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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 412, 416, 419, 475, 476, 486, and 495

[CMS–1601–P]

RIN 0938–AR54

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2014 to implement applicable statutory requirements and changes arising from our continuing experience with these systems. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Hospital Value-Based Purchasing (VBP) Program.

We are proposing changes to the conditions for coverage (CfCs) for organ procurement organizations (OPOs); revisions to the Quality Improvement Organization (QIO) regulations; changes to the Medicare fee-for-service Electronic Health Record (EHR) Incentive Program; and changes relating to provider reimbursement determinations and appeals.

DATES: *Comment Period:* To be assured consideration, comments on all sections of this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on September 6, 2013.

ADDRESSES: In commenting, please refer to file code CMS–1601–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1601–P, P.O. Box 8013, Baltimore, MD 21244–1850.

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

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1601–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

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

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

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

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

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

FOR FURTHER INFORMATION, CONTACT:

Marjorie Baldo, (401) 786–4617, for issues related to new CPT and Level II HCPCS codes, exceptions to the 2 times rule, and stereotactic radiosurgery services.

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

Chuck Braver, (410) 786–9379, for issues related to the Advisory Panel on Hospital Outpatient Payment (HOP Panel).

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

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

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

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

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

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

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

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

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

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

Barry Levi, (410) 786–4529, for issues related to OPPS pass-through devices, brachytherapy sources, intraoperative

radiation therapy (IORT), brachytherapy composite APC, multiple imaging composite APCs, and cardiac electrophysiologic evaluation and ablation composite APC.

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

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

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

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

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

SUPPLEMENTARY INFORMATION:

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

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

Electronic Access

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*.

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, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 106–554
BLS Bureau of Labor Statistics
CAH Critical access hospital
CAP Competitive Acquisition Program
CASPER Certification and Survey Provider Enhanced Reporting
CAUTI Catheter associated urinary tract infection
CBSA Core-Based Statistical Area
CCI Correct Coding Initiative
CCN CMS Certification Number
CCR Cost-to-charge ratio
CDC Centers for Disease Control and Prevention
CEO Chief executive officer
CERT Comprehensive Error Rate Testing
CfC [Medicare] Condition for coverage
CFR Code of Federal Regulations
CLFS Clinical Laboratory Fee Schedule
CMHC Community mental health center
CMS Centers for Medicare & Medicaid Services
CoP [Medicare] Condition of participation
CPI–U Consumer Price Index for All Urban Consumers
CPT Current Procedural Terminology (copyrighted by the American Medical Association)
CQM Clinical quality measure
CR Change request
CSAC Consensus Standards Approval Committee
CY Calendar year
DFO Designated Federal Official
DRA Deficit Reduction Act of 2005, Public Law 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, Public Law 92–463
FDA Food and Drug Administration
FFS [Medicare] Fee-for-service
FY Fiscal year
FFY Federal fiscal year
GAO Government Accountability Office
HAI Healthcare-associated infection
HCERA Health Care and Education Reconciliation Act of 2010, Public Law 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, Public Law 104–191
HITECH Health Information Technology for Economic and Clinical Health [Act] (found in the American Recovery and Reinvestment Act of 2009, Pub. L. 111–5)
HOP Hospital Outpatient Payment [Panel]
HOPD Hospital outpatient department
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD Implantable cardioverter defibrillator
ICU Intensive care unit
IHS Indian Health Service
IMRT Intensity Modulated Radiation Therapy
I/OCE Integrated Outpatient Code Editor
IOL Intraocular lens
IOM Institute of Medicine
IORT Intraoperative radiation treatment
IPPS [Hospital] Inpatient Prospective Payment System
IQR [Hospital] Inpatient Quality Reporting
LDR Low dose rate
LOS Length of Stay
LTCH Long-term care hospital
MAC Medicare Administrative Contractor
MAP Measure Application Partnership
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MFP Multifactor productivity
MGCRB Medicare Geographic Classification Review Board
MIEA–TRHCA Medicare Improvements and Extension Act under Division B, Title I of

the Tax Relief Health Care Act of 2006, Public Law 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173
MPFS Medicare Physician Fee Schedule
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, Public Law 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
PBD Provider-Based Department
PCR Payment-to-cost ratio
PE Practice expense
PEPPER Program for Evaluating Payment Patterns Electronic Report
PHP Partial hospitalization program
PHS Public Health Service [Act], Public Law 96–88
PPI Producer Price Index
PPS Prospective payment system
PQRS Physician Quality Reporting System
PT Physical therapy
QDC Quality data code
QIO Quality Improvement Organization
RFA Regulatory Flexibility Act
RTI Research Triangle Institute, International
RVU Relative value unit
SCH Sole community hospital
SCOD Specified covered outpatient drugs
SI Status indicator
SIR Standardized infection ratio
SLP Speech-language pathology
SNF Skilled Nursing Facility
SRS Stereotactic Radiosurgery
TEP Technical Expert Panel
TMS Transcranial Magnetic Stimulation Therapy
TOPs Transitional Outpatient Payments
UR Utilization review
USPSTF United States Preventive Services Task Force
UTI Urinary tract infection
VBP Value-based purchasing
WAC Wholesale acquisition cost

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I. Summary and Background

A. Executive Summary of This Proposed Rule

1. Purpose

In this proposed rule, we are proposing to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments and Ambulatory Surgical Centers (ASCs) beginning January 1, 2014. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the relative payment weights and the conversion factor for services payable under the Outpatient Prospective Payment System (OPPS). Under section 1833(i) of the Act, we annually review and update the ASC payment rates. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, we are proposing to update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Hospital Value-Based Purchasing (VBP) Program.

We are proposing changes to the conditions for coverage (CfCs) for organ procurement organizations (OPOs); revisions to the Quality Improvement Organization (QIO) regulations; changes to the Medicare fee-for-service Electronic Health Record (EHR) Incentive Program; and changes relating to provider reimbursement determinations and appeals.

2. Summary of the Major Provisions

- *OPPS Update:* For CY 2013, we are proposing to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.8 percent. This proposed increase is based on the proposed hospital inpatient market basket percentage increase of 2.5 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.4 percentage points, and minus a 0.3 percentage point adjustment required by the Affordable Care Act. Under this proposed rule, we estimate that proposed total payments for CY 2014, including beneficiary cost-sharing, to the almost 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 $50.4 billion, an increase of approximately $4.4 billion compared to CY 2013 payments, or $600 million excluding our estimated changes in enrollment, utilization, and case-mix

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

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

• *Cancer Hospital Payment Adjustment:* For CY 2014, we are proposing to continue 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 0.90 will be used to determine the proposed CY 2014 cancer hospital payment adjustment to be paid at cost report settlement. That is, the proposed payment amount associated with the cancer hospital payment adjustment will be the additional payment needed to result in a PCR equal to 0.90 for each cancer hospital.

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

• *Packaging Proposals:* The OPPS packages payment for multiple interrelated items and services into a single payment to create incentives for hospitals 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 2014, we are proposing to unconditionally package or conditionally package the following items and services and to add them to the list of OPPS packaged items and services in 42 CFR 419.2(b):

(1) Drugs, biologicals, and radiopharmaceuticals that function as supplies in a diagnostic test or procedure;

(2) Drugs and biologicals that function as supplies or devices in a surgical procedure;

(3) Laboratory tests;

(4) Procedures described by add-on codes;

(5) Ancillary services (status indicator ''X'');

(6) Diagnostic tests on the bypass list; and

(7) Device removal procedures.

We refer readers to section II.A.3. of this proposed rule for a complete description of our 2014 packaging proposals.

• *Establishing Comprehensive APCs:* In order to improve the accuracy and transparency of our payment for certain device-dependent services, for CY 2014, we are proposing to create 29 comprehensive APCs to prospectively pay for the most costly device-dependent services. We are proposing to define a comprehensive APC as a classification for the provision of a primary service and all adjunct services provided to support the delivery of the primary service. The comprehensive APC would treat all individually reported codes as representing components of the comprehensive service, resulting in a single prospective payment based on the cost of all individually reported codes that represent the delivery of a primary service as well as all adjunct services provided to support that delivery. We are proposing to make a single payment for the comprehensive service based on all charges on the claim, excluding only charges for services that cannot be covered by Medicare Part B or that are not payable under the OPPS.

• *Payment of Hospital Outpatient Visits:* For CY 2014 we are proposing to replace the current five levels of visit codes for each clinic, Type A ED, and Type B ED visits with three new alphanumeric Level II HCPCS codes representing a single level of payment for the three types of visits, respectively. We are proposing to assign the new alphanumeric Level II HCPCS to newly created APCs with CY 2014 OPPS payment rates based on the total mean costs of Level 1 through Level 5 visit codes obtained from CY 2012 OPPS claims data for each visit type.

• *Proposed OPPS Nonrecurring Policy Changes:* We note in this proposed rule that we expect to allow the enforcement instruction for the supervision of outpatient therapeutic services furnished in CAHs and small rural hospitals to expire at the end of CY 2013. In addition, we are proposing to amend the conditions of payment for ''incident to'' hospital or CAH outpatient services (sometimes referred to as hospital or CAH ''therapeutic'' services) to require that individuals furnishing these services be in compliance with State law. We are soliciting public comments regarding a potential new claims or other data element that would indicate that the services were furnished in an off-campus provider-based department. Finally, we refer readers to the CY 2014 Medicare Physician Fee Schedule (MPFS) proposed rule (CMS–1600–P) to review Medicare's proposal to apply the therapy caps and related provisions under section 1833(g) of the Act to physical therapy (PT), speech-language pathology (SLP) and occupational therapy (OT) (''therapy'') services that are furnished by a CAH, effective January 1, 2014.

• *Ambulatory Surgical Center Payment Update:* For CY 2014, we are proposing to increase payment rates under the ASC payment system by 0.9 percent. This proposed 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 0.5 percent. Based on this proposed update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2014 would be approximately $3.980 billion, an increase of approximately $133 million compared to estimated CY 2013 payments.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are proposing five quality measures for the CY 2016 and subsequent years payment determinations: four where aggregate data (numerators, denominators, and exclusions) are collected and data submitted via an online Web-based tool located on a CMS Web page and one HAI measure submitted through the CDC's NHSN. We also are proposing to remove two measures and are proposing to codify administrative procedures.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are proposing four quality measures for the CY 2016 and subsequent years payment determinations where data collection would begin in CY 2014. We are proposing to collect aggregate data (numerators, denominators, and exclusions) on all ASC patients for these

four proposed chart-abstracted measures via an online Web-based tool located on a CMS Web page. We also are proposing, for the CY 2016 payment determination and subsequent years' payment determinations, requirements for facility participation, data collection, and submission for claims-based, CMS Web-based, and NHSN measures.

• *Proposed Revisions to the Quality Improvement Organizations Regulations.* We are proposing to update the regulations at 42 CFR parts 475 and 476 based on the recently enacted Trade Adjustment Assistance Extension Act of 2011 (TAAEA) (Pub. L. 112–40, Section 261) where by Congress authorized numerous changes to the original legislation and included additional flexibility for the Secretary in the administration of the QIO program. Currently, 42 CFR Part 475 includes definitions and standards governing eligibility and the award of contracts to QIOs. In this proposed rule, we set forth proposals for the partial deletion and revision of the regulations under 42 CFR Parts 475 and 476, which relate to the QIO program, including the following: (1) Replace nomenclature in Part 475 and 476 that has been amended by the TAAEA; (2) revise the existing definition for the term ''physician''; (3) add new definitions as necessary to support the new substantive provisions in Subpart C; and (4) replace some of the substantive provisions in Subpart C in their entirety to fully exercise the Secretary's authority for the program and update the contracting requirements to align with contemporary quality improvement.

• *Proposed Changes to the Medicare Fee-for-Service Electronic Record (EHR) Incentive Program.* We are proposing to the regulations to provide a special method for making hospital-based determinations for 2013 only in the cases of those eligible professionals (EPs) who reassign their benefits to Method II CAHs. We have been unable to make EHR payments to these EPs for their CAH II claims, or to take those claims into consideration in making hospital-based determinations because of systems limitations. Adopting our proposed method for 2013 will allow us to begin making payments based on CAH II one year earlier than we would be able to do under current regulations. We also are proposing a minor clarification to the regulations concerning the cost reporting period to be used in determining final EHR payments for hospitals.

3. Summary of Costs and Benefits

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

a. Impacts of the OPPS Update

(1) Impacts of All Proposed OPPS Changes

Table 39 in section XXIII. of this proposed rule displays the distributional impact all the proposed OPPS changes on various groups of hospitals and CMHCs for CY 2014 compared to all estimated OPPS payments in CY 2013. We estimate that the proposed policies in this proposed rule would result in a 1.8 percent overall increase in OPPS payments to providers. We estimate that the proposed increase in OPPS expenditures, including beneficiary cost-sharing, would be approximately $600 million, not taking into account potential changes in enrollment, utilization, and case-mix. Taking into account estimated spending changes that are attributable to these factors, we estimate an increase of approximately $4.372 billion in OPPS expenditures, including beneficiary cost-sharing, for CY 2014 compared to CY 2013 OPPS expenditures. We estimate that proposed total OPPS payments, including beneficiary cost-sharing, would be $50.4 billion for CY 2014.

We estimated the isolated impact of our proposed OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure that we adopted for CY 2011 and basing payment fully on the type of provider furnishing the service, we estimate a 3.8 percent decrease in CY 2014 payments to CMHCs relative to their CY 2013 payments.

(2) Impacts of the Proposed Updated Wage Indices

We estimate no significant impacts related to our proposal to update the wage indices and apply the frontier State wage index. Proposed adjustments to the wage indices other than the frontier State wage adjustment would not significantly affect most hospitals.

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

There are no significant impacts of our proposed CY 2014 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not proposing to make any change in policies for determining the rural and cancer hospital payment adjustments, and the proposed adjustment amounts do not significantly impact the budget neutrality adjustments for these proposed policies.

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

We estimate that, for many hospitals, the application of the proposed OPD fee schedule increase factor of 1.8 percent to the conversion factor for CY 2014 would mitigate the small negative impacts of the budget neutrality adjustments. While most classes of hospitals would receive an increase that is in line with the proposed 1.8 percent overall increase after the update is applied to the budget neutrality adjustments, some hospitals would receive smaller but still generally positive overall increases.

b. Impacts of the Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The proposed percentage change in estimated total payments by specialty groups under the CY 2014 payment rates compared to estimated CY 2013 payment rates ranges between −12 percent for ancillary items and services and 17 percent for hemic and lymphatic system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our proposed CY 2014 policies to significantly affect the number of hospitals that do not receive a full annual payment update.

d. Impacts of the ASCQR Program

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

e. Impacts for the Proposed QIO Program Changes

We estimate the effects of the proposed QIO Program changes to be consistent with the Congressional Budget Office's 2011 Cost Estimate of the Trade Bill (H.R. 2832) which included a reduction in spending of $330 million over the 2012–2021 period. According to the CBO Estimate the Act and subsequently the proposed regulatory changes ''would modify the provisions under which CMS contracts with independent entities called ['']Quality Improvement Organizations [(QIOs)''] in Medicare. QIOs, generally staffed by health care professionals, review medical care, help beneficiaries with complaints about the quality of

care, and implement care improvements. H.R. 2832 would make several changes to the composition and operation of QIOs, and would harmonize QIO contracts with requirements of the Federal Acquisition Regulation. Among those changes are a modification to expand the geographic scope of QIO contracts and a lengthening of the contract period. CBO estimates that those provisions would reduce spending by $330 million over the 2012–2021 period.''

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; and most recently the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013.

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 proposed rule. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Part B.

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

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

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

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary originally 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 at the Clinical Laboratory Fee Schedule (CLFS) rates; services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22. This proposed rule includes proposals to modify 42 CFR 419.22 and include in the OPPS some of these currently excluded services.

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

2. Establishment of the Panel

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

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS Web site at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage.*

3. Panel Meetings and Organizational Structure

The Panel has held multiple meetings, with the last meeting taking place on March 11, 2013. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting and, when necessary, to solicit nominations for Panel membership and to announce new members.

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

The Data Subcommittee is responsible for studying the data issues confronting the Panel and for recommending options for resolving them. The Visits and Observation Subcommittee reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the 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 2013 Panel meeting. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the March 2013 Panel meeting 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 on the CY 2013 OPPS/ASC Final Rule With Comment Period

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

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

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

For the CY 2014 OPPS, we are proposing to recalibrate the APC relative payment weights for services furnished on or after January 1, 2014, and before January 1, 2015 (CY 2014), using the same basic methodology that we described in the CY 2013 OPPS/ASC final rule with comment period. That is, we are proposing to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights. Therefore, for the purpose of recalibrating the proposed APC relative payment weights for CY 2014, we used approximately 146 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for hospital outpatient department services furnished on or after January 1, 2012, and before January 1, 2013. For exact counts of claims used, we refer readers to the claims accounting narrative under supporting documentation for this proposed rule on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Of the approximately 146 million final action claims for services provided in hospital outpatient settings used to calculate the CY 2014 OPPS payment rates for this proposed rule, approximately 117 million claims were the type of bill potentially appropriate for use in setting rates for OPPS services (but did not necessarily contain services payable under the OPPS). Of the approximately 117 million claims, approximately 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 112 million claims, we created approximately 82 million single records, of which approximately 34 million were ''pseudo'' single or ''single session'' claims (created from approximately 19 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 82 million single bills for ratesetting. As described in section II.A.2. of this proposed rule, our data development process is designed with the goal of using appropriate cost information in setting the APC relative payment weights. The bypass process is described in section II.A.1.b. of this proposed rule. This section discusses how we develop ''pseudo'' single procedure claims (as defined below), with the intention of using more appropriate data from the available claims. In some cases, the bypass process allows us to use some portion of the submitted claim for cost estimation purposes, while the remaining information on the claim continues to be unusable. Consistent with the goal of using appropriate information in our data development process, we only use claims (or portions of each claim) that are appropriate for ratesetting purposes.

The proposed APC relative weights and payments for CY 2014 in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) were calculated using claims from CY 2012 that were processed through December 31, 2012. While prior to CY 2013 we historically based the payments on median hospital costs for services in the APC groups, beginning with the CY 2013 OPPS, we established the cost-based relative payment weights for the OPPS using geometric mean costs, as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271). For the CY 2014 OPPS, we are proposing to use this same methodology, basing payments on geometric mean costs. Under this methodology, we select claims for services paid under the OPPS and match these claims to the most recent cost report filed by the individual hospitals represented in our claims data. We continue to believe that it is appropriate to use the most current full calendar year claims data and the most recently submitted cost reports to calculate the relative costs underpinning the APC relative payment weights and the CY 2014 payment rates.

b. Proposed Use of Single and Multiple Procedure Claims

For CY 2014, in general, we are proposing to continue to use single procedure claims to set the costs on which the APC relative payment weights are based. We generally use single procedure claims to set the estimated costs for APCs because we believe that the OPPS relative weights on which payment rates are based should be derived from the costs of furnishing one unit of one procedure and because, in many circumstances, we are unable to ensure that packaged costs can be appropriately allocated across multiple procedures performed on the same date of service.

It is generally desirable to use the data from as many claims as possible to recalibrate the APC relative payment weights, including those claims for multiple procedures. As we have for several years, we are proposing to continue to use date of service stratification and a list of codes to be bypassed to convert multiple procedure claims to ''pseudo'' single procedure claims. Through bypassing specified codes that we believe do not have significant packaged costs, we are able to use more data from multiple procedure claims. In many cases, this enables us to create multiple ''pseudo'' single procedure claims from claims that were submitted as multiple procedure claims spanning multiple dates of service, or claims that contained numerous separately paid procedures reported on the same date on one claim. We refer to these newly created single procedure claims as ''pseudo'' single procedure claims. The history of our use of a bypass list to generate ''pseudo'' single procedure claims is well documented, most recently in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68227 through 68229). In addition, for CY 2008 (72 FR 66614 through 66664), we increased packaging and created the first composite APCs, and continued those policies through CY 2013. Increased packaging and creation of composite APCs also increased the number of bills that we were able to use for ratesetting by enabling us to use claims that contained multiple major procedures that previously would not have been usable. Further, for CY 2009, we expanded the composite APC model to one additional clinical area, multiple imaging services (73 FR 68559 through 68569), which also increased the number of bills we were able to use in developing the OPPS relative weights on which payments are based. We have continued the composite APCs for

multiple imaging services through CY 2013, and are proposing to continue this policy for CY 2014. We also are proposing to further expand our packaging policies for CY 2014. We refer readers to section II.A.2.f. of this proposed rule for a discussion of the use of claims in modeling the costs for composite APCs and to section II.A.3. of this proposed rule for a discussion of our proposed packaging policies for CY 2014.

We are proposing to continue to apply these processes to enable us to use as much claims data as possible for ratesetting for the CY 2014 OPPS. This methodology enabled us to create, for this proposed rule, approximately 34 million ''pseudo'' single procedure claims, including multiple imaging composite ''single session'' bills (we refer readers to section II.A.2.f.(5) of this proposed rule for further discussion), to add to the approximately 48 million ''natural'' single procedure claims.

For CY 2014, we are proposing to bypass 179 HCPCS codes that are identified in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site). Since the inception of the bypass list, which is the list of codes to be bypassed to convert multiple procedure claims to ''pseudo'' single procedure claims, we have calculated the percent of ''natural'' single bills that contained packaging for each HCPCS code and the amount of packaging on each ''natural'' single bill for each code. Each year, we generally retain the codes on the previous year's bypass list and use the updated year's data (for CY 2014, data available for the March 11, 2013 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) from CY 2012 claims processed through September 30, 2012, and CY 2011 claims data processed through June 30, 2012, used to model the payment rates for CY 2013) to determine whether it would be appropriate to add additional codes to the previous year's bypass list. For CY 2014, we are proposing to continue to bypass all of the HCPCS codes on the CY 2013 OPPS bypass list, with the exception of HCPCS codes that we are proposing to delete for CY 2014, which are listed in Table 1 of this proposed rule. We also are proposing to remove HCPCS codes that are not separately paid under the OPPS because the purpose of the bypass list is to obtain more data for those codes relevant to ratesetting. Some of the codes we are proposing to remove from the CY 2014 bypass list are affected by the CY 2014 packaging proposal, discussed in section II.A.3. of this proposed rule. In addition, we are proposing to add to the bypass list for CY 2014 HCPCS codes not on the CY 2013 bypass list that, using either the CY 2013 final rule data (CY 2011 claims) or the March 11, 2013 Panel data (first 9 months of CY 2012 claims), met the empirical criteria for the bypass list that are summarized below. Finally, to remain consistent with the CY 2014 proposal to continue to develop OPPS relative payment weights based on geometric mean costs, we also are proposing that the packaged cost criterion continue to be based on the geometric mean cost. The entire list proposed for CY 2014 (including the codes that remain on the bypass list from prior years) is open to public comment. Because we must make some assumptions about packaging in the multiple procedure claims in order to assess a HCPCS code for addition to the bypass list, we assumed that the representation of packaging on ''natural'' single procedure claims for any given code is comparable to packaging for that code in the multiple procedure claims. The proposed criteria for the bypass list are:

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

We note that, as we did for CY 2013, we are proposing to continue to establish the CY 2014 OPPS relative payment weights based on geometric mean costs. To remain consistent in the metric used for identifying cost patterns, we are proposing to use the geometric mean cost of packaging to identify potential codes to add to the bypass list.

In response to public comments on the CY 2010 OPPS/ASC proposed rule requesting that the packaged cost threshold be updated, we considered whether it would be appropriate to update the $50 packaged cost threshold for inflation when examining potential bypass list additions. As discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60328), the real value of this packaged cost threshold criterion has declined due to inflation, making the packaged cost threshold more restrictive over time when considering additions to the bypass list. Therefore, adjusting the threshold by the market basket increase would prevent continuing decline in the threshold's real value. Based on the same rationale described for the CY 2013 OPPS/ASC final rule with comment period (77 FR 68221), we are proposing for CY 2014 to continue to update the packaged cost threshold by the market basket increase. By applying the final CY 2013 market basket increase of 1.8 percent to the prior nonrounded dollar threshold of $53.76 (77 FR 68221), we determined that the threshold would remain for CY 2014 at $55 ($54.73 rounded to $55, the nearest $5 increment). Therefore, we are proposing to set the geometric mean packaged cost threshold on the CY 2012 claims at $55 for a code to be considered for addition to the CY 2014 OPPS bypass list.

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

In addition, we are proposing to continue to include on the bypass list HCPCS codes that CMS medical advisors believe have minimal associated packaging based on their clinical assessment of the complete CY 2014 OPPS proposal. Some of these codes were identified by CMS medical advisors and some were identified in prior years by commenters with specialized knowledge of the packaging associated with specific services. We also are proposing to continue to include certain HCPCS codes on the bypass list in order to purposefully direct the assignment of packaged costs to a companion code where services always appear together and where there would otherwise be few single procedure claims available for ratesetting. For example, we have previously discussed our reasoning for adding HCPCS code G0390 (Trauma response team associated with hospital

critical care service) to the bypass list (73 FR 68513).

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

Addendum N to this proposed rule includes the proposed list of bypass codes for CY 2014. The list of bypass codes contains codes that were reported on claims for services in CY 2012 and, therefore, includes codes that were in effect in 2012 and used for billing but were deleted for CY 2013. We retained these deleted bypass codes on the proposed CY 2014 bypass list because these codes existed in CY 2012 and were covered OPD services in that period, and CY 2012 claims data are used to calculate CY 2014 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that were members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we are proposing to add for CY 2014 are identified by asterisks (*) in the fourth column of Addendum N.

Table 1 below contains the list of codes that we are proposing to remove from the CY 2014 bypass list because these codes were either deleted from the HCPCS before CY 2012 (and therefore were not covered OPD services in CY 2012) or were not separately payable codes under the proposed CY 2014 OPPS because these codes are not used for ratesetting through the bypass process. The list of codes proposed for removal from the bypass list includes those that would be affected by the CY 2014 OPPS proposed packaging policy described in section II.A.3. of this proposed rule.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2014 BYPASS LIST

HCPCS Code	HCPCS Short descriptor
17003	Destruct premalg les 2–14.
31231	Nasal endoscopy dx.
31505	Diagnostic laryngoscopy.
31579	Diagnostic laryngoscopy.
51741	Electro-uroflowmetry first.
51798	Us urine capacity measure.
54240	Penis study.
56820	Exam of vulva w/scope.
57452	Exam of cervix w/scope.
57454	Bx/curett of cervix w/scope.
69210	Remove impacted ear wax.
70030	X-ray eye for foreign body.
70100	X-ray exam of jaw <4 views.
70110	X-ray exam of jaw 4/> views.
70120	X-ray exam of mastoids.
70130	X-ray exam of mastoids.
70140	X-ray exam of facial bones.
70150	X-ray exam of facial bones.
70160	X-ray exam of nasal bones.
70200	X-ray exam of eye sockets.
70210	X-ray exam of sinuses.
70220	X-ray exam of sinuses.
70240	X-ray exam pituitary saddle.
70250	X-ray exam of skull.
70260	X-ray exam of skull.
70320	Full mouth x-ray of teeth.
70328	X-ray exam of jaw joint.
70330	X-ray exam of jaw joints.
70355	Panoramic x-ray of jaws.
70360	X-ray exam of neck.
70370	Throat x-ray & fluoroscopy.
70371	Speech evaluation complex.
71021	Chest x-ray frnt lat lordotc.
71022	Chest x-ray frnt lat oblique.
71023	Chest x-ray and fluoroscopy.
71030	Chest x-ray 4/> views.
71034	Chest x-ray&fluoro 4/> views.
71035	Chest x-ray special views.
71100	X-ray exam ribs uni 2 views.
71101	X-ray exam unilat ribs/chest.
71110	X-ray exam ribs bil 3 views.
71111	X-ray exam ribs/chest 4/> vws.
71120	X-ray exam breastbone 2/>vws.
71130	X-ray strenoclavic jt 3/>vws.
72010	X-ray exam spine ap&lat.
72020	X-ray exam of spine 1 view.
72040	X-ray exam neck spine 3/<vws.
72050	X-ray exam neck spine 4/5vws.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2014 BYPASS LIST—Continued

HCPCS Code	HCPCS Short descriptor
72052	X-ray exam neck spine 6/>vws.
72069	X-ray exam trunk spine stand.
72070	X-ray exam thorac spine 2vws.
72072	X-ray exam thorac spine 3vws.
72074	X-ray exam thorac spine 4/>vw.
72080	X-ray exam trunk spine 2 vws.
72090	X-ray exam scloiosis erect.
72100	X-ray exam l-s spine ⅔ vws.
72110	X-ray exam l-2 spine 4/>vws.
72114	X-ray exam l-s spine bending.
72120	X-ray bend only l-s spine.
72170	X-ray exam of pelvis.
72190	X-ray exam of pelvis.
72202	X-ray exam si joints 3/> vws.
72220	X-ray exam sacrum tailbone.
73000	X-ray exam of collar bone.
73010	X-ray exam of shoulder blade.
73020	X-ray exam of shoulder.
73030	X-ray exam of shoulder.
73050	X-ray exam of shoulders.
73060	X-ray exam of humerus.
73070	X-ray exam of elbow.
73080	X-ray exam of elbow.
73090	X-ray exam of forearm.
73100	X-ray exam of wrist.
73110	X-ray exam of wrist.
73120	X-ray exam of hand.
73130	X-ray exam of hand.
73140	X-ray exam of finger(s).
73510	X-ray exam of hip.
73520	X-ray exam of hips.
73540	X-ray exam of pelvis & hips.
73550	X-ray exam of thigh.
73560	X-ray exam of knee 1 or 2.
73562	X-ray exam of knee 3.
73564	X-ray exam knee 4 or more.
73565	X-ray exam of knees.
73590	X-ray exam of lower leg.
73600	X-ray exam of ankle.
73610	X-ray exam of ankle.
73620	X-ray exam of foot.
73630	X-ray exam of foot.
73650	X-ray exam of heel.
73660	X-ray exam of toe(s).
74000	X-ray exam of abdomen.
74010	X-ray exam of abdomen.
74020	X-ray exam of abdomen.
74022	X-ray exam series abdomen.
74210	Contrst x-ray exam of throat.
74220	Contrast x-ray esophagus.
74230	Cine/vid x-ray throat/esoph.
74246	Contrst x-ray uppr gi tract.
74247	Contrst x-ray uppr gi tract.
74249	Contrst x-ray uppr gi tract.
76100	X-ray exam of body section.
76510	Ophth us b & quant a.
76511	Ophth us quant a only.
76512	Ophth us b w/non-quant a.
76513	Echo exam of eye water bath.
76514	Echo exam of eye thickness.
76516	Echo exam of eye.
76519	Echo exam of eye.
76536	Us exam of head and neck.
76645	Us exam breast(s).
76801	Ob us < 14 wks single fetus.
76805	Ob us >/= 14 wks sngl fetus.
76811	Ob us detailed sngl fetus.
76816	Ob us follow-up per fetus.
76817	Transvaginal us obstetric.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2014 BYPASS LIST—Continued

HCPCS Code	HCPCS Short descriptor
76830	Transvaginal us non-ob.
76881	Us xtr non-vasc complete.
76882	Us xtr non-vasc lmtd.
76970	Ultrasound exam follow-up.
77072	X-rays for bone age.
77073	X-rays bone length studies.
77074	X-rays bone survey limited.
77075	X-rays bone survey complete.
77076	X-rays bone survey infant.
77077	Joint survey single view.
77082	Dxa bone density vert fx.
77084	Magnetic image bone marrow.
77300	Radiation therapy dose plan.
77301	Radiotherapy dose plan imrt.
77305	Teletx isodose plan simple.
77310	Teletx isodose plan intermed.
77315	Teletx isodose plan complex.
77327	Brachytx isodose calc interm.
77331	Special radiation dosimetry.
77336	Radiation physics consult.
77338	Design mlc device for imrt.
77370	Radiation physics consult.
80500	Lab pathology consultation.
80502	Lab pathology consultation.
85097	Bone marrow interpretation.
86510	Histoplasmosis skin test.
86850	RBC antibody screen.
86870	RBC antibody identification.
86880	Coombs test direct.
86885	Coombs test indirect qual.
86886	Coombs test indirect titer.
86890	Autologous blood process.
86900	Blood typing abo.
86901	Blood typing rh (d).
86904	Blood typing patient serum.
86905	Blood typing rbc antigens.
86906	Blood typing rh phenotype.
86930	Frozen blood prep.
86970	Rbc pretx incubatj w/chemicl.
86977	Rbc serum pretx incubj/inhib.
88104	Cytopath fl nongyn smears.
88106	Cytopath fl nongyn filter.
88108	Cytopath concentrate tech.
88112	Cytopath cell enhance tech.
88120	Cytp urne 3–5 probes ea spec.
88160	Cytopath smear other source.
88161	Cytopath smear other source.
88162	Cytopath smear other source.
88172	Cytp dx eval fna 1st ea site.
88173	Cytopath eval fna report.
88182	Cell marker study.
88184	Flowcytometry/tc 1 marker.
88185	Flowcytometry/tc add-on.
88189	Flowcytometry/read 16 & >.
88300	Surgical path gross.
88302	Tissue exam by pathologist.
88304	Tissue exam by pathologist.
88305	Tissue exam by pathologist.
88307	Tissue exam by pathologist.
88311	Decalcify tissue.
88312	Special stains group 1.
88313	Special stains group 2.
88314	Histochemical stains add-on.
88321	Microslide consultation.
88323	Microslide consultation.
88325	Comprehensive review of data.
88329	Path consult introp.
88331	Path consult intraop 1 bloc.
88342	Immunohistochemistry.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2014 BYPASS LIST—Continued

HCPCS Code	HCPCS Short descriptor
88346	Immunofluorescent study.
88347	Immunofluorescent study.
88348	Electron microscopy.
88358	Analysis tumor.
88360	Tumor immunohistochem/manual.
88361	Tumor immunohistochem/comput.
88365	Insitu hybridization (fish).
88368	Insitu hybridization manual.
88385	Eval molecul probes 51–250.
88386	Eval molecul probes 251–500.
89049	Chct for mal hyperthermia.
89220	Sputum specimen collection.
89230	Collect sweat for test.
89240	Pathology lab procedure.
90472	Immunization admin each add.
90474	Immune admin oral/nasal addl.
92020	Special eye evaluation.
92025	Corneal topography.
92060	Special eye evaluation.
92081	Visual field examination(s).
92082	Visual field examination(s).
92083	Visual field examination(s).
92133	Cmptr ophth img optic nerve.
92134	Cptr ophth dx img post segmt.
92136	Ophthalmic biometry.
92225	Special eye exam initial.
92226	Special eye exam subsequent.
92230	Eye exam with photos.
92240	Icg angiography.
92250	Eye exam with photos.
92275	Electroretinography.
92285	Eye photography.
92286	Internal eye photography.
92520	Laryngeal function studies.
92541	Spontaneous nystagmus test.
92542	Positional nystagmus test.
92546	Sinusoidal rotational test.
92548	Posturography.
92550	Tympanometry & reflex thresh.
92552	Pure tone audiometry air.
92553	Audiometry air & bone.
92555	Speech threshold audiometry.
92556	Speech audiometry complete.
92557	Comprehensive hearing test.
92567	Tympanometry.
92570	Acoustic immitance testing.
92582	Conditioning play audiometry.
92585	Auditor evoke potent compre.
92603	Cochlear implt f/up exam 7/>.
92604	Reprogram cochlear implt 7/>.
92626	Eval aud rehab status.
93005	Electrocardiogram tracing.
93017	Cardiovascular stress test.
93225	Ecg monit/reprt up to 48 hrs.
93226	Ecg monit/reprt up to 48 hrs.
93229	Remote 30 day ecg tech supp.
93270	Remote 30 day ecg rev/report.
93271	Ecg/monitoring and analysis.
93278	ECG/signal-averaged.
93290	Icm device eval.
93306	Tte w/doppler complete.
93701	Bioimpedance cv analysis.
93786	Ambulatory BP recording.
93788	Ambulatory BP analysis.
93880	Extracranial bilat study.
93882	Extracranial uni/ltd study.
93886	Intracranial complete study.
93888	Intracranial limited study.
93922	Upr/l xtremity art 2 levels.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2014 BYPASS LIST—Continued

HCPCS Code	HCPCS Short descriptor
93923	Upr/lxtr art stdy 3+ lvls.
93924	Lwr xtr vasc stdy bilat.
93925	Lower extremity study.
93926	Lower extremity study.
93930	Upper extremity study.
93931	Upper extremity study.
93965	Extremity study.
93970	Extremity study.
93971	Extremity study.
93975	Vascular study.
93976	Vascular study.
93978	Vascular study.
93979	Vascular study.
93990	Doppler flow testing.
94015	Patient recorded spirometry.
94690	Exhaled air analysis.
95250	Glucose monitoring cont.
95800	Slp stdy unattended.
95803	Actigraphy testing.
95805	Multiple sleep latency test.
95806	Sleep study unatt&resp efft.
95807	Sleep study attended.
95808	Polysom any age 1–3> param.
95810	Polysom 6/> yrs 4/> param.
95812	Eeg 41–60 minutes.
95813	Eeg over 1 hour.
95816	Eeg awake and drowsy.
95819	Eeg awake and asleep.
95822	Eeg coma or sleep only.
95869	Muscle test thor paraspinal.
95872	Muscle test one fiber.
95900	Motor nerve conduction test.
95921	Autonomic nrv parasym inervj.
95925	Somatosensory testing.
95926	Somatosensory testing.
95930	Visual evoked potential test.
95950	Ambulatory eeg monitoring.
95953	EEG monitoring/computer.
96000	Motion analysis video/3d.
96361	Hydrate iv infusion add-on.
96366	Ther/proph/diag iv inf addon.
96367	Tx/proph/dg addl seq iv inf.
96370	Sc ther infusion addl hr.
96371	Sc ther infusion reset pump.
96375	Tx/pro/dx inj new drug addon.
96411	Chemo iv push addl drug.
96415	Chemo iv infusion addl hr.
96417	Chemo iv infus each addl seq.
96423	Chemo ia infuse each addl hr.
G0365	Vessel mapping hemo access.
G0399	Home sleep test/type 3 Porta.
G0416	Sat biopsy 10–20.

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

For CY 2014, we are proposing to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 2014 APC payment rates are based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for

which we had CY 2012 claims data from the most recent available hospital cost reports, in most cases, cost reports beginning in CY 2011. For the CY 2014 OPPS proposed rates, we used the set of claims processed during CY 2012. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. That crosswalk is available for review and continuous comment on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2012 (the year of claims data we used to calculate the proposed CY 2014 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2012 Data Specifications Manual.

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

For the CCR calculation process, we used the same general approach that we used in developing the final APC rates for CY 2007 and thereafter, using the revised CCR calculation that excluded the costs of paramedical education programs and weighted the outpatient charges by the volume of outpatient services furnished by the hospital. We refer readers to the CY 2007 OPPS/ASC final rule with comment period for more information (71 FR 67983 through 67985). We first limited the population of cost reports to only those hospitals that filed outpatient claims in CY 2012 before determining whether the CCRs for such hospitals were valid.

We then calculated the CCRs for each cost center and the overall ancillary CCR for each hospital for which we had claims data. We did this using hospital-specific data from the Hospital Cost Report Information System (HCRIS). We used the most recent available cost report data, in most cases, cost reports with cost reporting periods beginning in CY 2011. For this proposed rule, we used the most recently submitted cost reports to calculate the CCRs to be used to calculate costs for the proposed CY 2014 OPPS payment rates. If the most recently available cost report was submitted but not settled, we looked at the last settled cost report to determine the ratio of submitted to settled cost using the overall ancillary CCR, and we then adjusted the most recent available submitted, but not settled, cost report using that ratio. We then calculated both an overall ancillary CCR and cost center-specific CCRs for each hospital. We used the overall ancillary CCR referenced above for all purposes that require use of an overall ancillary CCR. We are proposing to continue this longstanding methodology for the calculation of costs for CY 2014.

Since the implementation of the OPPS, some commenters have raised concerns about potential bias in the OPPS cost-based weights due to ''charge compression,'' which is the practice of applying a lower charge markup to higher cost services and a higher charge markup to lower cost services. As a result, the cost-based weights may reflect some aggregation bias, undervaluing high-cost items and overvaluing low-cost items when an estimate of average markup, embodied in a single CCR, is applied to items of widely varying costs in the same cost center. This issue was evaluated in a report by 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. In the CY 2013 OPPS/ASC final rule with comment period, we determined that a significant volume of hospitals were utilizing the ''Implantable Devices Charged to Patients'' cost center. Because a sufficient amount of data from which to generate a meaningful analysis was available, we established in the CY 2013 OPPS/ASC final rule with comment period a policy to create a distinct CCR using the ''Implantable Devices Charged to Patients'' cost center (77 FR 68225). For the CY 2014 OPPS, we are proposing to continue to use data from the ''Implantable Devices Charged to Patients'' cost center to create a distinct CCR for use in calculating the OPPS relative payment weights.

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

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

Using the December 2012 HCRIS update which we use to estimate costs in the CY 2014 OPPS ratesetting process, we were able to calculate a valid implantable device CCR for 2,936 hospitals, a valid MRI CCR for 1,853 hospitals, a valid CT scan CCR for 1,956 hospitals, and a valid Cardiac Catheterization CCR for 1,367 hospitals. We believe that there is a sufficient amount of data in the Form CMS 2552–10 cost reports from which to generate a meaningful analysis of CCRs. Therefore, we are providing various data analyses below in Tables 2 and 3 demonstrating the changes as a result of including the new CCRs calculated from the new standard cost centers into the CY 2014 OPPS ratesetting process.

TABLE 2—MEDIAN CCRS CALCULATED USING DIFFERENT COST REPORT DISTRIBUTIONS

Calculated CCR	"New" standard cost center	Using Form 2552–96 CCRs only	Using Form 2552–96 and Form 2552–10 CCRs
Cardiology		0.2915	0.5112
Cardiac Catheterization	*	0.1685	0.1590
Radiology—Diagnostic		0.2025	0.2279
Magnetic Resonance Imaging (MRI)	*	0.1074	0.0959
CT Scan	*	0.0568	0.0502
Medical Supplies Charged to Patient		0.3389	0.3315
Implantable Devices Charged to Patient	*	0.4371	0.4190

TABLE 3—PERCENTAGE CHANGE IN ESTIMATED COST FOR THOSE APCS SIGNIFICANTLY AFFECTED BY USE OF THE NEW STANDARD COST CENTER CCRS IN THE CMS FORM 2552–10 COST REPORTS

APC	APC Descriptor	Percentage change in estimated cost (percent)
0282	Miscellaneous Computed Axial Tomography	−38.1
0332	Computed Tomography without Contrast	−34.0
8005	CT and CTA without Contrast Composite	−33.9
0331	Combined Abdomen and Pelvis CT without Contrast	−32.9
8006	CT and CTA with Contrast Composite	−29.0
0334	Combined Abdomen and Pelvis CT with Contrast	−28.8
0662	CT Angiography	−27.0
0283	Computed Tomography with Contrast	−27.0
0333	Computed Tomography without Contrast followed by Contrast	−26.3
0383	Cardiac Computed Tomographic Imaging	−24.8
0336	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast	−19.3
8008	MRI and MRA with Contrast Composite	−18.9
8007	MRI and MRA without Contrast Composite	−18.5
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast	−18.2
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast	−14.9
0080	Diagnostic Cardiac Catheterization	−8.7
0276	Level I Digestive Radiology	15.2
0378	Level II Pulmonary Imaging	15.2
0396	Bone Imaging	15.5
0390	Level I Endocrine Imaging	15.8
0395	GI Tract Imaging	16.2
0402	Level II Nervous System Imaging	16.2
0398	Level I Cardiac Imaging	16.3
0262	Plain Film of Teeth	16.9
0377	Level II Cardiac Imaging	17.0
0267	Level III Diagnostic and Screening Ultrasound	17.2
0406	Level I Tumor/Infection Imaging	17.4
0403	Level I Nervous System Imaging	18.9
0266	Level II Diagnostic and Screening Ultrasound	25.1
0265	Level I Diagnostic and Screening Ultrasound	29.9
8004	Ultrasound Composite	30.2

We note that the estimated changes in geometric mean estimated APC cost of using data from the new standard cost centers cited above appear consistent with the expected results based on RTI's analysis of cost report and claims data in the July 2008 final report (pages 5 and 6), which state "in hospitals that aggregate data for CT scanning, MRI, or

nuclear medicine services with the standard line for Diagnostic Radiology, costs for these services all appear substantially overstated, while the costs for plain films, ultrasound and other imaging procedures are correspondingly understated.'' We also note that there are limited additional impacts in the implantable device related APCs due to using the new cost report form CMS 2552–10 because the standard cost center for implantable medical devices was previously incorporated into cost report form CMS 2552–96.

As we have discussed in prior rulemaking (77 FR 68223 through 68225), once we determined that cost report data were available for analysis, we would propose, if appropriate to use the distinct CCRs described above in the calculation of the OPPS relative payment weights. We believe that the analytic findings described above support the original decision to develop distinct standard cost centers for implantable devices, MRIs, CT scans, and cardiac catheterization, and we see no reason to further delay proposing to implement the CCRs of each of these cost centers. Therefore, beginning in CY 2014, we are proposing to calculate the OPPS relative payment weights using distinct CCRs for cardiac catheterization, CT scan, and MRI and to continue using a distinct CCR for implantable medical devices. Section XXIII. of this proposed rule includes the impacts of calculating the proposed CY 2014 OPPS relative payment weights using these new standard cost centers.

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

In this section of this proposed rule, we discuss the use of claims to calculate the proposed OPPS payment rates for CY 2014. The Hospital OPPS page on the CMS Web site on which this proposed rule is posted (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, below in this section we discuss the file of claims that comprises the data set that is available for purchase under a CMS data use agreement. The CMS Web site, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*, includes information about purchasing the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–9–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2012 claims that were used to calculate the proposed payment rates for the CY 2014 OPPS.

In the history of the OPPS, we have traditionally established the scaled relative weights on which payments are based using APC median costs, which is a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same, under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost. For CY 2014, we are proposing to continue to use geometric mean costs to calculate the relative weights on which the proposed CY 2014 OPPS payments rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.f. of this proposed rule to calculate the costs we used to establish the proposed relative weights used in calculating the proposed OPPS payment rates for CY 2014 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

a. Claims Preparation

For this proposed rule, we used the CY 2012 hospital outpatient claims processed through December 31, 2012, to calculate the geometric mean costs of APCs that underpin the proposed relative payment weights for CY 2014. To begin the calculation of the proposed relative payment weights for CY 2014, we pulled all claims for outpatient services furnished in CY 2012 from the national claims history file. This is not the population of claims paid under the OPPS, but all outpatient claims (including, for example, critical access hospital (CAH) claims and hospital claims for clinical laboratory tests for persons who are neither inpatients nor outpatients of the hospital).

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

We divided the remaining claims into the three groups shown below. Groups 2 and 3 comprise the 116 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 proposed rule. We then flagged and excluded CAH claims (which are not paid under the OPPS) and claims from hospitals with invalid CCRs. The latter included claims from hospitals without a CCR; those from hospitals paid an all-inclusive rate; those from hospitals with obviously erroneous CCRs (greater than 90 or less than 0.0001); and those from hospitals with overall ancillary CCRs that were identified as outliers (that exceeded +/− 3 standard deviations from the geometric mean after removing error CCRs). In addition, we trimmed the CCRs at the cost center (that is, departmental) level by removing the CCRs for each cost center as outliers if they exceeded +/− 3 standard deviations from the geometric mean. We used a four-tiered hierarchy of cost center CCRs, which is the revenue code-to-cost center crosswalk, to match a cost center to every possible revenue code appearing in the outpatient claims that

is relevant to OPPS services, with the top tier being the most common cost center and the last tier being the default CCR. If a hospital's cost center CCR was deleted by trimming, we set the CCR for that cost center to ''missing'' so that another cost center CCR in the revenue center hierarchy could apply. If no other cost center CCR could apply to the revenue code on the claim, we used the hospital's overall ancillary CCR for the revenue code in question as the default CCR. For example, if a visit was reported under the clinic revenue code but the hospital did not have a clinic cost center, we mapped the hospital-specific overall ancillary CCR to the clinic revenue code. The revenue code-to-cost center crosswalk is available for inspection on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Revenue codes that we do not use in establishing relative costs or to model impacts are identified with an ''N'' in the revenue code-to-cost center crosswalk.

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

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

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

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

Prior to CY 2013, our payment policy for nonpass-through separately paid drugs and biologicals was based on a redistribution methodology that accounted for pharmacy overhead by allocating cost from packaged drugs to separately paid drugs. This methodology typically would have required us to reduce the cost associated with packaged coded and uncoded drugs in order to allocate that cost. However, for CY 2013, we paid for separately payable drugs and biologicals under the OPPS at ASP+6 percent, based upon the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. Under that policy, we did not redistribute the pharmacy overhead costs from packaged drugs to separately paid drugs. For the CY 2014 OPPS, we are proposing to continue the CY 2013 payment policy for separately payable drugs and biologicals. We refer readers to section V.B.3. of this proposed rule for a complete discussion of our CY 2014 proposed payment policy for separately paid drugs and biologicals.

We then removed line-items that were not paid during claim processing, presumably for a line-item rejection or denial. The number of edits for valid OPPS payment in the Integrated Outpatient Code Editor (I/OCE) and elsewhere has grown significantly in the past few years, especially with the implementation of the full spectrum of National Correct Coding Initiative (NCCI) edits. To ensure that we are using valid claims that represent the cost of payable services to set payment rates, we removed line-items with an OPPS status indicator that were not paid during claims processing in the claim year, but have a status indicator of ''S,'' ''T,'' or ''V,'' in the prospective year's payment system. This logic preserves charges for services that would not have been paid in the claim year but for which some estimate of cost is needed for the prospective year, such as services newly removed from the inpatient list for CY 2013 that were assigned status indicator ''C'' in the claim year. It also preserves charges for packaged services so that the costs can be included in the cost of the services with which they are reported, even if the CPT codes for the packaged services were not paid because the service is part of another service that was reported on the same claim or the code otherwise violates claims processing edits.

For CY 2014, we are proposing to continue the policy we implemented for CY 2013 to exclude line-item data for pass-through drugs and biologicals (status indicator ''G'' for CY 2012) and nonpass-through drugs and biologicals (status indicator ''K'' for CY 2012) where the charges reported on the claim for the line were either denied or rejected during claims processing. Removing lines that were eligible for payment but were not paid ensures that we are using appropriate data. The trim avoids using cost data on lines that we believe were defective or invalid because those rejected or denied lines did not meet the Medicare requirements for payment. For example, edits may reject a line for a separately paid drug because the number of units billed exceeded the number of units that would be reasonable and, therefore, is likely a billing error (for example, a line reporting 55 units of a drug for which 5 units is known to be a fatal dose). As with our trimming in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68226) of line-items with a status indicator of ''S,'' ''T,'' ''V,'' or ''X,'' we believe that unpaid line-items represent services that are invalidly reported and, therefore, should not be used for ratesetting. We believe that removing lines with valid status indicators that were edited and not paid during claims processing increases the accuracy of the data used for ratesetting purposes.

For the CY 2014 OPPS, as part of the proposal to package clinical diagnostic laboratory tests, we also are proposing to apply the line item trim to these services if they did not receive payment in the claims year. Removing these lines ensures that, in establishing the CY 2014 OPPS relative payments weights, we appropriately allocate the costs associated with packaging these services. For a more detailed discussion of the proposal to package clinical diagnostic laboratory tests, we refer readers to section II.A.3.b.(3) of this proposed rule.

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

(1) Splitting Claims

For the CY 2014 OPPS, we then split the remaining claims into five groups: single majors; multiple majors; single minors; multiple minors; and other claims. (Specific definitions of these groups are presented below.) We note that, under the proposed CY 2014 OPPS packaging policy, we are proposing to delete status indicator ''X'' and revise the title and description of status indicator ''Q1'' to reflect that deletion, as discussed in sections II.A.3. and XI. of this proposed rule. For CY 2014, we are proposing to define major procedures as any HCPCS code having a status indicator of ''S,'' ''T,'' or ''V''; to define minor procedures as any code

having a status indicator of ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N''; and to classify ''other'' procedures as any code having a status indicator other than one that we have classified as major or minor. For CY 2014, we are proposing to continue to assign status indicator ''R'' to blood and blood products; status indicator ''U'' to brachytherapy sources; status indicator ''Q1'' to all ''STV-packaged codes''; status indicator ''Q2'' to all ''T-packaged codes''; and status indicator ''Q3'' to all codes that may be paid through a composite APC based on composite-specific criteria or paid separately through single code APCs when the criteria are not met.

As discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68709), we established status indicators ''Q1,'' ''Q2,'' and ''Q3'' to facilitate identification of the different categories of codes. We are proposing to treat these codes in the same manner for data purposes for CY 2014 as we have treated them since CY 2008. Specifically, we are continuing to evaluate whether the criteria for separate payment of codes with status indicator ''Q1'' or ''Q2'' are met in determining whether they are treated as major or minor codes. Codes with status indicator ''Q1'' or ''Q2'' are carried through the data either with status indicator ''N'' as packaged or, if they meet the criteria for separate payment, they are given the status indicator of the APC to which they are assigned and are considered as ''pseudo'' single procedure claims for major codes. Codes assigned status indicator ''Q3'' are paid under individual APCs unless they occur in the combinations that qualify for payment as composite APCs and, therefore, they carry the status indicator of the individual APC to which they are assigned through the data process and are treated as major codes during both the split and ''pseudo'' single creation process. The calculation of the geometric mean costs for composite APCs from multiple procedure major claims is discussed in section II.A.2.f. of this proposed rule.

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

1. *Single Procedure Major Claims:* Claims with a single separately payable procedure (that is, status indicator ''S,'' ''T,'' or ''V'' which includes codes with status indicator ''Q3''); claims with one unit of a status indicator ''Q1'' code (''STV-packaged'') where there was no code with status indicator ''S,'' ''T,'' or ''V'' on the same claim on the same date; or claims with one unit of a status indicator ''Q2'' code (''T-packaged'') where there was no code with a status indicator ''T'' on the same claim on the same date.

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

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

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

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

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

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

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

We also are proposing to use the bypass codes listed in Addendum N to this proposed rule (which is available via the Internet on our Web site) and discussed in section II.A.1.b. of this proposed rule to remove separately payable procedures which we determined contained limited or no packaged costs or that were otherwise suitable for inclusion on the bypass list from a multiple procedure bill. As discussed above, we ignore the ''overlap bypass codes,'' that is, those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs, in this initial assessment for ''pseudo'' single procedure claims. The proposed CY 2014 ''overlap bypass codes'' are listed in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site). When one of the two separately payable procedures on a multiple procedure claim was on the bypass list, we split the claim into two ''pseudo'' single procedure claim records. The single procedure claim record that contained the bypass code did not retain packaged services. The single procedure claim record that contained the other separately payable procedure (but no bypass code) retained the packaged revenue code charges and

the packaged HCPCS code charges. We also removed lines that contained multiple units of codes on the bypass list and treated them as ''pseudo'' single procedure claims by dividing the cost for the multiple units by the number of units on the line. If one unit of a single, separately payable procedure code remained on the claim after removal of the multiple units of the bypass code, we created a ''pseudo'' single procedure claim from that residual claim record, which retained the costs of packaged revenue codes and packaged HCPCS codes. This enabled us to use claims that would otherwise be multiple procedure claims and could not be used.

