process enable beneficiaries to obtain resolution of complaints quicker, but it would decrease the amount of time and energy practitioners and providers would devote to responding to the complaints. This is especially true for certain types of complaints where the issues involved are not even documented in the medical information the physician reviewers would review in the traditional complaint process. Typically, we have estimated a total cost per case of $960 for each case processed using the traditional peer review process. We estimate that, for those instances where immediate advocacy is used, the average cost per case would be approximately $87. On average, QIOs complete approximately 3,500 complaint reviews each year, and we estimate that approximately 10 percent of these reviews (350) would be resolved using immediate advocacy instead of the traditional peer review process. This would result in savings of $305,550 each year (($960 x 350 = $336,000) – ($87 x 350 = $30,450)).

Comment: One commenter stated that the estimate of $87 for immediate advocacy "seems unreasonably low for the actual staff time involved in these cases."

Response: We appreciate the comment. However, our ability to evaluate the substance of the comment is limited because the commenter did not give any specific information regarding why the commenter believes the estimated amount is unreasonably low. In identifying the estimated amount, we considered the significantly reduced time frame within which these cases are resolved, the fact that the types of complaints are less severe than what can be handled through the traditional complaint process, and the fact that QIOs will be able to use review analysts in completing these reviews compared to other more costly peer reviewers used as many as three times as part of the traditional complaint review process. While we recognize that the time needed to achieve an actual resolution may be longer, we estimated that, on average, the actual amount of time spent working on these cases to be approximately 70 minutes, and using an hourly rate of approximately $43.17 and adding in other costs, such as leave and other indirect costs, we believe $87 is appropriate. In light of the above, we see no need to adjust the estimated cost.

The technical changes to the QIO regulations under section XVIII.F. of this final rule with comment period that we are making to improve the regulations reflect CMS' commitment to the principles of the President's Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011).

Below is a table summarizing the savings associated with both of these provisions.

Provision	Savings per Year
Authority to transmit information electronically	$2,388,622 total per year

Quality Reporting Information (Copying)	$901,152
Quality Reporting Information (Mailing)	$142,220
Other QIO Activities (Copying)	$1,487,500
Other QIO Activities (Mailing)	$164,000
Immediate Advocacy	$305,550 total per year
Total Savings	**$3,000,422 per year**

d. 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 three accounting statements to illustrate the impacts of this final rule with comment period. The first accounting statement, Table 60 below, illustrates the classification of expenditures for the CY 2013 estimated hospital OPPS incurred benefit impacts associated with the CY 2013 OPD fee schedule increase, based on the FY 2013 President's Budget. The second accounting statement, Table 61 below, illustrates the classification of expenditures associated with the 0.6 percent CY 2013 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 FY 2013 President's Budget. The third accounting statement, Table 62 below, illustrates the estimated impact based on the provisions allowing QIOs to securely send and receive electronic versions of health information as well as the use of alternative dispute resolution process called immediate advocacy. Lastly, the three tables classify most estimated impacts as transfers.

TABLE 60.--ACCOUNTING STATEMENT: CY 2013 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2012 TO CY 2013 ASSOCIATED WITH THE CY 2013 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 received payment under the hospital OPPS
Total	$600 million

TABLE 61.--ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2012 TO CY 2013 AS A RESULT OF THE FINAL CY 2013 UPDATE TO THE REVISED ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$18 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$18 million

TABLE 62.--ACCOUNTING STATEMENT: CY 2013 ESTIMATED SAVINGS TO MEDICARE FROM THE REVISIONS OF THE QIO REGULATIONS

Category	Transfers
Annualized Monetized Transfers	-$3.0 million
From whom to Whom	Federal Government to Medicare Providers
Total	-$3.0 million

e. Effects of Requirements for the Hospital OQR Program

In section XVI. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68758 through 68781), section XVI. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60629 through 60655), section XVI. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72110), and section XVI. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74451 through 74492), we

discussed the requirements for subsection (d) hospitals to report quality data under the Hospital OQR Program in order to receive the full OPD fee schedule increase factor for CY 2010, CY 2011, and CYs 2012 through 2014, respectively. In section XV. of this final rule with comment period, we adopted additional policies affecting the Hospital OQR Program.

We determined that 114 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor for CY 2012. Most of these hospitals (106 of the 114) received little or no OPPS payment on an annual basis and did not participate in the Hospital OQR Program. We estimate that 106 hospitals may not receive the full OPD fee schedule increase factor in CY 2014. 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 2015.

In section XVI.E.3.a. of the CY 2010 OPPS/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 OPPS/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. Additionally, this level is consistent with what we adopted in the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) 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 OPPS/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 this final rule with comment period, for CY 2014 and subsequent years payment determinations, we are making 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 are not making any modifications to our validation requirements. We expect these policies to have minimal impact on the 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 2015. We also are unable to estimate the number of hospitals that would fail the validation documentation submission requirement for the CY 2015 payment update.

The validation requirements for CY 2014 would 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 7,300 total cases for up to 500 hospitals for CY 2014 represents a minimal burden to Hospital OQR Program participating hospitals.