We then assessed the claims to determine if the proposed criteria for the multiple imaging composite APCs, discussed in section II.A.2.f.(5) of this proposed rule, were met. If the criteria for the imaging composite APCs were met, we created a ''single session'' claim for the applicable imaging composite service and determined whether we could use the claim in ratesetting. For HCPCS codes that are both conditionally packaged and are members of a multiple imaging composite APC, we first assessed whether the code would be packaged and, if so, the code ceased to be available for further assessment as part of the composite APC. Because the packaged code would not be a separately payable procedure, we considered it to be unavailable for use in setting the composite APC costs on which the proposed CY 2014 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.

We also are proposing to examine the multiple procedure minor claims to determine whether we could create ''pseudo'' single procedure claims. Specifically, where the claim contained multiple codes with status indicator ''Q1'' (''STV-packaged'') on the same date of service or contained multiple units of a single code with status indicator ''Q1,'' we selected the status indicator ''Q1'' HCPCS code that had the highest CY 2013 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 2013 relative payment weight to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q1'' HCPCS code with the highest CY 2013 relative payment weight; other codes with status indicator ''Q1''; and all other packaged HCPCS codes and packaged revenue code costs. We changed the status indicator for the selected code from the data status indicator of ''N'' to the status indicator of the APC to which the selected procedure was assigned for further data processing and considered this claim as a major procedure claim. We used this claim in the calculation of the APC geometric mean cost for the status indicator ''Q1'' HCPCS code.

Similarly, if a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') or multiple units of a single code with status indicator ''Q2,'' we selected the status indicator ''Q2'' HCPCS code that had the highest CY 2013 relative payment weight and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q2.'' We then packaged all costs for the following into a single cost for the ''Q2'' HCPCS code that had the highest CY 2013 relative payment weight to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2013 relative payment weight; other codes with status indicator ''Q2''; and other packaged HCPCS codes and packaged revenue code costs. We changed the status indicator for the selected code from a data status indicator of ''N'' to the status indicator of the APC to which the selected code was assigned, and we considered this claim as a major procedure claim.

If a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') and status indicator ''Q1'' (''STV-packaged''), we selected the T-packaged status indicator ''Q2'' HCPCS code that had the highest relative payment weight for CY 2013 and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q2.'' We then packaged all costs for the following into a single cost for the selected (''T packaged'') HCPCS code to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2013 relative payment weight; other codes with status indicator ''Q2''; codes with status indicator ''Q1'' (''STV-packaged''); and other packaged HCPCS codes and packaged revenue code costs. We selected status indicator ''Q2'' HCPCS codes instead of ''Q1'' HCPCS codes because ''Q2'' HCPCS codes have higher CY 2013 relative payment weights. If a status indicator ''Q1'' HCPCS code had a higher CY 2013 relative payment weight, it became the primary code for the simulated single bill process. We changed the status indicator for the selected status indicator ''Q2'' (''T-packaged'') code from a data status indicator of ''N'' to the status indicator of the APC to which the selected code was assigned and we considered this claim as a major procedure claim.

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

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

We are proposing to continue to apply the methodology described above for the purpose of creating ''pseudo'' single procedure claims for the CY 2014 OPPS.

c. Completion of Claim Records and Geometric Mean Cost Calculations

(1) General Process

We then packaged the costs of packaged HCPCS codes (codes with status indicator ''N'' listed in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) and the costs of those

lines for codes with status indicator ''Q1'' or ''Q2'' when they are not separately paid), and the costs of the services reported under packaged revenue codes in Table 4 below that appeared on the claim without a HCPCS code into the cost of the single major procedure remaining on the claim. For a more complete discussion of our proposed CY 2014 OPPS packaging policy, we refer readers to section II.A.3. of this proposed rule.

As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66606), for the CY 2008 OPPS, we adopted an APC Panel recommendation that CMS should review the final list of packaged revenue codes for consistency with OPPS policy and ensure that future versions of the I/OCE edit accordingly. As we have in the past, we are proposing to continue to compare the final list of packaged revenue codes that we adopt for CY 2014 to the revenue codes that the I/OCE will package for CY 2014 to ensure consistency.

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

For CY 2014, as we did for CY 2013, we reviewed the changes to revenue codes that were effective during CY 2012 for purposes of determining the charges reported with revenue codes but without HCPCS codes that we would propose to package for CY 2014. We believe that the charges reported under the revenue codes listed in Table 4 below continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes. Therefore, for CY 2014, we are proposing to continue to package the costs that we derive from the charges reported without HCPCS codes under the revenue codes displayed in Table 4 below for purposes of calculating the geometric mean costs on which the proposed CY 2014 OPPS/ASC payment rates are based.

TABLE 4—PROPOSED CY 2014 PACKAGED REVENUE CODES

Revenue code	Description
0250	Pharmacy; General Classification.
0251	Pharmacy; Generic Drugs.
0252	Pharmacy; Non-Generic Drugs.
0254	Pharmacy; Drugs Incident to Other Diagnostic Services.
0255	Pharmacy; Drugs Incident to Radiology.
0257	Pharmacy; Non-Prescription.
0258	Pharmacy; IV Solutions.
0259	Pharmacy; Other Pharmacy.
0260	IV Therapy; General Classification.
0261	IV Therapy; Infusion Pump.
0262	IV Therapy; IV Therapy/Pharmacy Svcs.
0263	IV Therapy; IV Therapy/Drug/Supply Delivery.
0264	IV Therapy; IV Therapy/Supplies.
0269	IV Therapy; Other IV Therapy.
0270	Medical/Surgical Supplies and Devices; General Classification.
0271	Medical/Surgical Supplies and Devices; Non-sterile Supply.
0272	Medical/Surgical Supplies and Devices; Sterile Supply.
0275	Medical/Surgical Supplies and Devices; Pacemaker.
0276	Medical/Surgical Supplies and Devices; Intraocular Lens.
0278	Medical/Surgical Supplies and Devices; Other Implants.
0279	Medical/Surgical Supplies and Devices; Other Supplies/Devices.
0280	Oncology; General Classification.
0289	Oncology; Other Oncology.
0343	Nuclear Medicine; Diagnostic Radiopharmaceuticals.
0344	Nuclear Medicine; Therapeutic Radiopharmaceuticals.
0370	Anesthesia; General Classification.
0371	Anesthesia; Anesthesia Incident to Radiology.
0372	Anesthesia; Anesthesia Incident to Other DX Services.
0379	Anesthesia; Other Anesthesia.
0390	Administration, Processing and Storage for Blood and Blood Components; General Classification.
0392	Administration, Processing and Storage for Blood and Blood Components; Processing and Storage.
0399	Administration, Processing and Storage for Blood and Blood Components; Other Blood Handling.
0621	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Radiology.
0622	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Other DX Services.
0623	Medical Supplies—Extension of 027X, Surgical Dressings.
0624	Medical Surgical Supplies—Extension of 027X; FDA Investigational Devices.
0630	Pharmacy—Extension of 025X; Reserved.
0631	Pharmacy—Extension of 025X; Single Source Drug.
0632	Pharmacy—Extension of 025X; Multiple Source Drug.
0633	Pharmacy—Extension of 025X; Restrictive Prescription.
0681	Trauma Response; Level I Trauma.
0682	Trauma Response; Level II Trauma.
0683	Trauma Response; Level III Trauma.
0684	Trauma Response; Level IV Trauma.
0689	Trauma Response; Other.

TABLE 4—PROPOSED CY 2014 PACKAGED REVENUE CODES—Continued

Revenue code	Description
0700	Cast Room; General Classification.
0710	Recovery Room; General Classification.
0720	Labor Room/Delivery; General Classification.
0721	Labor Room/Delivery; Labor.
0732	EKG/ECG (Electrocardiogram); Telemetry.
0762	Specialty services; Observation Hours.
0801	Inpatient Renal Dialysis; Inpatient Hemodialysis.
0802	Inpatient Renal Dialysis; Inpatient Peritoneal Dialysis (Non-CAPD).
0803	Inpatient Renal Dialysis; Inpatient Continuous Ambulatory Peritoneal Dialysis (CAPD).
0804	Inpatient Renal Dialysis; Inpatient Continuous Cycling Peritoneal Dialysis (CCPD).
0809	Inpatient Renal Dialysis; Other Inpatient Dialysis.
0810	Acquisition of Body Components; General Classification.
0819	Acquisition of Body Components; Other Donor.
0821	Hemodialysis-Outpatient or Home; Hemodialysis Composite or Other Rate.
0824	Hemodialysis-Outpatient or Home; Maintenance—100%.
0825	Hemodialysis-Outpatient or Home; Support Services.
0829	Hemodialysis-Outpatient or Home; Other OP Hemodialysis.
0942	Other Therapeutic Services (also see 095X, an extension of 094x); Education/Training.
0943	Other Therapeutic Services (also see 095X, an extension of 094X), Cardiac Rehabilitation.
0948	Other Therapeutic Services (also see 095X, an extension of 094X), Pulmonary Rehabilitation.

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

For the remaining claims, we are proposing to then standardize 60 percent of the costs of the claim (which we have previously determined to be the labor-related portion) for geographic differences in labor input costs. We made this adjustment by determining the wage index that applied to the hospital that furnished the service and dividing the cost for the separately paid HCPCS code furnished by the hospital by that wage index. The claims accounting that we provide for the proposed 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 are proposing to use the pre-reclassified wage indices for standardization because we believe that they better reflect the true costs of items and services in the area in which the hospital is located than the post-reclassification wage indices and, therefore, would result in the most accurate unadjusted geometric mean costs.

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

After removing claims for hospitals with error CCRs, claims without HCPCS codes, claims for immunizations not covered under the OPPS, and claims for services not paid under the OPPS, approximately 112 million claims were left. Using these approximately 112 million claims, we created approximately 82 million single and ''pseudo'' single procedure claims, of which we used slightly more than 82 million single bills (after trimming out approximately 1 million claims as discussed in section II.A.1.a. of this proposed rule) in the CY 2014 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 calculated the APC relative payment weights using geometric mean costs, and are proposing to do the same for CY 2014. Therefore, the following discussion of the 2 times rule violation and the development of the relative payment weight refers to geometric means. For more detail about the CY 2014 OPPS/ASC policy to calculate relative payment weights based on geometric means, we refer readers to section II.A.2.f. of this proposed rule.

We are proposing to use these claims to calculate the CY 2014 geometric mean costs for each separately payable HCPCS code and each APC. The comparison of HCPCS code-specific and APC geometric mean costs determines the applicability of the 2 times rule. Section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group shall not be treated as comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the same group (the 2 times rule). While we have historically applied the 2 times rule based on median costs, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68270), as part of the CY 2013 policy to develop the OPPS relative payment weights based on geometric mean costs, we also applied

the 2 times rule based on geometric mean costs. For the CY 2014 OPPS, we are proposing to continue to develop the APC relative payment weights based on geometric mean costs.

We note that, for purposes of identifying significant HCPCS codes for examination in the 2 times rule, we consider codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC geometric mean cost to be significant. This longstanding definition of when a HCPCS code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 82 million single procedure or single session claims we use for establishing geometric mean costs. Similarly, a HCPCS code for which there are fewer than 99 single bills and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC geometric mean. We note that this method of identifying significant HCPCS codes within an APC for purposes of the 2 times rule was used in prior years under the median-based cost methodology. Under our proposed CY 2014 policy to continue to base the relative payment weights on geometric mean costs, we believe that this same consideration for identifying significant HCPCS codes should apply because the principles are consistent with their use in the median-based cost methodology. Unlisted codes are not used in establishing the percent of claims contributing to the APC, nor are their costs used in the calculation of the APC geometric mean. Finally, we reviewed the geometric mean costs for the services for which we are proposing to pay separately under this proposed rule, and we reassigned HCPCS codes to different APCs where it was necessary to ensure clinical and resource homogeneity within the APCs. The APC geometric means were recalculated after we reassigned the affected HCPCS codes. Both the HCPCS code-specific geometric means and the APC geometric means were weighted to account for the inclusion of multiple units of the bypass codes in the creation of ''pseudo'' single procedure claims.

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

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

At the March 11, 2013 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 final rule costs based on CY 2011 claims processed through June 30, 2012, to those based on CY 2012 OPPS/ASC final rule data (CY 2011 claims processed through June 30, 2011). The Data Subcommittee reviewed the fluctuations in the APC costs and their respective weights.

At the March 2013 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 recommended that CMS provide data on the impact of the CY 2013 method of using geometric mean costs rather than median costs to establish relative APC weights.

CMS Response: We are accepting this recommendation and will provide the data at a future meeting.

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

(1) Device-Dependent APCs

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

For CY 2014, we are proposing in section II.A.2.e. of this proposed rule to define 29 device-dependent APCs as single complete services and to assign them to comprehensive APCs that would provide all-inclusive payments for those services. As we explain in that section, we are proposing this as a further step to improve the accuracy and transparency of our payments for these services where the cost of the device is large compared to the other costs that contribute to the cost of the service. Table 5 below provides a list of the 39 APCs currently recognized as device-dependent APCs and identifies those 29 APCs that we are proposing to include in the comprehensive APCs proposal. We are proposing to treat the remaining 10 device-dependent APCs by applying our standard APC ratesetting methodology to calculate their CY 2014 payment rates. We initially adopted a specific device-dependent APC ratesetting methodology because commenters had previously expressed concerns that the costs associated with certain high-cost devices were not always being accurately reported and included in the calculation of relative payment weights for the associated procedures. In this proposed rule, we do not believe that it is necessary to continue to apply the more specific device-dependent APC ratesetting methodology to ensure accurate ratesetting for the 10 APCs that are not included in the comprehensive APCs proposal because hospitals now have had several years of experience reporting procedures involving implantable devices and have grown accustomed to ensuring that they code and report charges so that their claims fully and appropriately reflect the costs of those devices. Therefore, we believe that it is possible to calculate the payment rates for these APCs using our standard APC ratesetting methodology.

Beginning in CY 2014, we also are proposing to no longer implement procedure-to-device edits and device-to-procedure edits for any APCs. Under this proposal, hospitals would still be expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable. However, claims would no longer be returned to providers when specific procedure and device code pairings do not appear on a claim. We believe that this is appropriate because of the experience hospitals now have had in coding and reporting these claims fully and because, for the more costly devices, the proposed comprehensive APCs would reliably reflect the cost of the device if it is included anywhere on the claim. Therefore, we do not believe that the burden on hospitals of adhering to the procedure-to-device edits and device-to-procedure edits, and the burden on the Medicare program of maintaining those edits, continue to be warranted. As with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

TABLE 5—APCs CURRENTLY RECOGNIZED AS DEVICE–DEPENDENT APCs

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

*Denotes proposed comprehensive APC.

(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.

For CY 2014, we are proposing to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, in order to address the differences in CCRs and to better reflect hospitals' costs, we are proposing to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio

of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We 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 2014 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe the hospital-specific, blood-specific CCR methodology best responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We continue to believe that this methodology in CY 2014 would result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that, as discussed in section II.A.2.e. of this proposed rule, we are proposing comprehensive APCs that would provide all-inclusive payments for certain device-dependent procedures. Under this proposal, we would include the costs of blood and blood products when calculating the overall costs of these comprehensive APCs. We note that we would continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the comprehensive APCs. Because the costs of blood and blood products would be reflected in the overall costs of the comprehensive APCs (and, as a result, in the payment rates of the comprehensive APCs), we would not make separate payments for blood and blood products when they appear on the same claims as services assigned to the comprehensive APCs.

We refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for the proposed CY 2014 payment rates for blood and blood products (which are identified with status indicator ''R''). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

e. Proposed Establishment of Comprehensive APCs

(1) Definition and General Principles

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

For CY 2014, we are proposing to create 29 comprehensive APCs to replace 29 existing device-dependent APCs. We are proposing to define a comprehensive APC as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Because a comprehensive APC would treat all individually reported codes as representing components of the comprehensive service, our proposal is to make a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service and all adjunctive services provided to support that delivery of the primary service. Specifically, we are proposing to create comprehensive APCs for the 29 most costly device-dependent services, where the cost of the device is large compared to the other costs that contribute to the cost of delivering the primary service.

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

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

We believe this proposal to establish comprehensive APCs will improve our ability to accurately set payment rates. In the normal process of setting payment rates, costs in certain cost centers (''uncoded costs'') are added to the costs of services reported with specific HCPCS codes only when they can be reliably assigned to a single service. Under the proposal, the entire claim would be associated with a single comprehensive service so all costs reported on the claim may be reliably assigned to that service. This increases the accuracy of the payment for the comprehensive service and also increases the stability of the payment from year to year. As an example, room and board revenue center charges are not included in OPPS rate setting calculations because room and board is typically not separately charged for outpatient services. In the case of these 29 device-dependent procedures, the patient typically stays overnight to recover from the procedure. Thus, for these 29 comprehensive services, the cost of the room, nutrition (board) and nursing care that is required to sustain the patient while the comprehensive device-dependent service is delivered will be associated with the service even if the hospital reports the costs in room and board revenue codes that are not usually used to report outpatient procedure costs.

We also believe our proposal will enhance beneficiary understanding and transparency. Typically beneficiaries understand the primary procedure to be the OPPS service they receive, and do not generally consider that the other HCPCS codes are separate services. For example, beneficiaries think of a single service such as ''getting my gall bladder removed'' or ''getting a pacemaker.'' We believe that defining certain services within the OPPS in terms of a single comprehensive service delivered to the beneficiary improves transparency for the beneficiary, for physicians, and for hospitals by creating a common reference point with a similar meaning for all three groups and using the comprehensive service concept that already identifies these same services when they are performed in an inpatient environment.

Finally, we believe that larger bundles that contain a wider mix of related services in the prospectively paid bundles increase the opportunities for

providers to tailor services to the specific needs of individual beneficiaries, thereby increasing the opportunities for efficiencies and improving the delivery of medical care.

(2) Comprehensive APCs for Device-Dependent Services

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

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

(b) Proposal To Create Comprehensive APCs for Certain Device-Dependent Procedures

For CY 2014, we are proposing to create 29 comprehensive APCs to prospectively pay for device-dependent services associated with 136 HCPCS codes. We are proposing to base the single all-inclusive comprehensive APC payment on all charges on the claim, excluding only charges that cannot be covered by Medicare Part B or that are not payable under the OPPS. This comprehensive APC payment would include, for example, payment for the following types of services.

• Inclusion of Otherwise Packaged Services and Supplies

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

• Inclusion of Adjunctive Services

We have previously noted in section II.A.3.a. of this proposed rule that it has been a goal of the OPPS to package services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service. We are proposing to package into the comprehensive APCs all these integral, ancillary, supportive, dependent, and adjunctive services, hereinafter collectively referred to as ''adjunctive services,'' provided during the delivery of the comprehensive service. This includes the diagnostic procedures, laboratory tests and other diagnostic tests, and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; outpatient department services delivered by therapists as part of the comprehensive service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that are provided during the comprehensive service, except for mammography services and ambulance services, which are never payable as OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act.

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

As part of the comprehensive service packaging proposal described above, we are proposing to package all devices; implantable durable medical equipment (DME); implantable prosthetics; DME, prosthetics, and orthotics when used as supplies in the delivery of the comprehensive service; and supplies used in support of these items when these items or supplies are provided as part of the delivery of a comprehensive service. We have a longstanding policy of providing payment under the OPPS for implantable DME, implantable prosthetics, and medical and surgical supplies, as provided at sections 1833(t)(1)(B)(i) and(iii) of the Act and 42 CFR 419.2(b)(4), (b)(10), and (b)(11). Under this proposal, DME, prosthetics, and orthotics, when used as supplies in the delivery of the comprehensive service, would be covered OPD services as provided under section 1833(t)(1)(B)(i) of the Act and 42 CFR 419.2(b)(4). Under this proposal, we believe that when such items and services are provided as adjunctive components in the delivery of a comprehensive service, such items are appropriate for coverage under the OPPS as covered OPD services, and for payment under the OPPS. We note that, at other times, such items when not provided as adjunctive components in the delivery of a comprehensive service would not constitute covered OPD services, and such items would be appropriately provided by suppliers and paid for under the DMEPOS benefit. More specifically, we do not believe that this proposed policy limits a hospital's ability to function as a DMEPOS supplier and bill DMEPOS items to the DME–MAC when those items are unrelated to the outpatient procedure and provided outside of the delivery of the comprehensive service.

In summary, we are proposing to consider all DMEPOS items to be covered OPD services and to be adjunctive to the primary service when they are delivered during the comprehensive service, as described above, and, therefore, are proposing to package such items into the applicable comprehensive service. This proposal includes any items described by codes that are otherwise covered and paid separately in accordance with the payment rules for DMEPOS items and services, and applies to those items when they are provided as part of the delivery of the comprehensive service. Under this proposal, when such items are provided during the delivery of a comprehensive service, we are proposing that they are covered OPD services as provided under sections 1833(t)(1)(B)(i) and (iii) of the Act and 42 CFR 419.2(b)(4), (b)(10), and (b)(11), and payable under the OPPS, as described above.

• Inclusion of OPD Services Reported by Therapy Codes

Generally, section 1833(t)(1)(B)(4) of the Act excludes therapy services from the OPPS. We have previously noted that therapy services are those provided by therapists under a plan of care, and are paid under section 1834(k) of the Act subject to an annual therapy cap, when applied. However, certain other activities similar to therapy services are considered and paid as outpatient services. Although some adjunctive services may be provided by therapists and reported with therapy codes, we do not believe they always constitute therapy services. In the case of adjunctive components of a comprehensive service that are described by codes that would, under other circumstances, be indicative of therapy services, we note that there are a number of factors that would more appropriately identify them as OPD services. They are not independent services but are delivered as an integral part of the OPD service on the order of the physician who is providing the service; they are not typically provided under an established plan of care but on a direct physician order; they may be performed by nontherapists; and they frequently do not contribute to a rehabilitative process. For example, we note that therapists might be asked to provide a detailed documentation of patient weaknesses to be used by the physician to help identify or quantify a possible procedure-associated stroke or help with the mobilization of the patient after surgery in order to prevent blood clots. We note that these nontherapy services furnished by a therapist are limited to the immediate perioperative period, consistent with their inclusion as part of the larger service to deliver the device, and are distinct from

subsequent therapy services furnished under a therapy plan of care which serve to establish rehabilitative needs and begin the process of rehabilitation.

For that reason, when provided within this very limited context of a comprehensive service such as the implantation of an expensive device, we are proposing that services reported by therapy HCPCS codes, including costs associated with revenue codes 042X, 043X and 044X, would be considered to be adjunctive OPD services in support of the primary service when those services occur within the peri-operative period; that is, during the delivery of this comprehensive service that is bracketed by the OPD registration to initiate the service and the OPD discharge at the conclusion of the service. They do not constitute therapy services provided under a plan of care, are not subject to a therapy cap, if applied, and are not paid separately as therapy services.

• Inclusion of Additional Hospital Room and Board Revenue Centers in the Calculation of Covered Costs

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

• Inclusion of Hospital-Administered Drugs

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

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

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

(c) Methodology

We calculated the proposed relative payment weights for these device-dependent comprehensive APCs by using relative costs derived from our standard process as described earlier in section II.A. of this proposed rule. Specifically, after converting charges to costs on the claims, we identified all claims containing one of the 136 HCPCS-defined procedures specified as constituting a comprehensive service. These claims were, by definition, classified as single major procedure claims. Any claims that contained more than one of these procedures were identified but were included in calculating the cost of the procedure that had the greatest cost when traditional HCPCS level accounting was applied. All other costs were summed to calculate the total cost of the comprehensive service, and statistics for those services were calculated in the usual manner. Claims with extreme costs were excluded in accordance with our usual process.

(d) Payments

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

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

• Impact on Medicare Payments

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

• Impact on APCs

Impact on Composite APCs. There is currently one device-dependent composite service in the OPPS, Cardiac Resynchronization Therapy, assigned to APC 0108. Because a comprehensive APC would treat all individually reported codes as representing components of the comprehensive service, all of the elements of the composite service are included in the proposed new comprehensive service. Therefore, Cardiac Resynchronization Therapy would no longer be identified as a composite service but would be identified as a comprehensive service. All services currently assigned to APC 0108, including Cardiac Resynchronization Therapy, would be assigned to the proposed new comprehensive APC, with the proposed payment for CY 2014 identified in Addendum B of this proposed rule (which is available via the Internet on the CMS Web site).

Impact on Claims Used to Calculate Other APCs. Some costs reported on claims for device-dependent procedures may no longer be available to contribute to the calculations for other services through the pseudo-single process, described in section II.A. of this proposed rule. However, the loss of usable cost data for these services would be small because most of these services currently cannot be isolated as the ''single services'' that can be used in the cost calculation process. The exceptions are services such as EKGs and chest x-rays that occur in very high frequency across all types of encounters, and laboratory services and drugs, neither of which are calculated based on average cost. Finally, it is important to note that any loss is a small impact when compared against the 400,000 new claims that could now be used because of the establishment of the proposed comprehensive APC.

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

• Impact on Beneficiary Payments

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

(f) Summary of Proposal To Create Comprehensive APCs for High-Cost Device-Dependent Procedures

For CY 2014, we are proposing to create 29 comprehensive APCs to prospectively pay for device-dependent services associated with 136 HCPCS codes. We are proposing to treat all individually reported codes as representing components of the comprehensive service, making a single payment for the comprehensive service based on all charges on the claim, excluding only charges for services that cannot be covered by Medicare Part B or that are not payable under the OPPS. This would create a single all-inclusive payment for the claim that is subject to a single beneficiary copayment, up to the cap set at the level of the inpatient hospital deductible, as provided at section 1833(t)(8)(C)(i) of the Act.

As part of the proposed comprehensive APC, we are proposing to—

• Continue to package all services that were packaged in CY 2013.

• Unconditionally package all services elsewhere proposed for unconditional or conditional packaging for CY 2014.

• Package all adjunctive services provided during the delivery of the comprehensive service.

• Package room, board, and nursing costs necessary to deliver the outpatient service, regardless of whether or not the stay extends beyond a single calendar day.

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

• Pay separately for mammography services and ambulance services as non-OPPS services, regardless of whether they are reported as part of a comprehensive service.

We are inviting public comment on this proposal.

f. Proposed Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care 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.

For CY 2014, we are proposing to continue our composite policies for extended assessment and management services, LDR prostate brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, and multiple imaging services, as discussed below. We are proposing to discontinue and supersede the cardiac resynchronization therapy composite APC by our proposed comprehensive APC 0108, as discussed in section II.A.2.e of this proposed rule.

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

(a) Background

Beginning in CY 2008, we included composite APC 8002 (Level I Extended Assessment and Management Composite) and composite APC 8003 (Level II Extended Assessment and Management Composite) in the OPPS to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur (an extended visit). In most of these circumstances, observation services are supportive and ancillary to the other services provided to a patient. From CY 2008 through CY 2013, in the circumstances when observation care is provided in conjunction with a high level visit, critical care, or direct referral and is an integral part of a patient's extended encounter of care, payment is made for the entire care encounter through one of the two composite APCs as appropriate. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163 through 74165) for a full discussion of this longstanding policy for CY 2013 and prior years.

For CY 2014, we are proposing to modify our longstanding policy to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur. Primarily, we are proposing to allow any visit furnished by a hospital in conjunction with observation services of substantial duration to qualify for payment through the Extended Assessment and Management (EAM) Composite APC. Also, rather than recognizing two levels of EAM Composite APCs, we are proposing to create a new composite APC entitled, ''Extended Assessment and Management (EAM) Composite,'' (APC 8009) to provide payment for all qualifying extended assessment and management encounters. These proposals are discussed in greater detail below.

(b) Proposed Payment for Extended Assessment and Management Services

As discussed in section VII. of this proposed rule, we are proposing to no longer recognize five distinct visit levels for clinic visits and emergency department visits based on the existing HCPCS E/M codes, and instead recognize three new alphanumeric HCPCS codes for each visit type. Currently, the payment criteria for the EAM composite APCs 8002 and 8003 include a high level visit represented by HCPCS code 99205, 99215, 99284, 99285, or G0304; critical care represented by CPT code 99281; or direct referral represented by HCPCS code G0379 provided in conjunction with observation care represented by HCPCS code G0378. In light of the proposal to no longer differentiate visit payment levels, and the fact that the current high level visit codes (HCPCS codes 99205, 99215, 99284, 99285 and G0304) would no longer be recognized under the OPPS, it would no longer be feasible to continue with our current payment criteria for the EAM composite APCs 8002 and 8003 for CY 2014. Therefore, to ensure that we continue to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur, for CY 2014, we are proposing to provide payment for the entire care encounter through proposed new EAM Composite APC 8009 when observation care is provided in conjunction with a visit, critical care, or direct referral and is an integral part of a patient's extended encounter of care. Specifically, for CY 2014, we are proposing to provide EAM composite APC payment, through a newly created composite APC in circumstances when a clinic or ED visit, identified by one of the three new alphanumeric HCPCS codes proposed in section VII. of this proposed rule, is accompanied by observation care of substantial duration on a claim. We would no longer recognize APC 8002 or APC 8003. The specific criteria we are proposing to be met for the proposed new EAM composite APC to be paid is provided below in the description of the claims that we are proposing to select for the calculation of the proposed CY 2016 mean costs for this composite APC.

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

- The claim does not contain a HCPCS code to which we have assigned status indicator ''T'' that is reported with a date of service 1 day earlier than the date of service associated with HCPCS code G0378. (By selecting these claims from single and ''pseudo'' single claims, we assured that they would not contain a code for a service with status indicator ''T'' on the same date of service.);
- The claim contains 8 or more units of HCPCS code G0378 (Observation services, per hour); and
- The claim contains one of the following codes: HCPCS code G0379 (Direct referral of patient for hospital observation care) on the same date of service as G0378; or CPT code 99201 (Office or other outpatient visit for the evaluation and management of a new patient (Level 1)); CPT code 99202 (Office or other outpatient visit for the evaluation and management of a new patient (Level 2)); CPT code 99203 (Office or other outpatient visit for the evaluation and management of a new patient (Level 3)); CPT code 99204 (Office or other outpatient visit for the evaluation and management of a new patient (Level 4)); CPT code 99205 (Office or other outpatient visit for the evaluation and management of a new patient (Level 5)); CPT code 99211 (Office or other outpatient visit for the evaluation and management of an established patient (Level 1)); CPT code 99212 (Office or other outpatient visit for the evaluation and management of an established patient (Level 2)); CPT code 99213 (Office or other outpatient visit for the evaluation and management of an established patient (Level 3)); CPT code 99214 (Office or other outpatient visit for the evaluation and management of an established patient (Level 4)); CPT code 99215 (Office or other outpatient visit for the evaluation and management of an established patient (Level 5)); CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)); or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); or CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) provided on the same date of service or 1 day before the date of service for HCPCS code G0378.

The proposed CY 2014 cost resulting from this methodology for the proposed new EAM composite APC (APC 8009) is approximately $1,357, which was calculated from 318,265 single and ''pseudo'' single claims that met the required criteria.

When hospital claims data for the CY 2014 proposed clinic and ED visit codes becomes available, we are proposing to

calculate the mean costs for the proposed new EAM composite APC (APC 8009) for CY 2016 using CY 2014 single and ''pseudo'' single procedure claims that meet each of the following criteria:

- The claims do not contain a HCPCS code to which we have assigned status indicator ''T'' that is reported with a date of service 1 day earlier than the date of service associated with HCPCS code G0378. (By selecting these claims from single and ''pseudo'' single claims, we ensure that they would not contain a code for a service with status indicator ''T'' on the same date of service.);
- The claims contain 8 or more units of HCPCS code G0378 (Observation services, per hour); and
- The claims contain one of the following codes: HCPCS code G0379 (Direct referral of patient for hospital observation care) on the same date of service as G0378; or CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or newly proposed alphanumeric Level II HCPCS code GXXXA (Type A ED visit); newly proposed alphanumeric Level II HCPCS code GXXXB (Type B ED visit); or newly proposed alphanumeric Level II HCPCS code GXXXC (Clinic visit) provided on the same date of service or 1 day before the date of service for HCPCS code G0378.

(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.

For CY 2014, we are proposing to continue to pay for LDR prostate brachytherapy services using the composite APC methodology proposed and implemented for CY 2008 through CY 2013. That is, we are proposing to use CY 2012 claims on which both CPT codes 55875 and 77778 were billed on the same date of service with no other separately paid procedure codes (other than those on the bypass list) to calculate the payment rate for composite APC 8001. Consistent with our CY 2008 through CY 2013 practice, we are proposing not to use the claims that meet 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 are proposing to continue to calculate the costs for APCs 0163 and 0651 using single and ''pseudo'' single procedure claims. We believe that this composite APC contributes to our goal of creating hospital incentives for efficiency and cost containment, while providing hospitals with the most flexibility to manage their resources. We also continue to believe that data from claims reporting both services required for LDR prostate brachytherapy provide the most accurate cost upon which to base the composite APC payment rate.

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

(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.

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, effective January 1, 2013. These five new codes are:

- CPT code 93653 (Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia

with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry);

- CPT code 93654 (Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of ventricular tachycardia or focus of ventricular ectopy including intracardiac electrophysiologic 3D mapping, when performed, and left ventricular pacing and recording, when performed);
- CPT code 93655 (Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure));
- CPT code 93656 (Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with atrial recording and pacing, when possible, right ventricular pacing and recording, His bundle recording with intracardiac catheter ablation of arrhythmogenic focus, with treatment of atrial fibrillation by ablation by pulmonary vein isolation); and
- CPT code 93657 (Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)).

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

As we described in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68425), new CPT codes 93653, 93654, and 93656 are primary electrophysiologic services that encompass evaluation as well as ablation, while new CPT codes 93655 and 93657 are add-on codes. Because CPT codes 93653, 93654, and 93656 already encompass both evaluation and ablation services, we assigned them to composite APC 8000 with no further requirement to have another electrophysiologic service from either Group A or Group B furnished on the same date of service, and we assigned them interim status indicator ''Q3'' (Codes that may be paid through a composite APC) in Addendum B to the CY 2013 OPPS/ASC final rule with comment period. To facilitate implementing this policy, we assigned CPT codes 93653, 93654, and 93656 to a new Group C, which is paid at the composite APC 8000 payment rate. (We noted that we will use single and ''pseudo'' single claims for CPT codes 93653, 93654, and 93656 when they become available for calculating the costs upon which the payment rate for APC 8000 will be based in future ratesetting.) Because CPT codes 93655 and 93657 are dependent services that may only be performed as ancillary services to the primary CPT codes 93653, 93654, and 93656, we believed that packaging CPT codes 93655 and 93657 with the primary procedures is appropriate, and we assigned them interim status indicator ''N.'' Because the CPT Editorial Panel deleted CPT codes 93651 and 93652, effective January 1, 2013, we deleted them from the Group B code list, leaving only CPT code 93650 (Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement) in Group B.

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

For CY 2014, we are proposing to continue to pay for cardiac electrophysiologic evaluation and ablation services using the composite APC methodology proposed and implemented for CY 2008 through CY 2013. We also are proposing to continue the new Group C methodology we first established for CY 2013, described above, in response to the CPT Editorial Panel's creation of primary CPT codes 93653, 93654, and 93656. We continue to believe that the cost for cardiac electrophysiologic evaluation and ablation services calculated from a high volume of correctly coded multiple procedure claims would result in an accurate and appropriate proposed payment for these services when at least one evaluation service is furnished during the same clinical encounter as at least one ablation service. Consistent with our practice since CY 2008, we are proposing not to use the claims that met the composite payment criteria in the calculation of the costs for APC 0085, to which the CPT codes in both Groups A and B for composite APC 8000 are otherwise assigned. We are proposing that the costs for APC 0085 would continue to be calculated using single procedure claims. For CY 2014, using a partial year of CY 2012 claims data available for this CY 2014 OPPS/ASC proposed rule, we were able to use 15,817 claims containing a combination of Group A and Group B CPT codes (Group C was not effective until January 1, 2013) to calculate a proposed cost of approximately $13,402 for composite APC 8000.

Table 6 below lists the proposed groups of procedures upon which we would base composite APC 8000 for CY 2014.

TABLE 6—PROPOSED 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 2014 CPT Code	Proposed single code CY 2014 APC	Proposed CY 2014 SI (composite)
Group A			
Comprehensive electrophysiologic evaluation with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording, including insertion and repositioning of multiple electrode catheters, without induction or attempted induction of arrhythmia	93619	0085	Q3
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording	93620	0085	Q3
Group B			
Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement	93650	0085	Q3
Group C			
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	93653	8000	Q3
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of ventricular tachycardia or focus of ventricular ectopy including intracardiac electrophysiologic 3D mapping, when performed, and left ventricular pacing and recording, when performed	93654	8000	Q3
Comprehensive electrophysiologic evaluation including 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)

For CY 2104, we are proposing to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health treatments. 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.

We are proposing that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on one date of service based on the payment rates associated with the APCs for the individual services exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be assigned to APC 0034 (Mental Health Services Composite). Specifically, we are proposing to continue to set the payment rate for APC 0034 at the same payment rate that we are proposing to establish for APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs), which is the maximum partial hospitalization per diem payment rate for a hospital and proposing that the hospital would continue to be paid one unit of APC 0034. Under this policy, the I/OCE would continue to determine whether to pay for these specified mental health services individually or to make a single payment at the same payment rate established for APC 0176 for all of the specified mental health services furnished by the hospital on that single date of service. We continue to believe that the costs associated with administering a partial hospitalization program represent the most resource-intensive of all outpatient mental health treatments. Therefore, we do not believe that we should pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

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

Effective January 1, 2009, we provide a single payment each time a hospital bills more than one imaging procedure within an imaging family on the same date of service, in order to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) Ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 6 of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68253 through 68257).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for 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).

For CY 2014, we are proposing to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session. The proposed CY 2014 payment rates for the five multiple imaging composite APCs (APC 8004, APC 8005, APC 8006, APC 8007, and APC 8008) are based on costs calculated from a partial year of CY 2012 claims available for this CY 2014 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 and CY 2013 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 referred to as ''overlap bypass 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), are identified by asterisks in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site) and are discussed in more detail in section II.A.1.b. of this proposed rule.

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

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

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

Proposed CY 2014 APC 8004 (ultrasound composite)	Proposed CY 2014 approximate APC cost = $322
Family 1—Ultrasound	
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.
Proposed CY 2014 APC 8005 (CT and CTA without contrast composite) *	Proposed CY 2014 approximate APC cost = $304
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.

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

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.
Proposed CY 2014 APC 8007 (CT and CTA with Contrast composite)	Proposed CY 2014 approximate APC cost = $522
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.

Proposed CY 2014 APC 8007 (MRI and MRA without Contrast composite) *	Proposed CY 2014 approximate APC cost = $612
Family 3—MRI and MRA with and without Contrast	
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.

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

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.
Proposed CY 2014 APC 8008 (MRI and MRA with contrast composite)	Proposed CY 2014 approximate APC cost = $908
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.

3. Proposed Changes to Packaged Items and 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 items and services into a single payment to create incentives for hospitals to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby encouraging long-term cost containment. Our packaging policies support our strategic goal of using larger payment bundles to maximize hospitals' incentives to provide care in the most efficient matter. In addition, the OPPS packages payment for multiple interrelated items and services into a single payment, regardless of whether dedicated CPT or HCPCS codes describe the services or the cost of the individual items and services. For example, where there are a variety of devices, drugs, items, supplies, etc. that could be used to furnish a service, some of which are more expensive than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely

use a more expensive item, which often results if separate payment is provided for the items. This encourages hospitals that are spending more per case than the payment they received to review their service patterns to ensure that they furnish services as efficiently as possible. Similarly, we believe that separate payment for items and services heightens the hospital's focus on the payment for individual services, rather than the efficient delivery of those services.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. Most, but not necessarily all, items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). For an extensive discussion of the history and background of the OPPS packaging policy, we refer readers to the CY 2008 OPPS/ASC proposed rule (72 FR 42628) and the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580).

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

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. The following description of the conditional packaging status indicators reflects our proposal to discontinue the use of status indicator ''X,'' which we discuss below. We assign status indicator ''Q1'' (STV-Packaged Codes), ''Q2'' (T-Packaged Codes), or ''Q3'' (Codes that may be paid through a composite APC) to each conditionally packaged HCPCS code. An STV-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,'' or ''V'' 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'' that are provided during the hospital outpatient encounter. STV-packaged codes and T-packaged codes are paid separately in those uncommon cases when they do not meet their respective criteria for packaged payment. STV-packaged codes and T-packaged codes are conditionally packaged. We refer readers to the discussion of proposed CY 2014 OPPS payment status and comment indicators in section XI. of this proposed rule and Addendum D1, which is available via the Internet on the CMS Web site, 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 specific guidance. The appropriateness of the OPPS payment rates depends on the quality and completeness of the claims data that hospitals submit for the services they furnish to Medicare beneficiaries.

In addition to the packaged items and services listed in 42 CFR 419.2(b), in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66610 through 66659), we adopted the packaging of payment for items and services in seven categories with the primary diagnostic or therapeutic modality to which we believe these items and services are typically ancillary and supportive. The seven categories are: (1) Guidance services; (2) image processing services; (3) intraoperative services; (4) imaging supervision and interpretation services; (5) diagnostic radiopharmaceuticals; (6) contrast media; and (7) observation services. We specifically chose these categories of HCPCS codes for packaging because we believe that the items and services described by the codes in these categories are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. In addition, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68634), we packaged products described as implantable biologicals. As discussed below, we are proposing to add each of these categories of packaged items and services that were packaged beginning in CYs 2008 and 2009, along with newly proposed packaged items and services for CY 2014 as described below to the OPPS packaging regulation at § 419.2(b). Packaging under the OPPS also includes composite APCs, which are described in section II.A.2.f. of this proposed rule.

b. Basis for Proposed New Packaging Policies for CY 2014

As discussed above, the OPPS is a prospective payment system. It is not intended to be a fee schedule, in which separate payment is made for each coded line item. However, the OPPS is currently a prospective payment system that packages some items and services but not others. Payment for some items and services in the OPPS is according to the principles of a prospective payment system, while the payment for other items and services is more like that of a fee schedule. Our overarching goal is to make OPPS payments for all services paid under the OPPS more consistent with those of a prospective payment system and less like those of a per service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided in the OPPS to determine which OPPS services can be packaged to achieve the objective of

advancing the OPPS as a prospective payment system.

Therefore, as we did in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66610 through 66659), we have examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment of the primary service they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) to see whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies. In general, we are proposing to package the costs of selected HCPCS codes into payment for services reported with other HCPCS codes where we believe that one code reported an item or service that was integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by another HCPCS code. Below we discuss categories and classes of items and services that we are proposing to package beginning in CY 2014. In several cases, we are proposing that services be conditionally packaged so that if they are provided without other services, there will be a separate payment for the service. The proposed policies detailed below are not exhaustive, and we expect to continue to review the OPPS and consider additional packaging policies in the future.

c. Proposed New Packaging Policies for CY 2014

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

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

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

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

(a) Stress Agents

Our review of OPPS drugs identified pharmacologic stress agents (''stress agents'') as a class of drugs that is described by the proposed packaged category of drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure. Stress agents are a class of drugs that are used in diagnostic tests to evaluate certain aspects of cardiac function. In many cases, these agents are used in patients who are unable to perform an exercise stress test, which typically precedes additional diagnostic testing. The primary diagnostic test in which these agents are used is myocardial perfusion imaging (MPI), which is the highest cost nuclear medicine procedure in the OPPS, with OPPS payments exceeding $800 million in CY 2012. Approximately 96 percent of MPI is billed with CPT code 78452. Stress agents include the following drugs described by these HCPCS codes: HCPCS codes J0152 (Injection, adenosine for diagnostic use, 30 mg); J1245 (Injection, dipyridamole, per 10 mg); J1250 (Injection, dobutamine hydrochloride, per 250 mg); and J2785 (Injection, regadenoson, 0.1 mg). For CY 2013, HCPCS codes J1245 and J1250 are packaged in the OPPS, and J0152 and J2785 are separately paid. OPPS payments for the two separately payable stress agents totaled approximately $111 million in CY 2012.

Beginning in CY 2014, we are proposing to package all stress agents that function as supplies into the diagnostic tests or procedures in which they are employed, consistent with the policy proposed above. The primary service in which stress agents are employed is MPI. MPI with stress encompasses the imaging service, the stress test, and either exercise to induce stress or the administration of a pharmacologic stress agent. The various combinations of items and services that constitute MPI with stress are depicted in the table below, which includes the CY 2013 separate payment rates versus the proposed CY 2014 packaged payment rate for MPI.

TABLE 8—CY 2013 SEPARATE PAYMENT VERSUS CY 2014 PROPOSED PACKAGED PAYMENT FOR MPI

Service or supply	CY 2013 Separate payment for MPI components	CY 2013 Separate payment for MPI components	CY 2013 Separate payment for MPI components	CY 2013 Separate payment for MPI components	CY 2014 Proposed packaged payment for MPI
78452	$672	$672	$672	$672	$1,235
93017	$178	$178	$178	$178	P €
Exercise or Stress Agent ¥	Exercise–$0	J1245–P	J2785–$215	* J0152–$219	P
Radiopharmaceutical	P	P	P	P	P
Total	$850	$850	$1,065	$1,069	$1,235

P = Packaged.
€ The stress test described by CPT code 93017 is proposed to be conditionally packaged as a result of the proposal described below to conditionally package ancillary services.
¥ April 2013 ASP Drug Pricing File.
* 70 kg patient.

The proposed CY 2014 payment rate for MPI with the stress test, stress agent, and diagnostic radiopharmaceutical packaged into MPI is 14 percent higher than the sum of the CY 2013 payments for separately paid MPI, a separately paid stress test, and either of the two separately paid stress agents.

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

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

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

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

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

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

Since the inception of the OPPS we have packaged medical devices, medical and surgical supplies, and surgical dressings into the related procedure under § 419.2(b)(4). Medical and surgical supplies are a broad category of items used in the hospital outpatient setting. Supplies is a large category of items that typically are either for single patient use or have a shorter life span in use than equipment. Supplies include not only minor, inexpensive, or commodity-type items but also include a wide range of products used in the hospital outpatient setting, including certain implantable medical devices. We consider implantable medical devices to be integral to, dependent on, and supportive to a surgical implantation procedure. For further discussion, we refer readers to the CY 2000 OPPS final rule (65 FR 18443 through 18444). Packaged supplies can include certain drugs, biologicals, and radiopharmaceuticals. Packaged supplies in the OPPS also include implantable biologicals, which are packaged because they function as implantable devices which, as noted above, are considered to be a type of supply in the OPPS. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68634) for a more detailed discussion. We believe that the existing packaging policy for implantable biologicals represents an example of a broader category of drugs and biologicals that should be packaged in the OPPS according to longstanding regulations and existing policies: drugs and biologicals that function as supplies or devices in a surgical procedure. Therefore, beginning in the CY 2014 OPPS, we are proposing to unconditionally package all drugs and biologicals that function as supplies or devices in a surgical procedure, following the current policy that is applied to implantable biologicals.

A class of products that we treat as biologicals in the OPPS that is described by the proposed packaging category of drugs and biologicals that function as supplies or devices in a surgical procedure is skin substitutes. The term ''skin substitutes'' refers to a category of products that are most commonly used in outpatient settings for the treatment

of diabetic foot ulcers and venous leg ulcers. Although the term ''skin substitute'' has been adopted to refer to this category of products in certain contexts, these products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are various types of wound dressings that, through various mechanisms of action, stimulate the host to regenerate lost tissue and replace the wound with functional skin. We refer readers to the ''Skin Substitutes for Treating Chronic Wounds Technology Assessment Report at ES–2'' which is available on the AHRQ Web site at: *http://www.ahrq.gov/research/findings/ta/skinsubs/HCPR0610_skinsubst-final.pdf*. Currently, available skin substitutes are regulated by the FDA as either medical devices (and classified as wound dressings) or as human cell, tissue, and cellular and tissue-based products (HCT/Ps) under section 361 of the Public Health Service Act. The different skin substitutes are applied to a wound during a surgical procedure described by CPT codes in the range 15271 through 15278. To be properly performed, every surgical procedure in this CPT code range requires the use of at least one skin substitute product. These surgical procedures include preparation of the wound and application of the skin substitute product through suturing or various other techniques. Currently skin substitutes are separately paid in the OPPS as if they are biologicals according to the ASP methodology and are subject to the drug and biological packaging threshold.

Because a skin substitute must be used to perform any of the procedures described by a CPT code in the range 15271 through 15278, and conversely because it is the surgical procedure of treating the wound and applying a covering to the wound that is the independent service, skin substitute products serve as a necessary supply for these surgical repair procedures. In addition, many skin substitutes are classified by the FDA as wound dressings, which make them the same or similar to surgical dressings that are packaged under § 419.2(b)(4). Finally, implantable biological products are very similar to (and in some instances the same as) skin substitute products, except that the clinical applications for implantable biologicals are typically an internal surgery versus the application to a wound for a skin substitute. Some products had or have dual uses as both skin substitutes and implantable biologicals, which underscores the similarity of these sometimes overlapping classes of products. Implantable biologicals and skin substitutes both function as supplies or devices that are used in surgical procedures and, therefore, should be packaged with the surgical procedure in which the products are used. Since CY 2009, we have packaged implantable biologicals and we are proposing to package skin substitutes with their associated surgeries beginning in CY 2014. We see no reason to distinguish skin substitutes from implantable biologicals for OPPS packaging purposes based on the clinical application of individual products. Therefore, we are proposing to unconditionally package skin substitutes into their associated surgical procedures. Packaging payment for these skin substitutes into the APC payment for the related surgical procedures also would result in a total prospective payment that is more reflective of the average resource costs of the procedures because prices for these products vary significantly from product to product. Packaging these products also would promote more efficient resource use by hospitals and would be more consistent with the treatment of similar products under the OPPS. We are proposing to revise the regulations at § 419.2(b)(4) to include skin substitutes as an example of a packaged surgical supply. Pass-through status would still be available to new skin substitutes that meet the pass-through criteria. The skin substitute products that would be unconditionally packaged under this proposal and assigned to status indicator ''N'' for CY 2014 are listed in Addendum P of this CY 2014 OPPS/ASC proposed rule. The proposed payment for CPT codes 15271 through 15278, including the cost of the packaged skin substitutes, for CY 2014 are listed in Addendum B of this proposed rule. These addenda are available on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

(3) Clinical Diagnostic Laboratory Tests

Since the beginning of the OPPS, clinical diagnostic laboratory tests (laboratory tests) provided in the hospital outpatient setting have been separately paid to hospitals at Clinical Laboratory Fee Schedule (CLFS) rates (65 FR 18442). Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. Under this authority, the Secretary excluded from the OPPS those services that are paid under fee schedules or other payment systems. As stated in the April 17, 2000 OPPS final rule with comment period: ''Rather than duplicate existing payment systems that are effectively achieving consistency of payments across different service delivery sites, we proposed to exclude from the outpatient PPS those services furnished in a hospital outpatient setting that were already subject to an existing fee schedule or other prospectively determined payment rate'' (65 FR 18442). Because payment rates for laboratory tests were based on the CLFS, laboratory tests are among the services excluded from the OPPS. We codified this policy at 42 CFR 419.22(l).

As discussed above, it is our intent to make the OPPS a more complete prospective payment system, and less of a fee schedule-type payment system that makes separate payment for each separately coded item. We have examined the services performed in the hospital outpatient setting to determine those services that we believe should be packaged in order to make the OPPS a more complete and robust prospective payment system. We were guided by our longstanding OPPS packaging principle of packaging the payment of items or services when they are provided along with primary services they support. Based on this approach, we believe that laboratory tests (other than molecular pathology tests, as discussed below) that are integral, ancillary, supportive, dependent, or adjunctive to the primary services provided in the hospital outpatient setting are services that should be packaged. Laboratory tests and their results support clinical decisionmaking for a broad spectrum of primary services provided in the hospital outpatient setting, including surgery and diagnostic evaluations. Therefore, except as discussed below for molecular pathology tests, we are proposing to package laboratory tests when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting. We are proposing that laboratory tests would be integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting when they are provided on the same date of service as the primary service and when they are ordered by the same practitioner who ordered the primary service. We would consider a laboratory test to be unrelated to a primary service and, thus, not part of this packaging policy when the laboratory test is the only service provided on that date of service or when the laboratory test is provided on the

same date of service as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service provided in the hospital outpatient setting. The laboratory tests not included in the packaging proposal would continue to be paid separately at CLFS rates when billed on a 14X bill type.

We are proposing an exception for molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 from this proposed packaging policy. We are not proposing that these services be packaged because we believe that these relatively new tests have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we are proposing to package. As we gain more experience with these molecular pathology tests, we will consider if packaging in the OPPS would be appropriate for these types of tests.

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

We recognize that the Medicare Part B deductible and coinsurance generally do not apply for laboratory tests paid to hospitals at CLFS rates, but that the deductible and coinsurance would apply to laboratory tests packaged into other services in the OPPS. The purpose of the laboratory packaging proposal is not to shift program costs onto beneficiaries, but to encourage greater efficiency by hospitals and the most economical delivery of medically necessary laboratory tests. We estimate that the combination of packaging laboratory tests into a wide array of primary services provided in the hospital outpatient setting combined with our long-standing methodology to adjust the copayment percentages to 20 percent as provided in section 1833(t)(3)(B)(ii) of the Act and as discussed in section II.I. of this proposed rule, and the limitation on the copayment amount for a procedure to the inpatient hospital deductible as set forth at section 1833(t)(8)(C)(i) of the Act would fully offset the financial impact on Medicare beneficiaries receiving laboratory tests that would be subject to the proposed packaging policy. Further, we believe that creating these larger bundles will result in a more efficient use of laboratory services when they are adjunctive to an outpatient service. In addition, to the extent that the coinsurance and deductible do not apply under the CLFS, they would continue not to apply for tests that are ordered, provided, and billed independently from a primary service as discussed above, or for molecular pathology tests. We are inviting public comments on the effect of packaging laboratory tests on beneficiary coinsurance.

The laboratory test codes that we are proposing to be packaged and assigned status indicator ''N'' for CY 2014 are listed in Addendum P of this proposed rule (which is available via the Internet on the CMS Web site. We are proposing to revise the regulation text at § 419.2(b) and § 419.22(l) to reflect this laboratory test packaging proposal.

(4) Procedures Described By Add-On Codes

Add-on codes describe procedures that are always performed in addition to a primary procedure. Add-on codes can be either CPT codes or Level II HCPCS codes. For example, the procedure described by CPT code 11001 is ''Debridement of extensive eczematous or infected skin; each additional 10% of the body surface, or part thereof (list separately in addition to code for primary procedure).'' This code is used for additional debridement beyond that described by the primary procedure code. Currently, add-on codes are treated like other codes in the OPPS. Add-on codes typically received separate payment based on an APC assignment, and are typically assigned status indicator ''T.''

Procedures described by add-on codes represent an extension or continuation of a primary procedure, which means that they are typically supportive, dependent, or adjunctive to a primary surgical procedure. The parent code defines the purpose of the patient encounter and the add-on code typically describes additional incremental work, when the extent of the procedure encompasses a range rather than a single defined endpoint applicable to all patients. For example, add-on CPT code 11001 is used for each additional 10 percent of debridement. Therefore, according to longstanding OPPS packaging principles described above and the dependent nature and adjunctive characteristics of procedures described by add-on codes, we believe that such procedures should be packaged with the primary procedure. For CY 2014, we are proposing to unconditionally package all procedures described by add-on codes in the OPPS.

There is an additional benefit to packaging add-on codes—more accurate OPPS payment for procedures described by add-on codes. Currently, calculating mean costs for procedures described by add-on codes is problematic in the OPPS because we cannot determine which costs on a claim are attributable to the primary procedure and which costs are attributable to the add-on procedure. Furthermore, because we use single claims and ''pseudo'' single procedure claims for ratesetting, we generally must rely on incorrectly coded claims containing only the add-on code to calculate payment rates for add-on procedures. Claims containing only an add-on code are incorrectly coded because they should be reported with (or ''added-on'') a primary procedure. Packaging the line item costs associated with an add-on code into the cost of the primary procedure will help address this ratesetting concern because the costs of the add-on code would be packaged into the primary procedure, and we would no longer have to calculate costs for add-on codes based on miscoded claims. In addition, packaging add-on codes would increase the number of single bills available for ratesetting for the primary procedures.