We are maintaining a 45-day timeframe for hospitals to submit requested medical record documentation to meet our validation requirement. The total burden would be a

maximum of 12 charts for each of the four quarters that must be copied and mailed within a 45-day period after the end of each quarter.

f. Effects of the EHR Electronic Reporting Pilot

Under section XV.K. of this final rule with comment period, we are allowing eligible hospitals and CAHs that are participating in the EHR Incentive Program to meet the CQM reporting requirement of the program in FY 2013 by participating in the Medicare EHR Incentive Program Electronic Reporting Pilot. This will facilitate the use of an electronic infrastructure that supports the use of EHRs by eligible hospitals and CAHs to meet the requirements in various CMS programs and reduce reporting burden simultaneously. Through this pilot, we have encouraged hospitals and CAHs to take steps toward the adoption of EHRs that will allow for reporting of clinical quality data from EHRs to a CMS data repository. We expect that the submission of quality data through EHRs will provide a foundation for establishing the capacity of hospitals to send, and for CMS, in the future, to receive, quality measures via hospital EHRs for the Hospital IQR Program's measures. Hospitals that choose to participate in the EHR Incentive Program by means of this pilot for the purpose of meeting the CQM reporting requirement of meaningful use will be taking those first steps toward reporting clinical quality data in such a way.

There are no changes to the costs or impact in the 2012 OPPS/ASC final rule for the 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs.

g. Effects of Proposals for the ASCQR Program

In section XVI. of this final rule with comment period, for the ASCQR Program, we discuss public comment on our approach for future measures selection and development as well as on certain measures for potential future inclusion in the ASCQR Program measure set. We are finalizing our approach to future measure selection and development for the ASCQR Program. For the CY 2015 payment determination and subsequent calendar year payment determinations, we are adopting requirements for claims-based measures regarding the dates for submission and payment and data completeness. We also are finalizing our policy regarding how the payment rates will be reduced in CY 2014 and in subsequent calendar years for ASCs that fail to meet program requirements, and we are clarifying our policy on updating 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 not expect our new policies to significantly affect the number of ASCs that do not receive a full annual payment update.

h. Effects of Updates to the IRF QRP

In section XVII. of this final rule with comment period, we discuss our policy that, once we initially adopt a measure for the IRF QRP for a payment determination, that measure will be automatically adopted for all subsequent fiscal years' payment determinations or until such time as we might propose and finalize the measure's removal, suspension, or replacement.

We also discuss how we will use the CAUTI measure previously finalized. We will use the CAUTI measure that was previously finalized in the FY 2012 IRF PPS final rule (76 FR 24214) with revisions which were made by the NQF after publication of the FY 2012 IRF PPS final rule. We will apply the revised CAUTI measure for the FY 2014 reporting period, which affects the FY 2012 APU, and each subsequent reporting period thereafter. We also are finalizing the use of a nonrisk-adjusted version of the NQF-endorsed pressure ulcer measure, which does not include public reporting of any nonrisk-adjusted pressure ulcer measure data.

There are no changes to the costs or impact as stated in FY 2012 IRF PPS final rule (76 FR 24214). IRFs will be required to submit CAUTI data on all patients that are admitted to their facility and pressure ulcer data only on those patients for which they are required to submit the IRF-PAI. This policy has not changed. Further, we do not expect our new policies to significantly affect the number of IRFs that do not receive a full annual payment update.

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 $34.5 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 2,053 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 708 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 $139 million. This final rule with comment period does not mandate any requirements for State, local, or tribal governments, or for the private sector.

D. Conclusion

The changes we are making in this final rule with comment period will affect all classes of hospitals paid under the OPPS and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS will experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2013. Table 57 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that will result in a 1.9 percent increase in payments for all services paid under the OPPS in CY 2013, after considering all changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, estimated payment for outliers, and changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS will experience more significant gains and others will experience modest losses in OPPS payments in CY 2013. We estimate that hospitals for whom DSH data are not available (non-IPPS, largely urban hospitals) will experience an increase of 8.3 percent due to increased payments for partial hospitalization, group psychotherapy and hemodialysis services. CMHCs will see an overall decrease in payment of 4.4 percent as a result of a decrease in their estimated costs.

The updates to the ASC payment system for CY 2013 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 58 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted CPI-U update factor of 0.6 percent for CY 2013.

XXIII. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined the OPPS and ASC provisions included in this final rule with comment period in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 57 of this final rule with comment period, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) will increase by 1.9 percent under this final rule with comment period. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this final rule with comment period, in conjunction with the remainder of this document, demonstrate that this final rule with comment period is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This final rule with comment period will affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 476

Health care, Health professional, Health record, Peer Review Organization (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 478

Administrative practice and procedure, Health care, Health professions, Peer Review Organizations (PRO), Reporting and recordkeeping requirements.

42 CFR Part 480

Health care, Health professions, Health records, Peer Review Organizations (PRO), Privacy, Reporting and recordkeeping requirements.

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 416—AMBULATORY SURGICAL SERVICES

1. The authority citation for Part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and1395hh).

2. Section 416.160 is amended by revising paragraph (a)(1) to read as follows:

§ 416.160 Basis and scope.

(a) * * *

(1) Section 1833(i)(2)(D) of the Act requires the Secretary to implement a revised payment system for payment of surgical services furnished in ASCs. The statute requires that, in the year such system is implemented, the system shall be designed to result in the same amount of aggregate expenditures for such services as would be made if there was no requirement for a revised payment system. The revised payment system shall be implemented no earlier than January 1, 2006, and no later than January 1, 2008. The statute provides that the Secretary may implement a reduction in any annual update for failure to report on quality measures as specified by the Secretary. The statute also requires that, for CY 2011 and each subsequent year, any annual update to the ASC payment system, after application of any reduction in the annual update for failure to report on quality measures as specified by the Secretary, be reduced by a productivity adjustment. There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, of the revised payment system.

* * * * *

3. Section 416.171 is amended by--

a. Redesignating paragraph (a)(2)(iii) as paragraph (a)(2)(iv) and revising it.

b. Adding new paragraph (a)(2)(iii).