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

(5) Ancillary Services (Status Indicator ''X'')

Under the OPPS, we currently pay separately for certain ancillary services that are assigned to status indicator ''X,'' defined as ''ancillary services.'' Some

other services that are ancillary to other services are currently packaged in the OPPS. Those ancillary services assigned status indicator ''X'' in the OPPS and paid separately are, by definition, ancillary relative to primary services provided in the OPPS and include many minor diagnostic tests that are typically performed with a primary service, although there are instances where such services are not always performed with a primary service and may be performed alone.

As mentioned above, our intent is that the OPPS be more of a prospective payment system through expanding packaging. Given that the longstanding OPPS policy is to package items and services that are integral, ancillary, supportive, dependent, or adjunctive to a primary service, we believe that these ancillary services, which are assigned status indicator ''X,'' should be packaged when they are performed with another service, but should continue to be separately paid when performed alone. This packaging approach is most consistent with a prospective payment system and the regulations at § 419.2(b) that packages ancillary services into primary services while preserving separate payment for those instances in which one of these services is provided alone (not with a separate primary service) to a hospital outpatient.

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

(6) Diagnostic Tests on the Bypass List

For the CY 2013 OPPS, we implemented a bypass list to convert lines from multiple procedure claims into ''pseudo'' single procedure claims. We are proposing to continue developing ''pseudo'' single procedure claims using a bypass list for the CY 2014 OPPS, as discussed in section II.A.1.b. of this proposed rule. The bypass list of separately paid services is used to convert claims with multiple separately payable procedures, which are generally not used for ratesetting purposes, into claims with a single separately paid procedure that can be used for ratesetting. Services on the bypass list have limited associated packaged costs so they can be bypassed when assigning packaged costs on a claim to a separately paid procedure on the same claim.

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

We are proposing that these codes be assigned status indicator ''Q1'' beginning in the CY 2014 OPPS. Some of these diagnostic tests on the bypass list are currently assigned to status indicator ''X'' and, therefore, would be conditionally packaged under the proposed policy to conditionally package ancillary services currently assigned status indicator ''X.'' The only diagnostic codes on the bypass list affected by this proposal are currently assigned to status indicator ''S.'' The specific codes for the diagnostic tests on the bypass list that we are proposing to be conditionally packaged and assigned to status indicator ''Q1'' for CY 2014 are listed in Addendum P of this proposed rule, which is available via the Internet on the CMS Web site. Similar to our conditional packaging proposal for services previously assigned to status indicator ''X,'' we are not proposing to conditionally package preventive services that are diagnostic tests on the bypass list.

(7) Device Removal Procedures

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

Given that a separately coded device removal that accompanies a device repair or replacement procedure represents a service that is integral and supportive to a primary service, we are proposing to conditionally package device removal codes when they are billed with other surgical procedures involving repair or replacement. We believe that this conditional packaging policy is appropriate under longstanding OPPS packaging principles because these device removal procedures are an integral and supportive step in a more comprehensive overall procedure. Furthermore, conditionally packaging these device removal procedures with the replacement or revision codes would be consistent with our packaging policies for other dependent services. The specific codes for the device removal procedures that we are proposing to be conditionally packaged and assigned to status indicator ''Q2'' for CY 2014 are listed in Addendum P of this proposed rule, which is available via the Internet on the CMS Web site.

d. Impact of the New Packaging Proposals

We have examined the proposed aggregate impact of making these proposed changes to packaging for CY

2014. Because the OPPS is a budget neutral payment system in which the amount of the relative payment weight in the system is annually adjusted for changes in expenditures created by changes in APC weights and codes (but is not currently adjusted based on estimated growth in service volume), the effects of the packaging changes that we are proposing would result in changes to scaled weights and, therefore, to the payment rates for all separately paid procedures. These proposed changes would result from shifts in mean costs as a result of increased packaging, changes in multiple procedure discounting patterns, and a higher weight scaler that is applied to all unscaled APC weights. Further, to properly budget neutralize the money that would previously have been paid through other payment systems, we have included those payments when performing OPPS budget neutrality calculations. We refer readers to section II.A.4. of this proposed rule for an explanation of the weight scaler for OPPS budget neutrality. In a budget neutral system, the monies previously paid for services that are now proposed to be packaged are not lost, but are redistributed to all other services. A higher weight scaler would increase payment rates relative to observed mean costs for independent services by redistributing the lost weight of packaged items that historically have been paid separately and the lost weight when the mean costs of independent services do not completely reflect the full incremental cost of the packaged services. The impact of this proposed change on proposed CY 2014 OPPS payments is discussed in section XXIII.A. of this proposed rule, and the impact on various classifications of hospitals is shown in Column 5 in Table 39 in that section.

We estimate that our CY 2014 packaging proposal would redistribute approximately 4 percent of the estimated CY 2013 base year expenditures under the OPPS. If the relative payment weight for a particular APC decreases as a result of the proposed packaging approach, the increased weight scaler may or may not result in a relative payment weight that is equal to or greater than the relative weight that would occur without the proposed packaging approach. In general, the packaging policies that we are proposing would have more effect on payment for some services than on payment for others because the dependent items and services that we are proposing for packaging are furnished more often with some independent services than with others. However, because of the amount of relative payment weight that would be redistributed by this proposal, there would be some impact on payments for all OPPS services whose rates are set based on relative payment weights, and the impact on any given hospital would vary based on the mix of services furnished by the hospital.

e. Clarification Regarding Supplies That Are Packaged in the OPPS

Under the regulations at § 419.2(b)(4), medical and surgical supplies and equipment are packaged in the OPPS. Supplies is a large category of items that typically are either for single patient use or have a shorter life span in use than equipment. Packaged supplies can include certain drugs, biologicals, and radiopharmaceuticals. The only supplies that are sometimes paid separately in the OPPS are prosthetic supplies under § 419.22(j), and if paid separately, they are paid according to the DMEPOS fee schedule. All other supplies are unconditionally packaged in the OPPS.

In our annual review of the OPPS for CY 2014, we discovered many supplies that should be packaged in the OPPS according to § 419.2(b)(4), but that are currently assigned to status indicator ''A'' and are separately paid in the hospital outpatient setting according to the DMEPOS fee schedule. For CY 2014, we are proposing to revise the status indicator for all supplies described by Level II HCPCS A-codes (except for prosthetic supplies) from status indicator ''A'' to ''N,'' so that these supplies would be unconditionally packaged as required by § 419.2(b)(4). The specific Level II HCPCS A-codes whose status indicator will be revised from ''A'' to ''N'' are listed in Addendum P of this CY 2014 OPPS/ASC proposed rule, which is available via the Internet on the CMS Web site.

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

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

g. Comment Solicitation on Increased Packaging for Imaging Services

We currently package several kinds of imaging services in the OPPS, including image guidance services, image processing services, intraoperative imaging, and imaging supervision and interpretation services. In addition, some imaging services are included in this year's proposal to conditionally package ancillary services and diagnostic tests on the bypass list. In addition to these imaging services that are either packaged or proposed to be packaged, we are contemplating a proposal for CY 2015 that would conditionally package all imaging services with any associated surgical procedures. Imaging services not provided with a surgical procedure would continue to either be separately paid according to a standard clinical APC or a composite APC. We are requesting public comments on this potential CY 2015 proposal.

h. Summary of CY 2014 Packaging Proposals

Beginning in CY 2014, we are proposing to unconditionally package or conditionally package the following items and services and to add them to the list of OPPS packaged items and services in § 419.2(b):

(1) Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure;

(2) Drugs and biologicals that function as supplies or devices when used in a surgical procedure;

(3) Clinical diagnostic laboratory tests;

(4) Procedures described by add-on codes;

(5) Ancillary services (status indicator ''X'');

(6) Diagnostic tests on the bypass list; and

(7) Device removal procedures.

We believe that each of the above proposed unconditionally or conditionally packaged categories of items or services is appropriate according to existing packaging policies or expansions of existing packaging policies. However, we recognize that

decisions about packaging payment involve a balance between ensuring that payment is adequate to enable the hospital to provide quality care while establishing incentives for efficiency through larger units of payment. Therefore, we are inviting public comments regarding our packaging proposals for the CY 2014 OPPS.

The HCPCS codes that we are proposing to be packaged either unconditionally (for which we are proposing to assign status indicator ''N''), or conditionally (for which we are proposing to assign status indicator ''Q1'' or ''Q2''), for CY 2014 are displayed in both Addendum P and Addendum B of this proposed rule. The supporting documents for this proposed rule, including but not limited to the Addenda, are available at the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

4. Proposed Calculation of OPPS Scaled Payment Weights

For CY 2014, we are proposing to calculate the relative payment weights for each APC for CY 2014 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) using the APC costs discussed in sections II.A.1. and II.A.2. of this proposed rule. In years prior to CY 2007, we standardized all the relative payment weights to APC 0601 (Mid-Level Clinic Visit) because mid-level clinic visits were among the most frequently performed services in the hospital outpatient setting. We assigned APC 0601 a relative payment weight of 1.00 and divided the median cost for each APC by the median cost for APC 0601 to derive the relative payment weight for each APC.

Beginning with the CY 2007 OPPS (71 FR 67990), we standardized all of the relative payment weights for APC 0606 (Level 3 Clinic Visits) because we deleted APC 0601 as part of the reconfiguration of the clinic visit APCs. We selected APC 0606 as the base because APC 0606 was the mid-level clinic visit APC (that is, Level 3 of five levels).

For the CY 2013 OPPS (77 FR 68283), we established a policy of using geometric mean-based APC costs to calculate relative payment weights. For the CY 2014 OPPS, we are proposing to continue basing the relative payment weights on which OPPS payments will be made by using geometric mean costs. As we discuss in section VII. of this proposed rule, we are proposing to reconfigure the CY 2014 visit APCs so that they would include a single level for each visit type. However, in an effort to maintain consistency in calculating unscaled weights that represent the cost of some of the most frequently provided services, we are proposing to use the cost of the clinic visit APC in calculating unscaled weights, which for CY 2014 is proposed APC 0634. While we have previously used APC 0606 as the base from which to develop the OPPS budget neutral weight scaler, under our proposal to reconfigure the visit APCs, we would have a single APC for each visit type. The proposal to reconfigure the visit APCs is discussed in more detail in section VII. of this proposed rule. Following our general methodology for establishing relative payment weights derived from APC costs, but using the proposed CY 2014 geometric mean cost for APC 0634, for CY 2014, we are proposing to assign APC 0634 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the proposed geometric mean cost for APC 0634 to derive the proposed unscaled relative payment weight for each APC. The choice of the APC on which to base the proposed relative payment weights for all other APCs does not affect the payments made under the OPPS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2014 is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To comply with this requirement concerning the APC changes, we are proposing to compare the estimated aggregate weight using the CY 2013 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2014 unscaled relative payment weights.

For CY 2013, we multiplied the CY 2013 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2012 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2014, we are proposing the same process using the proposed CY 2014 unscaled relative payment weights rather than scaled relative payment weights. We are proposing to calculate the weight scaler by dividing the CY 2013 estimated aggregate weight by the proposed CY 2014 estimated aggregate weight. The service-mix is the same in the current and prospective years because we use the same set of claims for service volume in calculating the aggregate weight for each year. We note that, as a result of the CY 2014 proposed OPPS packaging policy for laboratory tests described in section II.A.3.b.(3) of this proposed rule, we would need to incorporate the estimated relative payment weights from those services. Therefore, the CY 2013 estimated OPPS aggregate weight would include payments for outpatient laboratory tests paid at the CLFS rates.

For a detailed discussion of the weight scaler calculation, we refer readers to the OPPS claims accounting document available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

We are proposing to include estimated payments to CMHCs in our comparison of the estimated unscaled relative payment weights in CY 2014 to the estimated total relative payment weights in CY 2013 using CY 2012 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we adjusted the proposed CY 2014 unscaled relative payment weights for purposes of budget neutrality. The proposed CY 2014 unscaled relative payment weights were adjusted by multiplying them by a proposed weight scaler of 1.2143 to ensure that the proposed CY 2014 relative payment weights are budget neutral.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act states that ''Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.'' Therefore, the cost of those SCODs (as discussed in section V.B.3. of this proposed rule) is included in the proposed budget neutrality calculations for the CY 2014 OPPS.

The proposed CY 2014 unscaled relative payment weights listed in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) incorporate the proposed recalibration adjustments discussed in sections II.A.1. and II.A.2. of this proposed rule.

B. Proposed Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27572), consistent with current law, based on IHS Global Insight, Inc.'s first quarter 2013 forecast of the FY 2014 market basket increase, the proposed FY 2014 IPPS market basket update is 2.5 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(iii) of the Act, as added by section 3401(i) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) and as amended by section 10319(g) of that law and further amended by section 1105(e) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), provide adjustments to the OPD fee schedule increase factor for CY 2014.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27572), we discussed the calculation of the proposed MFP adjustment for FY 2014, which is 0.4 percentage point.

We are proposing that if more recent data become subsequently available after the publication of this proposed rule (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such data, if appropriate, to determine the CY 2014 market basket update and the MFP adjustment, components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in the CY 2014 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that for each of years 2010 through 2019, the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act be reduced by the adjustment described in section 1833(t)(3)(G) of the Act. For CY 2014, section 1833(t)(3)(G)(iii) of the Act provides a 0.3 percentage point reduction to the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act. Therefore, in accordance with sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(iii) of the Act, we are proposing to apply a 0.3 percentage point reduction to the OPD fee schedule increase factor for CY 2014.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 for a year, and may result in payment rates under the OPPS for a year being less than such payment rates for the preceding year. As described in further detail below, we are proposing to apply an OPD fee schedule increase factor of 1.8 percent for the CY 2014 OPPS (which is 2.5 percent, the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.4 percentage point MFP adjustment, and less the 0.3 percentage point additional adjustment).

We note that hospitals that fail to meet the Hospital OQR Program reporting requirements are subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. As a result, those hospitals failing to meet the Hospital OQR Program reporting requirements would receive an OPD fee schedule increase factor of −0.2 percent (which is 2.5 percent, the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.4 percentage point MFP adjustment, less the 0.3 percentage point additional adjustment, and less 2.0 percentage points for the Hospital OQR Program reduction). For further discussion of the Hospital OQR Program, we refer readers to section XIII. of this proposed rule.

In this proposed rule, we are proposing to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (*5*) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2014, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS, and to reflect the requirement in section 1833(t)(3)(G)(iii) of the Act, as required by section 1833(t)(3)(F)(ii) of the Act, that we reduce the OPD fee schedule increase factor by an additional 0.3 percentage point for CY 2014.

To set the OPPS conversion factor for CY 2014, we are proposing to increase the CY 2013 conversion factor of $71.313 by 1.8 percent. In accordance with section 1833(t)(9)(B) of the Act, we are proposing to further adjust the conversion factor for CY 2014 to ensure that any revisions made to the updates for a revised wage index and rural adjustment are made on a budget neutral basis. We are proposing to calculate an overall proposed budget neutrality factor of 1.004 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2014 IPPS wage indices to those payments using the current (FY 2013) IPPS wage indices, as adopted on a calendar year basis for the OPPS.

For CY 2014, we are not proposing to make a change to our rural adjustment policy, as discussed in section II.E. of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

For CY 2014, we are proposing to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this proposed rule. We are proposing to calculate a CY 2014 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing the estimated total CY 2014 payments under section 1833(t) of the Act, including the proposed CY 2014 cancer hospital payment adjustment, to the estimated CY 2014 total payments using the CY 2013 final cancer hospital payment adjustment as required under section 1833(t)(18)(B) of the Act. The difference in the CY 2014 estimated payments as a result of applying the proposed CY 2014 cancer hospital payment adjustment relative to the CY 2013 final cancer hospital payment adjustment has a limited impact on the budget neutrality calculation. Therefore, we are proposing to apply a proposed budget neutrality adjustment factor of 1.0001 to the conversion factor to ensure that the cancer hospital payment adjustment is budget neutral.

For this proposed rule, we estimate that pass-through spending for both drugs and biologicals and devices for CY 2014 would equal approximately $12 million, which represents 0.02

percent of total projected CY 2014 OPPS spending. Therefore, the proposed conversion factor also would be adjusted by the difference between the 0.15 percent estimate of pass-through spending for CY 2013 and the 0.02 percent estimate of CY 2014 pass-through spending, resulting in a proposed adjustment for CY 2014 of 0.13 percent. Finally, estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2014.

The proposed OPD fee schedule increase factor of 1.8 percent for CY 2014 (that is, the estimate of the hospital inpatient market basket percentage increase of 2.5 percent less the proposed 0.4 percentage point MFP adjustment and less the 0.3 percentage point required under section 1833(t)(3)(F) of the Act), the required proposed wage index budget neutrality adjustment of approximately 1.0004, the proposed cancer hospital payment adjustment of 1.0001, and the proposed adjustment of 0.13 percent of projected OPPS spending for the difference in the pass-through spending result in a proposed conversion factor for CY 2014 of $72.728.

Hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates made for their services as required by section 1833(t)(17) of the Act. For a complete discussion of the Hospital OQR Program requirements and the payment reduction for hospitals that fail to meet those requirements, we refer readers to section XIII.G. of this proposed rule. To calculate the proposed CY 2014 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the Hospital OQR Program for the full CY 2014 payment update, we are proposing to make all other adjustments discussed above, but using a proposed reduced OPD fee schedule update factor of −0.2 percent (that is, the proposed 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 proposed reduced conversion factor for CY 2014 of $71.273 for those hospitals that fail to meet the Hospital OQR requirements (a difference of −$1.455 in the conversion factor relative to those hospitals that met the Hospital OQR requirements).

In summary, for CY 2014, we are proposing to use a conversion factor of $72.728 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs. We are proposing to amend § 419.32(b)(1)(iv)(B) by adding a new paragraph (*5*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2014 in order to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(iii) of the Act. We also are proposing to use a reduced conversion factor of $71.273 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. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to ''determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner'' (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B. of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). Therefore, we are not proposing to revise this policy for the CY 2014 OPPS. We refer readers to section II.H. of this proposed rule 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 proposed rule, for estimating APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same proposed FY 2014 pre-reclassified wage index that the IPPS uses to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and the copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the original OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Thus, the wage index that applies to a particular acute care short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believed that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). As discussed in that final rule with comment period, section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines ''frontier State,'' and amended section 1833(t) of the Act to add new paragraph (19), which requires a ''frontier State'' wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements in § 419.43(c)(2) and (c)(3) of our regulations. For the CY 2014 OPPS, we will implement this provision in the same manner as we did since CY 2011. That is, frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, rural and imputed floor, and rural floor budget neutrality) is less than 1.00. Similar to our current policy for HOPDs that are affiliated with multicampus hospital systems, the HOPD would receive a wage index based on the geographic location of the specific inpatient hospital with which it is associated. Therefore, if the associated hospital is located in a frontier State, the wage index adjustment applicable for the hospital would also apply for the affiliated HOPD. We refer readers to the FY 2011, FY 2012, and FY 2013 IPPS/LTCH PPS final rules (75 FR 50160 through 50161, 76 FR 51793, 51795, and 51825, and 77 FR 53369 through 53370, respectively) and the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27556 through 27557) for discussions

regarding this provision, including our methodology for identifying which areas meet the definition of frontier States as provided for in section 1886(d)(3)(E)(iii)(II) of the Act.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2014 IPPS wage indices continue to reflect a number of adjustments implemented over the past few years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural and imputed floor provisions, an adjustment for occupational mix, and an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment). We refer readers to the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27552 through 27561) for a detailed discussion of all proposed changes to the FY 2014 IPPS wage indices. In addition, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65842 through 65844) and subsequent OPPS rules for a detailed discussion of the history of these wage index adjustments as applied under the OPPS.

For purposes of the OPPS, we are proposing to continue our policy for CY 2014 of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173)). We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage adjustment. Table 4J listed in the FY 2014 IPPS/LTCH PPS proposed rule (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) identifies counties eligible for the out-migration adjustment and hospitals that would receive the adjustment for FY 2014. We also 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 2014 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule with the addition of non-IPPS hospitals that would receive the section 505 out-migration adjustment under the CY 2014 OPPS. Addendum L is available via the Internet on the CMS Web site.

As discussed in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27552 through 27553), the Office of Management and Budget (OMB) issued revisions to the current geographic area designations on February 28, 2013, that included a number of significant changes such as new CBSAs, urban counties that become rural, rural counties that become urban, and splitting existing CBSAs (OMB Bulletin 13–01. This bulletin can be found at: *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b13-01.pdf*. All of these designations have corresponding effects on the wage index system and its adjustments. In order to allow for sufficient time to assess the new revisions and their ramifications, we intend to propose changes to the IPPS wage index based on the newest CBSA designations in the FY 2015 IPPS/LTCH PPS proposed rule. Similarly, in the OPPS, which uses the IPPS wage index, we intend to propose changes based on the new OMB revisions in the CY 2015 OPPS/ASC proposed rule, consistent with any proposals in the FY 2015 IPPS/LTCH PPS proposed rule.

As stated earlier in this section, we continue to believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. Therefore, we are not proposing to change our current regulations which require that we use the FY 2014 IPPS wage indices for calculating OPPS payments in CY 2014. With the exception of the proposed out-migration wage adjustment table (Addendum L to this proposed rule, which is available via the Internet on the CMS Web site), which includes non-IPPS hospitals paid under the OPPS, we are not reprinting the proposed FY 2014 IPPS wage indices referenced in this discussion of the wage index. We refer readers to the CMS Web site for the OPPS at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At this link, readers will find a link to the proposed FY 2014 IPPS wage index tables.

D. Proposed Statewide Average Default CCRs

In addition to using CCRs to estimate costs from charges on claims for ratesetting, CMS uses overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. Medicare contractors cannot calculate a CCR for some hospitals because there is no cost report available. For these hospitals, CMS uses the statewide average default CCRs to determine the payments mentioned above until a hospital's Medicare contractor is able to calculate the hospital's actual CCR from its most recently submitted Medicare cost report. These hospitals include, but are not limited to, hospitals that are new, have not accepted assignment of an existing hospital's provider agreement, and have not yet submitted a cost report. CMS also uses the statewide average default CCRs to determine payments for hospitals that appear to have a biased CCR (that is, the CCR falls outside the predetermined ceiling threshold for a valid CCR) or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11). In this proposed rule, we are proposing to update the default ratios for CY 2014 using the most recent cost report data. We discuss our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009.

For CY 2014, we are proposing to continue to use our standard methodology of calculating the statewide average default CCRs using the same hospital overall CCRs that we use to adjust charges to costs on claims data for setting the proposed CY 2014 OPPS relative payment weights. Table 9 below lists the proposed CY 2014 default urban and rural CCRs by State and compares them to last year's default CCRs. These proposed CCRs represent the ratio of total costs to total charges for those cost centers relevant to outpatient services from each hospital's most recently submitted cost report, weighted by Medicare Part B charges. We also are proposing to adjust ratios from submitted cost reports to reflect the final settled status by applying the differential between settled to submitted overall CCRs for the cost centers relevant to outpatient services from the most recent pair of final settled and submitted cost reports. We then are

proposing to weight each hospital's CCR by the volume of separately paid line-items on hospital claims corresponding to the year of the majority of cost reports used to calculate the overall CCRs. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66680 through 66682) and prior OPPS rules for a more detailed discussion of our established methodology for calculating the statewide average default CCRs, including the hospitals used in our calculations and our trimming criteria.

For Maryland, we used an overall weighted average CCR for all hospitals in the Nation as a substitute for Maryland CCRs. Few hospitals in Maryland are eligible to receive payment under the OPPS, which limits the data available to calculate an accurate and representative CCR. The weighted CCR is used for Maryland because it takes into account each hospital's volume, rather than treating each hospital equally. We refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65822) for further discussion and the rationale for our longstanding policy of using the national average CCR for Maryland. In general, observed changes in the statewide average default CCRs between CY 2013 and CY 2014 are modest and the few significant changes are associated with areas that have a small number of hospitals.

Table 9 below lists the proposed statewide average default CCRs for OPPS services furnished on or after January 1, 2014.

TABLE 9—PROPOSED CY 2014 STATEWIDE AVERAGE CCRS

State	Urban/rural	Proposed CY 2014 default CCR	Previous default CCR (CY 2013 OPPS final rule)
ALASKA	RURAL	0.472	0.489
ALASKA	URBAN	0.296	0.307
ALABAMA	RURAL	0.223	0.209
ALABAMA	URBAN	0.198	0.193
ARKANSAS	RURAL	0.227	0.219
ARKANSAS	URBAN	0.230	0.234
ARIZONA	RURAL	0.223	0.238
ARIZONA	URBAN	0.188	0.190
CALIFORNIA	RURAL	0.210	0.192
CALIFORNIA	URBAN	0.210	0.202
COLORADO	RURAL	0.396	0.331
COLORADO	URBAN	0.222	0.226
CONNECTICUT	RURAL	0.359	0.364
CONNECTICUT	URBAN	0.285	0.287
DISTRICT OF COLUMBIA	URBAN	0.282	0.302
DELAWARE	RURAL	0.278	0.282
DELAWARE	URBAN	0.331	0.353
FLORIDA	RURAL	0.172	0.182
FLORIDA	URBAN	0.166	0.167
GEORGIA	RURAL	0.271	0.237
GEORGIA	URBAN	0.209	0.214
HAWAII	RURAL	0.350	0.323
HAWAII	URBAN	0.311	0.306
IOWA	RURAL	0.312	0.296
IOWA	URBAN	0.284	0.269
IDAHO	RURAL	0.333	0.417
IDAHO	URBAN	0.491	0.357
ILLINOIS	RURAL	0.258	0.240
ILLINOIS	URBAN	0.235	0.230
INDIANA	RURAL	0.358	0.285
INDIANA	URBAN	0.288	0.256
KANSAS	RURAL	0.298	0.290
KANSAS	URBAN	0.245	0.210
KENTUCKY	RURAL	0.226	0.217
KENTUCKY	URBAN	0.232	0.241
LOUISIANA	RURAL	0.258	0.242
LOUISIANA	URBAN	0.229	0.225
MASSACHUSETTS	RURAL	0.436	0.427
MASSACHUSETTS	URBAN	0.330	0.323
MAINE	RURAL	0.443	0.445
MAINE	URBAN	0.455	0.449
MARYLAND	RURAL	0.286	0.275
MARYLAND	URBAN	0.251	0.246
MICHIGAN	RURAL	0.353	0.303
MICHIGAN	URBAN	0.316	0.303
MINNESOTA	RURAL	0.462	0.469
MINNESOTA	URBAN	0.339	0.321
MISSOURI	RURAL	0.282	0.241
MISSOURI	URBAN	0.287	0.262
MISSISSIPPI	RURAL	0.228	0.226
MISSISSIPPI	URBAN	0.187	0.182
MONTANA	RURAL	0.486	0.431

TABLE 9—PROPOSED CY 2014 STATEWIDE AVERAGE CCRS—Continued

State	Urban/rural	Proposed CY 2014 default CCR	Previous default CCR (CY 2013 OPPS final rule)
MONTANA	URBAN	0.407	0.384
NORTH CAROLINA	RURAL	0.251	0.253
NORTH CAROLINA	URBAN	0.255	0.254
NORTH DAKOTA	RURAL	0.667	0.322
NORTH DAKOTA	URBAN	0.376	0.414
NEBRASKA	RURAL	0.333	0.318
NEBRASKA	URBAN	0.251	0.254
NEW HAMPSHIRE	RURAL	0.325	0.317
NEW HAMPSHIRE	URBAN	0.300	0.292
NEW JERSEY	URBAN	0.212	0.207
NEW MEXICO	RURAL	0.294	0.256
NEW MEXICO	URBAN	0.307	0.279
NEVADA	RURAL	0.234	0.234
NEVADA	URBAN	0.159	0.162
NEW YORK	RURAL	0.347	0.420
NEW YORK	URBAN	0.347	0.369
OHIO	RURAL	0.337	0.321
OHIO	URBAN	0.237	0.237
OKLAHOMA	RURAL	0.253	0.239
OKLAHOMA	URBAN	0.210	0.212
OREGON	RURAL	0.332	0.314
OREGON	URBAN	0.352	0.335
PENNSYLVANIA	RURAL	0.270	0.267
PENNSYLVANIA	URBAN	0.199	0.200
PUERTO RICO	URBAN	0.600	0.504
RHODE ISLAND	URBAN	0.310	0.264
SOUTH CAROLINA	RURAL	0.196	0.211
SOUTH CAROLINA	URBAN	0.210	0.214
SOUTH DAKOTA	RURAL	0.309	0.307
SOUTH DAKOTA	URBAN	0.208	0.218
TENNESSEE	RURAL	0.212	0.209
TENNESSEE	URBAN	0.200	0.195
TEXAS	RURAL	0.233	0.235
TEXAS	URBAN	0.203	0.206
UTAH	RURAL	0.343	0.374
UTAH	URBAN	0.338	0.359
VIRGINIA	RURAL	0.223	0.227
VIRGINIA	URBAN	0.243	0.237
VERMONT	RURAL	0.429	0.408
VERMONT	URBAN	0.395	0.384
WASHINGTON	RURAL	0.315	0.366
WASHINGTON	URBAN	0.322	0.301
WISCONSIN	RURAL	0.347	0.345
WISCONSIN	URBAN	0.308	0.307
WEST VIRGINIA	RURAL	0.294	0.277
WEST VIRGINIA	URBAN	0.327	0.338
WYOMING	RURAL	0.444	0.379
WYOMING	URBAN	0.279	0.301
ALASKA	RURAL	0.472	0.489
ALASKA	URBAN	0.296	0.307

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

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

In 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) of the regulations to clarify that EACHs also are eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, three hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Public Law 105–33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 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 2013. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For the CY 2014 OPPS, we are proposing to continue our policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

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

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act 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 that are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), Congress established section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' to hold harmless cancer hospitals and children's hospitals based on their pre-BBA amount under the OPPS. As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a ''pre-BBA amount.'' That is, cancer hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive transitional outpatient payments (TOPS) or hold harmless payments to ensure that they do not receive a payment that is lower under the OPPS than the payment they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA amount'' is an amount equal to the product of the reasonable cost of the hospital for covered outpatient services for the portions of the hospital's cost reporting period (or periods) occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The ''pre-BBA amount,'' including the determination of the base PCR, are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital and Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, as applicable) each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act of 2010 amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the 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 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by such hospitals when studying cancer hospital costliness. Further, section 1833(t)(18)(B) of the Act provides that if the Secretary determines that costs by these cancer hospitals with respect to APC groups are determined to be greater than the costs of other hospitals furnishing services under section 1833(t) of the Act, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. After conducting the study required by section 1833(t)(18)(A) of the Act, we determined in 2011 that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other 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 CYs 2012 and 2013, the target PCR for purposes of the cancer hospital payment adjustment was 0.91.

2. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2014

For CY 2014, we are proposing 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 are available at the time of the development of this proposed rule. To calculate the proposed CY 2014 target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A. of this proposed rule, used to estimate costs for the CY 2014 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled. We then limited the dataset to the hospitals

with CY 2012 claims data that we used to model the impact of the proposed CY 2014 APC relative weights (3,951 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2014 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2011 to 2012. We then removed the cost report data of the 45 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 118 hospitals because the cost report data were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,788 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS are approximately 90 percent of reasonable cost (a weighted average PCR of 0.90). Based on these data, we are proposing a target PCR of 0.90 to determine the CY 2014 cancer hospital payment adjustment to be paid at cost report settlement. Therefore, we are proposing that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.90 for each cancer hospital.

Table 10 below indicates the estimated percentage increase in OPPS payments to each cancer hospital for CY 2014 due to the cancer hospital payment adjustment policy. The actual amount of the CY 2014 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2014 payments and costs. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 10—ESTIMATED CY 2014 HOSPITAL–SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider No.	Hospital name	Estimated percentage increase in OPPS payments for CY 2014 (percent)
050146	City of Hope Helford Clinical Research Hospital	15.0
050660	USC Kenneth Norris Jr. Cancer Hospital	28.9
100079	University of Miami Hospital & Clinic	16.7
100271	H. Lee Moffitt Cancer Center & Research Institute	23.7
220162	Dana-Farber Cancer Institute	48.2
330154	Memorial Hospital for Cancer and Allied Diseases	41.4
330354	Roswell Park Cancer Institute	35.2
360242	James Cancer Hospital & Solove Research Institute	35.6
390196	Hospital of the Fox Chase Cancer Center	16.7
450076	University of Texas M. D. Anderson Cancer Center	58.9
500138	Seattle Cancer Care Alliance	55.1

G. Proposed Hospital Outpatient Outlier Payments

1. Background

Currently, the OPPS provides outlier payments on a service-by-service basis. In CY 2012, the outlier threshold was determined to be met when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $2,025 fixed-dollar threshold. We introduced a fixed-dollar threshold in CY 2005, in addition to the traditional multiple threshold, in order to better target outlier payments to those high-cost and complex procedures where a very costly service could present a hospital with significant financial loss. If the cost of a service meets both of these conditions, the multiple threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate. Before CY 2009, this outlier payment had historically been considered a final payment by longstanding OPPS policy. However, we implemented a reconciliation process similar to the IPPS outlier reconciliation process for cost reports with cost reporting periods beginning on or after January 1, 2009, in our CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy for the past several years to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the proposed OPPS. Our current estimate of total outlier payments as a percent of total CY 2012 OPPS payment, using available CY 2012 claims and the revised OPPS expenditure estimate for the 2013 Trustee's Report, is approximately 1.1 percent of the total aggregated OPPS payments. Therefore, for CY 2012, we estimate that we paid 0.1 percent above the CY 2012 outlier target of 1.0 percent of total aggregated OPPS payments.

As explained in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68295 through 68297), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for CY 2013. The outlier thresholds were set so that estimated CY 2013 aggregate outlier payments would equal 1.0 percent of the total estimated aggregate payments under the OPPS. Using CY 2012 claims data and CY 2013 payment rates, we currently estimate that the aggregate outlier payments for CY 2013 will be approximately 1.2 percent of the total CY 2013 OPPS payments. The difference between 1.2 percent and 1.0 percent is reflected in the regulatory impact analysis in section

XXIII. of this proposed rule. We note that we provide estimated CY 2014 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts—Provider-Specific Data file on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

2. Proposed Outlier Calculation

For CY 2014, we are proposing to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. We are proposing that a portion of that 1.0 percent, an amount equal to 0.18 percent of outlier payments (or 0.0018 percent of total OPPS payments) would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. As discussed in section VIII.D. of this proposed rule, for CMHCs, we are proposing to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) or APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs), exceeds 3.40 times the payment rate for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. For further discussion of CMHC outlier payments, we refer readers to section VIII.D. of this proposed rule.

To ensure that the estimated CY 2014 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we are proposing that the hospital outlier threshold be set so that outlier payments would be triggered when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $2,775 fixed-dollar threshold.

We calculated the proposed fixed-dollar threshold using largely the standard methodology, most recently used for CY 2013 (77 FR 68295 through 68297). For purposes of estimating outlier payments for this proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2013 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCR, which are maintained by the Medicare contractors and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years.

In order to estimate the CY 2014 hospital outlier payments for this proposed rule, we inflated the charges on the CY 2012 claims using the same inflation factor of 1.0993 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27767). We used an inflation factor of 1.0485 to estimate CY 2013 charges from the CY 2012 charges reported on CY 2012 claims. The methodology for determining this charge inflation factor is discussed in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27767). As 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, for this CY 2014 OPPS/ASC proposed rule, we are proposing to apply the same CCR inflation adjustment factor that we are proposing to apply for the FY 2014 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2014 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2014, we are proposing to apply an adjustment factor of 0.9732 to the CCRs that were in the April 2013 OPSF to trend them forward from CY 2013 to CY 2014. The methodology for calculating this proposed adjustment was discussed in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27766 through 27768).

Therefore, to model hospital outlier payments for this proposed rule, we applied the overall CCRs from the April 2013 OPSF file after adjustment (using the proposed CCR inflation adjustment factor of 0.9732 to approximate CY 2014 CCRs) to charges on CY 2012 claims that were adjusted (using the proposed charge inflation factor of 1.0993 to approximate CY 2014 charges). We simulated aggregated CY 2014 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2014 OPPS payments. We estimated that a proposed fixed-dollar threshold of $2,775, combined with the proposed multiple threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. We are proposing to continue to make an outlier payment that equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the proposed fixed-dollar threshold of $2,775 are met. For CMHCs, we are proposing 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 are proposing to continue the policy that we implemented in CY 2010 that the hospitals' costs will be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XIII. of this proposed rule.

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

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR Part 419, Subparts C and D. For this CY

2014 OPPS/ASC proposed rule, 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 proposed rule and the relative payment weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) was calculated by multiplying the proposed CY 2014 scaled weight for the APC by the proposed CY 2014 conversion factor.

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

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: ''J1,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''U,'' or ''V'' (as defined in Addendum D1 to this proposed rule), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We note that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements. We note that we are also proposing to create status indicator ''J1'' to reflect the proposed comprehensive APCs discussed in section II.A.2.e. of this proposed rule.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the proposed national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the 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 proposed 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 proposed CY 2014 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. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

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

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

$X = .60 * (\text{national unadjusted payment rate})$

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. The wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2014 under the IPPS, reclassifications through the MGCRB, section 1886(d)(8)(B) ''Lugar'' hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in § 412.103 of the regulations, and hospitals designated as urban under section 601(g) of Public Law 98–21. (For further discussion of the proposed changes to the FY 2014 IPPS wage indices, as applied to the CY 2014 OPPS, we refer readers to section II.C. of this proposed rule.) We are proposing to continue to apply a wage index floor of 1.00 to frontier States, in accordance with section 10324 of the Affordable Care Act of 2010.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Public Law 108–173. Addendum L to this proposed rule (which is available via the Internet on the CMS Web site) contains the qualifying counties and the associated proposed wage index increase developed for the FY 2014 IPPS and listed as Table 4J in the FY 2014 IPPS/LTCH PPS proposed rule and available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

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

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

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

$X_a = .60 * (\text{national unadjusted payment rate}) * \text{applicable wage index}.$

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

payment rate for the relevant wage index area.

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

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

$Y = .40 * (\text{national unadjusted payment rate})$

$\text{Adjusted Medicare Payment} = Y + X_a$

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 proposed 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 proposed full and reduced national unadjusted payment rates that would 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 proposed CY 2014 full national unadjusted payment rate for APC 0019 is approximately $345.75. The proposed reduced national unadjusted payment rate for APC 0019 for a hospital that fails to meet the Hospital OQR Program requirements is approximately $338.84. This proposed reduced rate is calculated by multiplying the reporting ratio of 0.980 by the full unadjusted payment rate for APC 0019. The proposed FY 2014 wage index for a provider located in CBSA 35644 in New York is 1.3158. The proposed labor-related portion of the full national unadjusted payment is approximately $272.96 (.60 * $345.75 * 1.3158). The labor-related portion of the proposed reduced national unadjusted payment is approximately $267.51 (.60 * $338.84 * 1.3158). The proposed nonlabor-related portion of the full national unadjusted payment is approximately $138.30 (.40 * $345.75). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately $135.54 (.40 * $338.84). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately $411.26 ($272.96 + $138.30). The sum of the reduced national adjusted payment is approximately $403.05 ($267.51 + $135.54).

I. Proposed Beneficiary Copayments

1. Background

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

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

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

2. Proposed OPPS Copayment Policy

For CY 2014, we are proposing to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we are proposing to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2014, are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). As discussed in section XIII.G. of this proposed rule, for CY 2014, the proposed Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We 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. 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).

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

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

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 0019, approximately $69.15 is 20 percent of the proposed full national unadjusted payment rate of approximately $345.75.

For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site), the beneficiary payment percentage is 20 percent.

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

B is the beneficiary payment percentage.

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

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

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

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

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

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

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

The proposed unadjusted copayments for services payable under the OPPS that would be effective January 1, 2014, are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the proposed full CY 2014 OPD fee schedule increase factor discussed in section II.B. of this proposed rule.

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

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

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

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

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

CPT codes are established by the American Medical Association (the AMA) and 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 through OPPS quarterly update CRs. This quarterly update 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. In Table 11 below, we summarize our proposed process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing their treatment under the hospital OPPS. We note that because the payment rates associated with codes effective July 1 are not available to us in time for incorporation into the Addenda of this proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2013 OPPS quarterly update CR could not be included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site), while those codes based upon the April 2013 OPPS quarterly update CR are included in Addendum B. Nevertheless, we are requesting public comments on the codes included in the July 2013 OPPS quarterly update CR and including these codes in the preamble of this proposed rule (we refer readers to Tables 13 and 14 for the July 2013 CPT and Level II HCPCS codes).

TABLE 11—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April I, 2013	Level II HCPCS Codes	April 1, 2013	CY 2014 OPPS/ASC proposed rule.	CY 2014 OPPS/ASC final rule with comment period.
July 1, 2013	Level II HCPCS Codes	July 1, 2013	CY 2014 OPPS/ASC proposed rule.	CY 2014 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2013	CY 2014 OPPS/ASC proposed rule.	CY 2014 OPPS/ASC final rule with comment period.
October 1, 2013	Level II HCPCS Codes	October 1, 2013	CY 2014 OPPS/ASC final rule with comment period.	CY 2015 OPPS/ASC final rule with comment period.
January 1, 2014	Level II HCPCS Codes	January 1, 2014	CY 2014 OPPS/ASC final rule with comment period.	CY 2015 OPPS/ASC final rule with comment period.

TABLE 11—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES—Continued

OPPS Quarterly update CR	Type of code	Effective date	Comments sought	When finalized
	Category I and III CPT Codes.	January 1, 2014	CY 2014 OPPS/ASC final rule with comment period.	CY 2015 OPPS/ASC final rule with comment period.

This process is discussed in detail below. We have separated our discussion into two sections based on whether we are soliciting public comments in this CY 2014 OPPS/ASC proposed rule or whether we will be soliciting public comments in the CY 2014 OPPS/ASC final rule with comment period. We note that we sought public comments in the CY 2013 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2013. We also sought public comments in the CY 2013 OPPS/ASC final rule with comment period on the new Level II HCPCS codes that were effective October 1, 2012. These new codes, with an effective date of October 1, 2012, or January 1, 2013, were flagged with comment indicator ''NI'' (New code, interim APC assignment; comments will be accepted on the interim APC assignment for the new code) in Addendum B to the CY 2013 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and an APC and payment rate, if applicable, which were subject to public comment following publication of the CY 2013 OPPS/ASC final rule with comment period. We will respond to public comments and finalize our interim OPPS treatment of these codes in the CY 2014 OPPS/ASC final rule with comment period.

1. Proposed Treatment of New CY 2013 Level II HCPCS and CPT Codes Effective April 1, 2013 and July 1, 2013 for Which We Are Soliciting Public Comments in This CY 2014 OPPS/ASC Proposed Rule

Through the April 2013 OPPS quarterly update CR (Transmittal 2664, Change Request 8228, dated March 1, 2013), and the July 2013 OPPS quarterly update CR (Transmittal 2718, Change Request 8338, dated June 7, 2013), we recognized several new HCPCS codes for separate payment under the OPPS. Effective April 1 and July 1 of CY 2013, we made effective 18 new Level II HCPCS codes and 6 Category III CPT codes. Specifically, 8 new Level II HCPCS codes were effective for the April 2013 quarterly update and another 10 new Level II HCPCS codes were effective for the July 2013 quarterly update for a total of 18. In addition, six new Category III CPT codes were effective for the July 2013 quarterly update. Of the 24 new HCPCS codes, we recognized for separate payment under the OPPS 14 new codes from the April and July 2013 OPPS quarterly updates.

Through the April 2013 OPPS quarterly update CR, we allowed separate payment for five new Level II HCPCS codes. Specifically, as displayed in Table 12 below, we provided separate payment for HCPCS codes C9130, C9297, C9298, C9734, and C9735. HCPCS codes Q0507, Q0508, and Q0509 were assigned to OPPS status indicator ''A'' to indicate that they are paid through another Medicare payment system other than the OPPS. Although HCPCS codes Q0507, Q0508, and Q0509 were effective April 1, 2013, they were previously described by HCPCS code Q0505, which was deleted on March 31, 2013.

TABLE 12—NEW LEVEL II HCPCS CODES IMPLEMENTED IN APRIL 2013

CY 2013 HCPCS code	CY 2013 Long descriptor	Proposed CY 2014 status indicator	Proposed CY 2014 APC
C9130*	Injection, immune globulin (Bivigam), 500 mg	G	9130
C9297*	Injection, omacetaxine mepesuccinate, 0.01 mg	G	9297
C9298*	Injection, ocriplasmin, 0.125 mg	G	9298
C9734#	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with or without magnetic resonance (MR) guidance.	S	0065
C9735	Anoscopy; with directed submucosal injection(s), any substance	T	0150
Q0507	Miscellaneous supply or accessory for use with an external ventricular assist device	A	N/A
Q0508	Miscellaneous supply or accessory for use with an implanted ventricular assist device	A	N/A
Q0509	Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A.	A	N/A

* The proposed payment rate for HCPCS codes C9130, C9297, and C9298 are based on ASP+6 percent.
# HCPCS code C9734 has been revised to delete the words ''or without'' from the long descriptor effective July 1, 2013.

In this CY 2014 OPPS/ASC proposed rule, we are soliciting public comments on the proposed status indicators and APC assignments, where applicable, for the Level II HCPCS codes listed in Table 12 of this proposed rule. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

Through the July 2013 OPPS quarterly update CR, we allowed separate payment under the OPPS for 5 of the 10 new Level II HCPCS codes effective July 1, 2013. Specifically, as displayed in Table 13 below, we allowed separate payment for HCPCS codes C9131, C9736, G0460, Q2050, and Q2051. We note that two of the Level II HCPCS Q-codes that were made effective July 1, 2013, were previously described by HCPCS J-codes that were separately payable under the hospital OPPS. First, the HCPCS Workgroup replaced HCPCS code J9002 (Injection, doxorubicin hydrochloride, liposomal, Doxil, 10mg) with new HCPCS code Q2050, effective July 1, 2013, to appropriately identify and pay for both the brand and generic

forms of doxorubicin hydrochloride liposome. Consequently, the status indicator for HCPCS code J9002 was changed to ''E'' (Not Payable by Medicare), effective July 1, 2013. Because HCPCS code Q2050 describes the same product as HCPCS code J9002, we continued its separate payment status and assigned HCPCS code Q2050 to status indicator ''K'' (Nonpass-through drugs and nonimplantable biological, including therapeutic radiopharmaceuticals; paid under OPPS; separate APC payment). We also continued to assign HCPCS code Q2050 to the same APC as HCPCS code J9002, specifically APC 7046 (Doxil injection), effective July 1, 2013.

Secondly, the HCPCS Workgroup replaced HCPCS codes J3487 (Injection, zoledronic acid (Zometa), 1 mg) and J3488 (Injection, zoledronic acid (Reclast), 1 mg) with one new HCPCS code, specifically Q2051, effective July 1, 2013, to appropriately identify and pay for both the brand and generic forms of zoledronic acid. Consequently, the status indicators for both HCPCS code J3487 and J3488 were changed to ''E,'' effective July 1, 2013, to indicate that these codes are not separately payable by Medicare. Because HCPCS code Q2051 describes the same product as HCPCS codes J3487 and J3488, we assigned HCPCS code Q2051 to separate payment status indicator ''K,'' effective July 1, 2013. Because HCPCS codes J3487 and J3488, which were assigned to two separate APCs, were replaced with only one code, we assigned HCPCS code Q2051 to a new APC to maintain data consistency for future rulemaking. Specifically, HCPCS code Q2051 is assigned to APC 1356 (Zoldedronic acid 1mg), effective July 1, 2013.

Of the 10 Level II HCPCS codes that were made effective July 1, 2013, we did not recognize for separate payment under the hospital OPPS five HCPCS codes. Specifically, HCPCS codes K0008, K0013, and K0900 are assigned to status indicator ''Y'' (Non-implantable durable medical equipment; not paid under OPPS); HCPCS code Q2033 is assigned to status indicator ''L'' (Not paid under OPPS; paid at reasonable cost); and HCPCS code Q0090 is assigned to status indicator ''E'' (Not payable/Non-covered by Medicare; not paid under OPPS).

Table 13 below includes a complete list of the Level II HCPCS codes that were made effective July 1, 2013. As stated above, the codes effective July 1, 2013, do not appear in Addendum B of this proposed rule, and, as a result, their proposed payment rates along with their proposed status indicators and proposed APC assignments, where applicable, for CY 2014 are provided in Table 13.

TABLE 13—NEW LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2013

CY 2013 HCPCS code	CY 2013 Long descriptor	Proposed CY 2014 status indicator	Proposed CY 2014 APC	Proposed CY 2014 payment rate
C9131*	Injection, ado-trastuzumab emtansine, 1 mg	G	9131	$29.40
C9736	Laparoscopy, surgical, radiofrequency ablation of uterine fibroid(s), including intraoperative guidance and monitoring, when performed.	T	0131	3,765.67
G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment.	T	0013	83.85
K0008	Custom Manual Wheelchair Base	Y	N/A	N/A
K0013	Custom Motorized/Power Wheelchair Base	Y	N/A	N/A
K0900	Customized Durable Medical Equipment, Other Than Wheelchair	Y	N/A	N/A
Q0090	Levonorgestrel-Releasing Intrauterine Contraceptive System (SKYLA), 13.5 mg	E	N/A	N/A
Q2033	Influenza Vaccine, Recombinant Hemagglutinin Antigens, For Intramuscular Use (Flublok).	L	N/A	N/A
Q2050**	Injection, Doxorubicin Hydrochloride, Liposomal, Not Otherwise Specified, 10mg	K	7046	545.44
Q2051***	Injection, Zoledronic Acid, Not Otherwise Specified, 1mg	K	1356	196.42

*The proposed payment rate for HCPCS code C9131 is based on ASP+6 percent.

**HCPCS code Q2050 replaced HCPCS code J9002, effective July 1, 2013. The status indicator for HCPCS code J9002 was changed to ''E'' (Not Payable by Medicare), effective July 1, 2013. The proposed payment rate for HCPCS code Q2050 is based on ASP+6 percent.

***HCPCS code Q2051 replaced HCPCS codes J3487 and J3488 effective July 1, 2013. The status indicator for HCPCS codes J3487 and J3488 was changed to ''E'' (Not Payable by Medicare), effective July 1, 2013. The proposed payment rate for HCPCS code Q2051 is based on ASP+6 percent.

For CY 2014, we are proposing 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 OPPS quarterly update CR, consistent with the AMA's implementation date for the codes. For the July 2013 quarterly update, there were no new Category I CPT vaccine codes. However, we note that Level II HCPCS code Q2033, which is listed in Table 13, describes a flu vaccine that was effective July 1, 2013, and is separately payable by Medicare at reasonable cost.

Through the July 2013 OPPS quarterly update CR (Transmittal 2718, Change Request 8338, dated June 7, 2013), we allowed separate payment for four of the six new Category III CPT codes effective July 1, 2013. Specifically, as displayed in Table 14 below, we allowed separate payment for Category III CPT codes 0330T, 0331T, 0332T, and 0334T. We did not recognize for separate payment Category III CPT code 0329T because the device associated with this procedure has not received FDA approval. In addition, we did not recognize for separate payment Category III CPT code 0333T because this procedure is not covered by Medicare. As listed in Table 14, both CPT codes 0329T and 0333T are assigned to status indicator ''E'' (Not payable/Non-covered by Medicare; not paid under OPPS).

Table 14 below lists the Category III CPT codes that were implemented in July 2013, along with their proposed status indicators, proposed APC assignments, and proposed payment rates, where applicable, for CY 2014.

TABLE 14—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2013

CY 2013 CPT code	CY 2013 Long descriptor	Proposed CY 2014 status indicator	Proposed CY 2014 APC	Proposed CY 2014 payment rate
0329T	Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report.	E	N/A	N/A
0330T	Tear film imaging, unilateral or bilateral, with interpretation and report	S	0230	$51.83
0331T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment;.	S	0398	397.32
0332T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment; with tomographic SPECT.	S	0398	397.32
0333T	Visual evoked potential, screening of visual acuity, automated	E	N/A	N/A
0334T	Sacroiliac joint stabilization for arthrodesis, percutaneous or minimally invasive (indirect visualization), includes obtaining and applying autograft or allograft (structural or morselized), when performed, includes image guidance when performed (eg, CT or fluoroscopic).	T	0208	4,171.56

We are soliciting public comments on the CY 2014 proposed status indicators and the proposed APC assignments and payment rates for the Level II HCPCS codes and the Category III CPT codes that were effective April 1, 2013, and July 1, 2013. These codes are listed in Tables 12, 13, and 14 of this proposed rule. We are proposing to finalize their status indicators and their APC assignments and payment rates, if applicable, in the CY 2014 OPPS/ASC final rule with comment period. Because the new Category III CPT and Level II HCPCS codes that become effective for July are not available to us in time for incorporation into the Addenda to the OPPS/ASC proposed rule, our policy is to include the codes, their proposed status indicators, proposed APCs (where applicable), and proposed payment rates (where applicable) in the preamble of the proposed rule but not in the Addenda to the proposed rule. These codes are listed in Tables 13 and 14, respectively, of this proposed rule. We are proposing to incorporate these codes into Addendum B to the CY 2014 OPPS/ASC final rule with comment period, which is consistent with our annual OPPS update policy. The Level II HCPCS codes implemented or modified through the April 2013 OPPS quarterly update CR and displayed in Table 12 are included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site), where their proposed CY 2014 payment rates are also shown.

2. Proposed Process for New Level II HCPCS Codes That Will Be Effective October 1, 2013 and New CPT and Level II HCPCS Codes That Will Be Effective January 1, 2014 for Which We Will Be Soliciting Public Comments in the CY 2014 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Category I and III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the OPPS for the following calendar year. These codes are released to the public through the CMS HCPCS Workgroup (for Level II HCPCS codes) and the AMA's 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 2014, these codes will be 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, 2014, will be flagged with comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period. Specifically, the interim 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. We are proposing to continue this process for CY 2014. Specifically, for CY 2014, we are proposing to include in Addendum B to the CY 2014 OPPS/ASC final rule with comment period the following new HCPCS codes:

- New Level II HCPCS codes effective October 1, 2013 that would be incorporated in the October 2013 OPPS quarterly update CR;
- New Category I and III CPT codes effective January 1, 2014 that would be incorporated in the January 2014 OPPS quarterly update CR; and
- New Level II HCPCS codes effective January 1, 2014 that would be incorporated in the January 2014 OPPS quarterly update CR.

As stated above, the October 1, 2013 and January 1, 2014 codes would be flagged with comment indicator ''NI'' in Addendum B to the CY 2014 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim OPPS payment status for CY 2014. We are proposing that their status indicators and their APC assignments and payment rates, if applicable, would be open to public comment and would be finalized in the CY 2015 OPPS/ASC final rule with comment period.

B. Proposed OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in

§ 419.31 of the regulations. We use Level I and Level II HCPCS codes to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices.

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. In general, according to the regulations at § 419.2(b), packaged items and services include, but are not limited to:

(1) Use of an operating suite, procedure room, or treatment room;

(2) Use of recovery room;

(3) Use of an observation bed;

(4) Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations;

(5) Supplies and equipment for administering and monitoring anesthesia or sedation;

(6) Intraocular lenses (IOLs);

(7) Incidental services such as venipuncture;

(8) Capital-related costs;

(9) Implantable items used in connection with diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests;

(10) Durable medical equipment that is implantable;

(11) Implantable prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of these devices;

(12) Costs incurred to procure donor tissue other than corneal tissue.