The revision and addition read as follows:

§ 416.171 Determination of payment rates for ASC services.

(a) * * *

(2) * * *

(iii) For CY 2014 and subsequent calendar years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(ii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(iv) Productivity adjustment. (A) For calendar year 2011 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(ii) of this section, after application of any reduction under paragraph (a)(2)(iii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(B) The application of the provisions of paragraph (a)(2)(iv)(A) of this section may result in the update being less than zero percent for a year, and may result in payment rates for a year being less than the payment rates for the preceding year.

* * * * *

4. Section 416.195 is amended by revising paragraphs (a)(2) and (a)(4) introductory text to read as follows:

§ 416.195 Determination of membership in new classes of new technology IOLs.

(a) * * *

(2) The IOL shall have a new lens characteristic in comparison to currently available IOLs. The labeling, which must be approved by FDA, shall contain a claim of a specific clinical benefit imparted by the new lens characteristic.

* * * * *

(4) Any specific clinical benefit referred to in paragraph (a)(2) of this section must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved outcome. Improved outcomes include:

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

5. 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, 1395(t), and 1395hh).

6. Section 419.2 is amended by revising paragraph (b) introductory text 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 directly related and integral to performing a procedure or furnishing a service on an outpatient basis. In general, these costs include, but are not limited to, the following items and services, the payments for which are packaged into the payments for the related procedures or services.

* * * * *

7. Section 419.31 is amended by revising paragraphs (a)(1), (b), and (c)(2) to read as follows:

§ 419.31 Ambulatory payment classification (APC) system and payment weights.

(a) * * *

(1) CMS classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. Except as specified in paragraph (a)(2) of this section, items and services within a group are not comparable with respect to the use of resources if the highest geometric mean cost for an item or service within the group is more than 2 times greater than the lowest geometric mean cost for an item or service within the group.

* * * * *

(b) APC weighting factors. (1) Using hospital outpatient claims data from calendar year 1996 and data from the most recent available hospital cost reports, CMS

determines the geometric mean costs for the services and procedures within each APC group.

(2) CMS assigns to each APC group an appropriate weighting factor to reflect the relative geometric mean costs for the services within the APC group compared to the geometric mean costs for the services in all APC groups.

(c) * * *

(2) CMS standardizes the geometric mean costs determined in paragraph (b)(1) of this section by adjusting for variations in hospital labor costs across geographic areas.

8. Section 419.32 is amended by revising paragraph (b)(1)(iv)(A) and adding paragraph (b)(1)(iv)(B)(*4*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv)(A) For calendar year 2003 and subsequent years, by the OPD fee schedule increase factor, which, subject to the adjustments specified in paragraph (b)(1)(iv)(B) of this section, is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(B) * * *

(*4*) For calendar year 2013, a multifactor productivity adjustment (as determined by CMS) and 0.1 percentage point.

* * * * *

9. Section 419.70 is amended by revising paragraph (d)(2) introductory text and adding paragraph (d)(7) to read as follows:

§ 419.70 Transitional adjustments to limit decline in payments.

* * * * *

(d) * * *

(2) Temporary treatment for small rural hospitals on or after January 1, 2006. For covered hospital outpatient services furnished in a calendar year from January 1, 2006 through December 31, 2012, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 95 percent of that difference for services furnished during CY 2006, 90 percent of that difference for services furnished during CY 2007, and 85 percent of that difference for services furnished during CYs 2008, 2009, 2010, 2011, and 2012 if the hospital--

* * * * *

(7) Temporary treatment of small sole community hospitals on or after January 1, 2012 through December 31, 2012. (i) For covered hospital outpatient services furnished on or after January 1, 2012 through December 31, 2012, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 85 percent of that difference if the hospital--

(A) Is a sole community hospital as defined in § 412.92 of this chapter or is an essential access community hospital as described under § 412.109 of this chapter; and

(B) Has 100 or fewer beds as defined in § 412.105(b) of this chapter, except as provided in paragraph (d)(7)(ii) of this section.

(ii) For covered hospital outpatient services furnished on or after January 1, 2012 through February 29, 2012, the bed size limitation under paragraph (d)(7)(i)(B) of this section does not apply.

* * * * *

PART 476--UTILIZATION AND QUALITY CONTROL REVIEW

10. 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).

11. Section 476.1 is amended by--

a. Removing the definition of "Active staff privileges".

b. Adding definitions of "Appointed representative", "Authorized representative", "Beneficiary complaint", "Beneficiary complaint review", "Beneficiary representative", "General quality of care reviews", "Gross and flagrant violation", "Immediate advocacy", "Quality improvement initiative", "Quality of care concern", "Quality of care review", "Significant quality of care concern", and "Substantial violation in a substantial number of cases".

c. Revising the definition of "Preadmission certification".

The additions and revisions read as follows:

§ 476.1 Definitions.

* * * * *

Appointed representative means an individual appointed by a Medicare beneficiary to represent the beneficiary in the beneficiary complaint review process.

Authorized representative means an individual authorized, under State or other applicable law, to act on behalf of a Medicare beneficiary. An authorized representative has all of the rights and responsibilities of a Medicare beneficiary throughout the processing of a beneficiary complaint.

Beneficiary complaint means a complaint by a Medicare beneficiary or a Medicare beneficiary's representative alleging that the quality of Medicare covered services received by the beneficiary did not meet professionally recognized standards of care. A complaint may consist of one or more quality of care concerns.

Beneficiary complaint review means a review conducted by a QIO in response to the receipt of a written beneficiary complaint to determine whether the quality of Medicare covered services provided to the beneficiary was consistent with professionally recognized standards of health care.

Beneficiary representative means an individual identified as an authorized or appointed representative of a Medicare beneficiary.

* * * * *

General quality of care review means a review conducted by a QIO to determine whether the quality of Medicare covered services provided to a Medicare beneficiary was consistent with professionally recognized standards of health care. A general quality of care review may be carried out as a result of a referral to the QIO or a QIO's

identification of a potential concern during the course of another review activity or through the analysis of data.

Gross and flagrant violation means a violation of an obligation resulting from inappropriate or unnecessary services, services that do not meet recognized professional standards of care, or services that are not supported by evidence of medical necessity or quality as required by the QIO. The violation must have occurred in one or more instances that present an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations.

* * * * *

Immediate advocacy means an informal alternative dispute resolution process used to quickly resolve an oral complaint a Medicare beneficiary or his or her representation has regarding the quality of Medicare covered health care received. This process involves a QIO representative's direct contact with the provider and/or practitioner.

* * * * *

Preadmission certification means a favorable determination, transmitted to the hospital and the fiscal intermediary or the Medicare administrative contractor, approving the patient's admission for payment purposes.

* * * * *

Quality improvement initiative means any formal activity designed to serve as a catalyst and support for quality improvement that uses proven methodologies to achieve

these improvements. The improvements may relate to safety, health care, health and value and involve providers, practitioners, beneficiaries, and/or communities.

Quality of care concern means a concern that care provided did not meet a professionally recognized standard of health care. A general quality of care review or a beneficiary complaint review may cover a single or multiple concerns.

Quality of care review means a review conducted by a QIO to determine whether the quality of Medicare covered services provided to beneficiaries was consistent with professionally recognized standards of health care. A quality of care review can either be a beneficiary complaint review or a general quality of care review.

* * * * *

Significant quality of care concern means a determination by the QIO that the quality of care provided to a Medicare beneficiary did not meet the standard of care and, while not a gross and flagrant or substantial violation of the standard, represents a noticeable departure from the standard that could reasonably be expected to have a negative impact on the health of a beneficiary.

Substantial violation in a substantial number of cases means a pattern of providing care that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the QIO.

* * * * *

12. Section 476.70 is revised to read as follows:

§ 476.70 Statutory bases and applicability.

(a) Statutory bases. Sections 1154, 1866(a)(1)(F), and 1886(f)(2) of the Act require that a QIO review those services furnished by physicians, other health care professionals, providers and suppliers as specified in its contract with the Secretary.

(b) Applicability. The regulations in this subpart apply to review conducted by a QIO and its subcontractors.

13. Section 476.71 is amended by--

a. Revising paragraph (a)(2).

b. In paragraph (b) , removing the reference "§ 405.330(b)" and adding in its place the reference "§ 411.400(b) of this chapter".

c. Revising paragraph (c)(1).

The revisions read as follows:

§ 476.71 QIO review requirements.

(a) * * *

(2) Whether the quality of the services meets professionally recognized standards of health care, as determined through the resolution of oral beneficiary complaints as specified in § 476.110, written beneficiary complaints as specified in § 476.120, or the completion of general quality of care reviews as specified in § 476.160.

* * * * *

(c) * * *

(1) The QIO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare

administrative contractor, fiscal intermediary, or carrier if it determines that the information submitted by the hospital was incorrect.

* * * * *

§ 476.72 [Removed]

14. Section 476.72 is removed.

§ 476.73 [Amended]

15. In § 476.73--

a. In paragraph (a), first sentence, the phrase "and Medicare fiscal intermediaries and carriers." is removed and the phrase "Medicare administrative contractors, fiscal intermediaries, and carriers." is added in its place.

b. In paragraph (b)(1), the reference "§ 466.78(b)(3)" is removed and the reference "§ 476.78(b)(3)" is added in its place.

§ 476.74 [Amended]

16. In § 476.74--

a. In paragraph (b), the phrase "appropriate Medicare fiscal intermediary or carrier" is removed and the phrase "appropriate Medicare administrative contractor, fiscal intermediary, or carrier" is added in its place.

b. In paragraph (c)(1), the phrase "Medicare fiscal intermediaries and carriers" is removed, and the phrase "Medicare administrative contractors, fiscal intermediaries, and carriers" is added in its place.

c. In paragraph (e), the reference "§ 405.332" is removed and the reference "§ 411.402" is added in its place.

17. Section 476.78 is amended by—

a. Revising the section heading.

b. Revising paragraphs (b)(2)(i) and (ii).

The revisions read as follows:

§ 476.78 Responsibilities of providers and practitioners.

* * * * *

(b) * * *

(2) * * *

(i) Except as provided under §§ 476.130(b) and 476.160(b), relating to beneficiary complaint reviews and general quality of care reviews, photocopy and deliver to the QIO all required information within 14 calendar days of a request. A QIO is authorized to require the receipt of the medical information earlier than the 14-day timeframe if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial violation as specified in Part 1004 of this title and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(ii) Send secure transmission of an electronic version of medical information, if available, subject to the QIO's ability to support receipt and transmission of the electronic version. Providers and practitioners must deliver electronic versions of medical information within 14 calendar days of the request. A QIO is authorized to require the receipt of the medical information earlier than the 14-day timeframe if the QIO makes a

preliminary determination that the review involves a potential gross and flagrant or substantial violation as specified in Part 1004 of this title and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

* * * * *

§ 476.80 [Amended]