Significant revisions to the regulations at § 419.2(b) are being proposed. Further discussion of our packaging proposals is included in section II.A.3. of this proposed rule.

In CY 2008, we implemented composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service (72 FR 66650 through 66652). Under the CY 2013 OPPS (77 FR 68243 through 68258), we provided composite APC payments for 10 categories of services:

(1) Mental Health Services (APC 0034);

(2) Cardiac Electrophysiologic Evaluation and Ablation (APC 8000);

(3) Low Dose Rate (LDR) Prostate Brachytherapy (APC 8001);

(4) Level I Extended Assessment & Management Composite (APC 8002);

(5) Level II Extended Assessment & Management Composite (APC 8003);

(6) Ultrasound (APC 8004);

(7) CT and CTA without Contrast (APC 8005);

(8) CT and CTA with Contrast (APC 8006);

(9) MRI and MRA without Contrast Composite (APC 8007); and

(10) MRI and MRA with Contrast Composite (APC 8008)

Further discussion of composite APCs is included in section II.A.2.f. of this proposed rule.

Under the OPPS, we generally pay for hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. Each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in new proposed APC 0634 (Hospital Clinic Visits). The APC relative payment weights are scaled to new proposed APC 0634 because it is the hospital clinic visit APC and because clinic visits are among the most frequently furnished services in the hospital outpatient setting. We refer readers to section VII. (Proposed OPPS Payment for Hospital Outpatient Visits) of this proposed rule for further discussion of the establishment of new proposed APC 0634.

Section 1833(t)(9)(A) of the Act requires the Secretary to review, on a recurring basis occurring no less than annually, and revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights (the HOP Panel recommendations for specific services for the CY 2014 OPPS and our responses to them are discussed in the relevant specific sections throughout this proposed rule).

Finally, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the ''2 times rule''). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act).

2. Application of the 2 Times Rule

In accordance with section 1833(t)(2) of the Act and § 419.31 of the regulations, we annually review the items and services within an APC group to determine, with respect to comparability of the use of resources, if the cost of the highest cost item or service within an APC group is more than 2 times greater than the cost of the lowest cost item or service within that same group. In making this determination, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant HCPCS codes for examination 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 this proposed rule, we are proposing to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services, for CY 2014.

We have identified APCs with 2 times rule violations for which we are proposing changes to their HCPCS

codes' APC assignments in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of the CY 2014 OPPS/ASC proposed rule. Rather, it is published and made available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. In these cases, to eliminate a 2 times rule violation or to improve clinical and resource homogeneity, we are proposing to reassign the codes to APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed HCPCS code reassignments and associated APC reconfigurations for CY 2014 included in this proposed rule are related to changes in costs of services that were observed in the CY 2012 claims data newly available for CY 2014 ratesetting. We also are proposing changes to the status indicators for some codes that are not specifically and separately discussed in this proposed rule. In these cases, we are proposing 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 are proposing for CY 2014. In addition, we are proposing to rename existing APCs or create new clinical APCs to complement proposed HCPCS code reassignments. Addendum B of this CY 2014 OPPS/ASC proposed rule identifies with a comment indicator ''CH'' those HCPCS codes for which we are proposing a change to the APC assignment or status indicator, or both, that were initially assigned in the April 2013 Addendum B Update (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*).

3. Proposed 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 are proposing for CY 2014, we reviewed all the APCs to determine which APCs would not satisfy the 2 times rule. Then we used the following criteria to decide whether to propose exceptions to the 2 times rule for affected APCs:

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

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18457 and 18458).

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.

Table 15 of this proposed rule lists 10 APCs that we are proposing to exempt from the 2 times rule for CY 2014 based on the criteria cited above and based on claims data processed from January 1, 2012, through December 31, 2012. For the final rule with comment period, we plan to use claims data for dates of service between January 1, 2012, and December 31, 2012, that were processed on or before June 30, 2013, and updated CCRs, if available. Based on the CY 2012 claims data, we found 10 APCs with 2 times rule violations. We applied the criteria as described earlier to identify the APCs that we are proposing as exceptions to the 2 times rule for CY 2014, and identified 10 APCs that meet the criteria for exception to the 2 times rule for this proposed rule. 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 APCs, including those with criteria-based costs, those APCs listed under section II.A.2.f. of this proposed rule, with 2 times rule violations. These proposed APC exceptions are listed in Table 15 below.

TABLE 15—PROPOSED APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2014

APC	Description
0057	Bunion Procedures.
0060	Manipulation Therapy.
0075	Level V Endoscopy Upper Airway.
0105	Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices.
0148	Level I Anal/Rectal Procedures.
0272	Fluoroscopy.
0278	Diagnostic Urography.
0330	Dental Procedures.
0402	Level II Nervous System Imaging.
0690	Level I Electronic Analysis of Devices.

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

C. Proposed OPPS APC-Specific Policies

1. Intraoperative Radiation Therapy (IORT) Related Services (APCs 0028 and 0065)

HCPCS code C9726 (Placement and removal (if performed) of applicator into breast for radiation therapy) was created effective January 1, 2006 to describe the service of placing and removing (if performed) an applicator into the breast for radiation therapy. The service was brought to our attention by means of a New Technology APC application, and we created HCPCS code C9726 because there were no HCPCS codes that described this service. HCPCS code C9726 is assigned to APC 0028, which has a CY 2013 payment rate of $1,862.77. Based on our CY 2014 proposed rule claims data, APC 0028 has a geometric mean cost of approximately $2,147, and HCPCS code C9726 has a geometric mean cost of

approximately $2,165 based upon 8 single claims.

The AMA's CPT Editorial Panel created two new Category I CPT codes for intraoperative radiation therapy (IORT) treatment delivery, effective January 1, 2012: CPT codes 77424 (Intraoperative radiation treatment delivery, x-ray, single treatment session) and 77425 (Intraoperative radiation treatment delivery, electrons, single treatment session). For CY 2013, we finalized a policy to assign these CPT codes to APC 0065 (IORT, MRgFUS, and MEG), with a CY 2013 payment rate of $978.25 because we believed these IORT service codes were similar to services assigned to APC 0065 in terms of clinical characteristics, and the range of estimated costs for IORT services (77 FR 68345).

CPT codes 77424 and 77425 describe the placement and removal (if performed) of an applicator into the breast for radiation therapy, as well as the delivery of radiation therapy when performed intraoperatively, and HCPCS code C9726 is no longer required to report the placement and removal of the applicator. Therefore, we are proposing to delete HCPCS code C9726, effective January 1, 2014. Under this proposal, hospitals would report the costs of the service to place and remove (if performed) an applicator into the breast for radiation therapy, as well as the delivery of radiation therapy when performed intraoperatively, with CPT codes 77424 and 77425, which we are proposing to maintain assignment to APC 0065. We are inviting public comments on this proposal.

2. Proton Beam Radiation 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) with an estimated cost of approximately $417 (based on 217 single claims of 218 total claims submitted for CY 2012), and CPT code 77522 (Proton treatment delivery; simple, with compensation) with an estimated cost of approximately $883 (based on 10,629 single claims of 11,260 total claims submitted for CY 2012). APC 0667 (Level II Proton Beam Radiation Therapy) also includes two procedures: CPT code 77523 (Proton treatment delivery, intermediate), with an estimated cost of approximately $687 (based on 6,707 single claims of 7,104 total claims submitted for CY 2012); and CPT code 77525 (Proton treatment delivery, complex), with an estimated cost of approximately $1,044 (based on 438 single claims of 547 total claims submitted for CY 2012). Based on these CY 2012 claims data, the estimated cost of APC 0664 is approximately $870, and the estimated cost of APC 0667 is approximately $705.

The payment rates for proton beam radiation therapy services are set annually based on claims data according to the standard OPPS ratesetting methodology. Based on our updated data for CY 2014, we noted a violation of the 2 times rule in APC 0664. As we discuss in section III.B. of this proposed rule, a 2 times violation occurs when 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 codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant. If neither of these claims thresholds are met, there is not a 2 times violation even if the highest cost item or service is more than 2 times greater than the cost of the lowest cost item or service in the APC. In prior years, even though the cost of CPT code 77522 was more than 2 times the cost of CPT code 77520, there was no 2 times violation in APC 0664 because the claims volume for CPT code 77520 did not meet either of the claims volume tests discussed above (72 FR 66719; 75 FR 71901; and 77 FR 68341). However, for CY 2014, the claims volume for CPT code 77520 increased such that there is a 2 times violation within APC 0664, with the single claims for CPT code 77520 greater than 99 and contributing 2 percent of the single claims used to establish the cost of APC 0664.

To resolve the 2 times violation, we are proposing to reassign CPT codes 77520 and 77522 from APC 0664 to APC 0667, and to revise the title of APC 0667 to ''Proton Beam Radiation Therapy,'' which would now include all proton beam radiation therapy services. We also are proposing to delete APC 0664. The estimated cost of the new APC 0667 is approximately $998, which would be the payment rate for each of the four proton beam radiation therapy services. We are inviting public comments on this proposal.

3. Stereotactic Radiosurgery (SRS) Services (APCs 0066 and 0067)

Since 2001, we have distinguished the various methods of delivery of stereotactic radiosurgery (SRS) with HCPCS G-codes. SRS includes two different source types, specifically, Cobalt-60 and linear accelerator (linac). Among the linac-based SRS devices, the HCPCS G-codes distinguish between robotic and nonrobotic (66 FR 59865). In 2007 new CPT codes were established for SRS, and at that time, we recognized one of the three new CPT codes for SRS for separate payment under the OPPS, but we did not replace all of the HCPCS G-codes for SRS with the new CPT codes because we believed that the distinctions reflected in the HCPCS G-codes should be maintained for APC assignment purposes. Specifically, in 2007 we replaced HCPCS code G0243 (Multi-source photon stereotactic radiosurgery, delivery including collimator changes and custom plugging, complete course of treatment, all lesions) with CPT code 77371 because this CPT code corresponded directly to procedures for HCPCS code G0243. We refer readers to the CY 2007 OPPS final rule (71 FR 68023 through 68026) for a detailed discussion of the history of the SRS codes.

Since 2007, HCPCS G-codes G0173, G0251, G0339, G0340, and CPT code 77371 have been the codes used in the OPPS to describe SRS treatment delivery procedures. However, SRS techniques and equipment have evolved and advanced over time. In light of these considerations, we have reexamined the HCPCS G-codes and CPT codes for SRS with the intent of identifying the codes that would best capture the significant differences between the various procedures while eliminating unnecessary complexity, redundancy, and outdated distinctions that no longer represent meaningful distinctions, given current technology and clinical practice. Based on our review of the current SRS technology, it is our understanding that most current linac-based SRS technology incorporates some type of robotic feature. Therefore, we believe that it is no longer necessary to continue to distinguish robotic versus nonrobotic linac-based SRS through the HCPCS G-codes. For CY 2014, we are proposing to replace the existing four SRS HCPCS G-codes G0173, G0251, G0339, and G0340, with the SRS CPT codes 77372 and 77373. We believe that utilizing all of the CPT codes for SRS (77371, 77372, and 77373) will more accurately capture the most significant distinctions between the various SRS procedures that are currently used today, namely: (1) Cobalt-60 versus linac; and (2) single session cranial treatment versus fractionated treatments.

Table 16 below shows the complete list of HCPCS G-codes and CPT codes for SRS, along with their long descriptors. The table also shows the proposed CPT codes and their

associated status indicators and APC assignments for the current HCPCS G-codes for SRS that we are proposing to replace. We are proposing to assign CPT code 77373 as the only code assigned to APC 0066, which we are proposing to rename ''Level I Stereotactic Radiosurgery.'' We are proposing to assign both of the single session cranial treatment codes (CPT codes 77371 and 77372) as the only two codes assigned to APC 0067, which we are proposing to rename ''Level II Stereotactic Radiosurgery.'' We believe that the high degree of clinical similarity of CPT codes 77371 and 77372 supports the proposed grouping of these procedures together in the proposed renamed APC 0067 (Level II Stereotactic Radiosurgery). The CY 2014 APC proposed payment rates for the CPT codes for SRS can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site). We are proposing to finalize their status indicators and their APC assignments and payment rates in the CY 2014 OPPS/ASC final rule with comment period.

In addition, although the SRS HCPCS G-codes will no longer be separately payable under the OPPS, the codes will remain active in the MPFS for CY 2014. Consequently, we are proposing to reassign the HCPCS G-codes for SRS to OPPS status indicator ''B'' (Alternative code may be available under the OPPS) for CY 2014.

TABLE 16—PROPOSED SEPARATELY PAYABLE STEREOTACTIC RADIOSURGERY (SRS) SERVICES FOR CY 2014

CY 2013 CPT code	Long descriptor	CY 2014 CPT code	Long descriptor	CY 2014 SI	CY 2014 APC
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based.	77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based.	S	0067
G0173	Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session.	77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based.	S	0067
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.	77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions.	S	0066
G0339*	Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment.				
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.				

*Although not reflected in the above table (in order to avoid confusion), single session cranial cases currently billed with HCPCS code G0339 would be billed with CPT code 77372 beginning in CY 2014. Any other reporting of HCPCS code G0339 (other than single session cranial cases) would be reported beginning in CY 2014 with CPT code 77373.

IV. Proposed OPPS Payment for Devices

A. Proposed Pass-Through Payments for Devices

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

a. Background

Section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2, but not more than 3 years. This pass-through payment eligibility period begins with the first date on which transitional pass-through payments may be made for any medical device that is described by the category. We may establish a new device category for pass-through payment in any quarter. Under our established policy, we base the pass-through status expiration date for a device category on the date on which pass-through payment is effective for the category, which is the first date on which pass-through payment may be made for any medical device that is described by such category. We propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update.

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

There currently are three device categories eligible for pass-through payment. These device categories are described by HCPCS codes C1830 (Powered bone marrow biopsy needle) and C1840 (Lens, intraocular (telescopic)), which we made effective for pass-through payment as of October 1, 2011; and HCPCS code C1886 (Catheter, extravascular tissue ablation, any modality (insertable)), which we made effective for pass-through payment as of January 1, 2012. Recognizing that these three device categories were eligible for at least 2, but not more than 3, years of pass-through status, in the CY 2013 OPPS/ASC final rule with comment period, we finalized the expiration of pass-through payment for all three of these HCPCS codes, which will expire after December 31, 2013 (77 FR 68352). Therefore, in accordance with our established policy, after December 31, 2013, we will

package the respective costs of the HCPCS codes C1830, C1840, and C1886 devices into the costs of the procedures with which the devices are reported in the hospital claims data used in OPPS ratesetting.

b. Proposed CY 2014 Policy

As previously stated, we have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763). In the case of device category C1840, we are proposing that the device costs be packaged only when billed with CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens), which became effective on July 1, 2012. We announced the policy that device category C1840 must be billed with CPT code 0308T, effective July 1, 2012, in Transmittal 2483, dated June 8, 2012. CPT code 0308T is currently assigned to APC 0234 (Level IV Anterior Segment Eye Procedures), which has a proposed geometric mean cost of approximately $1,794. When the CPT code C1840 device costs are packaged into the cost of CPT code 0308T (and the equivalent procedure described by HCPCS code C9732 for the first half of 2012), the proposed mean cost of the procedure is approximately $15,249. Based on this mean cost for CPT code 0308T, we are proposing to create new APC 0351 (Level VII Anterior Segment Eye Procedures), and to assign CPT code 0308T to this APC, which has a proposed mean cost of approximately $15,249. The mean cost for CY 2014 that will be reported in the final rule for this new APC will depend on the mean cost of CPT code 0308T (including the cost of HCPCS code C1840) as calculated using claims data available for the final rule.

With the expiration of these three device categories at the end of CY 2013, there are no currently active categories for which we would propose expiration of pass-through status in CY 2014. If we create new device categories for pass-through payment status during the remainder of CY 2013 or during CY 2014, we will propose future expiration dates in accordance with the statutory requirement that they be eligible for pass-through payments for at least 2, but not more than 3, years from the date on which pass-through payment for any medical device described by the category may first be made.

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

a. Background

Section 1833(t)(6)(D)(ii) of the Act sets the amount of additional pass-through payment for an eligible device as the amount by which the hospital's charges for a device, adjusted to cost (the cost of the device) exceeds the portion of the otherwise applicable Medicare outpatient department fee schedule amount (the APC payment amount) associated with the device. We have an established policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of the associated devices that are eligible for pass-through payments (66 FR 59904) for purposes of estimating the portion of the otherwise applicable APC payment amount associated with pass-through devices. For eligible device categories, we deduct an amount that reflects the portion of the APC payment amount that we determine is associated with the cost of the device, defined as the device APC offset amount, from the charges adjusted to cost for the device, as provided by section 1833(t)(6)(D)(ii) of the Act, to determine the eligible device's pass-through payment amount. We have consistently used an established methodology to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of an associated device eligible for pass-through payment, using claims data from the period used for the most recent recalibration of the APC rates (72 FR 66751 through 66752). We establish and update the applicable device APC offset amounts for eligible pass-through device categories through the transmittals that implement the quarterly OPPS updates.

Currently, we have published a list of all procedural APCs with the CY 2013 portions (both percentages and dollar amounts) of the APC payment amounts that we determine are associated with the cost of devices on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The dollar amounts are used as the device APC offset amounts. In addition, in accordance with our established practice, the device APC offset amounts in a related APC are used in order to evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices, as specified in our regulations at § 419.66(d).

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

b. Proposed CY 2014 Policy

We are proposing to continue, for CY 2014, our established methodology to estimate the portion of each APC payment rate that could reasonably be attributed to (that is, reflect) the cost of an associated device eligible for pass-through payment, using claims data from the period used for the most recent recalibration of the APC payment rates. We are proposing to continue our policy, for CY 2014, that the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only. The rationale for this policy is provided in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60471 through 60477). We also are proposing to continue our established policies for calculating and setting the device APC offset amounts for each device category eligible for pass-through payment. In addition, we are proposing to continue to review each new device category on a case-by-case basis to determine whether device costs associated with the new category are already packaged into the existing APC structure. If device costs packaged into the existing APC structure are associated with the new category, we are proposing to deduct the device APC offset amount from the pass-through payment for the device category. As stated earlier, these device APC offset amounts also would be used in order to evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices (§ 419.66(d)).

For CY 2014, we also are proposing to continue our policy established in CY 2010 to include implantable biologicals in our calculation of the device APC offset amounts. In addition, we are

proposing to continue to calculate and set any device APC offset amount for any new device pass-through category that includes a newly eligible implantable biological beginning in CY 2014 using the same methodology we have historically used to calculate and set device APC offset amounts for device categories eligible for pass-through payment, and to include the costs of implantable biologicals in the calculation of the device APC offset amounts.

In addition, we are proposing to update the list of all procedural APCs with the final CY 2014 portions of the APC payment amounts that we determine are associated with the cost of devices on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html* so that this information is available for use by the public in developing potential CY 2014 device pass-through payment applications and by CMS in reviewing those applications.

3. Proposed Changes to Device Pass-Through Criteria: Integral and Subordinate Criterion

We established a number of specific criteria that new medical devices must meet to be considered eligible for pass-through payments under section 1833(t)(6) of the Act (42 CFR 419.66; 65 FR 18480 and 65 FR 47672 through 47674). In this proposed rule, we are proposing to change one of these criteria for device pass-through payment, described at § 419.66(b)(3), which requires that a device ''is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted whether or not it remains with the patient when the patient is released from the hospital'' (65 FR 47674).

Regarding the existing regulation at § 419.66(b)(3), applicants for device pass-through status have continued to ask what is meant by the phrase ''integral and subordinate part of the service furnished,'' and more specifically, what the terms ''integral'' and ''subordinate'' mean. These terms have not been specifically defined or described in prior regulatory language, preamble, or guidance. In an effort to reduce further confusion and ensure all applicants understand the intent of the existing regulation, we are proposing to provide guidance on the meaning of the term ''integral'' and delete the term ''subordinate'' from the existing regulation in this proposed rule. We have interpreted the term ''integral'' to mean that the device is necessary to furnish or deliver the primary procedure with which it is used. For example, a pacemaker is integral to the procedure of implantation of a pacemaker. We have interpreted the accompanying term ''subordinate'' in conjunction with the term ''integral,'' in that a ''subordinate'' device is dependent upon the overall procedure of implanting the device, and we have not interpreted the term separately, or applied the term ''subordinate'' as a separate criterion. Because of confusion among pass-through status applicants regarding the use of both terms ''integral'' and ''subordinate,'' and because we do not believe it is necessary that the regulation specifically state that a device must be subordinate to the procedure, in addition to the requirement that a device be integral to the procedure, and have not treated ''subordinate'' as a separate criterion, as previously explained, we are proposing to delete the term ''subordinate'' from this criterion's regulatory text under existing § 419.66(b)(3). The proposed revised § 419.66(b)(3) regulatory language reads: ''The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, whether or not it remains with the patient when the patient is released from the hospital.''

B. Proposed 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. Proposed Policy for CY 2014

Beginning in CY 2014, we are proposing to modify our existing policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy has been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we are proposing to reduce OPPS payment, for the applicable APCs listed below in Table 17, by the full or partial credit a provider receives for a replaced device. Specifically, under this proposed policy for CY 2014, hospitals would be required to report the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device listed in Table 18 that is 50 percent or greater than the cost of the device. Under this proposal, hospitals would no longer be required to append the ''FB'' or ''FC'' modifier when receiving a device at no cost or with a full or partial credit.

For CY 2014, we are proposing to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which our modified CY 2014 policy applies (71 FR 68072 through 68077). Specifically: (1) All procedures assigned to the selected APCs must involve implantable devices that would be reported if device insertion procedures were performed; (2) the required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least

temporarily); and (3) the device offset amount must be significant, which, for purposes of this policy, is defined as exceeding 40 percent of the APC cost. We also are proposing 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 continue to believe these criteria are appropriate because no cost devices and device credits are likely to be associated with particular cases only when the device must be reported on the claim and is of a type that is implanted and remains in the body when the beneficiary leaves the hospital. We believe that the reduction in payment is appropriate only when the cost of the device is a significant part of the total cost of the APC into which the device cost is packaged, and that the 40-percent threshold is a reasonable definition of a significant cost.

We examined the offset amounts calculated from the CY 2014 proposed rule data and the clinical characteristics of the proposed CY 2014 APCs to determine which APCs would meet the criteria for CY 2014. Based on the CY 2012 claims data available for this proposed rule, we are not proposing any changes to the APCs and devices to which this proposed modified policy would apply.

Table 17 below lists the proposed APCs to which the proposed modified payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2014.

Table 18 below lists the proposed devices to which the proposed modified payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2014. We are proposing to update the lists of APCs and devices to which the proposed modified no cost/full credit and partial credit device adjustment policy would apply for CY 2014, consistent with the three criteria discussed earlier in this section, based on the final CY 2012 claims data available for the CY 2014 OPPS/ASC final rule with comment period.

TABLE 17—PROPOSED APCS TO WHICH THE PROPOSED MODIFIED NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WOULD APPLY IN CY 2014

Proposed CY 2014 APC	Proposed CY 2014 APC title
0039	Level I Implantation of Neurostimulator Generator.
0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.
0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes.
0082	Coronary or Non-Coronary Atherectomy.
0083	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization.
0085	Level II Electrophysiologic Procedures.
0086	Level III Electrophysiologic Procedures.
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes.
0090	Level I Insertion/Replacement of Permanent Pacemaker.
0104	Transcatheter Placement of Intracoronary Stents.
0106	Insertion/Replacement of Pacemaker Leads and/or Electrodes.
0107	Level I Implantation of Cardioverter-Defibrillators (ICDs).
0108	Level II Implantation of Cardioverter-Defibrillators (ICDs).
0227	Implantation of Drug Infusion Device.
0229	Level II Endovascular Revascularization of the Lower Extremity.
0259	Level VII ENT Procedures.
0293	Level VI Anterior Segment Eye Procedures.
0315	Level II Implantation of Neurostimulator Generator.
0318	Implantation of Neurostimulator Pulse Generator and Electrode.
0319	Level III Endovascular Revascularization of the Lower Extremity.
0385	Level I Prosthetic Urological Procedures.
0386	Level II Prosthetic Urological Procedures.
0425	Level II Arthroplasty or Implantation with Prosthesis.
0648	Level IV Breast Surgery.
0654	Level II Insertion/Replacement of Permanent Pacemaker.
0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing.
0656	Transcatheter Placement of Intracoronary Drug-Eluting Stents.
0674	Prostate Cryoablation.
0680	Insertion of Patient Activated Event Recorders.

TABLE 18—PROPOSED DEVICES TO WHICH THE PROPOSED MODIFIED NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WOULD APPLY IN CY 2014

CY 2014 Device HCPCS code	CY 2014 Short descriptor
C1721	AICD, dual chamber.
C1722	AICD, single chamber.

TABLE 18—PROPOSED DEVICES TO WHICH THE PROPOSED MODIFIED NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WOULD APPLY IN CY 2014—Continued

CY 2014 Device HCPCS code	CY 2014 Short descriptor
C1728	Cath, brachytx seed adm.
C1764	Event recorder, cardiac.

TABLE 18—PROPOSED DEVICES TO WHICH THE PROPOSED MODIFIED NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WOULD APPLY IN CY 2014—Continued

CY 2014 Device HCPCS code	CY 2014 Short descriptor
C1767	Generator, neurostim, imp.
C1771	Rep dev, urinary, w/sling.

TABLE 18—PROPOSED DEVICES TO WHICH THE PROPOSED MODIFIED NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE PAYMENT ADJUSTMENT POLICY WOULD APPLY IN CY 2014—Continued

CY 2014 Device HCPCS code	CY 2014 Short descriptor
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.

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

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

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals (also referred to as biologics). As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this provision requires the Secretary to make additional payments to hospitals for: current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act (Pub. L. 107–186); current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to drugs or biologicals that are outpatient hospital services under Part B for which payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments are also provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996 and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Proposed CY 2014 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this proposed rule, which are available via the Internet on the CMS Web site.

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. If the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, the pass-through payment amount is determined by the Secretary to be equal to the average price for the drug or biological for all competitive acquisition areas and the year established under such section as calculated and adjusted by the Secretary. However, we note that the Part B drug CAP program has been postponed since CY 2009, and such a program has not been reinstated for CY 2014.

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

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

2. Proposed Drugs and Biologicals With Expiring Pass-Through Status in CY 2013

We are proposing that the pass-through status of 15 drugs and biologicals would expire on December 31, 2013, as listed in Table 19 below. All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2013. These drugs and biologicals were approved for pass-through status on or before January 1, 2012. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through status, specifically diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, and our new proposed groups of policy packaged products described in section II.A.3. of this proposed rule, namely drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure, our standard methodology for providing payment for drugs and biologicals with expiring pass-through status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed at $90 for CY 2014), as discussed further in section V.B.2. of this proposed rule. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we would provide separate payment at the applicable relative ASP-based payment amount (which is proposed at ASP+6 percent for

CY 2014, as discussed further in section V.B.3. of this proposed rule).

TABLE 19—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS WILL EXPIRE DECEMBER 31, 2013

Proposed CY 2014 HCPCS code	Proposed CY 2014 long descriptor	Proposed CY 2014 SI	Proposed CY 2014 APC
A9584	Iodine I–123 ioflupane, diagnostic, per study dose, up to 5 millicuries	N	N/A
C9285	Lidocaine 70 mg/tetracaine 70 mg, per patch	N	9285
J0131	Injection, acetaminophen, 10 mg	N	9283
J0485	Injection, belatacept, 1 mg	K	9286
J0490	Injection, belimumab, 10 mg	K	1353
J0638	Injection, canakinumab, 1mg	K	1311
J0712	Injection, ceftaroline fosamil, 10 mg	N	9282
J1572	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g., liquid), 500 mg.	K	0947
J2507	Injection, pegloticase, 1 mg	K	9281
J7180	Injection, factor xiii (antihemophilic factor, human), 1 i.u	K	1416
J9042	Injection, brentuximab vedotin, 1 mg	K	9287
J9179	Injection, eribulin mesylate, 0.1 mg	K	1426
J9228	Injection, ipilimumab, 10 mg	K	9284
Q4124	Oasis Ultra Tri-Layer matrix, per square centimeter	N	9365
Q4131	EpiFix, per square centimeter	N	9366

3. Proposed Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Status in CY 2014

We are proposing to continue pass-through status in CY 2014 for 18 drugs and biologicals. None of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2013. These drugs and biologicals, which were approved for pass-through status between April 1, 2012 and July 1, 2013, are listed in Table 20 below. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through April 1, 2013 are assigned status indicator ''G'' in Addenda A and B of this proposed rule. Addenda A and B of this proposed rule are available via the Internet on the CMS Web site.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. Payment for drugs and biologicals with pass-through status under the OPPS is currently made at the physician's office payment rate of ASP+6 percent. We believe it is consistent with the statute to propose to continue to provide payment for drugs and biologicals with pass-through status at a rate of ASP+6 percent in CY 2014, the amount that drugs and biologicals receive under section 1842(o) of the Act.

Therefore, for CY 2014, we are proposing to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2014. We are proposing that a $0.00 pass-through payment amount would be paid for most pass-through drugs and biologicals under the CY 2014 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, proposed at ASP+6 percent, is $0.

In the case of pass-through for policy packaged drugs (which include contrast agents, diagnostic radiopharmaceuticals, anesthesia drugs, and our new proposed groups of policy packaged products described in section II.A.3. of this proposed rule, namely drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure), we are proposing that their pass-through payment amount would be equal to ASP+6 percent for CY 2014 because, if not on pass-through status, payment for these products would be packaged into the associated procedure.

In addition, we are proposing to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2014 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 42722 and 42723).

In CY 2014, as is consistent with our CY 2013 policy for diagnostic and therapeutic radiopharmaceuticals, we are proposing to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through status based on the ASP methodology. As stated above, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through status during CY 2014, we are proposing to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we are proposing to provide pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information is also not available, we are proposing to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

As discussed in more detail in section II.A.3. of this proposed rule, over the last 6 years, we implemented a policy whereby payment for all nonpass-through diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs is packaged into payment for the associated procedure.

We are proposing to continue the packaging of these items and also are proposing new groups of policy packaged products described in section II.A.3. of this proposed rule, namely drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure, regardless of their per day cost, in CY 2014. As stated earlier, pass-through payment is the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. Because payment for a drug that is policy packaged would otherwise be packaged if the product did not have pass-through status, we believe the otherwise applicable OPPS payment amount would be equal to the policy packaged drug APC offset amount for the associated clinical APC in which the drug or biological is utilized. The proposed calculation of the policy packaged drug APC offset amounts is described in more detail in section IV.A.2. of this proposed rule. It follows that the copayment for the nonpass-through payment portion (the otherwise applicable fee schedule amount that we would also offset from payment for the drug or biological if a payment offset applies) of the total OPPS payment for those drugs and biologicals would, therefore, be accounted for in the copayment for the associated clinical APC in which the drug or biological is used.

According to section 1833(t)(8)(E) of the Act, the amount of copayment associated with pass-through items is equal to the amount of copayment that would be applicable if the pass-through adjustment was not applied. Therefore, as we did in CY 2013, we are proposing to continue to set the associated copayment amount to zero for CY 2014 for pass-through diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs that would otherwise be packaged if the item did not have pass-through status. We also are proposing to set the associated copayment amount to zero for the additional categories of policy-packaged products proposed for CY 2014 described in section II.A.3. of this proposed rule.

The separate OPPS payment to a hospital for the pass-through diagnostic radiopharmaceutical, contrast agent, anesthesia drug, and the additional categories of policy-packaged products proposed for CY 2014 is not subject to a copayment according to the statute. Therefore, we are proposing to not publish a copayment amount for these items in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

For CY 2013, we estimated the OPPS pass-through payment for drugs and biologicals to be $22 million. Our proposed OPPS pass-through payment estimate for drugs and biologicals in CY 2014 is $1 million, which is discussed in section VI.B. of this proposed rule. The 18 drugs and biologicals that we are proposing to continue on pass-through status for CY 2014 or have been granted pass-through status as of July 2013 are displayed in Table 20 below.

TABLE 20—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN CY 2014

Proposed CY 2014 HCPCS code	CY 2014 Long descriptor	Proposed CY 2014 SI	Proposed CY 2014 APC
C9130	Injection, immune globulin (Bivigam), 500 mg	G	9130
C9131*	Injection, ado-trastuzumab emtansine, 1 mg	G	9131
C9290	Injection, bupivicaine liposome, 1 mg	G	9290
C9292	Injection, pertuzumab, 10 mg	G	9292
C9293	Injection, glucarpidase, 10 units	G	9293
C9294	Injection, taliglucerase alfa, 10 units	G	9294
C9295	Injection, carfilzomib, 1 mg	G	9295
C9296	Injection, ziv-aflibercept, 1 mg	G	9296
C9297	Injection, omacetaxine mepesuccinate, 0.01 mg	G	9297
C9298	Injection, ocriplasmin, 0.125 mg	G	9298
J0178	Injection, aflibercept, 1 mg vial	G	1420
J0716	Injection, centruroides (scorpion) immune f(ab)2, up to 120 milligrams	G	1431
J7315	Mitomycin, ophthalmic, 0.2 mg	G	1448
J9019	Injection, asparaginase (erwinaze), 1,000 iu	G	9289
Q4122*	Dermacell, per square centimeter	G	1419
Q4127	Talymed, per square centimeter	G	1449
Q4132	Grafix core, per square centimeter	G	9368
Q4133	Grafix prime, per square centimeter	G	9369

* Because the payment rates associated with these codes effective July 1, 2013 are not available to us in time for incorporation into the Addenda of this proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2013 OPPS quarterly update CR could not be included in Addendum B to this proposed rule.

4. Proposed Provisions for Reducing Transitional Pass-Through Payments for Diagnostic Radiopharmaceuticals; Contrast Agents; Drugs, Biologicals, and Radiopharmaceuticals That Function as Supplies When Used in a Diagnostic Test or Procedure; and Drugs and Biologicals That Function as Supplies or Devices When Used in a Surgical Procedure to Offset Costs Packaged Into APC Groups

a. Background

Prior to CY 2008, diagnostic radiopharmaceuticals and contrast agents were paid separately under the OPPS if their mean per day costs were greater than the applicable year's drug packaging threshold. In CY 2008 (72 FR 66768), we began a policy of packaging payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents as ancillary and supportive items and services into their associated nuclear medicine procedures. Therefore, beginning in CY 2008, nonpass-through diagnostic radiopharmaceuticals and contrast agents were not subject to the annual OPPS drug packaging threshold to determine their packaged or separately payable payment status, and instead all nonpass-through diagnostic radiopharmaceuticals and contrast agents were packaged as a matter of policy. For CY 2014, we are proposing to continue to package payment for all nonpass-through diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs and to begin packaging all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure, as discussed in section II.A.3. of this proposed rule.

b. Proposed Payment Offset Policy for Diagnostic Radiopharmaceuticals

As previously noted, radiopharmaceuticals are considered to be drugs for OPPS pass-through payment purposes. As described above, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. 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 are proposing that its pass-through status would expire on December 31, 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 proposed rule, we are proposing that new pass-through diagnostic radiopharmaceuticals would be paid at ASP+6 percent, while those new pass-through diagnostic radiopharmaceuticals without ASP information would be paid at WAC+6 percent or, if WAC is not available, payment would be based on 95 percent of the product's most recently published AWP.

Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for diagnostic radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor radiopharmaceuticals in order to ensure no duplicate radiopharmaceutical payment is made. In CY 2009, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor diagnostic radiopharmaceuticals when considering a new diagnostic radiopharmaceutical for pass-through payment (73 FR 68638 through 68641). Specifically, we use the policy packaged drug offset fraction for APCs containing nuclear medicine procedures, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy packaged drugs divided by the cost from single procedure claims in the APC.

In the CY 2010 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 and to report a token charge of less than $1.01 in cases in which the diagnostic radiopharmaceutical is received without cost or with full credit. Beginning in CY 2014, we are proposing to no longer require hospitals to append modifier ''FB'' to specified nuclear medicine procedures or to report a token charge of less than $1.01 in cases in which the diagnostic radiopharmaceutical is received at no cost/full credit. Under this proposed policy, the OPPS payment amount for nuclear medicine procedures would not be reduced when a diagnostic radiopharmaceutical is received at no cost or full credit. Based on claims data, it appears that hospitals rarely receive diagnostic radiopharmaceuticals at no cost or full credit and, therefore, we do not believe that the burden on hospitals of adhering to the nuclear medicine ''FB'' modifier policy continues to be warranted.

For CY 2013, we finalized a policy to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals, as described above. For CY 2014, we are proposing to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals.

Table 21 below displays the proposed APCs to which nuclear medicine procedures would be assigned in CY 2014 and for which we expect that an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

TABLE 21—PROPOSED APCS TO WHICH NUCLEAR MEDICINE PROCEDURES WOULD BE ASSIGNED FOR CY 2014

Proposed CY 2014 APC	Proposed CY 2014 APC title
0308	Positron Emission Tomography (PET) Imaging.
0377	Level II Cardiac Imaging.
0378	Level II Pulmonary Imaging.
0389	Level I Non-imaging Nuclear Medicine.
0390	Level I Endocrine Imaging.
0391	Level II Endocrine Imaging.
0392	Level II Non-imaging Nuclear Medicine.
0393	Hematologic Processing & Studies.
0394	Hepatobiliary Imaging.
0395	GI Tract Imaging.
0396	Bone Imaging.
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. Proposed Payment Offset Policy for Contrast Agents

Section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. There currently are no contrast agents with pass-through status under the OPPS. As described in section V.A.3. of this proposed rule, we are proposing that new pass-through contrast agents would be paid at ASP+6 percent, while those new pass-through contrast agents without ASP information would be paid at WAC+6 percent or, if WAC is not available, payment would be based on 95 percent of the product's most recently published AWP.

Although there are currently no contrast agents with pass-through status, we believe that a payment offset is necessary in the event that a new contrast agent is approved for pass-through status during CY 2014 in order to provide an appropriate transitional pass-through payment for new contrast agents because all of these items are packaged when they do not have pass-through status. In accordance with our standard offset methodology, we are proposing for CY 2014 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 2014, 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 2014, as we did in CY 2013, we are proposing to continue to apply this same policy to contrast agents. Specifically, we are proposing to utilize the policy packaged drug offset fraction for procedural APCs, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy packaged drugs divided by the cost from single procedure claims in the APC. To determine the actual APC offset amount for pass-through contrast agents that takes into consideration the otherwise applicable OPPS payment amount, we are proposing to multiply the policy packaged drug offset fraction by the APC payment amount for the procedure with which the pass-through contrast agent is used and, accordingly, reduce the separate OPPS payment for the pass-through contrast agent by this amount. We are proposing to continue to apply this methodology for CY 2014 to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 22 of this proposed rule, a specific offset based on the procedural APC would be applied to the payment for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

Proposed procedural APCs for which we expect a contrast offset could be applicable in the case of a pass-through contrast agent have been identified as any procedural APC with a policy packaged drug amount greater than $20 that is not a nuclear medicine APC identified in Table 21 above, and these APCs are displayed in Table 22 below. The methodology used to determine a proposed threshold cost for application of a contrast agent offset policy is described in detail in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60483 through 60484). For CY 2014, we are proposing to continue to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 22, a specific offset based on the procedural APC would be applied to the payment for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

TABLE 22—PROPOSED APCS TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2014

Proposed CY 2014 APC	Proposed CY 2014 APC title
0080	Diagnostic Cardiac Catheterization.
0082	Coronary or Non-Coronary Atherectomy.
0083	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization.
0093	Vascular Reconstruction/Fistula Repair 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.

TABLE 22—PROPOSED APCS TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2014—Continued

Proposed CY 2014 APC	Proposed CY 2014 APC title
0375	Ancillary Outpatient Services When Patient Expires.
0383	Cardiac Computed Tomographic Imaging.
0388	Discography.
0442	Dosimetric Drug Administration.
0653	Vascular Reconstruction/Fistula Repair with Device.
0656	Transcatheter Placement of Intracoronary Drug-Eluting Stents.
0662	CT Angiography.
0668	Level I Angiography and Venography.
8006	CT and CTA with Contrast Composite.
8008	MRI and MRA with Contrast Composite.

d. Proposed Payment Offset Policy for Products Packaged According to the Proposed Policy to Package Drugs, Biologicals, and Radiopharmaceuticals That Function as Supplies When Used in a Diagnostic Test or Procedure and Drugs and Biologicals That Function as Supplies or Devices When Used in a Surgical Procedure

Section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. As discussed in section II.A.3. of this proposed rule, as a part of our proposed policy to package drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure, we are specifically proposing that skin substitutes and stress agents used in myocardial perfusion imaging (MPI) be policy packaged in CY 2014, in addition to diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs. We believe that a payment offset, similar to the offset currently in place for pass-through devices, diagnostic radiopharmaceuticals, and contrast agents, is necessary in order to provide an appropriate transitional pass-through payment for drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure because all of these are packaged, or proposed to be packaged, when they do not have pass-through status. In accordance with our standard offset methodology, we are proposing for CY 2014 to deduct from the payment for pass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure an amount that reflects the portion of the APC payment associated with predecessor products in order to ensure no duplicate 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). For CY 2014, we are proposing to apply this same policy to drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure. Specifically, in the case of pass-through skin substitutes, we are proposing to utilize the policy packaged drug offset fraction for skin substitute procedural APCs, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy packaged drugs divided by the cost from single procedure claims in the APC. Because policy packaged radiopharmaceuticals also would be included in the drug offset fraction for the APC to which MPI procedures are assigned, in the case of pass-through stress agents, we are proposing to utilize the policy packaged drug offset fraction for the procedural APC, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy packaged drugs excluding policy packaged diagnostic radiopharmaceuticals divided by the cost from single procedure claims in the APC. To determine the actual APC offset amount for pass-through skin substitutes and pass-through stress agents that takes into consideration the otherwise applicable OPPS payment amount, we are proposing to multiply the policy-packaged drug offset fraction by the APC payment amount for the procedure with which the pass-through skin substitute or pass-through stress agent is used and, accordingly, reduce the separate OPPS payment for the pass-through skin substitute or pass-through stress agent by this amount.

Table 23 below displays the proposed APCs to which skin substitute procedures would be assigned in CY 2014 and for which we expect that an APC offset could be applicable in the case of skin substitutes with pass-through status.

Table 24 below displays the proposed APC to which MPI procedures would be assigned in CY 2014 and for which we expect that an APC offset could be applicable in the case of a stress agent with pass-through status.

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

TABLE 23—PROPOSED APCS TO WHICH SKIN SUBSTITUTE PROCEDURES WOULD BE ASSIGNED FOR CY 2014

Proposed CY 2014 APC	Proposed CY 2014 APC title
0135	Level III Skin Repair.
0136	Level IV Skin Repair.

TABLE 24—PROPOSED APCS TO WHICH MPI PROCEDURES WOULD BE ASSIGNED FOR CY 2014

Proposed CY 2014 APC	Proposed CY 2014 APC title
0100	Cardiac Stress Tests.
0377	Level II Cardiac Imaging.

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

1. Background

Under the CY 2013 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. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Background

As indicated in section V.B.1. of this proposed rule, in accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $60 for CYs 2008 and 2009. For CY 2010, we set the packaging threshold at $65; for CY 2011, we set the packaging threshold at $70; for CY 2012, we set the packaging threshold at $75; and for CY 2013, we set the packaging threshold at $80.

Following the CY 2007 methodology, for this CY 2014 OPPS/ASC proposed rule, we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2014 and rounded the resulting dollar amount ($87.70) to the nearest $5 increment, which yielded a figure of $90. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics (BLS) series code WPUSI07003) from CMS' Office of the Actuary (OACT). (We note that we are not proposing a change to the PPI that is used to calculate the threshold for CY 2014; 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 the PPI for Prescription Drugs as it reflects price changes associated with the average mix of all pharmaceuticals in the overall economy. In addition, we chose this price series because it is publicly available and regularly published, improving public access and transparency. Forecasts of the PPI for Prescription Drugs are developed by IHS Global Insight, Inc., a nationally recognized economic and financial forecasting firm. As actual inflation for past quarters replaced forecasted amounts, the PPI estimates for prior quarters have been revised (compared with those used in the CY 2007 OPPS/ASC final rule with comment period) and have been incorporated into our calculation. Based on the calculations described above, we are proposing a packaging threshold for CY 2014 of $90. (For a more detailed discussion of the OPPS drug packaging threshold and the use of the PPI for Prescription Drugs, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086).)

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

To determine the proposed CY 2014 packaging status for all nonpass-through drugs and biologicals that are not policy packaged for this proposed rule, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals (collectively called ''threshold-packaged'' drugs) that had a HCPCS code in CY 2012 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2012 claims processed before January 1, 2013 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.2.c. of this proposed rule, or for diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, and implantable biologicals that we are proposing to continue to package in CY 2014, or for the new categories of policy-packaged products proposed for CY 2014, as discussed in section II.A.3. of this proposed rule.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2014, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 70 FR 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we are proposing for separately

payable drugs and biologicals for CY 2014, as discussed in more detail in section V.B.3.b. of this proposed rule) to calculate the CY 2014 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2012 (data that were used for payment purposes in the physician's office setting, effective April 1, 2013) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2014, we are proposing to use payment rates based on the ASP data from the fourth quarter of CY 2012 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) because these are the most recent data available for use at the time of development of this proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2013. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2012 hospital claims data to determine their per day cost.

We are proposing to package items with a per day cost less than or equal to $90, and identify items with a per day cost greater than $90 as separately payable. Consistent with our past practice, we crosswalked historical OPPS claims data from the CY 2012 HCPCS codes that were reported to the CY 2013 HCPCS codes that we display in Addendum B of this proposed rule (which is available via the Internet on the CMS Web site) for payment in CY 2014.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period will be subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in the CY 2014 OPPS/ASC final rule with comment period, we are proposing to use ASP data from the first quarter of CY 2013, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective July 1, 2013, along with updated hospital claims data from CY 2012. We note that we also are proposing to use these data for budget neutrality estimates and impact analyses for the CY 2014 OPPS/ASC final rule with comment period.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B to the final rule with comment period will be based on ASP data from the second quarter of CY 2013. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2013. These physician's office payment rates would then be updated in the January 2014 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2014. For items that do not currently have an ASP-based payment rate, we are proposing to recalculate their mean unit cost from all of the CY 2012 claims data and updated cost report information available for the CY 2014 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in this CY 2014 OPPS/ASC proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the CY 2014 OPPS/ASC final rule with comment period. Under such circumstances, we are proposing to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose cost fluctuates relative to the proposed CY 2014 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2013. Specifically, for CY 2014, consistent with our historical practice, we are proposing to apply the following policies to these HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2013 and that are proposed for separate payment in CY 2014, and that then have per day costs equal to or less than the CY 2014 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2014 final rule, would continue to receive separate payment in CY 2014.
- HCPCS codes for drugs and biologicals that were packaged in CY 2013 and that are proposed for separate payment in CY 2014, and that then have per day costs equal to or less than the CY 2014 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2014 final rule, would remain packaged in CY 2014.
- HCPCS codes for drugs and biologicals for which we are proposing packaged payment in CY 2014 but then have per day costs greater than the CY 2014 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2014 final rule, would receive separate payment in CY 2014.

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

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66776), we began recognizing, for OPPS payment purposes, multiple HCPCS codes reporting different dosages for the same covered Part B drugs or biologicals in order to reduce hospitals' administrative burden by permitting them to report all HCPCS codes for drugs and biologicals. In general, prior to CY 2008, the OPPS recognized for payment only the HCPCS code that described the lowest dosage of a drug or biological. 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 2014, we continue to believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to payment incentives for hospitals to report certain HCPCS codes for drugs instead of others. Making packaging determinations on a drug-specific basis eliminates these incentives and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we are proposing to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2014.

For CY 2014, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2012 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. We then multiplied the weighted average ASP+6 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to $90 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than $90 (so that all HCPCS codes for the same drug or biological would be separately payable). The following drugs did not have pricing information available for the ASP methodology for this CY 2014 OPPS/ASC proposed rule and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the fourth quarter CY 2012 claims data to make the packaging determinations for these drugs: HCPCS codes J3471 (Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)); J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units); Q0171 (Chlorpromazine hydrochloride, 10 mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen); Q0172 (Chlorpromazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen); 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). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply is displayed in Table 25 below.

TABLE 25—PROPOSED HCPCS CODES TO WHICH THE CY 2014 DRUG–SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY

Proposed CY 2014 HCPCS code	Proposed CY 2014 long descriptor	Proposed CY 2014 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1070	Injection, testosterone cypionate, up to 100 mg	N
J1080	Injection, testosterone cypionate, 1 cc, 200 mg	N
J1440	Injection, filgrastim (g-csf), 300 mcg	K
J1441	Injection, filgrastim (g-csf), 480 mcg	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	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

TABLE 25—PROPOSED HCPCS CODES TO WHICH THE CY 2014 DRUG–SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY—Continued

Proposed CY 2014 HCPCS code	Proposed CY 2014 long descriptor	Proposed CY 2014 SI
J2270	Injection, morphine sulfate, up to 10 mg	N
J2271	Injection, morphine sulfate, 100 mg	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
Q0167	Dronabinol, 2.5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0168	Dronabinol, 5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0169	Promethazine hydrochloride, 12.5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0170	Promethazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0171	Chlorpromazine hydrochloride, 10 mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0172	Chlorpromazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0175	Perphenazine, 4 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0176	Perphenazine, 8 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
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. Proposed Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

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

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

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

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

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

Most physician Part B drugs are paid at ASP+6 percent pursuant to section 1842(o) and section 1847A of the Act.

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

It has been our longstanding policy to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In this CY 2014 OPPS/ASC proposed rule, we are proposing to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

Since CY 2006, we have attempted to establish a drug payment methodology that reflects hospitals' acquisition costs for drugs and biologicals while taking into account relevant pharmacy overhead and related handling expenses. We have attempted to collect more data on hospital overhead charges for drugs and biologicals by making several proposals that would require hospitals to change the way they report the cost and charges for drugs. None of these proposals were adopted due to significant stakeholder concern, including that hospitals stated that it would be administratively burdensome to report hospital overhead charges. We established a payment policy for separately payable drugs and biologicals, authorized by section 1833(t)(14)(A)(iii)(I) of the Act, based on an ASP+X amount that is calculated by comparing the estimated aggregate cost of separately payable drugs and biologicals in our claims data to the estimated aggregate ASP dollars for separately payable drugs and biologicals, using the ASP as a proxy for average acquisition cost (70 FR 68642). We referred to this methodology as our standard drug payment methodology.

In CY 2010, taking into consideration comments made by the pharmacy stakeholders and acknowledging the limitations of the reported data due to charge compression and hospitals' reporting practices, we added an ''overhead adjustment'' (an internal adjustment of the data) by redistributing cost from coded and uncoded packaged drugs and biologicals to separately payable drugs in order to provide more appropriate payments for drugs and biologicals in the HOPD. We continued this overhead adjustment methodology through CY 2012, and further refined our overhead adjustment methodology by finalizing a policy to update the redistribution amount for inflation and to keep the redistribution ratio constant between the proposed rule and the final rule. For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385).

We noted in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386) that application of the standard drug payment methodology, with the overhead adjustment, has always yielded a finalized payment rate in the range of ASP+4 percent to ASP+6 percent for nonpass-through separately payable drugs. We stated that the historic ASP+4 to ASP+6 percentage range is an appropriate payment rate for separately payable drugs and biologicals administered within the HOPD, including acquisition and pharmacy overhead and related expenses. However, because of continuing uncertainty about the full cost of pharmacy overhead and acquisition cost, based in large part on the limitations of the submitted hospital charge and claims data for drugs, we indicated our concern that the continued use of the standard drug payment methodology (including the overhead adjustment) still may not appropriately account for average acquisition and pharmacy overhead cost and, therefore, may result in payment rates that are not as predictable, accurate, or appropriate as they could be.

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

b. Proposed CY 2014 Payment Policy

For CY 2014, we are proposing to continue our CY 2013 policy and pay

for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act, referred to as the statutory default. We are proposing that the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment, and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals. We also are proposing that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payments for these separately paid drugs and biologicals.

4. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

Beginning in CY 2010 and continuing for CY 2013, we established a policy to pay for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through separately payable therapeutic radiopharmaceuticals in CY 2014. Therefore, we are proposing for CY 2014 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also are proposing to rely on CY 2012 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals, according to our usual process for updating the payment rates for separately payable drugs and biologicals, on a quarterly basis if updated ASP information is available. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524).

The proposed CY 2014 payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

5. Proposed Payment for Blood Clotting Factors

For CY 2013, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee. That is, for CY 2013, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2013 updated furnishing fee was $0.188 per unit.

For CY 2014, we are proposing to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician office and inpatient hospital setting, and first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we are proposing to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

6. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes But Without OPPS Hospital Claims Data

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) did not address the OPPS payment in CY 2005 and subsequent years for drugs, biologicals, and radiopharmaceuticals that have assigned HCPCS codes, but that do not have a reference AWP or approval for payment as pass-through drugs or biologicals. Because there was no statutory provision that dictated payment for such drugs, biologicals, and radiopharmaceuticals in CY 2005, and because we had no hospital claims data to use in establishing a payment rate for them, we investigated several payment options for CY 2005 and discussed them in detail in the CY 2005 OPPS final rule with comment period (69 FR 65797 through 65799).

For CYs 2005 to 2007, we implemented a policy to provide separate payment for new drugs, biologicals, and radiopharmaceuticals with HCPCS codes (specifically those new drug, biological, and radiopharmaceutical HCPCS codes in each of those calendar years that did not crosswalk to predecessor HCPCS codes) but which did not have pass-through status, at a rate that was equivalent to the payment they received in the physician's office setting, established in accordance with the ASP methodology for drugs and biologicals, and based on charges adjusted to cost for radiopharmaceuticals. 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 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 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 CYs 2011, 2012, and 2013, paying for new drugs, biologicals, and radiopharmaceuticals that do not have pass-through status, and are without OPPS hospital claims data at ASP+5 percent, ASP+4 percent, and ASP+6 percent, respectively, consistent with the final OPPS payment methodology for other separately payable drugs and biological during those payment years.

For CY 2014, we are proposing to provide payment for new drugs, biologicals, and therapeutic radiopharmaceuticals that do not have pass-through status at ASP+6 percent, consistent with the proposed CY 2014 payment methodology for other separately payable nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals to pay at ASP+6 percent based on the statutory default. We believe this proposed policy would ensure that new nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals would be treated like other drugs, biologicals, and therapeutic radiopharmaceuticals under the OPPS.

For CY 2014, we also are proposing to package payment for all new nonpass-through diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies or devices when used in a surgical procedure, with HCPCS codes but without claims data (those new CY 2014 HCPCS codes that do not crosswalk to predecessor HCPCS codes). This is consistent with the proposed policy packaging all existing nonpass-through diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies or devices when used in a surgical procedure, as discussed in more detail in section II.A.3. of this proposed rule.

In accordance with the OPPS ASP methodology, in the absence of ASP data, for CY 2014, we are proposing 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 are proposing to assign status indicator ''K'' (for separately paid nonpass-through drugs and biologicals, including therapeutic radiopharmaceuticals) to HCPCS codes for new drugs and biologicals without OPPS claims data and for which we have not granted pass-through status. With respect to new, nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals for which we do not have ASP data, we are proposing that once their ASP data become available in later quarterly submissions, their payment rates under the OPPS would be adjusted so that the rates would be based on the ASP methodology and set to the finalized ASP-based amount (proposed for CY 2014 at ASP+6 percent) for items that have not been granted pass-through status. This proposed policy, which utilizes the ASP methodology that requires us to use WAC data when ASP data are unavailable and 95 percent of AWP when WAC and ASP data are unavailable, for new nonpass-through drugs and biologicals with an ASP, is consistent with prior years' policies for these items, and would ensure that new nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals would be treated like other drugs, biologicals, and therapeutic radiopharmaceuticals under the OPPS, unless they are granted pass-through status.

Similarly, we are proposing to continue to base the initial payment for new therapeutic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and are without claims data, on the WACs for these products if ASP data for these therapeutic radiopharmaceuticals are not available. If the WACs are also unavailable, we are proposing to make payment for new therapeutic radiopharmaceuticals at 95 percent of the products' most recent AWP because we would not have mean costs from hospital claims data upon which to base payment. As we are proposing with new drugs and biologicals, we are proposing to continue our policy of assigning status indicator ''K'' to HCPCS codes for new therapeutic radiopharmaceuticals without OPPS claims data for which we have not granted pass-through status.

Consistent with other ASP-based payment, for CY 2014 we are proposing to announce any changes to the payment amounts for new drugs and biologicals in the CY 2014 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2014 if later quarter ASP submissions (or more recent WACs or AWPs) indicate that changes to the payment rates for these drugs and biologicals are necessary. The payment rates for new therapeutic radiopharmaceuticals also would be changed accordingly based on later quarter ASP submissions. We note that the new CY 2014 HCPCS codes for drugs, biologicals and therapeutic radiopharmaceuticals are not available at the time of development of this proposed rule. However, these agents will be included in Addendum B to the CY 2014 OPPS/ASC final rule with comment period (which will be available via the Internet on the CMS Web site), where they will be assigned comment indicator ''NI.'' This comment indicator reflects that their interim final OPPS treatment is open to public comment in the CY 2014 OPPS/ASC final rule with comment period.

There are several nonpass-through drugs and biologicals that were payable in CY 2012 and/or CY 2013 for which we did not have CY 2012 hospital claims data available for this proposed rule and for which there are no other HCPCS codes that describe different doses of the same drug, but which have pricing information available for the ASP methodology. We note that there are currently no therapeutic radiopharmaceuticals in this category. In order to determine the packaging status of these products for CY 2014, 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 are proposing to package items for which we estimated the per day administration cost to be less than or equal to $90, which is the general

packaging threshold that we are proposing for drugs, biologicals, and therapeutic radiopharmaceuticals in CY 2014. We are proposing to pay separately for items with an estimated per day cost greater than $90 (with the exception of diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies or devices when used in a surgical procedure, which we are proposing to package regardless of cost, as discussed in more detail in section II.A.3. of this proposed rule) in CY 2014. We are proposing that the CY 2014 payment for separately payable items without CY 2012 claims data would be ASP+6 percent, similar to payment for other separately payable nonpass-through drugs and biologicals under the OPPS. In accordance with the ASP methodology paid in the physician's office setting, in the absence of ASP data, we are proposing 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.

The proposed estimated units per day and status indicators for these items are displayed in Table 26 below.

TABLE 26—DRUGS AND BIOLOGICALS WITHOUT CY 2012 CLAIMS DATA

CY 2014 HCPCS code	CY 2014 Long descriptor	Estimated average number of units per day	Proposed CY 2014 SI	Proposed CY 2014 APC
90581	Anthrax vaccine, for subcutaneous or intramuscular use	1	K	1422
J0205	Injection, alglucerase, per 10 units	420	K	0900
J0215	Injection, alefacept, 0. 5 mg	29	K	1633
J0220	Injection, alglucosidase alfa, 10 mg, not otherwise specified	150	K	9234
J0364	Injection, apomorphine hydrochloride, 1 mg	1	N	N/A
J0395	Injection, arbutamine hcl, 1 mg	20	K	1432
J0725	Injection, chorionic gonadotropin, per 1,000 usp units	1	N	N/A
J1324	Injection, enfuvirtide, 1 mg	216	K	1361
J1435	Injection, estrone, per 1 mg	150	K	1435
J1620	Injection, gonadorelin hydrochloride, per 100 mcg	11	N	N/A
J1730	Injection, diazoxide, up to 300 mg	1	N	N/A
J1835	Injection, itraconazole, 50 mg	80	N	N/A
J2724	Injection, protein c concentrate, intravenous, human, 10 iu	1540	K	1139
J2725	Injection, protirelin, per 250 mcg	4	K	1357
J3355	Injection, urofollitropin, 75 iu	2	K	1741
J7196	Injection, antithrombin recombinant, 50 i. U.	268	K	1332
J7513	Daclizumab, parenteral, 25 mg	2	K	1612
J8562	Fludarabine phosphate, oral, 10 mg	1	N	N/A
J8650	Nabilone, oral, 1 mg	4	K	1424
J9216	Injection, interferon, gamma 1–b, 3 million units	1	K	0838
J9226	Histrelin implant (supprelin la), 50 mg	1	K	1142
J9300	Injection, gemtuzumab ozogamicin, 5 mg	1	K	9004
Q0515	Injection, sermorelin acetate, 1 microgram	70	K	3050

Finally, there were 11 drugs and biologicals, shown in Table 27, that were payable in CY 2012 but for which we lacked CY 2012 claims data and any other pricing information for the ASP methodology for this CY 2014 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 CYs 2011, 2012, and 2013 (75 FR 71973, 76 FR 74334, and 77 FR 68396, respectively).

For CY 2014, we are proposing to continue to assign status indicator ''E'' to drugs and biologicals that lack CY 2012 claims data and pricing information for the ASP methodology. All drugs and biologicals without CY 2012 hospital claims data and data based on the ASP methodology that are assigned status indicator ''E'' on this basis at the time of this proposed rule for CY 2014 are displayed in Table 27 below. If pricing information becomes available, we are proposing to assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2014.

TABLE 27—DRUGS AND BIOLOGICALS WITHOUT CY 2012 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

CY 2014 HCPCS code	CY 2014 Long descriptor	Proposed CY 2014 SI
90393	Vaccina immune globulin, human, for intramuscular use	E
90644	Meningococcal conjugate vaccine, serogroups c & y and hemophilus influenza b vaccine (hib-mency), 4 dose schedule, when administered to children 2–15 months of age, for intramuscular use.	E
90727	Plague vaccine, for intramuscular use	E
J0190	Injection, biperiden lactate, per 5 mg	E
J0350	Injection, anistreplase, per 30 units	E
J1180	Injection, dyphylline, up to 500 mg	E
J2460	Injection, oxytetracycline hcl, up to 50 mg	E
J2940	Injection, somatrem, 1 mg	E
J7191	Factor viii (antihemophilic factor (porcine)), per i. U.	E
J9165	Injection, diethylstilbestrol diphosphate, 250 mg	E
J9215	Injection, interferon, alfa-n3, (human leukocyte derived), 250,000 iu	E

C. Nuclear Medicine Procedure-to-Radiolabeled Product Edits

Beginning January 1, 2008, CMS implemented OPPS edits that require hospitals to include a HCPCS code for a radiolabeled product when a separately payable nuclear medicine procedure is present on a claim. For CY 2014, we are proposing to no longer require the nuclear medicine procedure-to-radiolabeled product edits. Under this proposal, hospitals would still be expected to adhere to the guidelines of correct coding and append the correct radiolabeled product code to the claim when applicable. However, claims would no longer be returned to providers when HCPCS codes for radiolabeled products do not appear on claims with nuclear medicine procedures. We believe that this is appropriate because hospitals have now had several years of experience reporting procedures involving radiolabeled products and have grown accustomed to ensuring that they code and report charges so that their claims fully and appropriately reflect the costs of those radiolabeled products. Therefore, we do not believe that the burden on hospitals of adhering to the nuclear medicine procedure-to-radiolabeled product edits continues to be warranted. As with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

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

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate prorata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing an estimate of pass-through spending in CY 2014 entails estimating spending for two groups of items. The first group of items consists of device categories that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2014. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2013 or beginning in CY 2014. The sum of the CY 2014 pass-through estimates for these two groups of device categories would equal the total CY 2014 pass-through spending estimate for device categories with pass-through status. We base the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2013 OPPS/ASC final rule with comment period (77 FR 68397). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) is the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), we include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. We note that the Part B drug CAP program has been postponed since CY 2009, and such a program has

not been proposed to be reinstated for CY 2014. Because we are proposing to pay for most nonpass-through separately payable drugs and biologicals under the CY 2014 OPPS at ASP+6 percent, as we discussed in section V.B.3. of this proposed rule, which represents the otherwise applicable fee schedule amount associated with most pass-through drugs and biologicals, and because we are proposing to pay for CY 2014 pass-through drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of this proposed rule, our estimate of drug and biological pass-through payment for CY 2014 for this group of items is $0, as discussed below.

Payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents, without pass-through status will always be packaged into payment for the associated procedures and these products would not be separately paid. In addition, we are proposing to policy-package all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or devices when used in a surgical procedure for CY 2014, as discussed in section II.A.3. of this proposed rule. All of these policy-packaged drugs and biologicals with pass-through status would be paid at ASP+6 percent like other pass-through drugs and biologicals for CY 2014. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through status approved prior to CY 2014 is not $0. In section V.A.4. of this proposed rule, we discuss our proposed policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we are proposing to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological which we refer to as the policy-packaged drug APC offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we are proposing to reduce our estimate of pass-through payments for these drugs or biologicals by this amount.

Similar to pass-through estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that would continue to be eligible for pass-through payment in CY 2014. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2013 or beginning in CY 2014. The sum of the proposed CY 2014 pass-through estimates for these two groups of drugs and biologicals equals the proposed total CY 2014 pass-through spending estimate for drugs and biologicals with pass-through status.

B. Proposed Estimate of Pass-Through Spending

We are proposing to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2014, consistent with section 1833(t)(6)(E)(ii)(II) of the Act, and our OPPS policy from CY 2004 through CY 2013 (77 FR 68398).

For the first group of devices for pass-through payment estimation purposes, there currently are no device categories receiving pass-through payment in CY 2013 that would continue to be eligible for pass-through payment for CY 2014. As discussed in section IV.A. of this proposed rule, we finalized in the CY 2013 OPPS/ASC final rule with comment period the expiration of pass-through payment for three device categories after the end of CY 2013. Therefore, we estimate that CY 2014 pass-through expenditures for the first group of pass-through device categories to be $0. In estimating our CY 2014 pass-through spending for device categories in the second group, we include: Device categories that we knew at the time of the development of the proposed rule will be newly eligible for pass-through payment in CY 2014 (of which there are none); additional device categories that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2014; and contingent projections for new device categories established in the second through fourth quarters of CY 2014. We are proposing to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For this proposed rule, the estimate of CY 2014 pass-through spending for this second group of device categories is $10 million. Using our established methodology, we are proposing that the total estimated pass-through spending for device categories for CY 2014 (spending for the first group of device categories ($0) plus spending for the second group of device categories ($10 million)) would be $10 million.

To estimate CY 2014 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through status for CY 2014, we are proposing 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 biologicals to project the CY 2014 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals. contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies or devices when used in a surgical procedure) that will be continuing on pass-through status in CY 2014, we estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-through drugs and biologicals that will be separately paid at ASP+6 percent, which is zero for this group of drugs. Because payment for policy-packaged drugs and biologicals is proposed to be packaged if the product was not paid separately due to its pass-through status, we are proposing to include in the CY 2014 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determined that the policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment. For this proposed rule, using the proposed methodology described above, we calculated a CY 2014 proposed spending estimate for this first group of drugs and biologicals of approximately $0.962 million.

To estimate proposed CY 2014 pass-through spending for drugs and biologicals in the second group (that is,

drugs and biologicals that we knew at the time of development of the proposed rule are newly eligible for pass-through payment in CY 2014, additional drugs and biologicals that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2014, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2014), we are proposing to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2014 pass-through payment estimate. We also are proposing to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2014 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $0.165 million.

As discussed in section V.A. of this proposed rule, radiopharmaceuticals are considered drugs for pass-through purposes. Therefore, we include radiopharmaceuticals in our proposed CY 2014 pass-through spending estimate for drugs and biologicals. Our proposed CY 2014 estimate for total pass-through spending for drugs and biologicals (spending for the first group of drugs and biologicals ($0.962 million) plus spending for the second group of drugs and biologicals ($0.165 million)) equals $1.127 million.

In summary, in accordance with the methodology described above in this section, for this proposed rule, we estimate that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2014 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2014 would be approximately $11 million (approximately $10 million for device categories and approximately $1 million for drugs and biologicals), which represents 0.02 percent of total projected OPPS payments for CY 2014. We estimate that pass-through spending in CY 2014 would not amount to 2.0 percent of total projected OPPS CY 2014 program spending.

VII. Proposed OPPS Payment for Hospital Outpatient Visits

A. Background

Currently, hospitals report HCPCS visit codes to describe three types of OPPS services: clinic visits, emergency department (ED) visits, and critical care services, including trauma team activation. Historically, we have recognized the CPT and HCPCS codes describing clinic visits, Type A and Type B (ED) visits, and critical care services, which are listed below in Table 28. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74338 through 74346) for a full discussion of our policy on OPPS payment for hospital outpatient visits for CY 2013 and prior years.

TABLE 28—HCPCS CODES USED TO REPORT CLINIC AND EMERGENCY DEPARTMENT VISITS AND CRITICAL CARE SERVICES

CY 2013 HCPCS code	CY 2013 descriptor
Clinic Visit HCPCS Codes	
99201	Office or other outpatient visit for the evaluation and management of a new patient (Level 1).
99202	Office or other outpatient visit for the evaluation and management of a new patient (Level 2).
99203	Office or other outpatient visit for the evaluation and management of a new patient (Level 3).
99204	Office or other outpatient visit for the evaluation and management of a new patient (Level 4).
99205	Office or other outpatient visit for the evaluation and management of a new patient (Level 5).
99211	Office or other outpatient visit for the evaluation and management of an established patient (Level 1).
99212	Office or other outpatient visit for the evaluation and management of an established patient (Level 2).
99213	Office or other outpatient visit for the evaluation and management of an established patient (Level 3).
99214	Office or other outpatient visit for the evaluation and management of an established patient (Level 4).
99215	Office or other outpatient visit for the evaluation and management of an established patient (Level 5).
Emergency Department Visit HCPCS Codes	
99281	Emergency department visit for the evaluation and management of a patient (Level 1).
99282	Emergency department visit for the evaluation and management of a patient (Level 2).
99283	Emergency department visit for the evaluation and management of a patient (Level 3).
99284	Emergency department visit for the evaluation and management of a patient (Level 4).
99285	Emergency department visit for the evaluation and management of a patient (Level 5).
G0380	Type B emergency department visit (Level 1).
G0381	Type B emergency department visit (Level 2).
G0382	Type B emergency department visit (Level 3).
G0383	Type B emergency department visit (Level 4).
G0384	Type B emergency department visit (Level 5).
Critical Care Services HCPCS Codes	
99291	Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes.
99292	Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes.
G0390	Trauma response associated with hospital critical care service.

B. Proposed Payment for Hospital Outpatient Clinic and Emergency Department Visits

Since April 7, 2000, we have instructed hospitals to report facility resources for clinic and ED hospital outpatient visits using the CPT E/M codes and to develop internal hospital guidelines for reporting the appropriate visit level (65 FR 18451). Because a national set of hospital-specific codes and guidelines do not currently exist, we have advised hospitals that each hospital's internal guidelines that determine the levels of clinic and ED visits to be reported should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes.

While many hospitals have advocated for hospital-specific national guidelines for visit billing since the OPPS started in 2000, and we have signaled through rulemaking our intent to develop guidelines, this complex undertaking has proven challenging. Our work with interested stakeholders, such as hospital associations, along with a contractor, has confirmed that no single approach could consistently and accurately capture hospitals' relative costs. Public comments received on this issue, as well as our own knowledge of how clinics operate, have led us to conclude that it is not feasible to adopt a set of national guidelines for reporting hospital clinic visits that can accommodate the enormous variety of patient populations and service-mix provided by hospitals of all types and sizes throughout the country. Moreover, no single approach appears to be broadly endorsed by the stakeholder community.

For CY 2014, we are proposing to modify our longstanding policies related to hospital outpatient clinic and ED visits. Rather than recognizing five levels of clinic and ED visits respectively, we are proposing to create three new alphanumeric Level II HCPCS codes to describe all levels of each type of clinic and ED visit, as discussed in greater detail below. We believe a policy that recognizes a single visit level for clinic visits, Type A ED visits, and Type B ED visits for payment under the OPPS is appropriate for several reasons. First, the proposal is in line with our strategic goal of using larger payment bundles to maximize hospitals' incentives to provide care in the most efficient matter as stated in section II.A.3. of this proposed rule. We believe this proposal will remove any incentives hospitals may have to provide medically unnecessary services or expend additional, unnecessary resources to achieve a higher level of visit payment under the OPPS. Second, we believe that it is important to consider ways in which we can reduce the administrative burden that Medicare payment policies place on hospitals, while maintaining our ability to calculate accurate payment rates under the OPPS. We believe that replacing the 20 HCPCS codes currently recognized for clinic visits and ED visits with three new alphanumeric Level II HCPCS codes would reduce administrative burden and would be easily adopted by hospitals, because the three new codes would require hospitals to distinguish only among clinic visits, Type A ED visits, and Type B ED visits. Discontinuing the use of the five levels of HCPCS visit codes for clinic and Type A and Type B ED visits would reduce hospitals' administrative burden by eliminating the need for them to develop and apply their own internal guidelines to differentiate among five levels of resource use for every clinic visit and ED visit they provide, and by eliminating the need to distinguish between new and established patients. Third, our proposal allows a large universe of claims to be utilized for ratesetting for each of the three newly proposed alphanumeric Level II HCPCS visit codes. We believe this large volume of claims available for ratesetting for each of the newly proposed alphanumeric Level II HCPCS visit codes will allow us to capture a very broad spectrum of cases ranging from extremely low complexity cases to extremely high complexity cases. We believe this large and diverse spectrum of clinical complexity and resource variation within the claims as well as the very high volume of claims that we propose to use for ratesetting for the newly proposed alphanumeric Level II HCPCS visit new codes will allow us to have very accurate data upon which to develop accurate and appropriate payments. Lastly, we also believe that removing the differentiation among five levels of intensity for each visit will eliminate any incentive for hospitals to ''upcode'' patients whose visits do not fall clearly into one category or another.

For these reasons, for CY 2014, we are proposing to discontinue our longstanding policy of recognizing five distinct visit levels for clinic visits and ED visits based on the existing HCPCS E/M codes, and instead recognize three new alphanumeric HCPCS codes for each visit type. Specifically, we are proposing to create a new alphanumeric HCPCS code (GXXXC) for hospital use only representing any clinic visit under the OPPS and to assign the newly created alphanumeric clinic visit HCPCS code (GXXXC) to its own newly created APC 0634. Using CY 2012 claims data, we are proposing to develop CY 2014 OPPS payment rates for the new HCPCS code GXXXC based on the total mean cost of the levels one through five CPT E/M codes for clinic visits currently recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). While we would use data for CPT codes 99201 through 99205 and 99211 through 99215 from claims billed in CY 2012 to calculate the mean cost for new APC 0634, we would no longer recognize those CPT codes when they appear on hospital claims effective January 1, 2014. We also are proposing to no longer recognize a distinction between new and established patient clinic visits. Under this proposal, all clinic visits would be reported using new HCPCS code GXXXC, regardless of whether or not the patient has been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit.

In addition, we are proposing to discontinue our longstanding policy of recognizing five distinct visit levels for Type A ED visits and instead are proposing to create a new alphanumeric HCPCS code (GXXXA) for hospital use only representing any Type A ED visit under the OPPS. We are proposing to assign the newly created alphanumeric Type A ED visit HCPCS code (GXXXA) to its own newly created APC 0635. Using CY 2012 claims data, we are proposing to develop CY 2014 OPPS payment rates for new HCPCS code GXXXA based on the total mean cost of the levels 1 through 5 CPT E/M codes for Type A ED visits currently recognized under the OPPS (CPT codes 99281 through 99285). While we would use data for CPT codes 99281 through 99285 from claims billed in CY 2012 to calculate the mean cost for new APC 0635, we would no longer recognize those CPT codes when they appear on hospital claims effective January 1, 2014. Similarly, we also are proposing to discontinue our longstanding policy of recognizing five distinct visit levels for Type B ED visits and instead are proposing to create a new alphanumeric HCPCS code (GXXXB) representing all Type B ED visits under the OPPS. We are proposing to assign the newly created alphanumeric Type B ED visit HCPCS code (GXXXB) to its own newly created APC 0636. Using CY 2012 claims data, we are proposing to develop CY 2014 OPPS payment rates

for new HCPCS code GXXXB based on the total mean cost of the levels 1 through 5 HCPCS codes for Type B ED visits currently recognized under the OPPS (HCPCS codes G0380 through G0384). While we would use data for HCPCS codes G0380 through G0384 from claims billed in CY 2012 to calculate the mean cost for new APC 0636, we would no longer recognize those HCPCS codes for Type B ED visits when they appear on hospital claims effective January 1, 2014.

We note that we would use the hospital claims data for new HCPCS codes GXXXA, GXXXB, and GXXXC when available for future ratesetting. The proposed changes to the visit coding and payment structure are summarized below in Table 29. We welcome public comments on our CY 2014 proposal to recognize a single visit level for clinic, Type A ED, and Type B ED visits for payment under the OPPS. We believe this proposal will allow us to make accurate payments for visits broad-scale because we will be using data from the universe of hospital outpatient visits, for which we have an extremely high volume of claims representing the entire spectrum of costs incurred by hospitals. Nonetheless, we are interested in hearing from stakeholders regarding whether a different approach may be preferable to capture the resource utilization for extremely low complexity cases as well as extremely high complexity cases or to otherwise recognize a difference among visit levels. While we do not believe, based on our current assessment, that it is necessary to provide additional payment levels or carve out these cases to make accurate and appropriate payments for visits, we are interested in hearing from hospitals whether there are certain cases that would not be best accommodated by a single level of payment. If such cases exist, we welcome stakeholder input into whether and how this proposal could be changed in the final rule to either make exceptions for or accommodate these special cases. If commenters provide compelling comments describing such special cases or the need for additional payment levels, should they exist, and if there are alternative policies that would more accurately and appropriately pay for visits, we would consider implementing a different policy in the final rule. We note that, to the extent that commenters recommend that additional levels of payment or special high complexity or low complexity cases be recognized, we also would be interested in how we should define and differentiate those levels or cases.

TABLE 29—CY 2013 CLINIC AND EMERGENCY DEPARTMENT VISIT HCPCS CODES AND APC ASSIGNMENTS COMPARED TO PROPOSED CY 2014 CLINIC AND EMERGENCY DEPARTMENT VISIT HCPCS CODES AND APC ASSIGNMENTS

Visit type	CY 2013		Proposed CY 2014	
	HCPCS code	APC	HCPCS code	APC
CLINIC VISIT	99201	0604	GXXXC	0634
	99202	0605		
	99203	0606		
	99204	0607		
	99205	0608		
	99211	0604		
	99212	0605		
	99213	0605		
	99214	0606		
	99215	0607		
TYPE A ED VISIT	99281	0609	GXXXA	0635
	99282	0613		
	99283	0614		
	99284	0615		
	99285	0616		
TYPE B ED VISIT	G0380	0626	GXXXB	0636
	G0381	0627		
	G0382	0628		
	G0383	0629		
	G0384	0630		

C. Proposed Payment for Critical Care Services

We are proposing 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 reflected 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 final rule with comment period, the CY 2011 hospital claims data on which the CY 2013 payment rates are based reflect the first year of claims billed under the revised CPT guidance to allow the reporting of all the ancillary services and their associated charges separately when they are provided in conjunction with critical care (77 FR 68402). Because our policy to establish relative payment weights based on geometric mean cost data for CY 2013 represented a change from our historical practice to base payment rates on median costs, and because we 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 CY 2013 OPPS/ASC final rule with comment period and determined that the data showed 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, we noted that 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 were presented on the same claims as critical care services, and also showed continued low volumes of many ancillary services. We stated in the CY 2013 OPPS/ASC final rule with comment period that, had the majority of hospitals changed their billing practices to separately report and charge for the ancillary services formerly included in the definition of critical care CPT codes 99291 and 99292, we would have expected to see a decrease in the costs and charges for these CPT codes, and a significant increase in ancillary services reported on the same claims. We indicated that the lack of a substantial change in the services reported on critical care claims, along with the increases in the line item costs and charges for critical care services, strongly suggested that many hospitals did not change their billing practices for CPT code 99291 following the revision to the CPT coding guidance effective January 1, 2011.

In light of not having claims data to support a significant change in hospital billing practices, we stated in the CY 2013 OPPS/ASC final rule with comment period that we continued to believe that it is inappropriate to pay separately in CY 2013 for the ancillary services that hospitals may now report in addition to critical care services. Therefore, for CY 2013, we continued our CY 2011 and CY 2012 policy to recognize the existing CPT codes for critical care services and establish a payment rate based on historical claims data. We also continued to implement claims processing edits that conditionally packaged payment for the ancillary services that were reported on the same date of service as critical care services in order to avoid overpayment. We stated that we would continue to monitor the hospital claims data for CPT code 99291 in order to determine whether revisions to this policy are warranted based on changes in hospitals' billing practices.

When compared to CY 2011 hospital claims data used for the CY 2013 OPPS ratesetting, CY 2012 hospital claims data used for the CY 2014 OPPS ratesetting show increases in the mean line- item costs as well as the mean line-item charges for CPT code 99291, which continue to suggest that hospitals did not change their billing practices for CPT code 99291 following the revision to the CPT coding guidance effective January 1, 2011. In light of not having claims data to support a significant change in hospital billing practices, we continue to believe that it is inappropriate to pay separately in CY 2014 for the ancillary services that hospitals may now report in addition to critical care services. Therefore, for CY 2014, we are proposing to continue our CY 2011, CY 2012, and CY 2013 policy to recognize the existing CPT codes for critical care services and establish a payment rate based on historical claims data. We also are proposing to continue to implement claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment. We will continue to monitor the hospital claims data for CPT code 99291 in order to determine whether revisions to this policy are warranted based on changes in hospitals' billing practices.

VIII. Proposed Payment for Partial Hospitalization Services

A. Background

Partial hospitalization is an intensive outpatient program of psychiatric services provided to patients as an alternative to inpatient psychiatric care for individuals who have an acute mental illness. Section 1861(ff)(1) of the Act defines partial hospitalization services as ''the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan.'' Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a partial hospitalization program (PHP) is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC) (as defined in subparagraph (B)), and ''which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care other than in an individual's home or in an inpatient or residential setting.'' Section 1861(ff)(3)(B) of the Act defines a community mental health center for purposes of this benefit.

Section 1833(t)(1)(B)(i) of the Act provides the Secretary with the authority to designate the OPD services to be covered under the OPPS. The Medicare regulations that implement this provision specify, under 42 CFR 419.21, that payments under the OPPS will be made for partial hospitalization services furnished by CMHCs as well as Medicare Part B services furnished to hospital outpatients designated by the Secretary, which include partial hospitalization services (65 FR 18444 through 18445).

Section 1833(t)(2)(C) of the Act, in pertinent part, requires the Secretary to ''establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs'' using data on claims from 1996 and data from the most recent available cost reports. In pertinent part, subparagraph (B) provides that the Secretary may establish groups of covered OPD services, within a classification system developed by the Secretary for covered OPD services, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we have developed the PHP APCs. Section 1833(t)(9)(A) of the Act requires the Secretary to ''review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.''

Because a day of care is the unit that defines the structure and scheduling of partial hospitalization services, we established a per diem payment methodology for the PHP APCs, effective for services furnished on or after July 1, 2000 (65 FR 18452 through 18455). Under this methodology, the median per diem costs have been used to calculate the relative payment weights for PHP APCs.

From CY 2003 through CY 2006, the median per diem costs for CMHCs fluctuated significantly from year to year, while the median per diem costs for hospital-based PHPs remained relatively constant. We were concerned that CMHCs may have increased and decreased their charges in response to Medicare payment policies. Therefore, we began efforts to strengthen the PHP benefit through extensive data analysis and policy and payment changes finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). We made two refinements to the methodology for computing the PHP median: the first remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers; and the second refined our methodology for computing the PHP median per diem cost by computing a separate per diem cost for each day rather than for each bill. We refer readers to a complete discussion of these refinements in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676).

In CY 2009, we implemented several regulatory, policy, and payment changes, including a two-tiered payment approach for PHP services under which we paid one amount for days with 3 services (APC 0172 Level I Partial Hospitalization) and a higher amount for days with 4 or more services (APC 0173 Level II Partial Hospitalization). We refer readers to section X.B. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68693) for a full discussion of the two-tiered payment system. In addition, for CY 2009, we finalized our policy to deny payment for any PHP claims submitted for days when fewer than 3 units of therapeutic services are provided (73 FR 68694).

Furthermore, for CY 2009, we revised the regulations at 42 CFR 410.43 to codify existing basic PHP patient eligibility criteria and to add a reference to current physician certification requirements under 42 CFR 424.24 to conform our regulations to our longstanding policy (73 FR 68694 through 68695). These changes have helped to strengthen the PHP benefit. We also revised the partial hospitalization benefit to include several coding updates. We refer readers to section X.C.3. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68695 through 68697) for a full discussion of these requirements.

For CY 2010, we retained the two-tiered payment approach for PHP services and used only hospital-based PHP data in computing the APC per diem payment rates. We used only hospital-based PHP data because we were concerned about further reducing both PHP APC per diem payment rates without knowing the impact of the policy and payment changes we made in CY 2009. Because of the 2-year lag between data collection and rulemaking, the changes we made in CY 2009 were reflected for the first time in the claims data that we used to determine payment rates for the CY 2011 rulemaking (74 FR 60556 through 60559).

In CY 2011, in accordance with section 1301(b) of the Health Care and Education Reconciliation Act of 2010 (HCERA 2010), we amended the description of a PHP in our regulations to specify that a PHP must be a distinct and organized intensive ambulatory treatment program offering less than 24-hour daily care ''other than in an individual's home or in an inpatient or residential setting.'' In addition, in accordance with section 1301(a) of HCERA 2010, we revised the definition of a CMHC in the regulations to conform to the revised definition now set forth under section 1861(ff)(3)(B) of the Act. We discussed our finalized policies for these two provisions of HCERA 2010 in section X.C. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71990).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we also established four separate PHP APC per diem payment rates, two for CMHCs (for Level I and Level II services) and two for hospital-based PHPs (for Level

I and Level II services), based on each provider's own unique data. As stated in the CY 2011 OPPS/ASC proposed rule (75 FR 46300) and the final rule with comment period (75 FR 71991), for CY 2011, using CY 2009 claims data, CMHC costs had significantly decreased again. We attributed the decrease to the lower cost structure of CMHCs compared to hospital-based PHP providers, and not the impact of the CY 2009 policies. CMHCs have a lower cost structure than hospital-based PHP providers, in part, because the data showed that CMHCs generally provide fewer PHP services in a day and use less costly staff than hospital-based PHPs. Therefore, it was inappropriate to continue to treat CMHCs and hospital-based providers in the same manner regarding payment, particularly in light of such disparate differences in costs. We also were concerned that paying hospital-based PHPs at a lower rate than their cost structure reflects could lead to hospital-based PHP closures and possible access problems for Medicare beneficiaries because hospital-based PHPs are located throughout the country and, therefore, offer the widest access to PHP services. In contrast, CMHC-based PHPs are largely concentrated in certain geographical areas with particular prevalence in Florida, Texas, and Louisiana. Creating the four payment rates (two for CMHCs and two for hospital-based PHPs) based on each provider's data supported continued access to the PHP benefit, while also providing appropriate payment based on the unique cost structures of CMHCs and hospital-based PHPs. In addition, separation of data by provider type was supported by several hospital-based PHP commenters who responded to the CY 2011 OPPS/ASC proposed rule (75 FR 71992).

For CY 2011, we instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates based solely on CMHC data. For CY 2011, under the transition methodology, CMHC PHP APCs Level I and Level II per diem costs were calculated by taking 50 percent of the difference between the CY 2010 final hospital-based PHP median costs and the CY 2011 final CMHC median and then adding that number to the CY 2011 final CMHC median. A 2-year transition under this methodology moved us in the direction of our goal, which is to pay appropriately for PHP services based on each provider type's data, while at the same time allowing providers time to adjust their business operations and protect access to care for beneficiaries. We also stated that we would review and analyze the data during the CY 2012 rulemaking cycle and, based on these analyses, we might further refine the payment mechanism. We refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994) for a full discussion.

After publication of the CY 2011 OPPS/ASC final rule with comment period, a CMHC and one of its patients filed an application for a preliminary injunction, challenging the OPPS payment rates for PHP services provided by CMHCs in CY 2011 as adopted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71995). We refer readers to the court case, *Paladin Cmty. Mental Health Ctr.* v. *Sebelius,* No. 10–949, 2011 WL 3102049 (W.D.Tex. 2011), *aff'd,* No. 11–50682, 2012 WL 2161137 (5th Cir. June 15, 2012) (*Paladin*). The plaintiffs in the *Paladin* case challenged the agency's use of cost data derived from both hospitals and CMHCs in determining the relative payment weights for the OPPS payment rates for PHP services furnished by CMHCs, alleging that section 1833(t)(2)(C) of the Act requires that such relative payment weights be based on cost data derived solely from hospitals. As discussed above, section 1833(t)(2)(C) of the Act requires CMS to ''establish relative payment weights for covered OPD services (and any groups of such services . . .) . . . based on . . . hospital costs.'' Numerous courts have held that ''based on'' does not mean ''based exclusively on.'' On July 25, 2011, the District Court dismissed the plaintiffs' complaint and application for a preliminary injunction for lack of subject-matter jurisdiction, which the plaintiffs appealed to the United States Court of Appeals for the Fifth Circuit. On June 15, 2012, the Court of Appeals affirmed the District Court's dismissal for lack of subject-matter jurisdiction and found that the Secretary's payment rate determinations for PHP services are not a facial violation of a clear statutory mandate. (*Paladin* at *6).

For CY 2012, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74348 through 74352), we determined the relative payment weights for PHP services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for hospital-based PHP services based exclusively on hospital data. The statute is reasonably interpreted to allow the relative payment weights for the OPPS payment rates for PHP services provided by CMHCs to be based solely on CMHC data and relative payment weights for hospital-based PHP services to be based exclusively on hospital data. Section 1833(t)(2)(C) of the Act requires the Secretary to ''establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on . . . hospital costs.'' In pertinent part, subparagraph (B) provides that ''the Secretary may establish groups of covered OPD services . . . so that services classified within each group are comparable clinically and with respect to the use of resources.'' In accordance with subparagraph (B), we developed the PHP APCs, as set forth in § 419.31 of the regulations (65 FR 18446 and 18447; 63 FR 47559 through 47562 and 47567 through 47569). As discussed above, PHP services are grouped into APCs.

Based on section 1833(t)(2)(C) of the Act, we believe that the word ''establish'' can be interpreted as applying to APCs at the inception of the OPPS in 2000 or whenever a new APC is added to the OPPS. In creating the original APC for PHP services (APC 0033), we did ''establish'' the initial relative payment weight for PHP services, provided in both hospital-based and CMHC-based settings, only on the basis of hospital data. Subsequently, from CY 2003 through CY 2008, the relative payment weights for PHP services were based on a combination of hospital and CMHC data. For CY 2009, we established new APCs for PHP services based exclusively on hospital data. Specifically, we adopted a two-tiered APC methodology (in lieu of the original APC 0033) under which CMS paid one rate for days with 3 services (APC 0172) and a different payment rate for days with 4 or more services (APC 0173). These two new APCs were established using only hospital data. For CY 2011, we added two new APCs (APCs 0175 and 0176) for PHP services provided by hospitals and based the relative payment weights for these APCs solely on hospital data. APCs 0172 and 0173 were designated for PHP services provided by CMHCs and were based on a mixture of hospital and CMHC data. As the Secretary argued in the *Paladin* case, the courts have consistently held that the phrase ''based on'' does not mean ''based exclusively on.'' Thus, the relative payment weights for the two APCs for PHP services provided by CMHCs in CY 2011 were ''based on'' hospital data, no less than the relative payment weights for the two APCs for hospital-based PHP services.

Although we used hospital data to establish the relative payment weights for APCs 0033, 0172, 0173, 0175, and 0176 for PHP services, we believe that

we have the authority to discontinue the use of hospital data in determining the OPPS relative payment weights for PHP services provided by CMHCs. Other parts of section 1833(t)(2)(C) of the Act make plain that the data source for the relative payment weights is subject to change from one period to another. Section 1833(t)(2)(C) of the Act provides that, in establishing the relative payment weights, ''the Secretary shall [ ] us[e] data on claims from 1996 and us[e] data from the most recent available cost reports.'' We used 1996 data (in addition to 1997 data) in determining only the original relative payment weights for 2000. In the ensuing calendar year updates, we continually used more recent cost report data.

Moreover, section 1833(t)(9)(A) of the Act requires the Secretary to ''review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.'' For purposes of the CY 2012 update, we exercised our authority under section 1833(t)(9)(A) of the Act to change the data source for the relative payment weights for PHP services provided by CMHCs based on ''new cost data, and other relevant information and factors.''

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs, on geometric means rather than on the medians. For CY 2013, we established the four PHP APC per diem payment rates based on geometric mean cost levels calculated using the most recent claims data for each provider type. We refer readers to the CY 2013 OPPS/ASC final rule with comment period for a more detailed discussion (77 FR 68406 through 68412).

B. Proposed PHP APC Update for CY 2014

For CY 2014, we are proposing to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. We computed proposed CMHC PHP APC geometric mean per diem costs for Level I (3 services per day) and Level II (4 or more services per day) PHP services using only CY 2012 CMHC claims data, and proposed hospital-based PHP APC geometric mean per diem costs for Level I and Level II PHP services using only CY 2012 hospital-based PHP claims data. These proposed geometric mean per diem costs are shown in Table 30 below.

TABLE 30—PROPOSED CY 2014 GEOMETRIC MEAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHP SERVICES, BASED ON CY 2012 CLAIMS DATA

APC	Group title	Proposed geometric mean per diem costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$94.51
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	106.20
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	212.85
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	215.13

For CY 2014, the proposed geometric mean per diem costs for days with 3 services (Level I) is approximately $94.51 for CMHCs and approximately $212.85 for hospital-based PHPs. The proposed geometric mean per diem costs for days with 4 or more services (Level II) is approximately $106.20 for CMHCs and approximately $215.13 for hospital-based PHPs. Therefore, the proposed geometric mean per diem costs for CMHCs continue to be substantially lower than the proposed geometric mean per diem costs for hospital-based PHPs for the same level of service provided, which indicates that there continues to be fundamental differences between the cost structures of CMHCs and hospital-based PHPs.

The CY 2014 proposed geometric mean per diem costs for CMHCs calculated under the proposed CY 2014 methodology using CY 2012 claims data have remained relatively constant when compared to the CY 2013 final geometric mean per diem costs for CMHCs established in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68412), with proposed geometric mean per diem costs for Level I PHP services increasing from approximately $87 to approximately $95 for CY 2014, and proposed geometric mean per diem costs for Level II PHP services decreasing from approximately $113 to approximately $106 for CY 2014.

The CY 2014 proposed geometric mean per diem costs for hospital-based PHPs calculated under the proposed CY 2014 methodology using CY 2012 claims data show more variation when compared to the CY 2013 final geometric mean per diem costs for hospital-based PHPs, with proposed geometric mean per diem costs for Level I PHP services increasing from approximately $186 to approximately $213 for CY 2014, and proposed geometric mean per diem costs for Level II PHP services decreasing from approximately $235 to approximately $215 for CY 2014.

In summary, the proposed CY 2014 geometric mean per diem costs for the PHP APCs are shown in Tables 31 and 32 below. We are inviting public comments on these proposals.

TABLE 31—PROPOSED CY 2014 GEOMETRIC MEAN PER DIEM COSTS FOR CMHC PHP SERVICES

APC	Group title	Proposed geometric mean per diem costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$94.51
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	106.20

TABLE 32—PROPOSED CY 2014 GEOMETRIC MEAN PER DIEM COSTS FOR HOSPITAL-BASED PHP SERVICES

APC	Group title	Proposed geometric mean per diem costs
0175	Level I Partial Hospitalization (3 services) for Hospital-based PHPs	$212.85
0176	Level II Partial Hospitalization (4 or more services) for Hospital-based PHPs	215.13

C. Discussion of Possible Future Initiatives and Request for Public Comments

We are considering a number of possible future initiatives that may help to ensure the long-term stability of PHPs and further improve the accuracy of payment for PHP services. Along with our broad, ongoing objectives of ensuring stability of the PHP benefit and promoting payment accuracy for PHPs, we want to ensure that PHPs are used by individuals who are specifically in need of such services. The PHP benefit was designed to assist individuals with an acute exacerbation of a psychiatric illness to manage debilitating symptoms and prevent the need for admission and readmission into hospitals. Accordingly, we are considering a number of possible future modifications to certain aspects of the PHP benefit. We are not proposing new Medicare policy in this discussion of possible future modifications. Instead, we are requesting public comments on possible future initiatives.

Under the current methodology, we use the most recent claims data to compute geometric mean per diem costs for Level I (3 services per day) and Level II (4 or more services per day) PHP services for CMHCs and for hospital-based PHPs. We are interested in examining the payment structure for PHP services to determine alternative methodologies to pay for PHP services that would reduce unnecessary care while maintaining or increasing the quality of care. We are inviting public comments on alternative payment methodologies.

One of the areas on which we would like to receive public comments is whether payment based on an episode of care, or a per diem similar to the inpatient psychiatric facility (IPF) PPS, would result in more appropriate payment for PHP services than the current payment structure. The IPF PPS is a per diem prospective payment system for inpatient psychiatric hospital services furnished in psychiatric hospitals, and psychiatric units in acute care hospitals and critical access hospitals. The IPF PPS base rate is adjusted to account for patient and facility characteristics that contribute to higher costs per day, including age, diagnosis-related group assignment, comorbidities, days of the stay, geographic wage area, rural location, teaching status, cost of living for IPFs located in Alaska and Hawaii, and the presence of a qualifying emergency department. The IPF PPS methodology includes a payment provision for interrupted stays, additional payment for outlier cases, and a per treatment payment for electroconvulsive therapy (ECT) treatments. For detailed information regarding the implementation of the IPF PPS, we refer readers to the FY 2005 IPF PPS final rule published in the **Federal Register** on November 15, 2004 (69 FR 66922). To find additional information about the IPF PPS, we refer readers to the CMS Web site at: *http://www.cms.hhs.gov/inpatientpsychfacilpps*.

Another area on which we would like to receive public comments is on physician certification/recertification that the individual would require inpatient psychiatric care in the absence of PHP services. In order for a hospital or CMHC to be paid for partial hospitalization services on behalf of a Medicare beneficiary, a physician must certify (and recertify when such services are furnished over a period of time), among other things, that the individual would require inpatient psychiatric care in the absence of such services. In addition, an individualized written plan of treatment for furnishing such services must be established and reviewed periodically by a physician, and such services must be furnished while the individual is under the care of a physician (We refer readers to 42 CFR 424.24(e)).

Currently, the recertification requirements specify that the physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment. The recertification is required as of the 18th day of partial hospitalization services. Subsequent recertifications are required at intervals established by the provider, but no less frequently than every 30 days. We are inviting public comments on whether the current requirement under § 424.24(e)(3)(ii) of the regulations, which requires the first recertification by the physician to be as of the 18th day of partial hospitalization services, reflects current PHP treatment practices. Specifically, we are interested in whether the first recertification date should be changed to some other standard that accords with best practices and why.

With respect to the individualized written plan of treatment for furnishing partial hospitalization services, as discussed above, a physician must establish and periodically review the written plan of treatment. The written plan of treatment sets forth the physician's diagnosis, the type, amount, duration, and frequency of the services, and the treatment goals under the written plan. The physician determines the frequency and duration of the PHP services taking into account accepted norms of medical practice and a reasonable expectation of improvement in the patient's condition. (We refer readers to § 424.24(e)(2) of the regulations.) We are interested in what requirements should be included in the written plan of treatment to better direct PHP resources toward appropriate discharge and follow-up with appropriate support services. Specifically, we are inviting public comments on two issues: (1) The best way that discharge from a PHP be expedited for those individuals no longer at risk of inpatient psychiatric hospitalization; and (2) whether the written plan of treatment requirements under § 424.24(e)(2)(i)(C), which require that the written plan of treatment set forth the treatment goals, should be revised to require that specific actions be taken by the physician and/or staff to assist a beneficiary in transitioning from a PHP to a lower level of care. For example, we are interested in whether the written plan of treatment should require that, upon discharge, patients have written instructions that include:

- A full list of their medications, dosages and any necessary prescriptions;
- Their next scheduled appointment with a psychiatrist or qualified practitioner who may bill for his or her professional services under Medicare Part B, including the phone number,

address, and appointment date and time;

- Confirmed place to live in a stable environment with support services; and
- Other care coordination information.

We also are interested in receiving public feedback about quality measures for a PHP. Quality health care is a high priority for CMS. We implement quality initiatives to ensure quality health care for Medicare beneficiaries through accountability and public disclosure. We use quality measures under various quality initiatives, which utilize pay-for-reporting and public reporting mechanisms. We are requesting public comments on quality measures for PHP services for future consideration. Specifically, if we were to establish quality measures for PHP services and require quality data reporting, what should be included in those measures? In addition, should the quality measures be similar or identical to those measures established for IPFs under the IPF Quality Reporting (IPFQR) Program?

We would appreciate feedback on all of these areas for future consideration. Therefore, we are inviting public comments on these issues.

D. Proposed Separate Threshold for Outlier Payments to CMHCs

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), after examining the costs, charges, and outlier payments for CMHCs, we believed that establishing a separate OPPS outlier policy for CMHCs would be appropriate. A CMHC-specific outlier policy would direct OPPS outlier payments towards genuine cost of outlier cases, and address situations where charges were being artificially increased to enhance outlier payments. We created a separate outlier policy that would be specific to the estimated costs and OPPS payments provided to CMHCs. We note that, in the CY 2009 OPPS/ASC final rule with comment period, we established an outlier reconciliation policy to comprehensively address charging aberrations related to OPPS outlier payments (73 FR 68594 through 68599). Therefore, beginning for CY 2004, we designated a portion of the estimated OPPS outlier target amount specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs.

The separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004, and $0.5 million in outlier payments to CMHCs in CY 2005. In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments. We believe that this difference in outlier payments indicates that the separate outlier threshold for CMHCs has been successful in keeping outlier payments to CMHCs in line with the percentage of OPPS payments made to CMHCs.

In this CY 2014 OPPS/ASC proposed rule, we are proposing to continue designating a portion of the estimated 1.0 percent outlier target amount specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS in CY 2014, excluding outlier payments. CMHCs are projected to receive 0.18 percent of total OPPS payments in CY 2014, excluding outlier payments. Therefore, we are proposing to designate 0.0018 percent of the estimated 1.0 percent outlier target amount for CMHCs, and establish a threshold to achieve that level of outlier payments. Based on our simulations of CMHC payments for CY 2014, we are proposing to continue to set the threshold for CY 2014 at 3.40 times the highest CMHC PHP APC payment rate (that is, APC 0173 (Level II Partial Hospitalization)). We continue to believe that this approach would neutralize the impact of inflated CMHC charges on outlier payments and better target outlier payments to those truly exceptionally high-cost cases that might otherwise limit beneficiary access. In addition, we are proposing to continue to apply the same outlier payment percentage that applies to hospitals. Therefore, for CY 2014, we are proposing to continue to pay 50 percent of CMHC per diem costs over the threshold. In section II.G. of this proposed rule, for the hospital outpatient outlier payment policy, we are proposing to set a dollar threshold in addition to an APC multiplier threshold. Because the PHP APCs are the only APCs for which CMHCs may receive payment under the OPPS, we would not expect to redirect outlier payments by imposing a dollar threshold. Therefore, we are not proposing to set a dollar threshold for CMHC outlier payments.

In summary, we are proposing to establish that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment rate for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. We are inviting public comments on these proposals.

IX. Proposed Procedures That Would Be Paid Only as Inpatient Procedures

A. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full historical discussion of our longstanding policies on how we identify procedures that are typically provided only in an inpatient setting (referred to as the inpatient 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. Proposed Changes to the Inpatient List

For the CY 2014 OPPS, we are proposing to use the same methodology (described in the November 15, 2004 final rule with comment period (69 FR 65835)) of reviewing the current list of procedures on the inpatient list to identify any procedures that may be removed from the list. The established criteria upon which we make such a determination are as follows:

1. Most outpatient departments are equipped to provide the services to the Medicare population.

2. The simplest procedure described by the code may be performed in most outpatient departments.

3. The procedure is related to codes that we have already removed from the inpatient list.

4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.

5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

Using this methodology, we did not identify any procedures that potentially could be removed from the inpatient list for CY 2014. Therefore, we are proposing to not remove any procedures from the inpatient list for CY 2014.

The complete list of codes that we are proposing to be paid by Medicare in CY 2014 only as inpatient procedures is included as Addendum E to this proposed rule (which is available via the Internet on the CMS Web site).

X. Proposed Nonrecurring Policy Changes

A. Supervision of Hospital Outpatient Therapeutic Services

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

In the CY 2009 OPPS/ASC proposed rule and final rule with comment period (73 FR 41518 through 41519 and 73 FR 68702 through 68704, respectively), we clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare in hospitals as well as in provider-based departments of hospitals, as set forth in the CY 2000 OPPS final rule with comment period (65 FR 18525). In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60575 through 60591), we finalized a technical correction to the title and text of the applicable regulations at 42 CFR 410.27 to clarify that this standard applies in CAHs as well as hospitals. In response to concerns expressed by the hospital community, in particular CAHs and small rural hospitals, that they would have difficulty meeting this standard, on March 15, 2010, we instructed all Medicare contractors not to evaluate or enforce the supervision requirements for therapeutic services provided to outpatients in CAHs from January 1, 2010 through December 31, 2010, while the agency revisited the supervision policy during the CY 2011 OPPS/ASC rulemaking cycle.

Due to continued concerns expressed by CAHs and small rural hospitals, we extended this notice of nonenforcement (''enforcement instruction'') as an interim measure for CY 2011, and expanded it to apply to small rural hospitals having 100 or fewer beds (75 FR 72007). We continued to consider the issue further in our annual OPPS notice-and-comment rulemaking, and implemented an independent review process to obtain advice from the Hospital Outpatient Payment Panel (the Panel) on this matter (76 FR 74360 through 74371). Under this process used since CY 2012, the Panel considers and advises CMS regarding stakeholder requests for changes in the required level of supervision of individual hospital outpatient therapeutic services. We extended the enforcement instruction the past 2 years (through CY 2012 and CY 2013) to provide hospitals with adequate opportunity to become familiar with the new independent review process and submit evaluation requests, and to meet the required supervision levels for all hospital outpatient therapeutic services (we refer readers to 76 FR 74371 and 77 FR 68425). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68426), we stated that we expect CY 2013 to be the final year that the enforcement instruction would be in effect, as during this year there would be additional opportunities for stakeholders to bring their issues to the Panel, and for the Panel to evaluate and provide us with recommendations on those issues. The current enforcement instruction is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html?redirect=/HospitalOutpatientPPS/01_overview.asp*.

In CY 2012 and CY 2013, the Panel met and considered several requests from CAHs and other stakeholders for changes in the required level of supervision for observation and other services. Based on the Panel's recommendations, we modified our supervision requirements to provide that most of the services considered may be furnished under general supervision, in accordance with applicable Medicare regulations and policies. These decisions are posted on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CY2013-OPPS-General-Supervision.pdf*. We did not receive any requests from stakeholders for evaluation of the supervision levels of any other hospital outpatient therapeutic services at the March 2013 Panel meeting. We continue to believe that direct supervision is the most appropriate level of supervision for most hospital outpatient therapeutic services under the ''incident to'' provisions of section 1861(s)(2)(B) of the Act, as we discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72006). We believe the independent Panel review advisory process has proved an effective means for the hospital community to identify hospital outpatient therapeutic services that can safely be furnished under general supervision, where the supervising practitioner does not have to be immediately available in person to provide assistance and direction. We encourage hospitals to continue using the Panel process for bringing services to CMS' attention that may not require the immediate availability of a supervising practitioner, especially where it is possible to reduce the burden on the workforce available to small rural hospitals and CAHs while ensuring the quality and safety of patient care. We encourage hospitals and CAHs to continue using the established Panel process to request changes they believe would be appropriate in supervision levels for individual hospital outpatient therapeutic services. Instructions for submitting evaluation requests are available on the Panel Web site at *http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*).

We believe it is appropriate to allow the enforcement instruction to expire at the end of CY 2013, to ensure the quality and safety of hospital and CAH outpatient therapeutic services paid by Medicare. For CY 2014, we anticipate allowing the enforcement instruction to expire, such that all outpatient therapeutic services furnished in hospitals and CAHs would require a minimum of direct supervision unless the service is on the list of services that may be furnished under general supervision or is designated as a nonsurgical extended duration therapeutic service (the list of services is available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CY2013-OPPS-General-Supervision.pdf*). We are interested in receiving public comments on any potential impacts on access to care and quality of care for specific services that may result from allowing the enforcement instruction to expire at the end of CY 2013. We are requesting public comments on specific services for which CAHs and small rural hospitals anticipate difficulty furnishing the required direct supervision, including specific factors that may contribute to the lack of available staff.

2. Supervision Requirements for Observation Services

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71999 through 72013), we revised the supervision requirements for observation services furnished in the hospital by designating observation services (HCPCS codes G0378 (Hospital observation services, per hour) and G0379 (Direct admission of patient for observation care)) as nonsurgical extended duration therapeutic services (''extended duration services''). As we provided in the CY 2011 OPPS/ASC final rule with comment period and 42 CFR 410.27(a)(1)(iv)(E), extended duration services require direct supervision at the initiation of the service, which may be followed by general supervision for the remainder of

the service at the discretion of the supervising physician or appropriate nonphysician practitioner, once that practitioner has determined that the patient is stable. The determination by the supervising physician or appropriate nonphysician practitioner that the beneficiary is stable and may be transitioned to general supervision must be documented in progress notes or in the medical record (75 FR 72011).

Since we designated observation services as extended duration services, we have received several inquiries from stakeholders regarding whether Medicare requires multiple evaluations of the beneficiary during the provision of observation services. Specifically, stakeholders asked whether, once the supervising physician or appropriate nonphysician practitioner transitions the beneficiary to general supervision and documents the transition in the medical record, Medicare require further assessment of the beneficiary either per hour (because observation services are billed per hour) or at some other point during provision of the service. We are clarifying that, for observation services, if the supervising physician or appropriate nonphysician practitioner determines and documents in the medical record that the beneficiary is stable and may be transitioned to general supervision, general supervision may be furnished for the duration of the service. Medicare does not require an additional initiation period(s) of direct supervision during the service. We believe that this clarification will assist hospitals in furnishing the required supervision of observation services without undue burden on their staff.