18. In § 476.80--

a. In the section heading and paragraphs (b)(1) introductory text and (c)(1) (two places), the phrase "Medicare fiscal intermediaries and carriers" is removed and the phrase "Medicare administrative contractors, fiscal intermediaries, and carries" is added in its place.

b. In paragraph (a) introductory text, the phrase "Medicare fiscal intermediary or carrier" is removed and the phrase "Medicare administrative contractor, fiscal intermediary, or carrier" is added in its place.

c. In paragraphs (a)(1), (a)(2) introductory text (two places), (c)(3)(ii), (d)(1), and (d)(2), the phrase "fiscal intermediary or carrier" is removed and the phrase "Medicare administrative contractor, fiscal intermediary, or carrier" is added in its place.

d. In paragraph (e), in the paragraph heading and in paragraphs (e)(1) and (e)(2), the phrase "fiscal intermediary" is removed and the phrase "Medicare administrative contractor or fiscal intermediary" is added in its place.

§ 476.86 [Amended]

19. In § 476.86--

a. In paragraph (a)(1)(iii), the reference "§ 405.310(g) or § 405.310(k)" is removed and the reference "§ 411.15(g) or § 411.15(k)" is added in its place.

b. In paragraph (a)(2) and (d), the phrase "Medicare fiscal intermediaries and carriers" is removed and the phrase "Medicare administrative contractors, fiscal intermediaries, and carriers" is added in its place.

c. In paragraph (c) introductory text, the phrase "Medicare fiscal intermediary or carrier" is removed and the phrase "Medicare administrative contractor, fiscal intermediary, or carrier" is added in its place.

d. In paragraph (c)(1), the phrase "fiscal intermediary or carrier" is removed and the phrase "Medicare administrative contractor, fiscal intermediary, or carrier" is added in its place.

e. In paragraph (e), the phrase "intermediaries and carriers" is removed and the phrase "Medicare administrative contractors, fiscal intermediaries, and carriers" is added in its place.

f. In paragraph (f), the reference "part 473" is removed and the reference "part 478" is added in its place.

§ 476.94 [Amended]

20. In § 476.94--

a. In paragraph (a)(1)(iv), the phrase "fiscal intermediary or carrier" is removed and the phrase "Medicare administrative contractor, fiscal intermediary, or carrier" is added in its place.

b. In paragraph (d), the phrase "Medicare fiscal intermediary or carrier" is removed and the phrase "Medicare administrative contractor, fiscal intermediary, or carrier" is added in its place.

c. In paragraph (c)(3), the reference "part 473" is removed and the reference "part 478" is added in its place.

§ 476.98 [Amended]

21. In § 476.98, in paragraph (a)(1), the phrase "with active staff privileges in one or more hospitals" is removed.

22. Section 476.104 is amended by revising paragraph (a) to read as follows:

§ 476.104 Coordination of activities.

* * * * *

(a) Medicare administrative contractors, fiscal intermediaries, and carriers.

* * * * *

23. Sections 476.110, 476.120, 476.130, 476.140, 476.150, 476.160, 476.170 are added to subpart C to read as follows:

Subpart C--Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations (QIOs)

Sec.

* * * * *

476.110 Use of immediate advocacy to resolve oral beneficiary complaints.

476.120 Submission of written beneficiary complaints.

476.130 Beneficiary complaint review procedures.

476.140 Beneficiary complaint reconsideration procedures.

476.150 Abandoned complaints and reopening rights.

476.160 General quality of care review procedures.

476.170 General quality of care reconsideration procedures.

* * * * *

§ 476.110 Use of immediate advocacy to resolve oral beneficiary complaints.

(a) Immediate advocacy. A QIO may offer the option of resolving an oral complaint through the use of immediate advocacy if:

(1) The complaint is received not later than 6 months from the date on which the care giving rise to the complaint occurred.

(2) After initial screening of the complaint, the QIO makes a preliminary determination that--

(i) The complaint is unrelated to the clinical quality of health care itself but relates to items or services that accompany or are incidental to the medical care and are provided by a practitioner and/or provider; or

(ii) The complaint, while related to the clinical quality of health care received by the beneficiary, does not rise to the level of being a gross and flagrant, substantial, or significant quality of care concern.

(3) The beneficiary agrees to the disclosure of his or her name to the involved provider and/or practitioner.

(4) All parties orally consent to the use of immediate advocacy.

(5) All parties agree to the limitations on redisclosure set forth in § 480.107 of this subchapter.

(b) Discontinuation of immediate advocacy. The QIO or either party may discontinue participation in immediate advocacy at any time.

(1) The QIO must inform the parties that immediate advocacy will be discontinued; and

(2) The beneficiary must be informed of his or her right to submit a written complaint in accordance with the procedures in § 476.120.

(c) Confidentiality requirements. All communications, written and oral, exchanged during the immediate advocacy process must not be redisclosed without the written consent of all parties.

(d) Abandoned complaints. If any party fails to participate or otherwise comply with the requirements of the immediate advocacy process, the QIO may determine that the complaint has been abandoned and--

(1) Inform the parties that immediate advocacy will be discontinued; and

(2) Inform the Medicare beneficiary of his or her right to submit a written complaint in accordance with the procedures in § 476.120.

§ 476.120 Submission of written beneficiary complaints.

(a) Timeframe for submission of written complaints. A QIO shall be responsible for conducting a review of any written complaint received from a Medicare beneficiary or a Medicare beneficiary's representative about the quality of health care if the

complaint is received not later than 3 years from the date on which the care giving rise to the complaint occurred.

(1) A written complaint includes a complaint submitted electronically to the QIO.