B. Application of Therapy Caps in CAHs

For outpatient physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP) (collectively, ''outpatient therapy'') services covered under Medicare Part B, section 1833(g) of the Act applies annual, per beneficiary limitations on incurred expenses, commonly referred to as ''therapy caps.'' There is one therapy cap for OT services and another separate therapy cap for PT and SLP services combined. In the CY 2014 Medicare Physician Fee Schedule (MPFS) proposed rule, we are proposing to subject outpatient therapy services that are furnished by a CAH to the therapy caps, the exceptions process, and the manual medical review process beginning on January 1, 2014. The American Taxpayer Relief Act of 2012 (Pub. L. 112–240) required that therapy services furnished by a CAH during 2013 are counted toward the therapy caps using the MPFS rate, and we are proposing to continue this methodology for 2014 and subsequent years. CAHs would still be paid for therapy services under the reasonable cost methodology for CAH outpatient services described at section 1834(g) of the Act. We refer readers to the CY 2014 MPFS proposed rule for detailed information about the proposed application of the therapy caps and related provisions to CAHs. We are including in this CY 2014 OPPS/ASC proposed rule a reference to this proposal as an additional means to direct CAHs' attention to our proposal in the CY 2014 MPFS proposed rule. We refer readers to the CY 2014 MPFS proposed rule for instructions for submitting public comments related to this proposal to apply the therapy cap to services furnished by CAHs. We look forward to reviewing the comments on this proposal.

C. Requirements for Payment of Outpatient Therapeutic (''Incident To'') Hospital or CAH Services

1. Overview

In this section, we are proposing to amend the Medicare conditions of payment for therapeutic outpatient hospital or CAH services and supplies furnished ''incident to'' a physician's or nonphysician practitioner's service (which we refer to as hospital or CAH outpatient therapeutic services) to require that individuals furnishing these services do so in compliance with applicable State law. Under current policy, we generally defer to hospitals to ensure that State scope of practice and other State rules relating to health care delivery are followed, such that these services are performed only by qualified personnel in accordance with all applicable laws and regulations. We are proposing to revise the existing regulations to explicitly require that individuals who perform hospital or CAH outpatient therapeutic services must do so in compliance with applicable State laws and regulations as a condition of payment under Medicare Part B. In this section of this proposed rule, we are using the term ''hospital'' to include a CAH unless otherwise specified. Although the term ''hospital'' does not generally include a CAH, section 1861(e) of the Act provides that the term ''hospital'' includes a CAH if the context otherwise requires. We believe it would be appropriate to apply our proposed policy regarding compliance with applicable State law, as we do for other conditions of payment for hospital outpatient therapeutic services, to CAHs as well as other hospitals.

2. Background

Section 1861(s)(2)(B) of the Act establishes the benefit category for hospital ''incident to'' medical and other health services, which are paid under Medicare Part B. The statute specifies that ''incident to'' services are ''hospital services (including drugs and biological which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services.'' In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74369 through 74370), we clarified that Medicare defines these services as hospital outpatient therapeutic services, which are, according to our policy, furnished ''incident to'' a physician's service even when described by benefit categories other than the specific ''incident to'' provision in section 1861(s)(2)(B) of the Act (for example, radiation therapy services described under section 1861(s)(4) of the Act). Because hospital outpatient therapeutic services are furnished ''incident to'' a physician's professional service, we believe the conditions of payment that derive from the ''incident to'' nature of the services paid under section 1861(s)(2)(B) of the Act apply to all hospital outpatient therapeutic services, including those described under benefit categories other the specific ''incident to'' provision in section 1861(s)(2)(B) of the Act.

In addition to the requirements of the statute, the regulation at 42 CFR 410.27 sets forth specific requirements that must be met in order for hospital to be paid under Medicare Part B for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service (hospital or CAH outpatient therapeutic services). Section 410.27 describes hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's services as therapeutic services and provides the conditions of payment. Specifically, § 410.27(a) provides that Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service. These are defined, in part, as all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals that cannot be self-administered, if they are furnished—

- By or under arrangements made by the participating hospital or CAH,

except in the case of a SNF resident as provided in 42 CFR 411.15(p);

- As an integral although incidental part of a physician's or nonphysician practitioner's services;
- In the hospital or CAH or in a department of the hospital or CAH, as defined in 42 CFR 413.65 [a provider-based department]; and
- Under the direct supervision (or other level of supervision as specified by CMS for the particular service) of a physician or a nonphysician practitioner. For purposes of this section, ''nonphysician practitioner,'' as defined in § 410.27(g), means a clinical psychologist, licensed clinical social worker, physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse-midwife.

Sections 410.27(b) through (f) provide additional conditions of payment for partial hospitalization services, drugs and biologicals, emergency services, and services furnished by an entity other than the hospital (or CAH). We commonly refer to the services described in § 410.27 as ''incident to'' services.

In recent years, we have discussed and refined the supervision regulations under § 410.27, which are conditions of Medicare Part B payment for hospital outpatient ''incident to'' (''therapeutic'') services. For example, we have discussed our belief that direct supervision is the most appropriate level of supervision for most of these services, unless personal supervision or personal performance of the services by the physician or nonphysician practitioner is more appropriate, given the incident to nature of the services as an integral although incidental part of a physician's or nonphysician practitioner's services (74 FR 60584, 75 FR 72006, and 76 FR 42281). We have stated our historical interpretation of section 1861(s)(2)(B) of the Act, specifically, that ''incident to'' services are furnished under the order of a physician (or nonphysician practitioner), the physician is involved in the management of the patient, and the physician supervises the provision of those services when he or she does not provide them directly (75 FR 72006). This is reflected in our requirement for a minimum of direct supervision, except for a limited set of services that may be furnished under general supervision or are designated as nonsurgical extended duration therapeutic services which require direct supervision initially with potential transition to general supervision (we refer readers to the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CY2013-OPPS-General-Supervision.pdf*).

In 42 CFR 410.27(a)(1)(iv), we regulate the qualifications of physicians and nonphysician practitioners supervising other personnel that are personally performing a service, or part of a service: ''(C) Nonphysician practitioners may provide the required supervision of services that they may personally furnish in accordance with State law and all additional requirements, including those specified in §§ 410.71, 410.73, 410.74, 410.75, 410.76, and 410.77'' and ''(D) For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§ 410.47 and 410.49, respectively.''

Similarly, we provide in the Medicare Benefit Policy Manual (MBPM, Pub. 100–02) that hospital outpatient therapeutic services and supplies must be furnished under the order of a physician or other practitioner practicing within the extent of the Act, the Code of Federal Regulations, and State law (Chapter 6, Section 20.5.2 of the MBPM). Section 20.5.2 of the MBPM specifies that the services must be furnished by hospital personnel under the appropriate supervision of a physician or nonphysician practitioner in accordance with 42 CFR 410.27 and 482.12. This does not mean that each occasion of service by a nonphysician need also be the occasion of the actual rendition of a personal professional service by the physician responsible for care of the patient. However, during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, when necessary, to change the treatment regimen. A hospital service or supply would not be considered incident to a physician's service if the attending physician merely wrote an order for the services or supplies and referred the patient to the hospital without being involved in the management of that course of treatment.

Central to the issue of services that hospitals may bill to Medicare that are not performed personally by the physician is the assessment of the qualifications of the individuals to whom the services are delegated. As medical practice has evolved over time, the services performed in the hospital outpatient setting have expanded to include more complicated services such as advanced surgery and a complex variety of radiation therapy. In addition, the types of services that can be furnished ''incident to'' a physician's or nonphysician practitioner's services have increased. Under current Medicare Part B payment policy, we generally defer to hospitals to ensure that State scope of practice laws are followed and that the personnel who furnish hospital outpatient therapeutic (''incident to'') services are licensed and are otherwise qualified to do so. Specifically, we have stated that, considering that hospitals furnish a wide array of complex outpatient services and procedures, including surgical procedures, we would expect that hospitals have the credentialing procedures, bylaws, and other policies in place to ensure that hospital outpatient services furnished to Medicare beneficiaries are being provided only by qualified practitioners in accordance with all applicable laws and regulations (74 FR 60584; Chapter 6, Section 20.5.4 of the MBPM). However, our payment regulations do not contain restrictions on the types of auxiliary personnel that can perform hospital outpatient therapeutic (''incident to'') services, other than rules relating to supervision by a physician or qualified nonphysician practitioner, and do not specifically require that performance of these services be in compliance with applicable State law. Over the past years, several situations have come to our attention where Medicare was billed for ''incident to'' services that were performed by an individual who did not meet the State standards for those services in the State in which services were performed. The physician or nonphysician practitioner billing for the services would have been permitted under State law to personally furnish the services, but the services were actually provided by other individuals who were not in compliance with State law in providing the particular services (or aspect of the services).

Although we would expect that all hospital services for which Medicare payment is made would be furnished in accordance with State law, the Medicare requirements for hospital outpatient therapeutic services and supplies incident to a physician's services (§ 410.27, discussed above) do not specifically make compliance with State law a condition of payment for services (or aspects of services) and supplies furnished and billed as ''incident to'' services. Nor do any of the regulations regarding hospital outpatient therapeutic services and supplies incident to the services of nonphysician practitioners contain this requirement.

Thus, Medicare has had limited recourse when hospital outpatient therapeutic (''incident to'') services are not furnished in compliance with State law.

In 2009, the Office of the Inspector General (OIG) issued a report entitled ''Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services'' (OEI–09–06–00430) that considered, in part, the qualifications of auxiliary personnel providing ''incident to'' physician services. After finding that services were being provided and billed to Medicare by auxiliary personnel ''. . . who did not possess the required licenses or certifications according to State laws, regulations, and/or Medicare rules,'' the OIG recommended that we revise the ''incident to'' rules to, among other things, ''require that physicians who do not personally perform the services they bill to Medicare ensure that no persons except . . . nonphysicians who have the necessary training, certification, and/or licensure pursuant to State laws, State regulations, and Medicare regulations personally perform the services under the direct supervision of a licensed physician.'' We are proposing amendments to our regulations in order to address this recommendation.

To ensure that the practitioners and other personnel providing hospital outpatient therapeutic services to Medicare beneficiaries incident to a physician's or nonphysician practitioner's service do so in accordance with the requirements of the State in which the services are furnished, and to ensure that Medicare payments can be recovered when such services are not furnished in compliance with the State law, we are proposing to add a new condition of payment to the ''incident to'' regulations at § 410.27, Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions. Specifically, we are proposing to add a provision under a new paragraph (a)(1)(vi) under § 410.27 to provide that ''Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service . . . if they are furnished ''In accordance with applicable State law.'' The proposed policy would recognize the role of States in establishing the licensure and other qualifications of physicians and other health care professionals for the delivery of hospital (or CAH) outpatient therapeutic services.

This proposal is consistent with other areas of the Medicare program where CMS defers to State rules regarding the delivery of hospital services. For example, the hospital conditions of participation (CoPs) at 42 CFR 482.12(c)(2) defer to State law in determining who can admit patients as inpatients of a hospital: ''Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital.'' The CoP also provides that, ''If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section (that lists practitioners that must care for Medicare patients), that patient is under the care of a doctor of medicine or osteopathy.'' Thus, in determining who may admit inpatients to a hospital, Medicare defers to State law rules. Also, as we stated in a recent rule addressing credentialing and privileging and telemedicine services under the CoPs (77 FR 29047): ''CMS recognizes that practitioner licensure laws and regulations have traditionally been, and continue to be, the provenance of individual States, and we are not seeking to preempt State authority in this matter.'' We believe it is appropriate to similarly require that all hospital outpatient services furnished incident to a physician's or nonphysician practitioner's services be furnished in accordance with State law requirements. As evidenced by these examples, throughout the Medicare program the qualifications required for the delivery of health care services are generally determined with reference to State law. In addition to the health and safety benefits we believe would accrue to the Medicare patient population, this approach would assure that Federal dollars are not expended for services that do not meet the standards of the States in which they are being furnished, and provides the ability for the Federal government to recover funds paid where services and supplies are not furnished in accordance with State law.

This proposal would not impose any new requirements on hospitals billing the Medicare program because practitioners and other personnel furnishing services in a given State would already be required to comply with the laws of that State. This regulatory change would simply adopt the existing requirements as a condition of payment under Medicare. Codifying this requirement would provide the Federal government with a clear basis to deny a claim for Medicare payment when services are not furnished in accordance with applicable State law, and the ability to recover funds, as well as assure that Medicare pays for services furnished to beneficiaries only when the services meet the requirements imposed by the States to regulate health care delivery for the health and safety of their citizens. We welcome public comments on this proposal.

3. Technical Correction

In our review of § 410.27, we noted that paragraph (a) defines therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service as ''all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals that cannot be self-administered.'' Section 1861(s)(2)(B) of the Act describes these services as ''hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services.'' The statute includes in this benefit category ''drugs and biologicals which are not usually self-administered by the patient.'' We are proposing to make a technical correction that would amend the description of these drugs and biologicals at § 410.27(a) to more appropriately reflect the statutory language. Specifically, we are proposing to delete the phrase ''drugs and biologicals that cannot be self-administered'' and replace it with the phrase ''drugs and biologicals which are not usually self-administered.'' Under this proposed technical correction, the language of § 410.27(a) would read, ''Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service, which are defined as all services and supplies furnished to hopital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals which are not usually self-administered. . . .''

D. Collecting Data on Services Furnished in Off-Campus Provider-Based Departments

In recent years, the research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resultant increase in the delivery of physicians' services in a hospital setting (for example, we refer readers to

Ostrom, Carol M., ''Why you might pay twice for one visit to a doctor,'' *Seattle Times,* November 3, 2012, and O'Malley, Ann, Amelia M. Bond, and Robert Berenson, *Rising hospital employment of physicians: better quality, higher costs?* Issue Brief No. 136, Center for Studying Health System Change, August 2011). When a Medicare beneficiary receives outpatient services in a hospital, the total payment amount for outpatient services made by Medicare is generally higher than the total payment amount made by Medicare when a physician furnishes those same services in a freestanding clinic or in a physician office. As more physician practices become hospital-based, news articles have highlighted beneficiary liability for an additional ''facility fee,'' which is the payment Medicare makes when services are furnished in a hospital in addition to the payment to the physician. MedPAC has questioned the appropriateness of increased Medicare payment and beneficiary cost-sharing when physicians' offices become hospital outpatient departments and has recommended that Medicare pay selected hospital outpatient services at the Medicare Physician Fee Schedule (MPFS) rates (MedPAC March 2012 Report to Congress; ''Addressing Medicare Payment Differences across Settings,'' presentation to the Commission on March 7, 2013).

The total payment (including both Medicare program payment and beneficiary cost-sharing) generally is higher when outpatient services are furnished in the hospital outpatient setting rather than a freestanding clinic or a physician office. Both the OPPS and the MPFS establish payment based on the relative resources involved in furnishing a service. In general, we expect hospitals to have overall higher resource requirements than physician offices because hospitals are required to meet the conditions of participation, to maintain standby capacity for emergency situations, and to be available to address a wide variety of complex medical needs in a community. When services are furnished in the hospital setting such as in off-campus provider-based departments, Medicare pays the physician a lower facility payment under the MPFS, but then also pays the hospital under the OPPS. The beneficiary pays coinsurance for both the physician payment and the hospital outpatient payment. The term ''facility fee'' refers to this additional hospital outpatient payment.

Upon acquisition of a physician practice, hospitals frequently treat the practice locations as off-campus provider-based departments of the hospital and bill Medicare for services furnished at those locations under the OPPS. (For further information on the provider-based regulations at § 413.65, we refer readers to *http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol2/pdf/CFR-2010-title42-vol2-sec413-65.pdf.* Since October 1, 2002, we have not required hospitals to seek from CMS a determination of provider-based status for a facility that is located off campus. We also do not have a formal process for gathering information on the frequency, type, and payment for services furnished in off-campus provider-based departments of the hospital.

In order to better understand the growing trend toward hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments, we are considering collecting information that would allow us to analyze the frequency, type, and payment for services furnished in off-campus provider-based hospital departments. We have considered several potential methods. Claims-based approaches could include creating a HCPCS modifier that could be reported with every code for services furnished in an off-campus provider-based department of a hospital on the CMS–1500 claim form for physician services and the UB–04 (CMS form 1450) for hospital outpatient claims. In addition, we have considered asking hospitals to break out the costs and charges for their provider-based departments as outpatient service cost centers on the Medicare hospital cost report, form 2552–10. We note that some hospitals already break out these costs voluntarily or because of cost reporting requirements for the 340B Drug Discount Program but this practice is not consistent or standardized. We are inviting public comments on the best means for collecting information on the frequency, type, and payment for services furnished in off-campus provider-based departments of hospitals.

XI. Proposed CY 2014 OPPS Payment Status and Comment Indicators

A. Proposed CY 2014 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code. The complete list of the proposed CY 2014 status indicators and their definitions is displayed in Addendum D1 on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* The proposed CY 2014 status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* The proposed changes to CY 2014 status indicators and their definitions are discussed in detail below.

For CY 2014, we are proposing to create a new status indicator ''J1'' to identify HCPCS codes that are paid under a comprehensive APC. A claim with the new proposed status indicator ''J1'' will trigger a comprehensive APC payment for the claim. The comprehensive APCs that we are proposing to establish are described in detail in section II.A.2.e. of this proposed rule.

For CY 2014, we are proposing to delete status indicator ''X'' and assign ancillary services that are currently assigned status indicator ''X'' to either status indicator ''Q1'' or ''S''. First, services that are proposed to be assigned status indicator ''Q1'' include many minor diagnostic tests that are generally ancillary to and performed with another service. However, services that are proposed to be assigned to status indicator ''Q1'' also may be performed alone. Given the nature of these services and their role in hospital outpatient care, we believe that when these services are performed with another service they should be packaged, but that they should be separately paid when performed alone. Therefore, we believe it is appropriate to conditionally package all ancillary services that are currently assigned to status indicator ''X,'' and are proposing to assign them to status indicator ''Q1.'' We also are proposing that preventive services currently assigned status indicator ''X'' continue to receive separate payment in all cases and be assigned status indicator ''S'' for CY 2014. These proposed changes are discussed in greater detail in section II.A.3. of this proposed rule. In addition, we are proposing to revise the definition of status indicator ''Q1'' by removing status indicator ''X'' from the packaging criteria, so that codes assigned status indicator ''Q1'' are STV-packaged, rather than STVX-packaged, because status indicator ''X'' is proposed for deletion.

For CY 2014, we are proposing to revise the definitions of status indicators ''S'' and ''T'' to remove the word ''significant'' from these definitions. It is no longer necessary to distinguish significant procedures from ancillary services because we are proposing to delete the status indicator that describes ancillary services. We also are proposing to add the word ''service'' to the definitions of status indicators ''S'' and ''T'' to indicate ''procedure or service; not discounted when multiple,'' as applicable to status indicator ''S'' and ''procedure or service; multiple reduction applies,'' as applicable to status indicator ''T.''

In addition, we are proposing to update the definition of status indicator ''A'' for CY 2014. We are proposing to remove ''Routine Dialysis Services for ESRD Patients Provided in a Certified Dialysis Unit of a Hospital'' from the list of items and services applicable for the definition of status indicator ''A'' because these services are not recognized by OPPS when submitted on an outpatient hospital Part B bill type and are instead assigned to status indicator ''B.''

B. Proposed CY 2014 Comment Indicator Definitions

For the CY 2014 OPPS, we are proposing to use the same two comment indicators that are in effect for the CY 2013 OPPS.

- ''CH''—Active HCPCS codes in current and next calendar year; status indicator and/or APC assignment have changed or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

We are proposing to use the ''CH'' comment indicator in this CY 2014 OPPS/ASC proposed rule to indicate HCPCS codes for which the status indicator or APC assignment, or both, are proposed for change in CY 2014 compared to their assignment as of June 30, 2013. We believe that using the ''CH'' indicator in this proposed rule would facilitate the public's review of the changes that we are proposing for CY 2014. 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 2014 OPPS/ASC final rule with comment period.

We are proposing to use the ''CH'' comment indicator in the CY 2014 OPPS/ASC final rule with comment period to indicate HCPCS codes for which the status indicator or APC assignment, or both, would change in CY 2014 compared to their assignment as of December 31, 2013.

In addition, we are proposing that any existing HCPCS codes with substantial revisions to the code descriptors for CY 2014 compared to the CY 2013 descriptors will be labeled with comment indicator ''NI'' in Addendum B to the CY 2014 OPPS/ASC final rule with comment period. However, in order to receive the comment indicator ''NI,'' the CY 2014 revision to the code descriptor (compared to the CY 2013 descriptor) must be significant such that the new code descriptor describes a new service or procedure for which the OPPS treatment may change. We use comment indicator ''NI'' to indicate that these HCPCS codes will be open for comment as part of the CY 2014 OPPS/ASC final rule with comment period. Like all codes labeled with comment indicator ''NI,'' we will respond to public comments and finalize their OPPS treatment in the CY 2015 OPPS/ASC final rule with comment period.

In accordance with our usual practice, we are proposing that CPT and Level II HCPCS codes that are new for CY 2014 also will be labeled with comment indicator ''NI'' in Addendum B to the CY 2014 OPPS/ASC final rule with comment period.

Only HCPCS codes with comment indicator ''NI'' in the CY 2014 OPPS/ASC final rule with comment period will be subject to comment. HCPCS codes that do not appear with comment indicator ''NI'' in the CY 2014 OPPS/ASC final rule with comment period will not be open to public comment, unless we specifically request additional comments elsewhere in the final rule with comment period.

We believe that the CY 2013 definitions of the OPPS status indicators continue to be appropriate for CY 2014. Therefore, we are proposing to continue to use those definitions without modification for CY 2014. The proposed definitions are listed in Addendum D2 on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

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

A. Background

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

For a detailed discussion of the legislative history and statutory authority related to 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) and the CY 2013 OPPS/ASC final rule with comment period (77 FR 68434 through 68467).

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

Under § 416.2 and § 416.166 of the regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the 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 to be furnished to Medicare beneficiaries in ASCs. We define surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999, as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to ASC covered surgical procedures (72 FR 42478).

In the August 2, 2007 final rule, we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) Brachytherapy sources; (2) certain implantable items that have pass-through status under the OPPS; (3) certain items and services that we

designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. These covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment (72 FR 42495). Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (§ 416.173; 72 FR 42535). In addition, as discussed in detail in section XII.B. of this proposed rule, because we base ASC payment policies for covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, we also provide quarterly update change requests (CRs) for ASC services throughout the year (January, April, July, and October). CMS releases new Level II codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes are recognized on Medicare claims) outside of the formal rulemaking process via these ASC quarterly update CRs. Thus, these quarterly updates are to implement newly created Level II HCPCS and Category III CPT codes for ASC payment and to update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New Category I CPT codes, except vaccine codes, are released only once a year and, therefore, are implemented only through the January quarterly update. New Category I CPT vaccine codes are released twice a year and, therefore, are implemented through the January and July quarterly updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for the process used to update the HCPCS and CPT codes (76 FR 42291).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures (including all procedures newly proposed for removal from the OPPS inpatient list), new procedures, and procedures for which there is revised coding, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

B. Proposed Treatment of New Codes

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

Category I CPT, Category III CPT, and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims: (1) Category I CPT codes, which describe surgical procedures; (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 are proposing to solicit public comments in this CY 2014 OPPS/ASC proposed rule (and respond to those comments in the CY 2014 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2014 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2015 OPPS/ASC final rule with comment period).

We note that we sought public comment in the CY 2013 OPPS/ASC final rule with comment period on the new Category I and III CPT and Level II HCPCS codes that were effective January 1, 2013. We also sought public comment in the CY 2013 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2012. These new codes, with an effective date of October 1, 2012, or January 1, 2013, were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2013 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 2013 OPPS/ASC final rule with comment period. We will respond to public comments and finalize the treatment of these codes under the ASC payment system in the CY 2014 OPPS/ASC final rule with comment period.

2. Proposed Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April 2013 and July 2013 for Which We Are Soliciting Public Comments in This CY 2014 OPPS/ASC Proposed Rule

In the April 2013 and July 2013 CRs, we made effective for April 1, 2013 and July 1, 2013, respectively, a total of nine new Level II HCPCS codes and two new Category III CPT codes that describe covered ASC services that were not addressed in the CY 2013 OPPS/ASC final rule with comment period. In the April 2013 ASC quarterly update (Transmittal 2662, CR 8237, dated March 1, 2013), we added one new surgical Level II HCPCS code and three new drug and biological Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services, respectively. Table 33 below lists the new Level II HCPCS codes that were implemented April 1 2013, along with their proposed payment indicators for CY 2014.

In the July 2013 quarterly update (Transmittal 2717, Change Request 8328, dated May 31, 2013), we added one new surgical Level II HCPCS code to the list of covered surgical procedures and, one new vaccine Level II HCPCS code, and three new drug and biological Level II HCPCS codes to the list of covered ancillary services. Table 34 below lists the new Level II HCPCS codes that were implemented July 1, 2013, along with their proposed payment indicators and proposed ASC payment rates for CY 2014.

We assigned payment indicator ''K2'' (Drugs and biologicals paid separately when provided integral to a surgical

procedure on the ASC list; payment based on OPPS rate) to the six new drug and biological Level II HCPCS codes that are separately paid when provided in ASCs. We assigned payment indicator ''L1'' (Influenza vaccine; pneumococcal vaccine. Packaged item/service; no separate payment made) to the new vaccine Level II HCPCS code and payment indicator ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) to the two new surgical Level II HCPCS codes.

We are soliciting public comment on the proposed CY 2014 ASC payment indicators and payment rates for the covered surgical procedures and covered ancillary services listed in Tables 33 and 34 below. Those HCPCS codes became payable in ASCs, beginning April 1, or July 1, 2013, and are paid at the ASC rates posted for the appropriate calendar quarter on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html.*

The HCPCS codes listed in Table 33 are included in Addenda AA or BB to this proposed rule (which is available via the Internet on the CMS Web site). We note that all ASC addenda are only available via the Internet on the CMS Web site. Because the payment rates associated with the new Level II HCPCS codes that became effective July 1, 2013 (listed in Table 34 of this proposed rule) are not available to us in time for incorporation into the Addenda to this 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 will be included in the appropriate Addendum to the CY 2014 OPPS/ASC final rule with comment period. Thus, the codes implemented by the July 2013 ASC quarterly update CR and their proposed CY 2014 payment rates (based on July 2013 ASP data) that are displayed in Table 34 are not included in Addenda AA or BB to this proposed rule (which is available via the Internet on the CMS Web site). The final list of ASC covered surgical procedures and covered ancillary services and the associated payment weights and payment indicators will be included in Addenda AA or BB to the CY 2014 OPPS/ASC final rule with comment period, consistent with our annual update policy.

We are soliciting public comment on these proposed payment indicators and the proposed payment rates for the new Level II HCPCS codes that were newly recognized as ASC covered surgical procedures or covered ancillary services in April 2013 and July 2013 through the quarterly update CRs, as listed in Tables 33 and 34 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2014 OPPS/ASC final rule with comment period.

TABLE 33—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2013

CY 2013 HCPCS Code	CY 2013 Long descriptor	Proposed CY 2014 payment indicator
C9130	Injection, immune globulin (Bivigam), 500 mg	K2
C9297	Injection, omacetaxine mepesuccinate, 0.01 mg	K2
C9298	Injection, ocriplasmin, 0.125 mg	K2
C9735	Anoscopy; with directed submucosal injection(s), any substance	G2

TABLE 34—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2013

CY 2013 HCPCS Code	CY 2013 Long descriptor	Proposed CY 2014 payment indicator	Proposed CY 2014 payment rate
C9131	Injection, ado-trastuzumab emtansine, 1 mg	K2	$29.40
C9736	Laparoscopy, surgical, radiofrequency ablation of uterine fibroid(s), including intraoperative guidance and monitoring, when performed.	G2	2,010.00
Q2033	Influenza Vaccine, Recombinant Himagglutinin Antigens, for Intramuscular Use (Flublok)	L1	N/A
Q2050*	Injection, Doxorubicin Hydrochloride, Liposomal, Not Otherwise Specified, 10 mg	K2	545.44
Q2051*	Injection, Zoledronic Acid, Not Otherwise Specified, 1 mg	K2	196.42

***Note:** HCPCS code Q2050 replaced code J9002 and HCPCS code Q2051 replaced HCPCS codes J3487 and J3488 beginning July 1, 2013.

Through the July 2013 quarterly update CR, we also implemented ASC payment for two new Category III CPT codes as ASC covered ancillary services, effective July 1, 2013. These codes are listed in Table 35 below, along with their proposed payment indicators and proposed payment rates for CY 2014. Because the payment rates associated with the new Category III CPT codes that became effective for July are not available to us in time for incorporation into the Addenda to this OPPS/ASC proposed rule, our policy is to include the codes, their proposed payment indicators, and proposed payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. The codes listed in Table 35 of this proposed rule and their final payment indicators and rates will be included in Addendum BB to the CY 2014 OPPS/ASC final rule with comment period.

We are proposing to assign payment indicator ''Z2'' (Radiology service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight) to the two new Category III CPT codes implemented in July 2013. ASC covered ancillary services are certain items and services that are integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS. We are soliciting

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 ancillary services in July 2013 through the quarterly update CR, as listed in Table 35 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2014 OPPS/ASC final rule with comment period.

TABLE 35—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2013 AS ASC COVERED ANCILLARY SERVICES

CY 2013 CPT Code	CY 2013 Long descriptor	Proposed CY 2014 payment indicator	Proposed CY 2014 payment rate
0331T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment	Z2	$212.08
0332T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment; with tomographic SPECT.	Z2	212.08

3. Proposed Process for New Level II HCPCS Codes and Category I and III CPT Codes for Which We Will Be Soliciting Public Comments in the CY 2014 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Category I and Category III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January ASC quarterly update CRs. In the past, we also have released new Level II HCPCS codes that are effective October 1 through the October ASC quarterly update CRs and incorporated these new codes in the final rule with comment period updating the ASC payment system for the following calendar year. All of these codes are flagged with comment indicator ''NI'' in Addenda AA and BB to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. The payment indicator and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the OPPS/ASC final rule with comment period, and we respond to these comments in the final rule with comment period for the next calendar year's OPPS/ASC update.

We are proposing to continue this process for CY 2014. Specifically, for CY 2014, we are proposing to include in Addenda AA and BB to the CY 2014 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2014, that would be incorporated in the January 2014 ASC quarterly update CR and the new Level II HCPCS codes, effective October 1, 2013 or January 1, 2014, that would be released by CMS in its October 2013 and January 2014 ASC quarterly update CRs. These codes would be flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2014 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim payment status. Their payment indicators and payment rates, if applicable, would be open to public comment in the CY 2014 OPPS/ASC final rule with comment period and would be finalized in the CY 2015 OPPS/ASC final rule with comment period.

C. Proposed Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Additions to the List of ASC Covered Surgical Procedures

We conducted a review of all HCPCS codes that currently are paid under the OPPS, but not included on the ASC list of covered surgical procedures, to determine if changes in technology and/or medical practice affected the clinical appropriateness of these procedures for the ASC setting. Upon review, we did not identify any procedures that are currently excluded from the ASC list of procedures that met the definition of a covered surgical procedure based on our expectation that they would not pose a significant safety risk to Medicare beneficiaries or would require an overnight stay if performed in ASCs. Therefore, we are not proposing additions to the list of ASC covered surgical procedures for CY 2014.

b. Proposed Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years that we determine are performed predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC list of covered surgical procedures beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated 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) Proposed Changes for CY 2014 to Covered Surgical Procedures Designated as Office-Based

In developing this proposed rule, we followed our policy to annually review and update the surgical procedures for which ASC payment is made and to identify new procedures that may be

appropriate for ASC payment, including their potential designation as office-based. We reviewed CY 2012 volume and utilization data and the clinical characteristics for all surgical procedures that are assigned payment indicator ''G2'' (Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in CY 2013, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2*,'' ''P3*,'' or ''R2*'' in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68444 through 68448).

Our review of the CY 2012 volume and utilization data resulted in our identification of three covered surgical procedures that we believe meet the criteria for designation as office-based. The data indicate that the procedures are performed more than 50 percent of the time in physicians' offices, and our medical advisors believe the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The three CPT codes we are proposing to permanently designate as office-based are listed in Table 36 below.

TABLE 36—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR PERMANENT OFFICE-BASED DESIGNATION FOR CY 2014

CY 2013 CPT Code	CY 2013 Long descriptor	CY 2013 ASC Payment indicator	Proposed CY 2014 ASC payment indicator*
26341	Manipulation, palmar fascial cord (ie, dupuytren's cord), post enzyme injection (eg, collagenase), single cord.	G2	P3
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg	G2	R2
36595	Mechanical removal of pericatheter obstructive material (eg, fibrin sheath) from central venous device via separate venous access.	G2	P3

*Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. According to the statutory formula, current law requires a negative update to the MPFS payment rates for CY 2014. For a discussion of those rates, we refer readers to the CY 2014 MPFS proposed rule.

We invite public comment on this proposal.

We also reviewed CY 2012 volume and utilization data and other information for the eight procedures finalized for temporary office-based status in Table 51 and Table 53 in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68442, 68446 through 68448). Among these eight procedures, there were very few claims data for four procedures: CPT code 0099T (Implantation of intrastromal corneal ring segments); CPT code 0124T (Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication)); CPT code C9800 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies); and CPT code 67229 (Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy). Consequently, we are proposing to maintain their temporary office-based designations for CY 2014.

The volume and utilization data for one procedure that has a temporary office-based designation for CY 2013, CPT code 0227T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)), is sufficient to indicate that this procedure is not performed predominantly in physicians' offices and, therefore, should not be assigned an office-based payment indicator in CY 2014. Consequently, we are proposing to assign payment indicator ''G2'' to this covered surgical procedure code in CY 2014.

The three remaining procedures that have temporary office-based designations for CY 2013 are proposed to be packaged under the OPPS for CY 2014 as discussed in section II.A.3. of this proposed rule. Consequently, we are proposing the assign payment indicator ''N1'' to the following three covered surgical procedure codes in CY 2014:

- CPT code 0226T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed);
- CPT code 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound); and
- CPT code 0300T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; each additional wound (list separately in addition to code for primary procedure)).

The proposed CY 2014 payment indicator designations for the eight procedures that were temporarily designated as office-based in CY 2013 are displayed in Table 37 below. The procedures for which the proposed office-based designations for CY 2014 are temporary also are indicated by asterisks in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 37—PROPOSED CY 2014 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2013 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2013 CPT Code	CY 2013 Long descriptor	CY 2013 ASC payment indicator	Proposed CY 2014 ASC payment indicator**
0099T	Implantation of intrastromal corneal ring segments	R2*	R2*

TABLE 37—PROPOSED CY 2014 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2013 OPPS/ASC FINAL RULE WITH COMMENT PERIOD—Continued

CY 2013 CPT Code	CY 2013 Long descriptor	CY 2013 ASC payment indicator	Proposed CY 2014 ASC payment indicator**
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*	N1
0227T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)	R2*	G2
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound.	R2*	N1
0300T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; each additional wound (list separately in addition to code for primary procedure).	R2*	N1
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies.	R2*	R2*
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy.	R2*	R2*

* If designation is temporary.

** Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. According to the statutory formula, current law requires a negative update to the MPFS payment rates for CY 2014. For a discussion of those rates, we refer readers to the CY 2014 MPFS proposed rule.

We invite public comment on this proposal.

c. ASC Covered Surgical Procedures Proposed to be Designated as Device-Intensive

(1) Background

As discussed in the August 2, 2007 final rule (72 FR 42503 through 42508), we adopted a modified payment methodology for calculating the ASC payment rates for covered surgical procedures that are assigned to the subset of OPPS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS, in order to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures.

(2) Proposed Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2014

As discussed in section II.A.2.e of this proposed rule, for CY 2014, we are proposing to create 29 comprehensive APCs to replace 29 of the most costly device-dependent APCs under the OPPS. We are proposing to define a comprehensive APC as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Because a comprehensive APC would treat all individually reported codes as representing components of the comprehensive service, our OPPS proposal is to make a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We are proposing to apply our standard APC ratesetting methodology to the remaining 10 device-dependent APCs to calculate their CY 2014 OPPS payment rates.

Unlike the OPPS claims processing system that can be configured to make a single payment for the encounter-based comprehensive service whenever a HCPCS code that is assigned to a comprehensive APC appears on the claim, the ASC claims processing system does not allow for this type of conditional packaging. Therefore, we are proposing that all separately paid ancillary services that are provided integral to surgical procedures that map to comprehensive APCs would continue to be separately paid under the ASC payment system instead of being packaged into the payment for the comprehensive APC as under the OPPS. In addition, to avoid duplicate payment for separately paid ancillary services provided integral to the surgical procedure because the OPPS relative weights for comprehensive APCs include costs for ancillary services, we are proposing that the ASC payment rates and device offset amounts for comprehensive APCs would be based on the CY 2014 OPPS relative payments weights that have been calculated using the standard APC ratesetting methodology instead of the relative payment weights that are based on the comprehensive service.

Payment rates for ASC device-intensive procedures are based on a modified payment methodology to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures. Device-intensive procedures are currently defined as those procedures that are assigned to device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS. Because we are proposing to create comprehensive APCs to replace 29 of the 39 device-dependent APCs under the OPPS, we are proposing to define ASC device-intensive procedures as those procedures that are assigned to any APC with a device offset percentage greater than 50 percent based on the standard OPPS APC ratesetting methodology. We are proposing changes to § 416.171(b)(2) to reflect this proposal.

We also are proposing to update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with this modified definition of device-intensive procedures, reflecting the proposed APC assignments of procedures and APC device offset percentages based on the CY 2012 OPPS claims and cost report data available for the proposed rule.

The ASC covered surgical procedures that we are proposing to designate as device-intensive and that would be subject to the device-intensive procedure payment methodology for CY 2014 are listed in Table 38 below. The CPT code, the CPT code short descriptor, the proposed CY 2014 ASC

payment indicator (PI), the proposed CY 2014 OPPS APC assignment, the proposed CY 2014 OPPS APC device offset percentage, and an indication if the full credit/partial credit (FB/FC) device adjustment policy would apply are also listed in Table 38 below. All of these procedures are included in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We invite public comment on this proposal.

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

Our ASC policy with regard to payment for costly devices implanted in ASCs at no cost/full credit or partial credit as set forth in § 416.179 is consistent with the current OPPS policy. The established ASC policy adopts the OPPS policy and reduces payment to ASCs when a specified device is furnished without cost or with full credit or partial credit for the cost of the device for those ASC covered surgical procedures that are assigned to APCs under the OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/ASC final rule with comment period for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices (73 FR 68742 through 68744).

As discussed in section IV.B. of this proposed rule, we are proposing to modify our existing policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Currently under the OPPS, our policy is to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we are proposing to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a replaced device.

Although we are proposing to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, we are proposing to maintain our current ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the actual amount received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we are proposing to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively. We also are proposing to update the list of ASC covered device-intensive procedures that would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2014. Table 38 below displays the ASC covered device-intensive procedures that we are proposing would be subject to the no cost/full credit or partial credit device adjustment policy for CY 2014. Specifically, when a procedure that is listed in Table 38 is subject to the no cost/full credit or partial credit device adjustment policy and is performed to implant a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS ''FB'' modifier on the line with the procedure to implant the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost to the ASC or with full credit. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure being furnished by the ASC.

For partial credit, we are proposing to reduce the payment for implantation procedures listed in Table 38 that are subject to the no cost/full credit or partial credit device adjustment policy by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more of the cost of the new device. The ASC would append the HCPCS ''FC'' modifier to the HCPCS code for a surgical procedure listed in Table 38 that is subject to the no cost/full credit or partial credit device adjustment policy, when the facility receives a partial credit of 50 percent or more of the cost of a device. In order to report that they received a partial credit of 50 percent or more of the cost of a new device, ASCs would have the option of either: (1) Submitting the claim for the device replacement procedure to their Medicare contractor after the procedure's performance but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment once the credit determination is made; or (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more of the cost of the replacement device. Beneficiary coinsurance would continue to be based on the reduced payment amount.

TABLE 38—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE-INTENSIVE DESIGNATION FOR CY 2014, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH WE PROPOSE THAT THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY

CPT Code	Short descriptor	Proposed CY 2014 ASC PI	Proposed CY 2014 OPPS APC	Proposed CY 2014 device-dependent APC offset percent	Proposing that FB/FC policy will apply
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.

TABLE 38—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE-INTENSIVE DESIGNATION FOR CY 2014, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH WE PROPOSE THAT THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY—Continued

CPT Code	Short descriptor	Proposed CY 2014 ASC PI	Proposed CY 2014 OPPS APC	Proposed CY 2014 device-dependent APC offset percent	Proposing that FB/FC policy will apply
27446	Revision of knee joint	J8	0425	59	Yes.
33206	Insert heart pm atrial	J8	0089	68	Yes.
33207	Insert heart pm ventricular	J8	0089	68	Yes.
33208	Insrt heart pm atrial & vent	J8	0655	72	Yes.
33212	Insert pulse gen sngl lead	J8	0090	67	Yes.
33213	Insert pulse gen dual leads	J8	0654	69	Yes.
33214	Upgrade of pacemaker system	J8	0655	72	Yes.
33221	Insert pulse gen mult leads	J8	0654	69	Yes.
33224	Insert pacing lead & connect	J8	0655	72	Yes.
33227	Remove&replace pm gen singl	J8	0090	67	Yes.
33228	Remv&replc pm gen dual lead	J8	0654	69	Yes.
33229	Remv&replc pm gen mult leads	J8	0654	69	Yes.
33230	Insrt pulse gen w/dual leads	J8	0107	80	Yes.
33231	Insrt pulse gen w/mult leads	J8	0107	80	Yes.
33240	Insrt pulse gen w/singl lead	J8	0107	80	Yes.
33249	Nsert pace-defib w/lead	J8	0108	82	Yes.
33262	Remv&replc cvd gen sing lead	J8	0107	80	Yes.
33263	Remv&replc cvd gen dual lead	J8	0107	80	Yes.
33264	Remv&replc cvd gen mult lead	J8	0107	80	Yes.
33282	Implant pat-active ht record	J8	0680	74	Yes.
37227	Fem/popl revasc stnt & ather	J8	0319	52	No
37231	Tib/per revasc stent & ather	J8	0319	52	No
53440	Male sling procedure	J8	0385	63	Yes.
53444	Insert tandem cuff	J8	0385	63	Yes.
53445	Insert uro/ves nck sphincter	J8	0386	70	Yes.
53447	Remove/replace ur sphincter	J8	0386	70	Yes.
54400	Insert semi-rigid prosthesis	J8	0385	63	Yes.
54401	Insert self-contd prosthesis	J8	0386	70	Yes.
54405	Insert multi-comp penis pros	J8	0386	70	Yes.
54410	Remove/replace penis prosth	J8	0386	70	Yes.
54416	Remv/repl penis contain pros	J8	0386	70	Yes.
55873	Cryoablate prostate	J8	0674	55	No
61885	Insrt/redo neurostim 1 array	J8	0039	86	Yes.
61886	Implant neurostim arrays	J8	0315	88	Yes.
62361	Implant spine infusion pump	J8	0227	81	Yes.
62362	Implant spine infusion pump	J8	0227	81	Yes.
63650	Implant neuroelectrodes	J8	0040	54	Yes.
63655	Implant neuroelectrodes	J8	0061	65	Yes.
63663	Revise spine eltrd perq aray	J8	0040	54	Yes.
63664	Revise spine eltrd plate	J8	0040	54	Yes.
63685	Insrt/redo spine n generator	J8	0039	86	Yes.
64553	Implant neuroelectrodes	J8	0040	54	Yes.
64555	Implant neuroelectrodes	J8	0040	54	Yes.
64561	Implant neuroelectrodes	J8	0040	54	Yes.
64565	Implant neuroelectrodes	J8	0040	54	Yes.
64568	Inc for vagus n elect impl	J8	0318	87	Yes.
64569	Revise/repl vagus n eltrd	J8	0040	54	Yes.
64575	Implant neuroelectrodes	J8	0061	65	Yes.
64580	Implant neuroelectrodes	J8	0061	65	Yes.
64581	Implant neuroelectrodes	J8	0061	65	Yes.
64590	Insrt/redo pn/gastr stimul	J8	0039	86	Yes.
65770	Revise cornea with implant	J8	0293	64	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.
0282T	Periph field stimul trial	J8	0040	54	Yes.
0283T	Periph field stimul perm	J8	0318	87	Yes.
0308T	Insj ocular telescope prosth	J8	0351	85	Yes.
0316T	Replc vagus nerve pls gen	J8	0039	86	Yes.
0319T	Insert subq defib w/eltrd	J8	0107	80	Yes.
0321T	Insert subq defib pls gen	J8	0107	80	Yes.

We invite public comment on these proposals.

e. ASC Treatment of Surgical Procedures Proposed for Removal From the OPPS Inpatient List for CY 2014

As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68724), we adopted a policy to include in our annual evaluation of the ASC list of covered surgical procedures, a review of the procedures that are being proposed for removal from the OPPS inpatient list for possible inclusion on the ASC list of covered surgical procedures. There are no procedures proposed for removal from the OPPS inpatient list for CY 2014, so we are not proposing any procedures for possible inclusion on the ASC list of covered surgical procedures under this section.

2. Covered Ancillary Services

Consistent with the established ASC payment system policy, we are proposing to update the ASC list of covered ancillary services to reflect the proposed payment status for the services under the CY 2014 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary items and services because of changes that are being proposed under the OPPS for CY 2014. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2013 may be proposed for packaged status under the CY 2014 OPPS and, therefore, also under the ASC payment system for CY 2014. More specifically, as discussed in section II.A.3 of this proposed rule, we are proposing to package the following categories of ancillary or adjunctive services under the OPPS for CY 2014: drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; drugs and biologicals that function as supplies or devices when used in a surgical procedure; clinical diagnostic laboratory tests; procedures described by add-on codes; ancillary services (status indicator ''X''); diagnostic tests on the bypass list; and device removal procedures.

To maintain consistency with the OPPS, we are proposing that these services would be also packaged under the ASC payment system for CY 2014. Comment indicator ''CH,'' discussed in section XII.F. of the this proposed rule, is used in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site) to indicate covered ancillary services for which we are proposing a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2014.

Except for the Level II HCPCS codes and Level III CPT codes listed in Table 34 and Table 35 of this proposed rule, all ASC covered ancillary services and their proposed payment indicators for CY 2014 are included in Addendum BB to this proposed rule.

We invite public comment on this proposal.

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

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are fully described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy for the revised ASC payment system, the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year is used to calculate the national unadjusted payment rates for procedures with payment indicators ''G2'' and ''A2.'' Payment indicator ''A2'' was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and were, therefore, subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we retained payment indicator ''A2'' because it is used to identify procedures that are exempted from application of the office-based designation.

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so that the packaged device payment amount is the same as under the OPPS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68434 through 68467), we updated the CY 2012 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2,'' ''G2,'' and ''J8'' using CY 2011 data, consistent with the CY 2013 OPPS update. Payment rates for device-intensive procedures also were updated to incorporate the CY 2013 OPPS device offset percentages.

Payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') are the lower of the MPFS nonfacility PE RVU-based amount (we refer readers to the CY 2014 MPFS proposed rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2013 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') using the most recent available MPFS and OPPS data. We compared the estimated CY 2013 rate for each of the office-based procedures, calculated according to the ASC standard ratesetting methodology, to the MPFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2013 payment rate for the procedure according to the final policy of the revised ASC payment system (§ 416.171(d)).

b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2014

We are proposing to update ASC payment rates for CY 2014 using the established rate calculation methodologies under § 416.171 and using our proposed modified definition for device-intensive procedures as discussed above. Because the proposed OPPS relative payment weights are based on geometric mean costs for CY 2014, the ASC system will use geometric means to determine proposed relative payment weights under the ASC standard methodology. We are proposing to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2.''

We are proposing that payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') and device-intensive procedures (payment indicator ''J8'') be calculated according to our established policies, incorporating the device-intensive procedure methodology as appropriate. Thus, we are proposing to update the payment amounts for device-intensive procedures, using our proposed modified definition of device intensive procedures, based on the CY 2014 OPPS device offset percentages that have been calculated using the standard APC ratesetting methodology, and to make payment for office-based procedures at the lesser of the proposed CY 2014 MPFS nonfacility PE RVU-based amount or the proposed CY 2014 ASC payment amount calculated according to the standard ratesetting methodology.

We invite public comment on these proposals.

c. Waiver of Coinsurance and Deductible for Certain Preventive Services

Section 1833(a)(1) and section 1833(b)(1) of the Act waive the coinsurance and the Part B deductible for those preventive services under section 1861(ddd)(3)(A) of the Act as described in section 1861(ww)(2) of the Act (excluding electrocardiograms) that are recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population and that are appropriate for the individual. Section 1833(b) of the Act also waives the Part B deductible for colorectal cancer screening tests that become diagnostic. In the CY 2011 OPPS/ASC final rule with comment period, we finalized our policies with respect to these provisions and identified the ASC covered surgical procedures and covered ancillary services that are preventive services that are recommended by the USPSTF with a grade of A or B for which the coinsurance and the deductible are waived. For a complete discussion of our policies and categories of services, we refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72047 through 72049). We are not proposing any changes to our policies or the categories of services for CY 2014. We identify the specific services with a double asterisk in Addenda AA and BB to this proposed rule.

d. Proposed Payment for Cardiac Resynchronization Therapy Services

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. CRT utilizes a pacing electrode implanted in combination with either a pacemaker or an implantable cardioverter defibrillator (ICD). CRT performed by the implantation of an ICD along with a pacing electrode is referred to as ''CRT–D.'' In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to establish the CY 2012 ASC payment rate for CRT–D services based on the OPPS payment rate applicable to APC 0108 when procedures described by CPT codes 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (eg, for upgrade to dual chamber system) (list separately in addition to code for primary procedure)) and 33249 (Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber) are performed on the same date of service in an ASC. ASCs use the corresponding HCPCS Level II G-code (G0448) for proper reporting when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service. For a complete discussion of our policy regarding payment for CRT–D services in ASCs, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74427 through 74428). For CY 2014, CPT code 33249, the primary code for CRT–D services, is proposed for continued assignment to APC 0108 but CPT code 33225 is proposed to be packaged under the OPPS.

Consequently, we are proposing that CPT code 33225 would also be packaged under the ASC payment system for CY 2014. Because CPT code 33225 is proposed to be packaged under the ASC payment system and, therefore, would not receive separate payment, it would no longer be necessary that ASCs use the HCPCS Level II G-code (G0448) for proper reporting when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service. Therefore, we are proposing that the ASC payment rate for CRT–D services (procedures described by CPT codes 33249 and 33225) would be based on the OPPS relative payment weight for APC 0108 for CY 2014 and that ASCs would no longer be required to assign HCPCS code G0448 when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service.

We invite public comment on these proposals.

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

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through the needles/catheters. At least two CPT codes are used to report the treatment service because there are separate codes that describe placement of the needles/catheters and the application of the brachytherapy sources: CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy); and CPT code 77778 (Interstitial radiation source application; complex). Generally, the component services represented by both codes are provided in the same operative session on the same date of service to the Medicare beneficiary being treated with LDR brachytherapy for prostate cancer.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to establish the CY 2013 ASC payment rate for LDR prostate brachytherapy services based on the OPPS relative payment weight applicable to APC 8001 when CPT codes 55875 and 77778 are performed on the same date of service in an ASC. ASCs use the corresponding HCPCS Level II G-code (G0458) for proper reporting when the procedures described by CPT codes 55875 and 77778 are performed on the same date of service, and therefore receive the appropriate LDR prostate brachytherapy composite payment. When not performed on the same day as the service described by CPT code 55875, the service described by CPT code 77778 will continue to be assigned to APC 0651. When not performed on the same day as the service described by CPT code 77778, the service described by CPT code 55875 will continue to be assigned to APC 0163. For a complete discussion of our policy regarding payment for LDR prostate brachytherapy services in ASCs, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68457). We are not proposing any changes to our current policy regarding ASC payment for LDR prostate brachytherapy services for CY 2014.

2. Proposed Payment for Covered Ancillary Services

a. Background

Our final payment policies under the revised ASC payment system for covered ancillary services vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N,'' ''Q1,'' and ''Q2'') under the OPPS. In the CY 2013 OPPS/ASC 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 generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates. We generally pay for separately payable radiology services at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount, regardless of which is lower. This modification to the ASC payment methodology for ancillary services was finalized in response to a comment on the CY 2011 OPPS/ASC proposed rule that suggested it is inappropriate to use the MPFS-based payment methodology for nuclear medicine procedures because the associated diagnostic radiopharmaceutical, although packaged under the ASC payment system, is separately paid under the MPFS (42 CFR 416.171(d)(1)). We set the payment indicator to ''Z2'' for these nuclear medicine procedures in the ASC setting so that payment for these procedures would be based on the OPPS relative payment weight rather than the MPFS nonfacility PE RVU-based amount to ensure that the ASC will be compensated for the cost associated with the diagnostic radiopharmaceuticals.

In addition, because the same issue exists for radiology procedures that use contrast agents (the contrast agent is packaged under the ASC payment system but is separately paid under the MPFS), we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430) to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight and will, therefore, include the cost for the contrast agent (42 CFR 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the 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 three devices that are eligible for pass-through payment in the OPPS are described by 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 C1830, C1840, and C1886 under the ASC payment system are contractor priced. In the CY 2013 OPPS/ASC final rule with comment period, we finalized the expiration of pass-through payment for HCPCS codes C1830, C1840, and C1886, which will expire after December 31, 2013 (77 FR 68353). Therefore, after December 31, 2013, the costs for devices described by HCPCS codes C1830, C1840, and C1886, will be packaged into the costs of the procedures with which the devices are reported in the hospital claims data used in the development of the OPPS relative payment weights that will be used to establish ASC payment rates for CY 2014.

b. Proposed Payment for Covered Ancillary Services for CY 2014

For CY 2014, we are proposing 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 2014 OPPS and ASC payment rates. The proposed CY 2014 OPPS payment methodologies for brachytherapy sources and separately payable drugs and biologicals are discussed in section II.A. and section V.B. of this proposed rule, respectively, and we are proposing to set the CY 2014 ASC payment rates for those services equal to the proposed CY 2014 OPPS rates.

Consistent with established ASC payment policy (72 FR 42497), the proposed CY 2014 payment for separately payable covered radiology services is based on a comparison of the CY 2014 proposed MPFS nonfacility PE RVU-based amounts (we refer readers to the CY 2014 MPFS proposed rule) and the proposed CY 2014 ASC payment rates calculated according to the ASC standard ratesetting methodology and then set at the lower of the two amounts (except as discussed below for nuclear medicine procedures and radiology services that use contrast agents). Alternatively, payment for a radiology service may be packaged into the payment for the ASC covered surgical procedure if the radiology service is packaged or conditionally packaged under the OPPS. The payment indicators in Addendum BB to this 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 are proposing 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 for these procedures will be based on the OPPS relative payment weight (rather than the MPFS nonfacility PE RVU-based amount, regardless of which is lower) and, therefore, will include the cost for the diagnostic radiopharmaceutical. We are proposing to continue this modification to the payment methodology in CY 2014 and, therefore, set the payment indicator to ''Z2'' for nuclear medicine procedures.

As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430), payment indicators for radiology services that use contrast agents are set to ''Z2'' so that payment for these procedures will be based on the OPPS relative payment weight and, therefore, will include the cost for the contrast agent. We are proposing to continue this modification to the payment methodology in CY 2014 and, therefore, set the payment indicator to ''Z2'' for radiology services that use contrast agents.

Most covered ancillary services and their proposed payment indicators are listed in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site). We invite public comment on these proposals.

E. New Technology Intraocular Lenses (NTIOLs)

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of new technology intraocular lenses (NTIOLs) is as follows:

- Applicants submit their NTIOL requests for review to CMS by the deadline. For a request to be considered complete, we require submission of the information that is found in the guidance document entitled ''Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an existing NTIOL Class'' posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*.
- We announce annually in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 103–432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.
- In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—
  - Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments;
  - When a new NTIOL class is created, we identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.
  - The date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class would be set prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.
  - Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2014

We did not receive any requests for review to establish a new NTIOL class for CY 2014 by the March 1, 2013, the due date published in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68461).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we are not proposing to revise the payment adjustment amount for CY 2014.

F. Proposed ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we also created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC list of covered services prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators used in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NI'' is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' 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 the CY 2014 OPPS/ASC final rule with comment period, we will respond to public comments and finalize the ASC treatment of all codes that are labeled with comment indicator ''NI'' in Addenda AA and BB to the CY 2013 OPPS/ASC final rule with comment period.

The ''CH'' comment indicator is used in Addenda AA and BB to this proposed rule (which are available via the Internet on the CMS Web site) to indicate that the payment indicator assignment has changed for an active HCPCS code in current year and next calendar year; an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

2. Proposed ASC Payment and Comment Indicators

We are not proposing any changes to the definitions of the ASC payment and comment indicators for CY 2014. We refer readers to Addenda DD1 and DD2 to this proposed rule (which are available via the Internet on the CMS Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2014 update.

G. Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 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 XII.D.2.b. of this proposed rule), the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage indices to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor cost when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003. The reclassification provision provided at section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available raw pre-floor and pre-reclassified hospital wage indices results in the most appropriate adjustment to the labor portion of ASC costs. In addition, use of the unadjusted hospital wage data avoids further reductions in certain rural statewide wage index values that result from reclassification. We continue to believe that the unadjusted hospital wage indices, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs.

We note that in certain instances there might be urban or rural areas for which there is no IPPS hospital whose wage index data would be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indices for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a border). We have applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA).

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.

2. Proposed Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2014 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). Consistent with our established policy, we are proposing to scale the CY 2014 relative payment weights for ASCs according to the following method. Holding ASC utilization and the mix of services constant from CY 2012, we are

proposing to compare the total payment using the CY 2013 ASC relative payment weights with the total payment using the CY 2014 relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2013 and CY 2014. We are proposing to use the ratio of CY 2013 to CY 2014 total payment (the weight scaler) to scale the ASC relative payment weights for CY 2014. The proposed CY 2014 ASC scaler is 0.8961 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. We currently have available 98 percent of CY 2012 ASC claims data.

To create an analytic file to support calculation of the weight scaler and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2012 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2012 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for the proposed rule, is posted on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html*.

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 2014 ASC payment system, we are proposing to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2014, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2012 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2014 pre-floor and pre-reclassified hospital wage indices. Specifically, holding CY 2012 ASC utilization and service-mix and the proposed CY 2014 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2013 pre-floor and pre-reclassified hospital wage indices and the total adjusted payment using the proposed CY 2014 pre-floor and pre-reclassified hospital wage indices. We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2013 pre-floor and pre-reclassified hospital wage indices to the total adjusted payment calculated with the proposed CY 2014 pre-floor and pre-reclassified hospital wage indices and applied the resulting ratio of 1.0004 (the proposed CY 2014 ASC wage index budget neutrality adjustment) to the CY 2013 ASC conversion factor to calculate the proposed CY 2014 ASC conversion factor. We note that, on February 28, 2013, OMB issued OMB Bulletin No. 13–01 announcing revisions to the delineation of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The proposed pre-floor and pre-reclassified hospital wage indices for FY 2014 do not reflect OMB's new area delineations. Because the ASC wage indices are the pre-floor and pre-reclassified hospital wage indices, the FY 2014 ASC wage indices will not reflect the OMB changes.

Section 1833(i)(2)(C)(i) of the Act requires that, ''if the Secretary has not updated amounts established'' under the revised ASC payment system in a calendar year, the payment amounts ''shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.'' The statute, therefore, does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at 42 CFR 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years. Therefore, the annual update to the ASC payment system is the CPI–U (referred to as the CPI–U update factor).

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new clause (v) which requires that ''any annual update under [the ASC payment] system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II)'' of the Act effective with the calendar year beginning January 1, 2011. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). Clause (iv) of section 1833(i)(2)(D) of the Act authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) of section 1833(i)(2)(D) of the Act states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized a policy that ASCs begin submitting data on quality measures for services beginning on October 1, 2012 for the CY 2014 payment determination under the ASCQR Program. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), we finalized a methodology to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for the CY 2014 payment determination and subsequent years.

The application of the 2.0 percentage point reduction to the annual update factor, which currently is the CPI–U, may result in the update to the ASC payment system being less than zero for a year for ASCs that fail to meet the ASCQR Program requirements. We amended §§ 416.160(a)(1) and 416.171 to reflect these policies.

In accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determines the ''percentage increase'' in the CPI–U, which we interpret cannot be a negative percentage. Thus, in the instance where the percentage change in the CPI–U for a year is negative, we would hold the CPI–U update factor for the ASC payment system to zero. For the CY 2014 payment determination and subsequent years, under section 1833(i)(2)(D)(iv) of the Act, we would reduce the annual update by 2.0 percentage points for an ASC that fails to submit quality information under the rules established by the Secretary in accordance with section 1833(i)(7) of the Act. Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that the Secretary reduce the annual update factor, after application of any quality reporting reduction, by the MFP adjustment, and states that application of the MFP adjustment to the annual update factor after application of any quality reporting reduction may result in the update being less than zero for a year. If the application of the MFP adjustment to the annual update factor after application of any quality reporting reduction would result in an MFP-adjusted update factor that is less than zero, the resulting update to the ASC payment rates would be negative and payments would decrease relative to the prior year. Illustrative examples of how the MFP adjustment would be applied to the ASC payment system update are found in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064).

For this proposed rule, based on IHS Global Insight (IGI) 2013 first quarter forecast with historical data through 2012 fourth quarter, for the 12-month period ending with the midpoint of CY 2014, the CPI–U update is projected to be 1.4 percent. Also based on IGI's 2013 first quarter forecast, the MFP adjustment for the period ending with the midpoint of CY 2014 is projected to be 0.5 percent. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of CMS' market baskets as well as the CPI–U and MFP. The methodology for calculating the MFP adjustment was finalized in the CY 2011 MPFS final rule with comment period (75 FR 73394 through 73396) as revised in the CY 2012 MPFS final rule with comment period (76 FR 73300 through 73301). Because the ASCQR Program affects payment rates beginning in CY 2014, there would be a 2.0 percentage point reduction to the CPI–U for ASCs that fail to meet the ASCQR Program requirements.

We are proposing to reduce the CPI–U update of 1.4 percent by the MFP adjustment of 0.5 percentage point, resulting in an MFP-adjusted CPI–U update factor of 0.9 percent for ASCs meeting the quality reporting requirements. Therefore, we are proposing to apply a 0.9 percent MFP-adjusted CPI–U update factor to the CY 2013 ASC conversion factor for ASCs meeting the quality reporting requirements. We are proposing to reduce the CPI–U update of 1.4 percent by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then apply the 0.5 percentage point MFP reduction. Therefore, we are proposing to apply a −1.1 percent quality reporting/MFP-adjusted CPI–U update factor to the CY 2013 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also are proposing that if more recent data are subsequently available (for example, a more recent estimate of the CY 2014 CPI–U update and MFP adjustment), we would use such data, if appropriate, to determine the CY 2014 ASC update for the final rule with comment period.

For CY 2014, we also are proposing to adjust the CY 2013 ASC conversion factor ($42.917) by the wage adjustment for budget neutrality of 1.0004 in addition to the MFP-adjusted update factor of 0.9 percent discussed above, which results in a proposed CY 2014 ASC conversion factor of $43.321 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we are proposing to adjust the CY 2013 ASC conversion factor ($42.917) by the wage adjustment for budget neutrality of 1.0004 in addition to the quality reporting/MFP-adjusted update factor of −1.1 percent discussed above, which results in a proposed CY 2014 ASC conversion factor of $42.462.

We invite public comment on these proposals.

3. Display of Proposed CY 2014 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available via the Internet on the CMS Web site) display the proposed updated ASC payment rates for CY 2014 for covered surgical procedures and covered ancillary services, respectively. These addenda contain several types of information related to the proposed CY 2014 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''Subject to Multiple Procedure Discounting'' indicates that the surgical procedure will be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 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 2014. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that the payment indicator assignment is an interim assignment that is open to comment in the final rule with comment period.

The values displayed in the column titled ''CY 2014 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2014. The payment weights for all covered surgical procedures and covered ancillary services whose ASC payment rates are based on 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 proposed CY 2014 payment rate displayed in the ''CY 2014 Payment'' column, each ASC payment weight in the ''CY 2014 Payment Weight'' column was multiplied by the proposed CY 2014 conversion factor of $43.321. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment (as

discussed in section XII.H.2.b. of this proposed rule).

In Addendum BB, there are no relative payment weights displayed in the ''CY 2014 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''CY 2014 Payment'' column displays the proposed CY 2014 national unadjusted ASC payment rates for all items and services. The proposed CY 2014 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in April 2013.

XIII. Hospital Outpatient Quality Reporting Program Updates

A. Background

1. Overview

CMS has implemented quality measure reporting programs for multiple settings of care. These programs promote higher quality, more efficient health care for Medicare beneficiaries. The quality data reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (Hospital OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), has been generally modeled after the quality data reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (Hospital IQR) Program (formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program). Both of these quality reporting programs for hospital services have financial incentives for the reporting of quality data to CMS.

CMS also has implemented quality measure reporting programs for other settings of care and for certain professionals, including:

- Care furnished by physicians and other eligible professionals, under the Physician Quality Reporting System (PQRS, formerly referred to as the Physician Quality Reporting Program Initiative (PQRI));
- Inpatient rehabilitation facilities, under the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP);
- Long-term care hospitals, under the Long-Term Care Hospital Quality Reporting (LTCHQR) Program;
- PPS-exempt cancer hospitals, under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;
- Ambulatory surgical centers, under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program;
- Inpatient psychiatric facilities, under the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program;
- Home health agencies, under the Home Health Quality Reporting Program (HH QRP); and
- Hospices, under the Hospice Quality Reporting Program.

Finally, CMS has implemented a Hospital Value-Based Purchasing Program and an end-stage renal disease (ESRD) Quality Incentive Program that link payment to performance.

In implementing the Hospital OQR Program and other quality reporting programs, we have focused on measures that have high impact and support national priorities for improved quality and efficiency of care for Medicare beneficiaries as reflected in the National Quality Strategy, as well as conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. To the extent possible under various authorizing statutes, our ultimate goal is to align the clinical quality measure requirements of the Hospital OQR Program and various other programs, such as the Hospital IQR Program, the ASCQR Program, and the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, authorized by the Health Information Technology for Economic and Clinical Health Act, so that the burden for reporting will be reduced. As appropriate, we will consider the adoption of measures with electronic specifications, to enable the collection of this information as part of care delivery. Establishing such an alignment will require interoperability between EHRs, and CMS data collection systems, with data being calculated and submitted via certified EHR technology; additional infrastructural development on the part of hospitals and CMS; and the adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. Once these activities are accomplished, the adoption of many measures that rely on data obtained directly from EHRs will enable us to expand the Hospital OQR Program measure set with less cost and burden to hospitals.

In implementing this and other quality reporting programs, we generally applied the same principles for the development and the use of measures, with some differences that relate to the specific characteristics of each program:

- 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 structural, 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 multi-stakeholder groups. Section 3014 of the Affordable Care Act added section 1890A of the Act, establishing a pre-rulemaking process, which, among other steps, requires the Secretary to take into consideration input from multi-stakeholder groups in selecting certain categories of quality and efficiency measures described in section 1890(b)(7)(B) of the Act. As part of the pre-rulemaking process, the consensus-based entity that CMS must contract with under section 1890 of the Act (currently the National Quality Forum (NQF)), convened the multi-stakeholder groups referred to as the Measure Applications Partnership (MAP). The MAP is a public-private partnership created for the primary purpose of providing input to HHS on the selection of the categories of measures in section 1890(B)(7)(B) of the Act, which include measures for use in certain specific Medicare programs, measures for use in reporting performance information to the public, and measures for use in health care programs other than for use under the Act. 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 strives to ensure that quality measures for the Medicare, Medicaid, and the Children's Health Insurance Programs are aligned with priority quality goals, that measure specifications are aligned across settings, that outcome measures are used, and that quality measures are collected from EHRs as appropriate. Quality goals are embedded in the CMS Strategy.

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 final rulemaking (77 FR 68467 through 68469), with a few minor differences, we generally applied the same principles for our considerations for future measures.

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. We believe that a measure can be updated through this subregulatory process provided it is a nonsubstantive change. We expect to make the determination of what constitutes a substantive versus a nonsubstantive change on a case-by-case basis.

Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe that non-substantive changes may include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. We will revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. As stated in CY 2009 OPPS/ASC, we also will post the updates on the QualityNet Web site at *https://www.QualityNet.org.* We will provide sufficient lead time for facilities to implement the changes where changes to the data collection systems would be necessary. We generally release the Hospital OQR Specifications Manual every 6 months and release addenda as necessary. This release schedule provides at least 3 months of advance notice for nonsubstantive changes such as changes to ICD–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.

We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the OQR Program. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example: changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice.

We believe that the policy finalized in the CY 2009 OPPS/ASC final rule adequately balances our need to incorporate non-substantive NQF updates to NQF-endorsed Hospital OQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process. These policies regarding what is considered substantive versus non-substantive apply to all measures in the Hospital OQR Program.

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 are usually displayed on our *Hospital Compare* Web site, *http://www.hospitalcompare.medicare.gov,* following the preview period, although we might use other Web sites, as discussed below. 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 measures, outcome of care measures, outpatient imaging efficiency measures and HCAHPS data.

In general, we strive to display hospital quality measure data on the *Hospital Compare* Web site as soon as possible after measure data have been submitted to CMS. However, if there are unresolved display issues or pending design considerations, we may make the data available on other CMS Web sites such as: *http://www.cms.hhs.gov/HospitalQualityInits/* or *https://data.medicare.gov/*. Publicly reporting the information in this manner, although not on the *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 email 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 an online 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.

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

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471), for the purpose of streamlining the rulemaking process, we finalized a policy that, beginning with the CY 2013 rulemaking, when we adopt measures for the Hospital OQR Program beginning with a payment determination and subsequent years, these measures are automatically adopted for all subsequent years payment determinations unless we propose to remove, suspend, or replace the measures.

C. Removal or Suspension of Quality Measures From the Hospital OQR Program Measure Set

1. Considerations in Removing Quality Measures From the Hospital OQR Program

In the FY 2010 IPPS/LTCH PPS rulemaking, we finalized a process for immediate retirement 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 final rule (77 FR 53506 through 53507) 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 final rule with comment period (77 FR 68472 through 68473), we adopted 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 final rule with comment period (77 FR 68472 through 68473), we finalized our proposal to apply these measure removal criteria in the Hospital OQR Program as well.

In addition to these criteria, we take into account the views of the MAP in the evaluation of measure removal. Furthermore, for efficiency and streamlining purposes, we strive to eliminate redundancy of similar measures.

2. Proposed Removal of Two Chart-Abstracted Measures From the Hospital OQR Program

In this rulemaking, we are proposing to remove two measures from the Hospital OQR Program for the CY 2016 payment determination and subsequent years: (1) OP–19: Transition Record with Specified Elements Received by Discharged ED Patients and (2) OP–24: Cardiac Rehabilitation Measure: Patient Referral from an Outpatient Setting. The rationales for these proposals are discussed below.

a. Proposed Removal of OP–19: Transition Record With Specified Elements Received by Discharged ED Patients

We previously adopted measure OP–19 for the Hospital OQR Program for the CY 2013 payment determination with data collection beginning with January 1, 2012 encounters in the CY 2011 OPPS/ASC final rule with comment period. Shortly after data collection for this measure began in January 2012, hospitals raised concerns about the measure specifications, including potential privacy issues related to releasing certain elements of the transition record to either the patient being discharged from an emergency department or the patient's caregiver. Some examples provided by hospitals are the release of sensitive lab results or radiological findings to a parent, spouse, or guardian of a minor patient, or to the responsible party for a physically incapacitated patient.

In order to address the safety concerns related to confidentiality as raised by the industry in the above discussion, in April 2012, we took immediate action to suspend OP–19. On April 12, 2012, we released a Memorandum entitled SDPS 12–100–OD, ''Revised: Temporary Suspension of Hospital Outpatient Quality Reporting Measure OP–19: Transition Record with Specified Elements Received by Discharged Patients'' to make clear our intent not to use any data submitted on this measure for payment determinations, public reporting, or data validation. This memorandum can be located at *http://qualitynet.org*) under the option ''Email Notifications'' within the ''Hospitals—Outpatient'' drop down menu found at the top of the page.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68474 through 68476) for the CY 2014 payment determination and subsequent years, we confirmed that we suspended the collection of data for the measure OP–19: Transition Record with Specified Elements Received by Discharged ED Patients, which specified that either patients *or their caregivers* (emphasis added) receive a transition record at the time of ED discharge.

We chose to suspend this measure rather than to immediately remove the measure from the program because the probability of harm occurring was relatively low; any potential harm that occurred would not be the direct result of patient care rendered at facilities; and the measure steward, the American Medical Association Physician Consortium for Performance Improvement (AMA–PCPI), believed that the measure could be quickly re-specified in a manner that would mitigate the concerns raised by hospitals and stakeholders. In the CY 2013 OPPS/ASC final rule with comment period, we noted that the measure steward was working to revise the measure specifications to address the concerns raised by affected parties. We also noted that the measure was scheduled for NQF maintenance review in 2013. We stated that after completion of the NQF maintenance process, we anticipated that normal program operations for this measure could resume once we updated the Hospital OQR Specifications Manual and made any necessary changes to our data collection infrastructure. In addition, we stated that we would notify hospitals of changes in the suspension status of the measure for the Hospital OQR Program via email blast. However, we indicated that if we determined that these concerns cannot be adequately addressed by measure specifications, we would propose to remove this measure in a future OPPS/ASC rule.

We have determined that the measure cannot be implemented with the degree of specificity that would be needed to fully address the concerns of stakeholders without being overly burdensome. The measure steward resolved the safety issue by refining the measure, but the refinement has made data abstraction more subjective because individual hospitals can determine which information should be included in the transition record in order to comply with this measure. In the absence of standardized data elements, we were not able to resolve this issue of data abstraction for common data elements, and therefore, could not ensure consistency of data submission and accuracy of measure results.

We also learned that all aspects for this transition record measure are currently required to meet the Medicare EHR Incentive Program's meaningful use (MU) core objective for eligible hospitals and critical access hospitals (CAHs) to provide patients the ability to view online, download, and transmit information about a hospital admission. This MU core objective provides patients discharged from the inpatient department or Emergency Department (ED) online access to their visit data. These ED visit data are the specified data elements included in the OP–19 Transition Record measure. This means that if we were to keep this measure, hospitals would need to submit this data for both the Hospital OQR Program using chart-abstraction and via attestation for the MU core objective. Therefore, to reduce duplicative requirements among programs and measurement burden, we are proposing to remove this measure from the Hospital OQR Program. We invite public comment on the proposed removal of this measure from the Hospital OQR Program.

b. Proposed Removal of OP–24: Cardiac Rehabilitation Measure: Patient Referral From an Outpatient Setting

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68476), we deferred data collection for this measure to January 1, 2014 encounters. This was due to the unavailability of detailed abstraction instructions for data collection in time for the July 2012 release of the Hospital OQR Specifications Manual which was needed for chart-abstraction beginning on January 1, 2013. We also indicated that this measure would be applied to the CY 2015 payment determination.

We are proposing to remove this measure from the Hospital OQR Program due to continued difficulties with defining the measure care setting.

The measure specifications provided by the measure steward, the American College of Cardiology (ACC), identify the applicable care setting as a 'Clinician Office/Clinic' and not as a hospital outpatient setting. In developing the specifications for this measure for a hospital outpatient setting, several issues arose. First, it is difficult to accurately identify the purpose of hospital outpatient visits, such as for evaluation and management purposes, using solely HOPD claims data. Second, it is difficult for hospitals to determine which particular clinic visit resulted in a cardiac rehabilitation referral for any given patient. Therefore, given the difficulties in accurately applying the measure to the hospital outpatient setting, we are proposing to remove OP–24 from the Hospital OQR Program. We invite public comment on this proposal to remove this measure from the Hospital OQR Program.

PROPOSED HOSPITAL OQR PROGRAM MEASURES TO BE REMOVED FOR THE CY 2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure
0649	OP–19: Transition Record with Specified Elements Received by Discharged ED Patients.
0643	OP–24: Cardiac Rehabilitation Measure: Patient Referral from an Outpatient Setting.

D. Quality Measures Previously Adopted for the CY 2014 and CY 2015 Payment Determinations and Subsequent Years

The table below lists 25 measures that we previously adopted and retained for the CY 2014 and CY 2015 payment determinations and subsequent years under the Hospital OQR Program. This list includes measures we are proposing to remove in this proposed rule.

HOSPITAL OQR PROGRAM MEASURES FOR THE CY 2014 AND CY 2015 PAYMENT DETERMINATIONS AND SUBSEQUENT YEARS

NQF No.	Measure name
0287	OP–1: Median Time to Fibrinolysis.
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes.
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286	OP–4: Aspirin at Arrival.
0289	OP–5: Median Time to ECG.
0270	OP–6: Timing of Antibiotic Prophylaxis.
0268	OP–7: Prophylactic Antibiotic Selection for Surgical Patients.
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
	OP–9: Mammography Follow-up Rates.
	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
0489	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery.
	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
	OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache. *
0491	OP–17: Tracking Clinical Results between Visits.
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
0649	OP–19: Transition Record with Specified Elements Received by Discharged ED Patients.
	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP–21: Median Time to Pain Management for Long Bone Fracture.
	OP–22: ED—Patient Left Without Being Seen.
0661	OP–23: ED—Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival.
0643	OP–24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting.
	OP–25: Safe Surgery Checklist Use.
	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures. **

* Public reporting for OP–15 continues to be deferred at the time of this CY 2014 OPPS/ASC proposed rule.

** OP–26 Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228889963089&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D1r_OP26MIF_v+6+0b.pdf&blobcol=urldata&blobtable=MungoBlobs.*

E. Proposed Quality Measures for the CY 2016 Payment Determination and Subsequent Years

In this rulemaking, we are proposing to adopt five new measures for the Hospital OQR Program for the CY 2016 payment determination and subsequent years. These measures include one HAI measure—Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), currently collected by the Centers for Disease Control and Prevention (CDC) via the National Healthcare Safety Network (NHSN)—and four chart-abstracted measures. The chart-abstracted measures are: (1) Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures (NQF #0564), (2) Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients (NQF #0658), (3) Endoscopy/Poly surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF

#0659), and (4) Cataracts: Improvement in Patient's Visional Function within 90 Days Following Cataract Surgery (NQF #1536).

The proposed measures were included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2012'' on the NQF Web site at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx* in compliance with section 1890A(a)(2) of the Act. They were reviewed by the MAP in its ''MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS,'' which has been made available on the NQF Web site at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*. We considered the input and recommendations provided by the MAP in selecting measures to propose for the Hospital OQR Program.

All five of the proposed measures are NQF-endorsed, and therefore meet the requirements that measures selected for the program ''reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities'' under section 1833(t)(17)(C)(i) of the Act. Furthermore, the services targeted in the proposed measures are services commonly provided to patients who visit hospital outpatient departments and, for this reason, we believe that these proposed measures are appropriate for the measurement of quality of care furnished by hospitals in outpatient settings as required under section 1833(t)(17)(C)(i) of the Act.

We are proposing to collect aggregate data (numerators, denominators, exclusions) for the four chart-abstracted measures via an online, Web-based tool that will be made available to HOPDs via the QualityNet Web site, just as we do for OP–22. This Web-based tool is currently in use in the Hospital OQR Program to collect structural measure information.

More information regarding this proposed method of collection is provided in section XIII.H.2. of this proposed rule.

To enhance our efforts to collect high quality data for the Hospital OQR measures while minimizing burden for HOPDs, we also seek public comment on whether we should collect patient-level data via certified EHR technology on the four proposed measures excluding the Influenza Vaccination Coverage among Healthcare Personnel measure, and the potential timing for doing so. Collecting patient-level data, as we do for other Hospital OQR Program measures such as OP–1 through OP–7, would allow CMS to validate the accuracy of the data and also link data for patients over time to assess patient outcomes of care related to treatment.

The proposed measures are described in greater detail below.

1. Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)

This proposed measure assesses the percentage of healthcare personnel (HCP) who have been immunized for influenza. Rates of serious illness and death resulting from influenza and its complications are increased in high-risk populations such as persons over 50 years or under four years of age, and persons of any age who have underlying conditions that put them at an increased risk. HCP can acquire influenza from patients and can transmit influenza to patients and other HCP. Many HCP provide care for, or are in frequent contact with, patients with influenza or patients at high risk for complications of influenza. The involvement of HCP in influenza transmission has been a long-standing concern.[1 2 3]

Vaccination is an effective preventive measure against influenza, and can prevent many illnesses, deaths, and losses in productivity.[4] HCP are considered a high priority for expanding influenza vaccine use. Achieving and sustaining high influenza vaccination coverage among HCP is intended to help protect HCP and their patients and reduce disease burden and healthcare costs. Due to the significant impact of HCP influenza vaccination on patient outcomes, we believe this measure is appropriate for measuring the quality of care in hospital outpatient departments.

We are proposing to adopt this process measure for the CY 2016 payment determination and subsequent years. We are also proposing that Hospital OPDs use the NHSN infrastructure and protocol to report the measure for Hospital OQR program purposes. The measure numerator is: HCP in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year: (a) Received an influenza vaccination administered at the healthcare facility, or reported in writing (paper or electronic) or provided documentation that influenza vaccination was received elsewhere; (b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other component(s) of the vaccine, or history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination; (c) declined; or (d) persons with unknown vaccination status or who do not otherwise meet any of the definitions of the above-mentioned numerator categories. The measure denominator is: the number of HCP who are working in the healthcare facility for at least 1 working day between October 1 and March 31 of the influenza season, regardless of clinical responsibility or patient contact. The specifications for this measure are available at *http://www.qualityforum.org/QPS/QPSTool.aspx?Exact=false&Keyword=0431*.

In its 2013 Pre-Rulemaking Report, (*http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*), the MAP supported inclusion of this measure in the Hospital OQR Program and noted that the measure would address a measure type that is not adequately represented in the program measure set. Furthermore, the adoption of this measure will align with both the Hospital IQR Program, which adopted the measure for the FY 2015 payment determination and subsequent years, and the ASCQR Program, which adopted the measure for the CY 2016 payment determination and subsequent years.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42323 through 42324), we proposed this measure for the CY 2015 payment determination. However, in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74470 through 74472), we decided not to finalize the measure (76 FR 74472) and, instead, decided to propose it in future rulemaking for the CY 2016 payment determination and subsequent years in order to address measure refinements in the denominator and operational issues. We believe that these refinements have been made and that the operational issues have been resolved.

We have learned that many States are proactively aligning their reporting requirements for this measure to mirror

[1] Maltezou, H.C., Drancourt, M.: Nosocomial influenza in children. Journal of Hospital Infection 2003; 55:83–91.

[2] Hurley, J.C., Flockhart, S.: An influenza outbreak in a regional residential facility. Journal of Infection Prevention 2010; 11:58–61.

[3] Salgado, C.D, Farr, B.M., Hall, K.K., Hayden, F.G.: Influenza in the acute hospital setting. The Lancet Infectious Diseases 2002; 2:145–155.

[4] Wilde, M.A., McMillan, J.A., Serwint, J., Butta, J., O'Riordan, M.A., Steinhoff, M.C.: Effectiveness of influenza vaccine in health care professionals; a randomized trial. The Journal of the American Medical Association 1999;281:908–913.

the federal requirements in an effort to reduce burden on providers and suppliers. We also recently learned that the measure may soon be undergoing some minor updates and review by NQF. Consistent with our policy to use a subregulatory process to adopt nonsubstantive changes to measures arising out of the NQF process (73 FR 68766 through 68767), we would use this process to adopt the upcoming NQF revisions for this measure, if the revisions are nonsubstantive.

We refer readers to section XIII.H.2. of this proposed rule for a detailed discussion of data collection. We invite public comment on this proposal.

2. Complications Within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures (NQF #0564)

This proposed measure assesses the percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: Retained nuclear fragments, endophthalmitis, dislocated or wrong power intraocular lens (IOL), retinal detachment, or wound dehiscence.

Although complications that may result in a permanent loss of vision following cataract surgery are uncommon, this outcome measure seeks to identify those complications from surgery that can reasonably be attributed to the surgery. It focuses on patient safety and monitoring for events that, while uncommon, can signify important issues in the care being provided. Advances in technology and surgical skills over the last 30 years have rendered cataract surgery safer and more effective. An analysis of Managed Care Organization data demonstrated that the rate of complications for this measure were 1 to 2 percent. However, with an annual volume of 2.8 million cataract surgeries in the United States, many of which are performed in hospital surgical outpatient departments, a 2-percent rate is a significant number of surgeries associated with complications.[5]

The measure numerator is: Patients who had one or more specified operative procedures for any of the following major complications within 30 days following cataract surgery: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence. The measure denominator is: All patients aged 18 years and older who had cataract surgery and no significant pre-operative ocular conditions impacting the surgical complication rate. This measure excludes patients with certain comorbid conditions impacting the surgical complication rate. The specifications for this measure are available at *http://www.qualityforum.org/QPS/0564*.

In its 2013 Pre-Rulemaking Report, (*http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*), the MAP supported this measure and noted that the measure addresses a high impact condition that is not adequately addressed in the Hospital OQR measure set. Currently the NQF endorsement is time-limited.

We refer readers to section XIII.H.2. of this proposed rule for a detailed discussion of data collection. We invite public comment on this proposal.

3. Endoscopy/Poly Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)

This proposed measure assesses the percentage of patients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.

In the average-risk population, colonoscopy screening is recommended in current guidelines at 10-year intervals.[6] Our analysis indicated that about 25 percent of surgeries/procedures performed in HOPDs and ASCs are colonoscopies. Performing colonoscopy too frequently increases patients' exposure to procedural harm. This measure aims to assess whether average risk patients with normal colonoscopies receive a recommendation to receive a repeat colonoscopy in an interval that is less than the recommended amount of 10 years.

The measure numerator is: Patients who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report. The measure denominator is: all patients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy. This measure excludes patients with documentation of medical reason(s) for recommending a follow-up interval of less than 10 years (for example, an above-average risk patient or inadequate prep). The specifications for this measure are available at: *http://www.qualityforum.org/QPS/0658*.

In its 2013 Pre-Rulemaking Report, (*http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*), the MAP supported the direction of the measure. Currently the NQF endorsement is time-limited.

We refer readers to section XIII.H.2. of this proposed rule for a detailed discussion of data collection. We invite public comment on this proposal.

4. Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients With a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659)

The proposed Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use measure assesses the percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report.

Colonoscopy is the recommended method of surveillance after the removal of adenomatous polyps, because it has been shown to significantly reduce subsequent colorectal cancer incidence. The timing of follow-up colonoscopy should be tailored to the number, size, and pathologic findings of the adenomatous polyps removed. A randomized trial of 699 patients showed that after newly diagnosed adenomatous polyps have been removed by colonoscopy, follow-up colonoscopy at 3 years detects important colonic lesions as effectively as follow-up colonoscopy at both 1 and 3 years.[7] [8]

[5] National Quality Measures Clearing House. Agency for Healthcare Research and Quality. Available at *http://qualitymeasures.ahrq.gov/content.aspx?id=27981&search=complications+within+30+days+following+cataract+surgery*.

[6] Davila RE, Rajan E, Baron TH, Adler DG, Egan JV, Faigel DO, Gan SI, Hirota WK, Leighton JA, Lichtenstein D, Qureshi WA, Shen B, Zuckerman MJ, VanGuilder T, Fanelli RD, Standards of Practice Committee, American Society for Gastrointestinal Endoscopy. ASGE guideline: colorectal cancer screening and surveillance. Gastrointest Endosc 2006 Apr;63(4):546–57. *http://www.ncbi.nlm.nih.gov/pubmed/16564851?dopt=Abstract*.

[7] National Quality Measures Clearing House. Agency for Healthcare Research and Quality. Available at *http://qualitymeasures.ahrq.gov/content.aspx?id=27981&search=complications+within+30+days+following+cataract+surgery*.

[8] Davila RE, Rajan E, Baron TH, Adler DG, Egan JV, Faigel DO, Gan SI, Hirota WK, Leighton JA,

Continued

The measure numerator for this proposed measure is: Patients who had an interval of 3 or more years since their last colonoscopy. The measure denominator is: all patients aged 18 years and older receiving a surveillance colonoscopy with a history of a prior colonic polyp in a previous colonoscopy. This measure excludes patients with: (1) Documentation of medical reason(s) for an interval of less than 3 years since the last colonoscopy (for example, last colonoscopy incomplete, last colonoscopy had inadequate prep, piecemeal removal of adenomas, or last colonoscopy found greater than 10 adenomas); or (2) documentation of a system reason(s) for an interval of less than 3 years since the last colonoscopy (for example, unable to locate previous colonoscopy report, previous colonoscopy report was incomplete). The specifications for this measure are available at *http://www.qualityforum.org/QPS/0659*.

In its 2013 Pre-Rulemaking Report, (*http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*), the MAP supported the direction of the measure. Currently the NQF endorsement is time-limited.

We refer readers to section XIII.H.2. of this proposed rule for a detailed discussion of data collection. We invite public comment on this proposal.

5. Cataracts—Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (NQF #1536)

This proposed measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery.

Cataract surgery is performed to improve a patient's vision and associated functioning. This outcome is achieved consistently through careful attention to the accurate measurement of axial length and corneal power and the appropriate selection of an IOL. Failure to achieve improved visual functioning after surgery in eyes without comorbid ocular conditions that could impact the success of the surgery would reflect care that should be assessed for opportunities for improvement. Evidence suggests that visual improvement occurs in about 86—98 percent of surgeries in eyes without comorbid conditions. However, with an annual volume of 2.8 million cataract surgeries in the United States, many of which are performed in hospital outpatient surgical departments, the impact could affect a significant number of patients per year.[9]

We are proposing to adopt this measure for the CY 2016 payment determination and subsequent years. The measure numerator is: Patients 18 years and older (with a diagnosis of uncomplicated cataract) in a sample who had improvement in visual function achieved within 90 days following cataract surgery, based on completing a pre-operative and post-operative visual function instrument. The measure denominator is: All patients aged 18 years and older in sample who had cataract surgery. There are no exclusions.

The specifications for this measure are available at *http://www.qualityforum.org/QPS/1536*. Additional information for the measure specifications can be found in the NQF Measure Evaluation available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=68317.*

In its 2013 Pre-Rulemaking Report, (*http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx*), the MAP supported the inclusion of the measure in the Hospital OQR Program and noted that the measure addresses a high impact condition not adequately addressed in the program measure set. The MAP added that this measure, which addresses outcomes, falls under a category of measures inadequately represented in the program measure set. Currently the NQF endorsement is time-limited.

We refer readers to section XIII.H.2. of this proposed rule for a detailed discussion of data collection. We invite public comment on this proposal.

The proposed measure set for the Hospital OQR Program for the CY 2016 payment determination and subsequent years is listed in the table below.

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF#	Measure name
0287 ...	OP–1: Median Time to Fibrinolysis.
0288 ...	OP–2: Fibrinolytic Therapy Received Within 30 Minutes.
0290 ...	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286 ...	OP–4: Aspirin at Arrival.
0289 ...	OP–5: Median Time to ECG.
0270 ...	OP–6: Timing of Antibiotic Prophylaxis.
0268 ...	OP–7: Prophylactic Antibiotic Selection for Surgical Patients.
0514 ...	OP–8: MRI Lumbar Spine for Low Back Pain.
	OP–9: Mammography Follow-up Rates.
	OP–10: Abdomen CT—Use of Contrast Material.
0513 ...	OP–11: Thorax CT—Use of Contrast Material.
0489 ...	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669 ...	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery.
	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
	OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache*.
0491 ...	OP–17: Tracking Clinical Results between Visits.
0496 ...	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662 ...	OP–21: Median Time to Pain Management for Long Bone Fracture.

Lichtenstein D, Qureshi WA, Shen B, Zuckerman MJ, VanGuilder T, Fanelli RD, Standards of Practice Committee, American Society for Gastrointestinal Endoscopy. ASGE guideline: colorectal cancer screening and surveillance. Gastrointest Endosc 2006 Apr;63(4):546–57. *http://www.ncbi.nlm.nih.gov/pubmed/16564851?dopt=Abstract.*

[9] National Quality Measures Clearing House. Agency for Healthcare Research and Quality. Available at *http://www.qualitymeasures.ahrq.gov/content.aspx?id=27982.*

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

NQF#	Measure name
	OP–22: ED- Patient Left Without Being Seen.
0661 ...	OP–23: ED- Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival.
	OP–25: Safe Surgery Checklist Use.
	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.**
0431 ...	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.***
0564 ...	OP–28: Complications within 30 days Following Cataract Surgery Requiring Additional Surgical Procedures.***
0658 ...	OP–29: Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients.***
0659 ...	OP–30: Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use***.
1536 ...	OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.***

* Public reporting for OP–15 continues to be deferred at the time of this CY 2014 OPPS/ASC proposed rule.

** OP–26: Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228889963089&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D1r_OP26MIF_v+6+0b.pdf&blobcol=urldata&blobtable=MungoBlobs*.

*** New measures proposed for the CY 2016 payment determination and subsequent years.

F. Possible Hospital OQR Program Measure Topics for Future Consideration

The current measure set for the Hospital OQR Program includes measures that assess process of care, imaging efficiency patterns, care transitions, ED throughput efficiency, the use of HIT care coordination, patient safety, and volume. We anticipate that as EHR technology evolves and more infrastructure is put into place, we will have the capacity to accept electronic reporting of many clinical chart-abstracted measures that are currently part of the Hospital OQR Program using certified EHR technology. We are working diligently toward this goal. We believe that this progress, at a near future date, would significantly reduce the administrative burden on hospitals under the Hospital OQR Program to report chart-abstracted measures. We recognize that considerable work needs to be done by measure owners and developers to make this possible with respect to the clinical quality measures targeted for 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, including partial hospitalization programs (PHPs) that are part of HOPDs.

We are considering the following measure domains for future measures: Clinical quality of care; care coordination; patient safety; patient and caregiver experience of care; population/community health; and efficiency. We believe this approach will promote better care while bringing the Hospital OQR Program in line with other established quality reporting programs such as the Hospital IQR Program and the ASCQR Program.

We invite public comment on this approach and on our suggestions and rationale for possible measure topics for future consideration in the Hospital OQR Program.

In addition, we are soliciting comments on the following potential quality measure topics for PHPs in HOPDs: Poly-therapy with antipsychotic medications; Post-discharge of continuity of care; Alcohol screening; Alcohol and drug use; Tobacco use assessment; and Follow-up after hospitalization for mental illness. These topics would align measurement of PHPs in HOPDs with that of the IPFQR Program.

XIII. Hospital Outpatient Quality Reporting Program Updates

G. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2014 Payment Update

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on the measures selected by the Secretary, in the form and manner, and at a time, required by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent payment year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. All other hospitals paid under the OPPS that meet the reporting requirement receive the full OPPS payment update without the reduction. For a more detailed discussion of how the payment reduction for failure to meet the administrative, data collection, and data submission requirements of the Hospital OQR Program was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to this proposed rule with comment period, which is available via the Internet on

the CMS Web site): ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' or ''U.'' We note that we are proposing to delete status indicator ''X'' as described in sections II.A.3. and XI. of this proposed rule. We also note that we are proposing to develop status indicator ''J1'' as part of the proposed comprehensive APC discussed in section II.A.2.e. of this proposed rule. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for applicable hospitals, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or ''T''. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To 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 multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for those hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply in those cases when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; the rural sole community hospital adjustment; and the adjustment for devices furnished with full or partial credit or without cost. We believe that these adjustments continue to be equally applicable to payments for hospitals that do not meet the Hospital OQR Program requirements. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when the criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. This policy conforms to current practice under the IPPS. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this proposed rule.

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2014

We are proposing to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2014 annual payment update factor. For the CY 2014 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of $71.273 by the proposed full conversion factor of $72.728. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2014 OPPS, we are proposing to apply the reporting ratio, when applicable, to all HCPCS codes to which we have assigned status indicators ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' and ''U'' (other than new technology APCs to which we have assigned status indicators ''S'' and ''T''). We note that we are proposing to delete status indicator ''X'' as described in sections II.A.3. and XI. of this proposed rule. We also note that we are proposing to develop status indicator ''J1'' as part of the proposed comprehensive APC discussed in section II.A.2.e. of this proposed rule and to apply the reporting ratio to the comprehensive APCs. We are proposing to continue to exclude services paid under New Technology APCs. We are proposing to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also are proposing to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we are proposing to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements.

We invite public comment on these proposals.

H. Proposed Requirements for Reporting of Hospital OQR Data for the CY 2015 Payment Determination and Subsequent Years

1. Administrative Requirements for the CY 2015 Payment Determination and Subsequent Years

To participate successfully in the Hospital OQR Program, hospitals must meet administrative, data collection and submission, and data validation requirements (if applicable). Hospitals that do not meet Hospital OQR Program requirements, as well as hospitals not participating in the program and hospitals that withdraw from the program, will not receive the full OPPS

payment rate update. Instead, in accordance with section 1833(t)(17)(A) of the Act, those hospitals will receive a reduction of 2.0 percentage points to their OPD fee schedule increase factor for the applicable payment year.

We established administrative requirements for the payment determination requirements for the CY 2013 payment update and subsequent years in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74479 through 74487). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68480 through 68481), we modified these requirements by extending the deadline for certain hospitals to submit a participation form. For the CY 2014 payment determination and subsequent years, we modified the deadline for hospitals that are not currently participating in the Hospital OQR Program and wish to participate, provided they have a Medicare acceptance date before January 1 of the year prior to the affected annual payment update. For example, 2013 would be the year prior to the affected CY 2014 annual payment update, and we are referring to an acceptance date before January 1, 2013. The hospitals must submit a participation form by July 31 rather than March 31 of the year prior to the affected annual payment update in order to participate in the Hospital OQR Program for purposes of the CY 2014 payment update. In the example, the deadline would be July 31, 2013.

The Hospital OQR Program procedural requirements are unchanged from those adopted in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68480 through 68481). We are proposing to codify these procedural requirements at § 419.46(a). To participate in the Hospital OQR Program, a hospital—as defined in section 1886(d)(1)(B) of the Act and that is reimbursed under the OPPS—must:

- Register with QualityNet before beginning to report data.
- Identify and register a QualityNet security administrator as part of the registration process located on the QualityNet Web site (*http://www.QualityNet.org*);
- Complete and submit an online participation form available at the QualityNet Web site if this form has not been previously completed, if a hospital has previously withdrawn, or if the hospital acquires a new CMS Certification Number (CCN). For Hospital OQR Program purposes, hospitals that share the same CCN are required to complete a single online participation form. Once a hospital has submitted a participation form, it is considered to be an active Hospital OQR Program participant until such time as it submits a withdrawal form to CMS or no longer has an effective Medicare provider agreement.

Deadlines to submit the notice of participation form are based on the date identified as a hospital's Medicare acceptance date:

- If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must complete and submit to CMS a completed Hospital OQR Notice of Participation Form by July 31 of the calendar year prior to the affected annual payment update.
- If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must submit a completed participation form no later than 180 days from the date identified as its Medicare acceptance date.

Hospitals may withdraw from participating in the Hospital OQR Program and the procedural requirements for this are unchanged from those adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 77480). We are proposing to codify these procedural requirements at § 419.46(b). Under these procedures, a participating hospital may withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet Web site. The hospital may withdraw any time from January 1 to November 1 of the year prior to the affected annual payment update. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under § 419.43(h), and is required to submit a new participation form in order to participate in any future year of the Hospital OQR Program.

We invite public comment on this proposal.

2. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

a. Background

We refer readers to the following OPPS/ASC final rules with comment period for a history of measures adopted for the Hospital OQR Program, including lists of: 11 measures finalized for the CY 2011 payment determination (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); 26 measures finalized for the CY 2014 and CY 2015 payment determination (76 FR 74469 and 74473) and no additional measures finalized for the CY 2015 payment determination (77 FR 68476 through 68478). In the CY 2013 OPPS/ASC final rule with comment period, we confirmed the removal of one measure for the CY 2013 payment determination and subsequent years (77 FR 68473 through 68474), confirmed the suspension of one measure for the CY 2014 payment determination (77 FR 68474 through 68476), and finalized the deferred data collection for one measure (77 FR 68476).

b. Effects of Proposed Changes on Data Submission for CY 2015 and CY 2016 Payment Determinations and Subsequent Years

For the CY 2015 payment determination and subsequent years, we are proposing to remove OP–19 as discussed in section XIII.C.2.a. of this proposed rule. Effective with January 1, 2013 encounters, we previously suspended OP–19 and have not used OP–19 data to meet requirements for any payment determination under the Hospital OQR Program or in public reporting. Therefore, our proposal to remove OP–19 from the Hospital OQR Program would not require a participating hospital to take any new action.

For the CY 2015 payment determination and subsequent years, we are proposing to remove OP–24 from the Hospital OQR program, as discussed in section XIII.C.2.b. of this proposed rule. To date, we have not required hospitals to submit data for OP–24. Based on this proposal, hospitals would not be required to take any new action; that is, they would continue having no requirement to abstract or submit data for OP–24.

For the CY 2016 payment determination and subsequent years, in section XIII.E. of this proposed rule we are proposing to add five additional measures to the program.

We would require hospitals to submit data for these measures annually via an online tool located on either the NHSN Web site or the QualityNet Web site depending on the measure. We discuss proposed data collection for each of these new measures by mode of data submission in the following sections of this proposed rule.

The proposed new measures are:

- OP–27: Influenza Vaccination Coverage among Healthcare Personnel;
- OP–28: Complications within 30 Days Following Cataract Surgery

Requiring Additional Surgical Procedures;

- OP–29: Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients;
- OP–30: Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and
- OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

c. General Requirements

The proposed Hospital OQR Program procedural requirements are unchanged from those discussed and adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74480 through 74482). We are proposing to codify the policy that, to be eligible to receive the full OPD fee schedule increase factor for any payment determination, hospitals that participate in the Hospital OQR Program must submit to CMS data on measures selected under section 1833(17)(C) of the Act in a form and manner, and at a time specified by CMS. This means that hospitals must comply with our submission requirements for chart-abstracted data, population and sampling data, claims-based measure data, and Web-based quality measure data. We are proposing to codify these general submission requirements at § 419.46(c).

Submission deadlines by measure and data type are posted on the QualityNet Web site. In general, deadlines for patient-level data submitted directly to CMS would be approximately 4 months after the last day of each calendar quarter. For example, the submission deadline for data for services furnished during the first quarter of CY 2014 (January–March 2014) would be on or around August 1, 2014. We are proposing to codify language at § 419.46(c)(2) stating our practice of posting actual submission deadlines by measure and by data type on the QualityNet Web site (*http://www.QualityNet.org*).

We are proposing to codify our policies for initial data collection periods and submission deadlines for a hospital that did not participate in the previous year's Hospital OQR Program in § 419.46(c)(3) of our regulations. We refer readers to our previously finalized policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481) to establish data collection and submission requirements for the CY 2014 payment determination and subsequent years. To determine when a hospital that did not participate in a previous year's payment determination must begin collecting and submitting data to meet Hospital OQR Program requirements for a full annual payment update, we continue to use the January 1 Medicare acceptance date. If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must collect data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update, in addition to submitting a completed Hospital OQR Notice of Participation Form. If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must collect data for encounters beginning with the first full quarter following submission of the completed Hospital OQR Notice of Participation Form. Hospitals with a Medicare acceptance date before or after January 1 of the year prior to an affected annual payment update must follow data submission deadlines as specified on the QualityNet Web site.

We invite public comment on these proposals.

d. Proposed Chart-Abstracted Measure Requirements for the CY 2015 and CY 2016 Payment Determinations and Subsequent Years

The following chart-abstracted measures in the Hospital OQR Program require data submission for the CY 2015 payment determination and subsequent years:

- OP–1: Median Time to Fibrinolysis;
- OP–2: Fibrinolytic Therapy Received Within 30 Minutes;
- OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention;
- OP–4: Aspirin at Arrival;
- OP–5: Median Time to ECG;
- OP–6: Timing of Antibiotic Prophylaxis;
- OP–7: Prophylactic Antibiotic Selection for Surgical Patients;
- OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients;
- OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional;
- OP–21: ED—Median Time to Pain Management for Long Bone Fracture;
- OP–22: ED Patient Left Without Being Seen; and
- OP–23: ED—Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 Minutes of Arrival.

The form and manner for submission of one of these measures, OP–22: ED Patient Left Without Being Seen, is unique, and is detailed in section XV.G.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484). As discussed above, we are not proposing any new chart-abstracted measures where patient-level data is submitted directly to CMS in this proposed rule.

e. Proposed Claims-Based Measure Data Requirements for the CY 2015 Payment Determination and Subsequent Years

The table in section XIII.D. of this proposed rule includes measures that the Hospital OQR Program collects by accessing electronic Medicare claims data submitted by hospitals for reimbursement.

We are not proposing new claims-based measures in this proposed rule. Therefore, the following 6 claims-based measures will be included for the CY 2015 payment determination and subsequent years:

- OP–8: MRI Lumbar Spine for Low Back Pain;
- OP–9: Mammography Follow-Up Rates;
- OP–10: Abdomen CT—Use of Contrast Material;
- OP–11: Thorax CT—Use of Contrast Material;
- OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery; and
- OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).

We deferred the public reporting of OP–15, a claims-based measure (76 FR 74456). We are not proposing any change to this policy. Public reporting for OP–15 continues to be deferred, and this deferral has no effect on any payment determinations at this time.

We will continue our policy of calculating the measures using 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 2014 payment update, we will use paid Medicare FFS claims for services furnished from January 1, 2011 to December 31, 2011.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68482 through 68485), for the CY 2015 payment determination, we finalized our proposal to use paid Medicare FFS claims for services from a 12 month period from July 1, 2012 through June 30, 2013 for the calculation of the claims-based measures. This is a departure from the traditional 12 month

calendar year period we have used for these measures. As stated in that final rule with comment period, we adopted this period in order to align the data period for inpatient and outpatient claims based measures reported on the *Hospital Compare* Web site, and also to be able to post more recent data for claims-based measures on the Web site. Under our policy prior to the CY 2013 final rule, the time period would have been January 1, 2011 to December 31, 2011, whereas, under the policy finalized in that final rule with comment period, the time period is July 1, 2012 to June 30, 2013.

For the CY 2016 payment determination and subsequent years, we are proposing to continue this approach and to use paid Medicare FFS claims for services from a 12 month period from July three years before the payment determination through June of the next year. For CY 2016, this 12 month period would be from July 1, 2013 through June 30, 2014 for the calculation of the claims-based measures. We invite public comment on this proposal.

f. Proposed Data Submission Requirements for Measure Data Submitted via Web-Based Tool for the CY 2016 Payment Determination and Subsequent Years

In previous rulemaking, we have referred to measures where data are submitted via a Web-based tool on a CMS Web site under our quality data reporting programs as structural measures (measures concerned with attributes of where care occurs, such as material resources, human resources, and organizational structure.[10] For example, the Hospital OQR Measure OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data is a structural measure. However, because measures where data is submitted in this manner may or may not be structural, for example, the Hospital IQR chart-abstracted, process of care measure PC–01: Elective Delivery Prior to 39 Completed Weeks Gestation, we have refined our terminology and now refer to the mode of data submission as Web-based.

Thus, the previously finalized Web-based measures where data is entered on a CMS Web site that we require for the CY 2015 payment determination and subsequent years are listed below:

- OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data;
- OP–17: Tracking Clinical Results Between Visits;
- OP–22: ED Patient Left Without Being Seen;
- OP 25: Safe Surgery Check List Use; and
- OP 26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68483 through 68484), we finalized that, for the CY 2014 payment determination, hospitals are required to submit data on all Web-based measures between July 1, 2013 and November 1, 2013 with respect to the time period from January 1, 2012 to December 31, 2012. This schedule also applies to the encounter periods and deadlines to submit data for OP–22: ED Patient Left Without Being Seen. While patient-level data for this measure is collected via chart-abstraction, aggregate data is submitted using an online tool.

We also finalized in the CY 2013 OPPS/ASC final rule with comment period for the CY 2015 payment determination, that hospitals are required to submit data on all Web-based measure data between July 1, 2014 and November 1, 2014 with respect to the time period from January 1, 2013 to December 31, 2013.

We are proposing to apply a similar schedule for the CY 2016 payment determination and subsequent years. For the CY 2016 payment determination and subsequent years, we are proposing that hospitals would be required to submit data between July 1 and November 1 of the year prior to a payment determination with respect to the time period of January 1 to December 31 of two years prior to a payment determination year. Thus, for example, for the CY 2016 payment determination, hospitals would be required to submit data between July 1, 2015 and November 1, 2015 with respect to the time period of January 1, 2014 to December 31, 2014.

We are also proposing to apply the same mode of data collection and deadlines to the following proposed measures:

- OP–28: Complications within 30 days Following Cataract Surgery Requiring Additional Surgical Procedures;
- OP–29: Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients;
- OP–30: Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and
- OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

Specifically, for data collection, we are proposing that hospitals submit aggregate-level data through the CMS Web-based tool (the QualityNet Web site). As with OP–22, hospitals would submit all the data required for a particular program year once annually during the data submission window we are proposing above, and would do so via the Outpatient section on the QualityNet secure Web site. While we are proposing submission deadlines with an annual frequency, the data input forms on the QualityNet Web site for such submission will require hospitals to submit aggregate data represented by each separate quarter. We are proposing to both use the Web-based collection tool and collect aggregate-level data because we believe these options are less burdensome to hospitals than patient-level reporting.

While this proposal applies to the CY 2016 payment determination and subsequent years, we summarize below, for chart-abstracted measures collected via the Web-based tool, the proposed and finalized measures, data collection periods, and deadlines for just the CY 2016 payment determination.

[10] Maintz, J. Defining and Classifying Clinical Indicators for Quality Improvement, Inter J Quality Health Care (2003) 15(6), 523–530).

PROPOSED AND FINALIZED CHART-ABSTRACTED MEASURES WITH DATA COLLECTION BY WEB-BASED TOOL: CY 2016 PAYMENT DETERMINATION

Measure	Hospital OQR program status	Encounter dates	Data submission timeframe
OP–22: ED Patient Left Without Being Seen	Finalized	January 1, 2014–December 31, 2014.	July 1, 2015–November 1, 2015.
OP–28: Complications within 30 days Following Cataract Surgery Requiring Additional Surgical Procedures.	Proposed	January 1, 2014–December 31, 2014.	July 1, 2015–November 1, 2015.
OP–29: Endoscopy/poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients.	Proposed	January 1, 2014–December 31, 2014.	July 1, 2015–November 1, 2015.
OP–30: Endoscopy/poly surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.	Proposed	January 1, 2014–December 31, 2014.	July 1, 2015–November 1, 2015.
OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.	Proposed	January 1, 2014–December 31, 2014.	July 1, 2015–November 1, 2015.

We recognize that aggregate-level reporting has the potential to result in less accurate measure rates than patient-level reporting. However, to reduce burden for hospitals, we believe that an aggregate data submission approach is the preferable approach at this time.

We invite public comment on these proposals.

g. Proposed Data Submission Requirements for a Measure Reported via NHSN for the CY 2016 Payment Determination and Subsequent Years

As discussed above, we are proposing to add the measure OP–27: Influenza Vaccination Coverage among Healthcare Personnel to the Hospital OQR Program measure set. We are also proposing to use the data submission and reporting standard procedures set forth by CDC for NHSN participation in general and for submission of this measure to NHSN. We refer readers to the CDC's NHSN Web site (*http://www.cdc.gov/nhsn*) for detailed data submission and reporting procedures. We believe that these procedures are feasible because they are already widely used by over 4,000 hospitals reporting HAI data using NHSN. Our proposal seeks to reduce hospital burden by aligning our data submission and reporting procedures with NHSN procedures currently used by hospitals who participate in the reporting requirements for the Hospital IQR Program as well as hospitals in the 30 States and the District of Columbia that mandate HAI reporting via NHSN.