(2) In those instances where a Medicare beneficiary contacts the QIO regarding a complaint but declines to submit the complaint in writing and immediate advocacy has not been offered, the QIO may complete a general quality of care review in accordance with § 476.160 if the QIO makes a preliminary determination that the complaint involves a potential gross and flagrant, substantial or significant quality of care concern.

(b) New concerns raised by a Medicare beneficiary. If a Medicare beneficiary raises new concerns relating to the same complaint after the completion of the interim initial determination in § 476.130(c), the concerns will be processed as a new complaint. The QIO may process new concerns raised after the receipt of the written complaint as part of the same complaint, provided they are received prior to the completion of the interim initial determination. Even if a concern is received before the interim initial determination, the QIO can address it as a separate complaint if the QIO determines that this is warranted by the circumstances.

§ 476.130 Beneficiary complaint review procedures.

(a) Scope of the QIO review. In completing its review, the QIO shall consider any information and materials submitted by the Medicare beneficiary or his or her representative and any information submitted by the provider and/or practitioner. All information obtained by the QIO that fits within the definition of "confidential information" under § 480.101, will be held by the QIO as confidential.

(1) The QIO's review will focus on the episode of care from which the complaint arose and address the specific concerns identified by the beneficiary and any additional concerns identified by the QIO. The QIO may separate concerns into different complaints if the QIO determine that the concerns relate to different episodes of care.

(2) The QIO will use evidence-based standards of care to the maximum extent practicable. If no standard of care exists, the QIO will use available norms, best practices and established guidelines to establish the standard that will be used in completing the review. The QIO's determination regarding the standard used is not subject to appeal.

(b) Medical information requests. (1) Upon request by the QIO, a provider or practitioner must deliver all medical information requested in response to a Medicare beneficiary complaint within 14 calendar days of the request. A QIO is authorized to require the receipt of the medical information sooner if the QIO make a preliminary determination that the complaint involves a potential gross and flagrant or substantial quality of care concern as specified in Part 1004 of this title and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(2) In requesting medical information in response to a Medicare beneficiary complaint, the QIO must notify the practitioner and/or provider that the medical record is being requested in response to a beneficiary complaint, explain the practitioner's and/or provider's right to discuss the QIO's interim initial determination, and request the name of a contact person in order to ensure timely completion of the discussion.

(c) Interim initial determination. The QIO peer reviewer will complete the review and the practitioner and/or provider will be notified of the interim initial determination within 10 calendar days of the receipt of all medical information.

(1) A practitioner and provider will be notified by telephone of the opportunity to discuss the QIO's interim initial determination with the QIO in those situations where the peer reviewer determines that the quality of services does not meet professionally recognized standards of care for any concern in the complaint. The discussion must be held no later than 7 calendar days from the date of the initial offer.

(2) The interim initial determination becomes the final initial determination if the discussion is not completed timely as a result of the practitioner's and/or provider's failure to respond.

(3) Written statements in lieu of a discussion must be received no later than 7 calendar days from the date of the initial offer.

(4) In rare circumstances, the QIO may grant additional time to complete the discussion or submission of a written statement in lieu of a discussion.

(d) Final initial determination. The QIO must issue written notification of its final initial determination in those cases in which the QIO has determined that care met professionally recognized standards, as well as in those cases in which the QIO determined that standards were not met and the opportunity for discussion has been completed.

(1) No later than 3 business days after completion of its review, or for cases in which the standard was not met, no later than 3 business days after the discussion or

receipt of the provider's and/or practitioner's written statement, the QIO will notify (by telephone) the beneficiary and the provider/practitioner of its final initial determination and of the right to request a reconsideration of the QIO's final initial determination.

(2) Written notice of the QIO's final initial determination will be forwarded to all parties within 5 calendar days after completion of its review, and must include:

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns; and

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings, including references to medical information and, if held, the discussion with the involved practitioner and/or provider.

§ 476.140 Beneficiary complaint reconsideration procedures.

(a) Right to request a reconsideration. Beginning with complaints filed after July 31, 2014, a Medicare beneficiary, a provider, or a practitioner who is dissatisfied with a QIO's final initial determination may request a reconsideration by the QIO.

(1) The reconsideration request must be received by the QIO, in writing or by telephone, no later than 3 calendar days following initial notification of the QIO's determination. If the QIO is unable to accept a request, the request must be submitted by noon of the next day the QIO is available to accept a request.

(2) The Medicare beneficiary, or his or her representative, and the practitioner and/or provider must be available to answer any questions or supply any information that the QIO requests in order to conduct its reconsideration.

(3) The QIO must offer the Medicare beneficiary and the practitioner and/or provider an opportunity to provide further information. A Medicare beneficiary, a practitioner, and a provider may, but are not required to, submit evidence to be considered by the QIO in making its reconsideration decision.

(b) Issuance of the QIO's final decision. No later than 5 calendar days after receipt of the request for a reconsideration, or, if later, 5 calendar days after receiving any medical or other records needed for such reconsideration, the QIO must complete the review and notify the beneficiary and the practitioner/provider of its decision.

(1) The QIO's initial notification may be done by telephone, followed by the mailing of a written notice by noon of the next calendar day that includes--

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns;

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings; and

(iv) A statement that the letter represents the QIO's final determination and that there is no right to further appeal.

(2) The QIO may provide information to the beneficiary, practitioner, and provider regarding opportunities for improving the care given to patients based on the specific findings of its review and the development of quality improvement initiatives.

§ 476.150 Abandoned complaints and reopening rights.

(a) Abandoned complaints. If a Medicare beneficiary fails to participate or otherwise comply with the requirements of the beneficiary complaint review process and the QIO does not have sufficient information to complete its review, the QIO may determine that the complaint has been abandoned and--

(1) Inform the parties that its complaint review will be discontinued; and

(2) Inform the beneficiary of his or her right to resubmit a written complaint in accordance with the procedures in § 476.120.

(b) Reopening complaint reviews. A QIO may reopen a Medicare beneficiary complaint review using the same procedures that the QIO would use for reopening initial denial determinations and changes as a result of DRG validation, as described in § 476.96.

§ 476.160 General quality of care review procedures.

(a) Scope of the QIO review. A QIO may conduct a general quality of care review in accordance with section 1154(a)(1)(B) of the Act.

(1) A QIO may conduct general quality of care reviews based on--

(i) Concerns identified during the course of other QIO review activities;

(ii) Referrals from other sources, including but not limited to individuals, contractors, other Federal or State agencies; or

(iii) Analysis of data.

(2) The QIO's review will focus on all concerns identified by the QIO and/or identified by those who have referred or reported the concerns, with consideration being given to the episode of care related to the concerns.

(3) The QIO will use evidence-based standards of care to the maximum extent practicable. If no standard of care exists, the QIO must use available norms, best practices, and established guidelines to establish the standard that will be used in completing the review. The QIO's determination regarding the standard used is not subject to appeal.

(b) Medical information requests. Upon request by the QIO, a provider or practitioner must deliver all medical information requested within 14 calendar days of the request. A QIO is authorized to require the receipt of the medical information sooner if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial quality of care concern and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(c) Initial determination. The QIO peer reviewer will complete the review and the practitioner and/or provider will be notified of the initial determination in writing within 10 calendar days of the receipt of all medical information.

§ 476.170 General quality of care reconsideration procedures.

(a) Right to request a reconsideration. Beginning with reviews initiated after July 31, 2014, a provider or practitioner who is dissatisfied with a QIO's initial determination may request a reconsideration by the QIO.

(1) The reconsideration request must be received by the QIO, in writing or by telephone, by no later than 3 calendar days following receipt of the QIO's initial

determination. If the QIO is unable to accept the request, the request must be submitted by noon of the next day the QIO is available to accept a request.

(2) The practitioner or provider must be available to answer any questions or supply any information that the QIO requests in order to conduct its reconsideration.

(3) The QIO must offer the practitioner or provider an opportunity to provide further information. A practitioner or provider may, but is not required to, submit evidence to be considered by the QIO in making its reconsideration decision.

(b) Issuance of the QIO's final decision. No later than 5 calendar days after receipt of the request for a reconsideration, or, if later, 5 calendar days after receiving any medical or other records needed for such reconsideration, the QIO must complete the review and notify the practitioner or provider of its decision.

(1) The QIO's initial notification may be done by telephone, followed by the mailing of a written notice by noon the next calendar day that includes:

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns;

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings; and

(iv) A statement that the letter represents the QIO's final determination and that there is no right to further appeal.

(2) The QIO may provide information regarding opportunities for improving the care given to patients based on the specific findings of its review.

PART 478--RECONSIDERATIONS AND APPEALS

24. The authority citation for Part 478 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 478.15 [Amended]

25. In § 478.15(b), the reference "§§ 473.18 through 473.36, and 473.48(a) and (c)" is removed and the reference "§§ 478.18 through 478.36 and 478.48(a) and (c)" is added in its place.

§ 478.16 [Amended]

26. In § 478.16, the reference "§ 473.14(a)" is removed and the reference "§ 478.14" is added in its place.

§ 478.20 [Amended]

27. In § 478.20—

a. In paragraph (a)(1), the reference "§ 473.22" is removed and the reference "§ 478.22" is added in its place.

b. In paragraph (b), the reference "§ 473.22" is removed and the reference "§ 478.22" is added in its place.

c. In paragraph (c), the reference "§ 473.18(c)" is removed and the reference "§ 478.18(c)" is added in its place.

§ 478.28 [Amended]

28. In § 478.28 (a), the reference "§ 466.98" is removed and the reference "§ 476.98" is added in its place.

§ 478.38 [Amended]

29. In § 478.38--

a. In paragraph (a), the reference "§ 473.40" is removed and the reference "§ 478.40" is added in its place.

b. In paragraph (b), the reference "§ 473.48" is removed and the reference "§ 478.48" is added in its place.

§ 478.42 [Amended]

30. In § 478.42--

a. In paragraph (a) introductory text, the reference "§ 473.40" is removed and the reference "§ 478.40" is added in its place.

b. In paragraph (b), the reference "§ 473.22" is removed and the reference "§ 478.22" is added in its place.

§ 478.48 [Amended]

31. In § 478.48--

a. In paragraph (a)(1), the reference "§ 473.15" is removed and the reference "§ 478.15" is added in its place.

b. In paragraph (a)(2) introductory text, the reference "§ 473.15" is removed and the reference "§ 478.15" is added in its place.

PART 480--ACQUISITION, PROTECTION, AND DISCLOSURE QUALITY IMPROVEMENT ORGANIZATION REVIEW INFORMATION

32. The authority citation for Part 480 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 480.105 [Amended]

33. In § 480.105(a), the phrase "Medicare fiscal intermediaries" is removed and the phrase "Medicare administrative contractors or fiscal intermediaries" is added in its place.

34. Section 480.107 is amended by adding paragraph (l) to read as follows:

§ 480.107 Limitations on redisclosure.

* * * * *

(l) Redisclosures of information that is confidential because it identifies the parties involved in immediate advocacy may occur if all parties have consented to the redisclosure, as provided for under § 476.110(c) of this chapter.

35. Section 480.132 is amended by—

a. Revising paragraphs (a) introductory text, (a)(1)(iii), and (a)(2).

b. Revising paragraph (b)(1).

c. Revising paragraph (c).

d. Removing the undesignated text following paragraph (c)(3).

The revisions read as follows.

§ 480.132 Disclosure of information about patients.

(a) General requirements for disclosure. Except as specified in §§ 476.130(d) and 476.140(b) of this chapter and paragraph (b) of this section, a QIO must—

(1) * * *

(iii) Except as provided under paragraph (b) of this section, all other patient and practitioner identifiers have been removed.

(2) Make disclosure to the patient or the patient's representative within 14 calendar days of receipt of the request.

(b) * * *

(1) If a request for information is in connection with an initial denial determination under section 1154(a)(2) of the Act, the QIO must provide only the information used to support that determination in accordance with the procedures for disclosure of information related to determinations under § 478.24, including relevant practitioner identifiers.

* * * * *

(c) Manner of disclosure. (1) The QIO must disclose the patient information directly to the patient or the patient's representative when the representative has been authorized or appointed to receive that information.

(2) In identifying a representative, the QIO must follow pertinent State law requirements regarding the designation of health care representatives and agents. If the patient is unable to designate a representative and the identity of the representative is not already dictated by State law, the QIO must disclose the information to a person whom the QIO determines is responsible for the patient.

* * * * *

36. Section 480.133 is amended by--

a. Adding paragraph (a)(2)(iv).

b. In paragraph (b)(1), removing the reference to "Part 466" and adding the reference "Part 476" in its place; and removing the reference "§ 473.24" and adding the reference "§ 478.24 of this subchapter" is its place.

The addition reads as follows:

§ 480.133 Disclosure of information about practitioners, reviewers, and institutions.

(a) * * *

(2) * * *

(iv) A QIO is not required to obtain the consent of a practitioner or provider prior to the release of information to a beneficiary in connection with an initial denial determination or in providing a beneficiary with the QIO's findings in response to a beneficiary complaint. Information that must be specified in a QIO's final decision in a complaint review is specified in §§ 476.130(d) and 476.140(b) of this subchapter.

* * * * *

§ 480.139 [Amended]

37. Section 480.139 is amended by redesignating the existing paragraph (1) as paragraph (a)(1).

38. Section 480.145 is added to read as follows:

§ 480.145 Beneficiary authorization of use of confidential information.

(a) Except as otherwise provided under this Part, a QIO may not use or disclose a beneficiary's confidential information without an authorization from the beneficiary. The QIO's use or disclosure must be consistent with the authorization.

(b) A valid authorization is a document that contains the following:

(1) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(2) The name or other specific identification of the QIO(s) and QIO point(s) of contact making the request to use or disclose the information.

(3) The name or other specific identification of the person(s), or class of persons, to whom the QIO(s) may disclose the information or allow the requested use.

(4) A description of each purpose of the requested use or disclosure. The statement "at the request of the individual" is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of purpose.

(5) An expiration date or an expiration event that relates to the beneficiary or the purpose of the use or disclosure. The statement "end of the QIO research study," "none," or similar language is sufficient if the authorization is for a use or disclosure of confidential information for QIO research, including for the creation and maintenance of a research database or research repository.

(6) Signature of the individual and date. If the authorization is signed by a beneficiary's representative, a description of such representative's authority to act for the beneficiary must also be provided.

(c) In addition to those items contained in paragraph (b) of this section, the authorization must contain statements adequate to place the individual on notice of all of the following:

(1) The individual's right to revoke the authorization in writing; and

(2) Any exceptions to the right to revoke and a description of how the individual may revoke the authorization;

(3) The ability or inability of the QIO to condition its review activities on the authorization, by stating either:

(i) That the QIO may not condition the review of complaints, appeals, or payment determinations, or any other QIO reviews or other tasks within the QIO's responsibility on whether the individual signs the authorization;

(ii) The consequences to the individual of a refusal to sign the authorization when the refusal will render the QIO unable to carry out an activity.

(4) The potential for information disclosed pursuant to the authorization to be subject to either appropriate or inappropriate redisclosure by a recipient, after which the information would no longer be protected by this subpart.

(d) The authorization must be written in plain language.

(e) If a QIO seeks an authorization from a beneficiary for a use or disclosure of confidential information, the QIO must provide the beneficiary with a copy of the signed authorization.

(f) A beneficiary may revoke an authorization provided under this section at any time, provided the revocation is in writing, except to the extent that the QIO has taken action in reliance upon the authorization.

PART 495--STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

45. 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).

46. Section 495.8 is amended by revising paragraph (b)(2)(vi) to read as follows:

§ 495.8 Demonstration of meaningful use criteria.

* * * * *

(b) * * *

(2) * * *

(vi) Exception for Medicare eligible hospitals and CAHs for FY 2012 and 2013—Participation in the Medicare EHR Incentive Program Electronic Reporting Pilot. In order to satisfy the clinical quality measure reporting requirements of meaningful use, aside from attestation, a Medicare eligible hospital or CAH may participate in the Medicare EHR Incentive Program Electronic Reporting Pilot.

* * * * *

(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: October 24, 2012

_____

Marilyn Tavenner

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: October 30, 2012

_____

Kathleen Sebelius,

Secretary.

BILLING CODE 4120-01-P

[FR Doc. 2012-26902 Filed 11/01/2012 at 4:15 pm; Publication Date: 11/15/2012]