We are proposing to adopt the NHSN HAI measure data collection timeframe of October 1 through March 31st, as previously finalized in the Hospital IQR Program (76 FR 51631 through 51633), which links data collection to the time period in which influenza vaccinations are administered during the influenza season. Because data for this measure would be collected seasonally, we are proposing that hospitals submit their data for this measure to NHSN for purposes of the Hospital OQR Program by May 15th of the calendar year in which the vaccination season has ended. For example, for vaccinations given from October 1, 2014 (or when the vaccine becomes available) to March 31, 2015, the submission deadline would be May 15, 2015. This data submission deadline for this measure corresponds to that proposed by the Hospital IQR Program (78 FR 27700).

We invite public comment on these proposals.

h. Population and Sampling Data Requirements for the CY 2015 Payment Determination and Subsequent Years

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484), for the CY 2014 payment determination and subsequent years, we continued our policy that hospitals may submit voluntarily on a quarterly basis, aggregate population and sample size counts for Medicare and non-Medicare encounters for the measure populations for which chart-abstracted data must be submitted, but they will not be required to do so. Where hospitals do choose to submit this data, the deadlines for submission are the same as those for reporting data for chart-abstracted measures, and hospitals may also choose to submit data prior to these deadlines. The deadline schedule is available on the QualityNet Web site. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72101 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of these policies.

We are not proposing any changes to this policy.

3. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2015 Payment Determination and Subsequent Years

a. Selection of Hospitals for Data Validation of Chart-Abstracted Measures for the CY 2015 Payment Determination and Subsequent Years

We refer readers to the CY 2012 and CY 2013 OPPS/ASC final rules with comment period (76 FR 74484 through 74487 and 77 FR 68484 through 68487) for a discussion of finalized policies regarding our sampling methodology, including sample size, eligibility for validation selection, and encounter minimums for patient-level data for measures where data is obtained from chart abstraction and submitted directly to CMS from selected hospitals. We are not proposing any changes to these policies.

We are, however, proposing to codify at § 419.46(e) of our regulations the existing policy that we may validate one or more measures selected under section 1833(17)(C) of the Act by reviewing documentation of patient encounters submitted by selected participating hospitals. Upon written request, a hospital must submit to CMS or its contractor supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 45 days of the date identified on the written request, in the form and manner specified in the written request. A hospital meets the validation requirement with respect to a fiscal year if it achieves at least a 75-percent reliability score, as determined by CMS.

We invite public comment on our proposal to codify these requirements.

b. Targeting Criteria for Data Validation Selection for the CY 2015 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68485 through 68486) for a discussion of our targeting criteria. We are not proposing any changes to this policy.

c. Methodology for Encounter Selection for the CY 2015 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486) for a discussion of our methodology for encounter selection. We are not proposing any changes to this policy.

d. Medical Record Documentation Requests for Validation and Validation Score Calculation for the CY 2015 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486 through 68487) for a discussion of our procedures for requesting medical record documentation for validation and validation score calculation. We are not proposing any changes to our procedures regarding medical record requests.

However, we are proposing to codify these procedures at § 419.46(e)(1) and (e)(2) as summarized below:

- CMS may validate one or more measures selected under section 1833(17)(C) of the Act by reviewing documentation of patient encounters submitted by selected participating hospitals.
- Upon written request by CMS or its contractor, a hospital must submit to CMS supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 45 days of the date identified on the written request, in the form and manner specified in the written request.
- A hospital meets the validation requirement with respect to a fiscal year if it achieves at least a 75-percent reliability score, as determined by CMS.

We invite public comment on our proposal to codify these procedures.

I. Proposed Hospital OQR Reconsideration and Appeals Procedures for the CY 2015 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487) for a discussion of our reconsideration and appeals procedures. We are proposing one change to the reconsideration request procedures to ensure our deadline for reconsideration requests will always fall on a business day. We also are proposing to codify the process, including our proposal to change the deadline by which participating hospitals may submit requests for reconsideration at § 419.46(f) of our regulations.

Under the proposed change to our procedures, a hospital seeking reconsideration would submit to CMS, via the QualityNet Web site, a Reconsideration Request form that will be made available on the QualityNet Web site. Where we have required that this form must be submitted by February 3 of the affected payment year (for example, for the CY 2014 payment determination, the request was required to be submitted by February 3, 2014), we are proposing to modify this requirement so that the Reconsideration Request form would be required to be submitted on the first business day in February of the affected payment year. If this proposal is finalized, the Reconsideration Request form for the CY 2014 payment determination would be required on February 3, 2014, which is a Monday, and the form for the CY 2015 payment determination would be required on February 2, 2015, which is also a Monday. We note that while we use the CY 2014 and 2015 payment determinations as examples, we are proposing this policy for the CY 2014 payment determination and subsequent years. The other requirements of the form would remain unchanged. We request public comment on this proposal.

We also are proposing to codify this process by which participating hospitals may submit requests for reconsideration including our proposal to change the reconsideration request deadline at § 419.46(f). Under these proposed procedures, the hospital must submit to CMS via QualityNet, a reconsideration request via the QualityNet Web site, no later than the first business day of the month of February of the affected year containing the following information:

- The hospital's CMS Certification Number (CCN);
- The name of the hospital;
- The CMS-identified reason for not meeting the requirements of the affected payment year's Hospital OQR Program as provided in any CMS notification to the hospital;
- The hospital's basis for requesting reconsideration. The hospital must identify its specific reason(s) for believing it should not be subject to the reduced annual payment update;
- The hospital-designated personnel contact information, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).
- The hospital-designated personnel's signature;
- A copy of all materials that the hospital submitted to comply with the requirements of the affected Hospital OQR Program payment determination year; and
- If the hospital is requesting reconsideration on the basis that CMS has determined it did not meet an affected payment determination year's validation requirement set forth in paragraph (e)(1) of this section, the hospital must provide a written justification for each appealed data element classified during the validation process as a mismatch. Only data elements that affect a hospital's validation score are eligible to be reconsidered.

We also are proposing to codify language at § 419.46(f)(3) stating that a hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board.

While we are not proposing to codify the following process, we note that, after receiving a request for reconsideration, CMS—

- Provides an email acknowledgement, using the contact information provided in the reconsideration request, to the designated hospital personnel notifying them that the hospital's request has been received.
- Provides a formal response to the hospital-designated personnel, using the contact information provided in the reconsideration request, notifying the hospital of the outcome of the reconsideration process.
- Applies policies regarding the scope of our review when a hospital requests reconsideration because it failed our validation requirement.

These policies are as follows:

- If a hospital requests reconsideration on the basis that it disagrees with a determination that one or more data elements were classified as mismatches, we only consider the

hospital's request if the hospital timely submitted all requested medical record documentation to the CMS contractor each quarter under the validation process.

- If a hospital requests reconsideration on the basis that it disagrees with a determination that one or more of the complete medical records it submitted during the quarterly validation process was classified as an invalid record selection (that is, the CMS contractor determined that one or more of the complete medical records submitted by the hospital did not match what was requested), thus resulting in a zero validation score for the encounter(s), our review is initially limited. We will review only to determine whether the medical documentation submitted in response to the designated CMS contractor's request was the correct and complete documentation. If we determine that the hospital did submit correct and complete medical documentation, we abstract the data elements and compute a new validation score for the encounter. If we conclude that the hospital did not submit correct and complete medical record documentation, we do not further consider the hospital's request.

- If a hospital requests reconsideration on the basis that it disagrees with a determination that it did not submit the requested medical record documentation to the CMS contractor within the proposed 30 calendar day timeframe, our review is initially limited to determining whether the CMS contractor received the requested medical record documentation within 30 calendar days, and whether the hospital received the initial medical record request and reminder notice. If we determine that the CMS contractor timely received copies of the requested medical record documentation, we abstract data elements from the medical record documentation submitted by the hospital and compute a validation score for the hospital. If we determine that the hospital received two letters requesting medical documentation but did not submit the requested documentation within the 30 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 invite public comment on these proposals.

J. Extraordinary Circumstances Extension or Waiver for the CY 2014 Payment Determination and Subsequent Years

In our experience, there have been times when facilities have been unable to submit information to meet program requirements due to extraordinary circumstances that are not within their control. It is our goal to not penalize such entities for such circumstances and we do not want to unduly increase their burden during these times. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489) for a complete discussion of our extraordinary circumstances extension or waiver process under the Hospital OQR Program.

We are proposing one change to our process for hospitals to request and for CMS to grant extensions or waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the hospital. Specifically, we are proposing that we may grant a waiver or extension to hospitals if we determine that a systemic problem with one of our data collection systems directly or indirectly affected the ability of hospitals to submit data. Because we do not anticipate that such systemic errors will happen often, we do not anticipate granting a waiver or extension on this basis frequently.

We also are proposing to codify language for the general requirements for our extension or waiver process including the proposal for systemic errors at § 419.46(d) as described below:

CMS may grant an extension or waiver of one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an extension or waiver as follows:

- Upon request by the hospital. Specific requirements for submission of a request for an extension or waiver are available on the QualityNet Web site.
- At the discretion of CMS. CMS may grant waivers or extensions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

For the hospital to request consideration for an extension or waiver of the requirement to submit quality data or medical record documentation for one or more quarters, a hospital would follow specific requirements for submission of a request available on QualityNet. While we are not proposing to codify the following process, we note that, the following information must appear on the request form:

- Hospital CCN;
- Hospital Name;
- CEO or other hospital-designated personnel contact information, including name, email address, telephone number, and mailing address (must include a physical address, a post office box address is not acceptable);
- Hospital's reason for requesting an extension or waiver;
- Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the hospital believes it would again be able to submit Hospital OQR data and/or medical record documentation, and a justification for the proposed date.

The request form must be signed by the hospital's designated contact, whether or not that individual is the CEO. A request form is required to be submitted within 45 days of the date that the extraordinary circumstance occurred.

Following receipt of such a request, CMS would—

(1) Provide an email acknowledgement using the contact information provided in the request notifying the designated contact that the hospital's request has been received;

(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 and communicate our response within 90 days following our receipt of such a request.

We can also grant waivers or extensions to hospitals that have not requested them when we determine that an extraordinary circumstance, such as when an act of nature (for example, hurricane) affects an entire region or locale or a systemic problem with one of our data collection systems directly or indirectly affects data submission. 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 emails and notices on the QualityNet Web site.

We invite public comment on these proposals.

XIV. Hospital Value-Based Purchasing (VBP) Program Updates

A. Background

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing program (the Hospital Value-Based Purchasing (VBP) Program) under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

B. Proposal for Additional CMS Appeals Review Process

1. Statutory Basis

Section 1886(o)(11)(A) of the Act requires the Secretary to establish a process by which hospitals may appeal the calculation of a hospital's performance assessment with respect to the performance standards (section 1886(o)(3)(A) of the Act) and the hospital performance score (section 1886(o)(5) of the Act).

Under section 1886(o)(11)(B) of the Act, there is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following: (1) The methodology used to determine the amount of the value-based incentive payment under section 1886(o)(6) of the Act and the determination of such amount; (2) the determination of the amount of funding available for the value-based incentive payments under section 1886(o)(7)(A) of the Act and the payment reduction under section 1886(o)(7)(B)(i) of the Act; (3) the establishment of the performance standards under section 1886(o)(3) of the Act and the performance period under section 1886(o)(4) of the Act; (4) the measures specified under section 1886(b)(3)(B)(viii) of the Act and the measures selected under section 1886(o)(2) of the Act; (5) the methodology developed under section 1886(o)(5) of the Act that is used to calculate hospital performance scores and the calculation of such scores; or (6) the validation methodology specified in section 1886(b)(3)(B)(XI) of the Act.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53581), we finalized an administrative appeals process and codified that process at 42 CFR 412.167.

2. Independent CMS Review Proposal

In this proposed rule, for the Hospital VBP Program, we are proposing to implement an independent CMS review that will be an additional appeal process available to the hospitals, beyond the existing review and corrections process (77 FR 53578 through 53581 and 76 FR 74544 through 74547) and appeal process codified at 42 CFR 412.167. We are proposing that a hospital would be able to request this additional independent CMS review only if it first completes the appeal process at 42 CFR 412.167(b) and is dissatisfied with the result. We believe that our proposal to require hospitals to complete the existing appeal process at 42 CFR 412.167(b) before they can request an additional independent CMS review will facilitate the efficient resolution of many disputed issues, thus decreasing the number of independent CMS reviews that are requested. We intend to provide hospitals with our independent review decision within 90 calendar days following the receipt of a hospital's independent review request. We also are proposing to codify this policy in our regulations at 42 CFR 412.167 by redesignating the existing paragraph (c) as paragraph (d), and inserting a new paragraph (c). We are inviting public comments on these proposals.

C. Proposed Performance and Baseline Periods for Certain Outcome Measures for the FY 2016 Hospital VBP Program

As described in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27610 through 27611), we have proposed to adopt CLABSI, CAUTI, and SSI, which are measures reported to CDC's National Healthcare Safety Network (NHSN), for the FY 2016 Hospital VBP Program. However, when we published that proposed rule, we inadvertently did not make FY 2016 performance and baseline period proposals for these proposed measures. We are proposing to adopt FY 2016 performance and baseline periods for these measures in this proposed rule so that we have enough time to consider and respond to public comments before the proposed start of the performance periods.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53597 through 53598), we finalized an 11-month performance period for the CLABSI measure for the FY 2015 Hospital VBP Program (February 1, 2013 through December 31, 2013), with a corresponding baseline period of January 1, 2011 through December 31, 2011. While we adopted an 11-month performance period for the CLABSI measure for FY 2015 based on its posting date on the *Hospital Compare* Web site, beginning with FY 2016, we are proposing to align the NHSN measures' performance and baseline periods with other domains' performance and baseline periods, where possible, and with the calendar year. As we have stated with regard to other domains, a 12-month performance period provides us more data on which to score hospital performance, which is an important goal both for CMS and for stakeholders.

Therefore, we are proposing to adopt CY 2014 (January 1, 2014 through December 31, 2014) as the performance period for the CLABSI, CAUTI, and SSI measures for the FY 2016 Hospital VBP Program, with CY 2012 (January 1, 2012 through December 31, 2012) as the baseline period. We are inviting public comments on these proposals.

The proposed performance and baseline periods for the CAUTI, CLABSI, and SSI measures for the FY 2016 Hospital VBP Program appear in the following table.

PROPOSED PERFORMANCE AND BASELINE PERIODS FOR CAUTI/CLABSI/SSI UNDER THE FY 2016 HOSPITAL VBP PROGRA

Domain	Baseline period	Performance period
Outcome • CAUTI/CLABSI/SSI ...	• January 1, 2012–December 31, 2012	• January 1, 2014–December 31, 2014.

XV. Proposed Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIII.A.1. of this proposed rule for a general overview of our quality reporting programs.

2. Statutory History of the 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. Regulatory 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 comment on 10 measures.

In addition to CMS preparing to propose implementation of a quality reporting program for ASCs, HHS developed a plan to implement a value-based purchasing (VBP) program for payments under title XVIII of the Act for ASCs, and submitted a report to Congress entitled ''Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan'' that details this plan. The plan and the report to Congress were required under section 3006(f) of the Affordable Care Act as added by section 10301(a) of the Affordable Care Act. The report is found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/Downloads/C_ASC_RTC–2011.pdf*. Currently, we do not have express statutory authority to implement an ASC VBP program.

In the CY 2012 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 determinations and subsequent years, and finalized some data collection and reporting timeframes for these measures. We also adopted policies with respect to the maintenance of technical specifications and the updating of measures, publication of ASCQR Program data, and, for the CY 2014 payment determination, 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 was to begin with services furnished on October 1, 2012. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53636 through 53644), we issued final policies for administrative requirements, data completeness requirements, extraordinary circumstances waiver or extension requests, and a reconsideration process. For a complete discussion of these policies, we refer readers to the FY 2013 IPPS/LTCH PPS final rule.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68492 through 68500), we issued final policies regarding our approach to selecting quality measures, reporting requirements, and payment reductions for ASCs that fail to meet the ASCQR Program requirements.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of the considerations we use for the selection of ASCQR Program quality measures.

2. ASCQR Program Quality Measures Adopted in Previous Rulemaking

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized our proposal to implement the ASCQR Program beginning with the CY 2014 payment determination and adopted measures for the CY 2014, CY 2015, and CY 2016 payment determinations. In an effort to streamline the rulemaking process, we also finalized our policy that, when we adopt measures for the ASCQR Program, these measures are automatically adopted for all subsequent years payment determinations unless we propose to remove, suspend, or replace the measures (76 FR 74494, 74504, 74509, and 74510).

The quality measures that we have previously adopted are listed below.

ASC PROGRAM MEASUREMENT SET ADOPTED IN PREVIOUS RULEMAKING

ASC–1: Patient Burn.*
ASC–2: Patient Fall.*
ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.*
ASC–4: Hospital Transfer/Admission.*
ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing.*
ASC–6: Safe Surgery Checklist Use.**
ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures.**
Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754*
ASC–8: Influenza Vaccination Coverage among Healthcare Personnel***

*New measure for the CY 2014 payment determination.
**New measure for the CY 2015 payment determination.
***New measure for the CY 2016 payment determination.

3. Proposed Additional ASCQR Program Quality Measures for the CY 2016 Payment Determination and Subsequent Years

We are proposing quality measures for the CY 2016 payment determination and subsequent years based on our approach for future measure selection and development finalized in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494), which includes, among other considerations, aligning the ASCQR Program measures with our efforts in other clinical care settings and taking into account the views of the MAP.

We believe that ASCs and HOPDs are similar in their delivery of surgical and related nonsurgical services. Therefore, we seek to propose quality measures that can be applied to both HOPDs and ASCs to the extent possible because many of the same surgical procedures are performed in both of these settings. Measure harmonization assures that quality of care for similar services is measured in a comparable manner across settings. This approach would provide meaningful information for Medicare beneficiaries to make informed decisions.

Section 3014 of the Affordable Care Act added section 1890A of the Act establishing a pre-rulemaking process, which, among other steps, requires the Secretary to take into consideration the input from multi-stakeholder groups in selecting certain categories of quality and efficiency measures described in section 1890(b)(7)(B) of the Act. As part of the pre-rulemaking process, the consensus-based entity that CMS must contract with under section 1890 of the Act (currently NQF), convened the multi-stakeholder groups, referred to as the MAP. The MAP is a public-private partnership created for the primary purpose of providing input to HHS on the selection of the categories of measures in section 1890(b)(7)(B), which includes measures for use in certain specific Medicare programs, measures for use in reporting performance information to the public, and measures for use in health care programs other than for use under the Act.

After we selected quality measures that we might propose for the ASCQR Program based on our established policies regarding the approach to selecting quality measures in CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494), we included the measures in a publicly available document entitled ''List of Measures Under Consideration for December 1, 2012'' in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP in its ''MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS,'' which has been made available on the NQF Web site at: *http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx.* We considered the input and recommendations provided by the MAP in selecting measures to propose for the ASCQR Program.

In addition, in its 2013 Pre-Rulemaking Report, the MAP also supports: (1) HHS' efforts to move toward greater alignment across the Hospital OQR and ASCQR Programs; and (2) the inclusion of ASCs within a broader approach to measuring performance and improving care that is aligned across health care settings (page 35, MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS).

For the CY 2016 payment determination and subsequent years, we are proposing to adopt four measures for the ASCQR Program, all of which were reviewed by the MAP and three of which are NQF-endorsed for the ASC setting: (a) Complications within 30 Days following Cataract Surgery Requiring Additional Surgical Procedures; (b) Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients (NQF #0658); (c) Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659); and (d) Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).

For purposes of the ASCQR Program, sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, read together, require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74465 and 74505), we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process; consensus shown through broad acceptance and use of measures; and consensus through public comment. The proposed measures are described in greater detail below.

We are proposing that data collection for these four measures would begin in CY 2014. We refer readers to section XV.D. of this proposed rule for detailed discussion of data collection and submission time frames. We are proposing to collect aggregate data (numerators, denominators, and exclusions) on all ASC patients for these four proposed chart-abstracted measures via an online Web-based tool that would be made available to ASCs via the QualityNet Web site. This online Web-based tool is currently in use in the ASCQR Program to collect measure information for ASC–6 (Safe Surgery Checklist Use) and ASC–7 (ASC Facility Volume Data on Selected ASC Surgical Procedures). We invite public comment on these proposals. More information regarding this proposed method of collection is provided in section XV.D.5.c. of this proposed rule.

To advance our efforts to collect high quality data on all ASC patients for the ASCQR measures while minimizing burden for ASCs, we also seek public comment on alternative data collection strategies for these four proposed measures. In particular, we seek comment on collection of patient-level data through registries or other third party data aggregators, and via certified EHR technology, along with the potential timing for doing so.

a. Complications Within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures

It is uncommon to have complications that may result in a permanent loss of vision following cataract surgery. Cataract surgery has become safer and more effective due to advances in technology and surgical skills over the last 30 years. Based on an analysis of Managed Care Organization data, it is estimated that the annual volume for cataract surgeries is 2.8 million in the U.S. with the rate of cataract surgery complications being 1 to 2 percent. However, with an annual volume of 2.8 million cataract surgeries in the United States, a 2 percent rate is significant and translates to over 36,000 surgeries associated with complications.[11]

Thus, for the CY 2016 payment determination and subsequent years, we are proposing to adopt the Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures

[11] National Quality Measures Clearing House. Agency for Healthcare Research and Quality. Available at *http://qualitymeasures.ahrq.gov/content.aspx?id=27981&search=complications+within+30+days+following+cataract+surgery.*

measure, which assesses the ''[p]ercentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL retinal detachment, or wound dehiscence.'' This outcome measure seeks to identify those complications from surgery that can reasonably be attributed to the surgery. It focuses on patient safety and monitoring for events that, while uncommon, can signify important issues in the care being provided. The numerator for this measure is the number of ''[p]atients who had one or more specified operative procedures for any of the following major complications within 30 days following cataract surgery: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.'' The denominator for this measure is the total number of ''[p]atients aged 18 years and older who had cataract surgery and no significant pre-operative ocular conditions impacting the surgical complication rate.'' This measure excludes ''[p]atients with certain comorbid conditions impacting the surgical complication rate.'' The measure specifications can be found at: *http://www.qualityforum.org/QPS/0564.* This measure has been endorsed by NQF for the ''Ambulatory Care: Clinic'' setting (NQF #0564) but, currently, is not NQF-endorsed for the ASC setting.

We believe this measure meets the statutory requirements discussed above. This measure is not NQF-endorsed in the ASC setting and we could not find any other comparable measure that is specifically endorsed for the ASC setting. However, we believe that this measure is appropriate for the measurement of quality of care furnished by ASCs because this procedure is commonly performed in ASCs and, as discussed above, can signify important issues in the care being provided in ASCs. Further, this measure reflects consensus among affected parties as it has been endorsed by NQF for the ''Ambulatory Care: Clinic'' setting. We believe that this consensus also applies to the same surgeries that are performed in other ambulatory settings, such as ASCs and HOPDs. Given the high volume of cataract surgeries performed in ambulatory care settings and the potential 2 percent complication rate, we believe it is important for us to include this measure in the ASCQR Program measure set, and that this is an appropriate application of NQF #0564 to the ASC setting.

We note that section 1833(t)(17) of the Act does not require that each measure we adopt be endorsed by a national consensus building entity. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act applies to the ASCQR program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures. In its 2013 Pre-Rulemaking Report, the MAP supported inclusion of this measure in the ASCQR Program and noted that this measure ''[a]ddresses a high impact condition not adequately addressed in the program measure set.'' Currently, the NQF endorsement for this measure is time-limited.

We invite public comment on this proposal.

b. Endoscopy/Poly Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)

The American Cancer Society's current guidelines recommend colonoscopy screening at 10-year intervals [12] for the average risk population (*http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/colorectal-cancer-early-detection-acs-recommendations*).

For the CY 2016 payment and subsequent years, we are proposing to adopt the Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients measure, which assesses the ''[p]ercentage of patients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.'' Performing colonoscopy too frequently increases a patients' exposure to procedural harm. This measure aims to assess whether average risk patients with normal colonoscopies receive a recommendation to receive a repeat colonoscopy in an interval that is less than the recommended amount of 10 years. This measure is NQF-endorsed for the ASC setting. The numerator for this measure is the number of ''[p]atients who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.'' The denominator for this measure is the total number of ''[p]atients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy.'' The measure excludes patients whose medical records contain reason(s) for recommending a follow up interval of less than 10 years. The specifications for this measure can be found at: *http://www.qualityforum.org/QPS/0658.*

We believe this measure meets the statutory requirements discussed above. This measure is appropriate for the measurement of quality of care furnished by ASCs because colonoscopy screening is commonly performed in ASCs and this measure was developed to specifically measure quality of care furnished by ASCs. We also believe it meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is NQF-endorsed for the ASC setting.

In its 2013 Pre-Rulemaking Report, the MAP supported the direction of this measure. Currently, the NQF endorsement for this measure is time-limited.

We invite public comment on this proposal.

c. Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients With a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659)

According to the American Cancer Society, in patients with increased or high risk of colorectal cancer, colonoscopy screening is recommended based on risk factors. One such factor is a history of adenomatous polyps. The frequency of colonoscopy screening varies depending on the size and amount of polyps found; however, the general recommendation is a 3 year follow-up (*http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/colorectal-cancer-early-detection-acs-recommendations*). A randomized trial of 699 patients showed that after newly diagnosed adenomatous polyps have been removed by colonoscopy, follow-up colonoscopy at 3 years detects important colonic

[12] Davila RE, Rajan E, Baron TH, Adler DG, Egan JV, Faigel DO, Gan SI, Hirota WK, Leighton JA, Lichtenstein D, Qureshi WA, Shen B, Zuckerman MJ, VanGuilder T, Fanelli RD, Standards of Practice Committee, American Society for Gastrointestinal Endoscopy. ASGE guideline: colorectal cancer screening and surveillance. Gastrointest Endosc 2006 Apr;63(4):546–57. *http://www.ncbi.nlm.nih.gov/pubmed/16564851?dopt=Abstract.*

lesions as effectively as follow-up colonoscopy at both 1 and 3 years.[13]

For the CY 2016 payment determination and subsequent years, we are proposing to adopt the Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use measure, which assesses the ''[p]ercentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report'' This measure is NQF-endorsed for the ASC setting. The numerator for this measure is the number of ''[p]atients who had an interval of 3 or more years since their last colonoscopy.'' The denominator for this measure is the total number of ''[p]atients aged 18 years and older receiving a surveillance colonoscopy with a history of a prior colonic polyp in a previous colonoscopy.'' This measure excludes patients with: (1) Documentation of medical reason(s) for an interval of less than 3 years since the last colonoscopy (for example, last colonoscopy incomplete, last colonoscopy had inadequate prep, piecemeal removal of adenomas, or last colonoscopy found greater than 10 adenomas); or (2) documentation of a system reason(s) for an interval of less than 3 years since the last colonoscopy (for example, unable to locate previous colonoscopy report, previous colonoscopy report was incomplete). The specifications for this measure can be found at: *http://www.qualityforum.org/QPS/0659*.

We believe this measure meets the statutory requirements discussed above. This measure is appropriate for the measurement of quality of care furnished by ASCs because colonoscopy is commonly performed in ASCs and this measure was developed to specifically measure quality of care furnished by ASCs. We also believe it meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is NQF-endorsed for the ASC setting.

In its 2013 Pre-Rulemaking Report, the MAP supported the direction of this measure. Currently, the NQF endorsement for this measure is time-limited.

We invite public comment on this proposal.

d. Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (NQF #1536)

Cataract surgery is performed to improve a patient's vision and associated functioning. This outcome is achieved consistently with careful attention to the accurate measurement of axial length and corneal power and the appropriate selection of an IOL lens. Failure to achieve improved visual functioning after surgery in eyes without comorbid ocular conditions that could impact the success of the surgery would reflect care that should be assessed for opportunities for improvement. Evidence suggests that visual improvement occurs in about 86 to 98 percent of surgeries in eyes without comorbid conditions. However, with an annual volume of 2.8 million cataract surgeries in the U.S., an improvement rate from 86 to 98 percent could impact a significant number of patients per year.[14]

For the CY 2016 payment determination and subsequent years, we are proposing to adopt the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure, which assesses the ''[p]ercentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery.'' This measure is NQF-endorsed for the ASC setting. The measure numerator is the number of ''[p]atients 18 years and older in sample who had improvement in visual function achieved within 90 days following cataract surgery, based on completing a pre-operative and post-operative visual function instrument.'' The measure denominator is the total number of ''[p]atients aged 18 years and older in sample who had cataract surgery.'' There are no exclusions. The specifications for this measure are available at: *http://www.qualityforum.org/QPS/1536.* Additional information for the measure specifications can be found in the NQF Measure Evaluation available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=68317.*

We believe this measure meets the statutory requirements discussed above. This measure is appropriate for the measurement of quality of care furnished by ASCs because cataract surgery is commonly performed in ASCs and this measure was developed to specifically measure quality of care furnished by ASCs.'' We believe it also meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is NQF-endorsed for the ASC setting.

In its 2013 Pre-Rulemaking Report, the MAP supported the inclusion of this measure in the ASCQR Program and noted that this measure ''[a]ddresses a high-impact condition not adequately addressed in the program measure set.''

We invite public comment on this proposal.

In summary, we are proposing to adopt four new measures for the ASCQR Program for the CY 2016 payment determination and subsequent years, with data collection beginning in CY 2014, as discussed in section XV.D.7.of this proposed rule. We are proposing to collect aggregate data (numerators, denominators, and exclusions) on all ASC patients for these four proposed chart-abstracted measures via an online Web-based tool that will be made available to ASCs via the QualityNet Web site. The proposed new measures for the CY 2016 payment determination and subsequent years for the ASCQR Program are listed in the table below.

PROPOSED NEW ASC PROGRAM MEASURE SET FOR THE CY 2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure name
0564*	Complications within 30 Days following Cataract Surgery Requiring Additional Surgical Procedures.
0658	Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients.
0659	Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.

[13] Davila RE, Rajan E, Baron TH, Adler DG, Egan JV, Faigel DO, Gan SI, Hirota WK, Leighton JA, Lichtenstein D, Qureshi WA, Shen B, Zuckerman MJ, VanGuilder T, Fanelli RD, Standards of Practice Committee, American Society for Gastrointestinal Endoscopy. ASGE guideline: colorectal cancer screening and surveillance. Gastrointest Endosc 2006 Apr;63(4):546–57. *http://www.ncbi.nlm.nih.gov/pubmed/16564851?dopt=Abstract.*

[14] National Quality Measures Clearing House. Agency for Healthcare Research and Quality. Available at *http://www.qualitymeasures.ahrq.gov/content.aspx?id=27982.*

PROPOSED NEW ASC PROGRAM MEASURE SET FOR THE CY 2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

NQF No.	Measure name
1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

*This measure has not been NQF endorsed for the ASC setting.

4. ASCQR Program Measure Topics for Future Consideration

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the ASC setting. Through future rulemaking, we intend to propose new measures that address clinical quality of care, patient safety, care coordination, patient experience of care, surgical outcomes, surgical complications, complications of anesthesia, and patient reported outcomes of care. We invite public comment on these measurement topics.

5. Technical Specification Updates and Data Publication

In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures (76 FR 74513 through 74514). 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. We believe that a measure can be updated through this subregulatory process provided it is a nonsubstantive change. We expect to make the determination of what constitutes a substantive versus a nonsubstantive change on a case-by-case basis.

Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe that non-substantive changes may include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. We will revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. As stated in CY 2009 OPPS/ASC final rule with comment period, we also will post the updates on the QualityNet Web site at: *https://www.QualityNet.org.* We will provide sufficient lead time for facilities to implement the changes where changes to the data collection systems would be necessary. We generally release the Hospital OQR Specifications Manual every 6 months and release addenda as necessary. This release schedule provides at least 3 months of advance notice for nonsubstantive changes such as changes to ICD–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.

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 consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example, changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice.

We believe that the policy finalized in the CY 2009 OPPS/ASC final rule with comment period adequately balances our need to incorporate non-substantive NQF updates to NQF-endorsed Hospital OQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We also note that the NQF endorsement process incorporates an opportunity for public comment and engagement in the measure maintenance process. These policies regarding what is considered substantive versus non-substantive apply to all measures in the Hospital OQR Program.

In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures (76 FR 74513 through 74514) and, in the CY 2013 OPPS/ASC final rule with comment period, we provided additional clarification regarding the ASCQR Program policy in the context of the previously finalized Hospital OQR program policy. We refer readers to the CY 2013 OPPS/ASC final rule with comment period for a discussion of the process for updating the ASCQR Program quality measures (77 FR 68496 through 68497).

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we also finalized a policy to make data that an ASC submitted for the ASCQR program publicly available on a CMS Web site after providing an ASC an opportunity to review the data to be made public. These data will be displayed at the CCN level.

We are not proposing any changes to these policies.

C. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

Section 1833(i)(2)(D)(iv) of the Act states that the Secretary may implement the revised ASC payment system ''in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).'' Paragraph (7) contains subparagraphs (A) and (B). Subparagraph (A) of paragraph (7) states the Secretary may provide that an ASC that does not submit ''data required to be submitted on measures selected under this paragraph with respect to a year'' to the Secretary in accordance with this paragraph will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year. It also specifies that this reduction applies only with respect to the year involved and will not be taken into account in computing any annual increase factor for a subsequent year. Subparagraph (B) of paragraph (7) makes many of the provisions of the Hospital OQR Program applicable to the ASCQR Program ''[e]xcept as the Secretary may otherwise provide.'' Finally, section 1833(i)(2)(D)(v) of the Act states that, in implementing the revised ASC payment

system for 2011 and each subsequent year, ''any annual update under such system for the year, after application of clause (iv) [regarding the reduction in the annual update for failure to report on quality measures] shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).'' Section 1833(i)(2)(D)(v) of the Act also states that the ''application of the preceding sentence may result in such update being less than 0.0 for a year, and may result in payment rates under the [revised ASC payment system] for a year being less than such payment rates for the preceding year.''

2. Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for the CY 2015 Payment Determination and Subsequent 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 XII.G. of this proposed rule.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: a full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the MFP adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to this proposed rule, which are available via the Internet on the CMS Web site): ''A2,'' ''G2,'' ''P2,'' ''R2,'' ''Z2,'' as well as the service portion of device- intensive procedures identified by ''J8.'' We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor.

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2,'' ''G2,'' ''J8,'' ''P2,'' ''R2,'' and ''Z2.'' These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures and radiology services where payment is based on the MPFS PE RVU amount and a few other specific services that receive cost-based payment. As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update.

Office-based surgical procedures (performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.C.1.b. of this proposed rule) are paid at the lesser of the MPFS non-facility PE RVU-based amounts and the standard ASC ratesetting methodology. We finalized our proposal that the standard ASC ratesetting methodology for this comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to an office-based or radiology procedure is consistent for each HCPCS code regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we believe that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced copayment liability for beneficiaries. Therefore, we finalized our proposal in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500) that the Medicare beneficiary's national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would be based on the reduced national unadjusted payment rate.

We finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program. For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: the wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, and the adjustment for devices furnished with full or partial credit or without cost. We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements.

We are not proposing any changes to these policies.

D. Administrative Requirements

1. Proposed Requirements Regarding QualityNet Account and Security Administrator

a. Background for the CY 2014 and CY 2015 Payment Determinations

A QualityNet account is required to submit quality measure data to the QualityNet Web site via a Web-based tool and, in accordance with CMS policy, a QualityNet security administrator is necessary to set-up such an account for the purpose of submitting this information to the QualityNet Web site. In previous rulemaking, we referred to this role as the QualityNet administrator; we are referring to this role in this rulemaking as the QualityNet security administrator, which emphasizes its security function and aligns terminology for the ASCQR Program with the

Hospital IQR and OQR Programs. While the main purpose of a QualityNet security administrator is to serve as a point of contact for security purposes for quality reporting programs, we believe from our experience that a QualityNet security administrator typically fulfills a variety of tasks related to quality reporting, such as creating, approving, editing, and terminating QualityNet user accounts within an organization, and monitoring QualityNet usage to maintain proper security and confidentiality measures. Thus, we highly recommend that ASCs have and maintain a QualityNet security administrator.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53638 through 53639), we did not require that ASCs do so for the CY 2014 payment determination because ASCs are not required to submit data directly to the quality data warehouse for the CY 2014 payment determination (76 FR 74504) and we do not want to unduly burden ASCs by requiring ASCs to have a QualityNet security administrator. We note that a QualityNet account is not necessary to access information that is posted to the QualityNet Web site, such as specifications manuals and educational materials.

As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74504 through 74509), for the CY 2015 payment determination, we require ASCs to submit some quality measure data via an online tool located on the QualityNet Web page. As set forth in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53638 through 53639), to enter these data into our data system, we require that ASCs identify and register a QualityNet security administrator who follows the registration process located on the QualityNet Web site and submits the information as specified on this site. Because submission of these data is not required until the July 1, 2013 to August 15, 2013 time period, we require that ASCs have a QualityNet security administrator at the time ASCs submit Web-based measure data in 2013 for the CY 2015 payment determination, which is no later than August 15, 2013. ASCs may have a QualityNet security administrator prior to this date, but we do not require that ASCs do so.

We noted that there are necessary mailing and processing procedures that must be completed in order to have a QualityNet security administrator which are separate from completion of the forms by the ASC that can require significant time to complete. We strongly cautioned ASCs to not wait until the deadline to apply; instead, we recommended allowing a minimum of 2 weeks, and strongly suggested allowing additional time prior to the deadline to submit required documentation in case of unforeseen issues. Because ASCs will need a QualityNet security administrator only to have the ability to set up a user account for the purpose of submitting such measure data once a year, we do not require that ASCs maintain a QualityNet security administrator after the entry of their data via an online tool located on the QualityNet Web site in 2013 for the CY 2015 payment determination.

We also note that QualityNet users must complete a user enrollment process, which is part of the registration process, to ensure access to the Secure QualityNet Portal beginning July 1, 2013. Portal access will be required for ASCs submitting data under the ASCQR Program using an online tool located on the QualityNet Web site.

b. Proposed Requirements for the CY 2016 Payment Determination and Subsequent Years

For the CY 2016 payment determination and subsequent years, we are proposing that, similar to the requirement for the CY 2015 payment determination, ASCs would be required to have a QualityNet security administrator for the purposes of setting up a QualityNet account for the purpose of entering data via an online tool located on the QualityNet Web site if this had not been completed previously or no current user accounts were available. If an ASC does not already have a QualityNet account, the facility would need to identify and register a QualityNet security administrator who follows the registration process located on the QualityNet Web site and submits the information as specified on this site. A QualityNet security administrator is not required for submitting data, a QualityNet security administrator is required to set up user accounts and for security purposes; a current user account is required for submitting data. Thus, an ASC would need to acquire a QualityNet security administrator only if no current QualityNet account existed for the ASC. An ASC would be required to have an active account by any specified data entry deadline. For example, the deadline would be August 15, 2014 for the CY 2016 payment determination. Although we highly recommend that ASCs have and maintain a QualityNet security administrator, we believe that requiring an ASC to maintain a QualityNet administrator throughout the year would unnecessarily increase burden on ASCs.

As noted previously, there are necessary mailing and processing procedures for having a QualityNet security administrator assigned by CMS separate from completion of the forms by the ASC that can require significant time to complete and we strongly caution ASCs to not wait until any data entry deadline to apply. While we previously recommended allowing a minimum of 2 weeks, based upon recent experience, we strongly suggest allowing 4 to 6 weeks prior to any data submission deadline to submit required documentation for processing and in case of unforeseen issues. Also, QualityNet users must complete a user enrollment process, which is part of the registration process, to ensure access to the Secure QualityNet Portal. Portal access will be required for ASCs submitting data under the ASCQR Program to meet CMS IT security requirements. The legislative source for this requirement originates in the Federal Information Security Management Act of 2002 which was amended by the Cybersecurity Act of 2012. The Document Library on the *http://www.idmanagement.gov* Web site contains documentation related to identity management including the Federal Identity, Credential and Access Management (FICAM) Roadmap and Implementation Guidance (version 2, 12/08/2011).

We invite public comment on these proposals.

2. Proposed Requirements Regarding Participation Status

a. Background for the CY 2014 Payment Determination and Subsequent Years

We finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516) a policy to consider an ASC as participating in the ASCQR Program for the CY 2014 payment determination if the ASC includes Quality Data Codes (QDCs) specified for the ASCQR Program on their CY 2012 claims relating to the finalized measures.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53639 through 53640), we stated that once an ASC submits any quality measure data, it would be considered to be participating in the ASCQR Program. Further, once an ASC submits any quality measure data and is considered to be participating in the ASCQR Program, an ASC would continue to be considered participating in the ASCQR Program, regardless of whether the ASC continues to submit quality measure data, unless the ASC withdraws from the Program by indicating on a participation form that it is withdrawing, as discussed below.

For example, if an ASC includes any QDCs on its claims for the CY 2014 payment determination, it would be considered participating in the ASCQR Program for the CY 2014 payment determination and for each subsequent year's payment determination unless the ASC withdraws.

Likewise, if an ASC did not submit any QDCs for the CY 2014 payment determination, but submitted quality measure data for the CY 2015 payment determination, the ASC would be considered participating in the ASCQR Program starting with the CY 2015 payment determination and continuing for each subsequent year's payment determination unless the ASC withdraws from the ASCQR Program.

We considered whether to require that an ASC complete and submit a notice of participation form for each year's payment determination to indicate that the ASC is participating in the ASCQR Program as we require for hospitals, but decided against this approach because we were concerned about the burden on ASCs. We believe these requirements will reduce burden on ASCs while accomplishing the purpose of notifying us of an ASC's participation in the ASCQR Program.

We stated that any and all quality measure data submitted by the ASC while participating in the ASCQR Program could be made publicly available. This policy allows us to provide information on the quality of care provided to Medicare beneficiaries which promotes transparency.

Once an ASC submits quality measure data indicating its participation in the ASCQR Program, an ASC must complete and submit an online form indicating withdrawal in order to withdraw from the ASCQR Program. This form will be located on the QualityNet Web site starting in July 2013. We also require that an ASC indicate on the form the initial payment determination year to which the withdrawal applies. We established a different process for ASCs to withdraw from participation than the process we established for an ASC to participate in the ASCQR Program because of the payment implications of withdrawal. We stated that, in withdrawing from the ASCQR Program, the ASC would incur a 2.0 percentage point reduction in its annual payment update for that payment determination year and any subsequent payment determinations in which it is withdrawn.

We stated that we will not make quality measure data publicly available for that payment determination year and any subsequent payment determinations for which the ASC is withdrawn from the ASCQR Program.

We established that an ASC would continue to be deemed withdrawn unless the ASC starts submitting quality measure data again. Once an ASC starts submitting quality measure data, the ASC would be considered participating unless the ASC withdraws, as discussed above. We believe that these policies reduce the burden on ASCs by not having to notify us as to when they are participating.

We established that an ASC can withdraw from the ASCQR Program at any time up to August 31, 2013 for the CY 2014 payment determination. We anticipated that this will be the latest date possible to allow an ASC to withdraw before payment determinations affecting CY 2014 payment are made. We established that an ASC can withdraw from the ASCQR Program at any time up to August 31, 2014 for the CY 2015 payment determination. We clarify here that these deadlines include August 31st for each respective year.

We stated that these program requirements would apply to all ASCs designated as open in the CASPER system before January 1, 2012 for the CY 2014 payment determination. Because ASCs were not required to include QDCs on claims until October 2012 for the CY 2014 payment determination, an ASC designated as open in the CASPER system before January 1, 2012 was operating for at least 10 months before having to report any data. We believe this is a sufficient amount of time for ASCs to be established to report quality data for the CY 2014 payment determination.

For the CY 2015 payment determination, we established that program requirements would apply to all ASCs designated as open in the CASPER system for at least 4 months prior to January 1, 2013. We believe that this date and length of operations experience would provide new ASCs sufficient time before having to meet quality data reporting requirements after the ASCQR Program's initial implementation year.

b. Proposed Requirements for the CY 2016 Payment Determination and Subsequent Years

For the CY 2016 payment determination and subsequent years, we are proposing that an ASC can withdraw from the ASCQR Program at any time up to and including August 31 of the year preceding a payment determination. We anticipate that this will be the latest date possible to allow an ASC to withdraw before payment determinations affecting the next calendar year's payment are made. Thus, for example, for the CY 2016 payment determination, an ASC would be able to withdraw from the ASCQR Program at any time up to and including August 31, 2015. Once an ASC has withdrawn for any payment determination year, it would have a 2.0 percentage point reduction in their annual payment update and it would not be possible to reinstate participation status for that year.

For the CY 2016 payment determination and subsequent years, we are proposing that all program requirements would apply to all ASCs designated as open in the CASPER system at least 4 months prior to the beginning of data collection for a payment determination. Thus, for the CY 2016 payment determination, data collection begins with January 1, 2014 services; these program requirements would apply to all ASCs designated as open in the CASPER system for at least 4 months prior to January 1, 2014 (that is, an open date of September 1, 2013 or earlier). We believe that this date and length of operations experience would provide any new ASCs sufficient time before having to meet quality data reporting requirements.

We invite public comment on these proposals.

3. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures for the CY 2014 Payment Determination and Subsequent Years

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74496 through 74511), we adopted five claims-based measures for the CY 2014, CY 2015, and CY 2016 payment determinations and subsequent years. We also finalized that, to be eligible for the full CY 2014 ASC annual payment update, for the claims-based measures, an ASC must submit complete data on individual quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims (76 FR 74515 through 74516). Further, we finalized the data collection period for the CY 2014 payment determination, as the Medicare fee-for-service ASC claims submitted for services furnished between October 1, 2012 and December 31, 2012. ASCs will add the appropriate QDCs on their Medicare Part B claims, using the Form CMS–1500 or associated electronic data set submitted for payment, to submit the applicable quality data. A listing of the QDCs with long and short descriptors is available in Transmittal 2425, Change Request 7754

released March 16, 2012 (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Transmittals-Items/ASC-CR7754-R2425CP.html*). Details on how to use these codes for submitting numerator and denominator information are available in the ASCQR Program Specifications Manual located on the QualityNet Web site (*https://www.QualityNet.org*).

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53640), we adopted a policy that claims for services furnished between October 1, 2012 and December 31, 2012 would have to be paid by the administrative contractor by April 30, 2013 to be included in the data used for the CY 2014 payment determination. We believe that this claim paid date allows ASCs sufficient time to submit claims while allowing sufficient time for CMS to complete required data analysis and processing to make payment determinations and to supply this information to administrative contractors.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68497 through 68498), we finalized a data collection and processing period for the CY 2015 payment determination and subsequent years. For the CY 2015 payment determination and subsequent years, an ASC must submit complete data on individual claims-based quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims. The data collection period for such claims-based quality measures is the calendar year 2 years prior to a payment determination year. The claims for services furnished in each calendar year have to be paid by the administrative contractor 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 year. Thus, for example, for the CY 2015 payment determination, the data collection period is claims for services furnished in CY 2013 (January 1, 2013 through December 31, 2013) which are paid by the administrative contractor by April 30, 2014.

We are not proposing any changes to these policies.

4. Proposed Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

a. Background for the CY 2014 Payment Determination and Subsequent Years

In the CY 2012 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 for the initial implementation years of the ASCQR Program because ASCs are not familiar with how to report quality data under the ASCQR Program and because many ASCs are relatively small and may need more time to set up reporting systems. We stated in that final rule that we intend to propose to increase this percentage for subsequent years' payment determinations as ASCs become more familiar with reporting requirements for the ASCQR Program.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53641), we stated that, because private payers would not have QDCs in their required HCPCS data files until January 1, 2013, claims with QDCs received prior to January 1, 2013 could be rejected for invalid codes. Because it is not possible for ASCs to submit differing codes on primary versus secondary payer claims for at least some payers, we specified that only claims where Medicare is the primary payer—not the secondary payer—will be used in the calculation of data completeness for the CY 2014 payment determination.

We also finalized our proposal in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68498 through 68499) that data completeness for claims-based quality measures for the CY 2015 payment determination and subsequent years will be determined by comparing the number of Medicare claims (where Medicare is the primary or secondary payer) meeting measure specifications that contain the appropriate QDCs with the number of Medicare claims (where Medicare is the primary or secondary payer) that would meet measure specifications, but did not have the appropriate QDCs on the submitted claims for the CY 2015 payment determination and subsequent years. We made this change based on the fact that private payers had QDCs in their required HCPCS data files beginning January 1, 2013.

b. Proposed Requirements for the CY 2016 Payment Determination and Subsequent Years

For the CY 2016 payment determination and subsequent years, we are proposing to continue our policy that the minimum threshold for successful reporting be that at least 50 percent of claims meeting measure specifications contain QDCs. We believe that 50 percent is a reasonable minimum threshold for the initial implementation years of the ASCQR Program. Because ASCs cannot re-submit claims for the sole purpose of adding QDCs (such claims are rejected by administrative contractors as duplicate claims), we believe maintaining this minimum as the program matures is reasonable. We intend to propose to increase this percentage for future payment determinations as ASCs, administrative contractors, and billing clearing houses become more familiar with reporting requirements for the ASCQR Program and the program itself becomes more established.

As finalized in the FY 2013 IPPS/LTCH PPS final rule, data completeness for claims-based quality measures will be determined by comparing the number of Medicare claims (where Medicare is the primary or secondary payer) meeting measure specifications that contain the appropriate QDCs with the number of Medicare claims (where Medicare is the primary or secondary payer) that would meet measure specifications, but did not have the appropriate QDCs on the submitted claims for the CY 2015 payment determination and subsequent years.

In our initial implementation of claims-based measures, we determined that some ASCs have relatively small numbers of Medicare claims. Thus, for the CY 2016 payment determination and subsequent years, we are proposing a minimum case volume of 240 Medicare claims (primary plus secondary payer) per year (which is an average of 60 per quarter). ASCs that have fewer than 240 Medicare claims per year during a reporting period for a payment determination year would not be required to participate in the ASCQR Program for the subsequent reporting period for that subsequent payment determination year. For example, if an ASC had 200 Medicare claims during the calendar year of January 1, 2013 to December 31, 2013 (data submitted on claims during this year would be applied to CY 2015 payment determinations), the ASC would not be

required to participate in the ASCQR Program for the CY 2016 payment determination (which would use data submitted on claims during the January 1, 2014 to December 31, 2014 calendar year). We are proposing a minimum case threshold to exempt smaller facilities where program implementation can be overly burdensome. We have selected 240 Medicare claims per year because 10 percent of ASCs have less than 240 Medicare claims per year so this policy would exempt only those ASCs with the fewest number of Medicare claims. If an ASC exceeds this 240 Medicare claim threshold in any given calendar year, the ASC would be required to participate in the ASCQR Program the subsequent calendar year and would be subject to all program requirements.

We invite public comment on this proposal.

5. Proposed Requirements for Data Submitted Via a CMS Online Data Submission Tool

a. Background for the CY 2015 Payment Determination and Subsequent Years

In the CY 2012 OPPS/ASC final rule with comment period, we finalized two measures with data submission required using an online measure submission Web page available at *http://www.qualitynet.org* beginning with the CY 2015 payment determination: Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures (76 FR 74509). In that final rule with comment period, we finalized that, for the CY 2015 payment determination, ASCs would report data for these two measures between July 1, 2013 and August 15, 2013 for services furnished between January 1, 2012 and December 31, 2012.

b. Proposed Requirements for the CY 2016 Payment Determination and Subsequent Years for Measures Currently Finalized

For the CY 2016 payment determination and subsequent years, we are proposing for the Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures for which data will be submitted via a using an online data submission tool available on *http://www.qualitynet.org,* that the data collection time periods would be for services furnished during the calendar year two years prior to the payment determination year and that data would be submitted during the January 1 to August 15 time period in the year prior to the payment determination. Thus, for the CY 2016 payment determination, the data collection time period for these measures would be calendar year 2014 (January 1, 2014 to December 31, 2014) and the data submission time period would be January 1, 2015 to August 15, 2015. We are proposing these changes to increase the timeframe for allowing data submission for these measures and to align the data collection time periods for the claims-based and Web-based measures. This alignment has the additional benefit of providing more current data for these Web-based measures for a payment determination and would prevent the need for retrospective data collection by ASCs which can be burdensome.

Under this proposal, no data would be collected for calendar year 2013 (January 1, 2013 to December 31, 2013) for the Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures because the CY 2015 payment determination will use data from services performed in the January 1, 2012 to December 31, 2012 time period and, under our proposal, the CY 2016 payment determination would use data from services performed in January 1, 2014 to December 1, 2014.

We invite public comment on these proposals.

c. Proposed Requirements for the CY 2016 Payment Determination and Subsequent Years for Proposed New Measures With Data Submission Via a CMS Web-Based Tool

We are proposing to adopt four additional chart-abstracted measures for the ASCQR Program and proposing that aggregate data (numerators, denominators, and exclusions) on all ASC patients would be collected via an online Web-based tool that would be made available to ASCs via the QualityNet Web site.

These measures are: (1) Complications within 30 Days following Cataract Surgery Requiring Additional Surgical Procedures; (2) Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients; (3) Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and (4) Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. We describe our timeframes and process for measure specifications in section XV.B.5. of this proposed rule.

We wish to clarify that, while we have referred to measures where data are submitted via a Web-based tool on a CMS Web site under our quality data reporting programs by the type of measure, that is, structural measures (measures concerned with attributes of where care occurs, such as material resources, human resources, and organizational structure [15]), not all quality measures where data are submitted via a Web-based tool on a CMS Web site are structural measures. For example, the four proposed new measures proposed are not structural measures. Thus, we have refined our terminology and now refer to the mode of data submission, Web-based, rather than the type of measure.

We are proposing that data collection and reporting for these measures would begin with the CY 2016 payment determination.

Additionally, we are proposing for these measures, and any future measures for the ASCQR Program where data is submitted via a using an online measure submission Web page available on *http://www.qualitynet.org,* that beginning with the CY 2016 payment determination:

- The data collection time period would be the calendar year (January 1 to December 31) 2 years prior to the affected payment determination year, and;
- Data collected would be submitted during the time period of January 1 to August 15 in the year prior to the affected payment determination year.

Thus, for the CY 2016 payment determination, the data collection time period would be January 1, 2014 to December 31, 2014 and the data submission time period for the collected data would be January 1, 2015 to August 15, 2015. These proposals are in alignment with proposals in section XV.D.5. of this proposed rule regarding data collection and submission time frames for measures already adopted for the ASCQR Program where data is submitted via an online data submission tool available on *http://www.qualitynet.org.*

We invite public comment on these proposals.

6. Proposed Data Submission Requirements for a Measure Reported Via the National Healthcare Safety Network (NHSN) for the CY 2016 Payment Determination

a. Background for the CY 2016 Payment Determination

For the CY 2016 payment determination, we finalized the adoption of the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), a process of care,

[15] Maintz, J. Defining and Classifying Clinical Indicators for Quality Improvement, Inter J Quality Health Care (2003) 15(6), 523–530.

healthcare-associated infection (HAI) measure, in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74510). We specified that data collection for the influenza vaccination measure would be via the NHSN from October 1, 2014 to March 31, 2015 and that details for data submission would be made in future rulemaking.

b. Proposed Requirements for the CY 2016 Payment Determination

We are proposing to use the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of this measure to NHSN. We refer readers to the CDC's NHSN Web site (for detailed enrollment (*http://www.cdc.gov/nhsn/ambulatory-surgery/enroll.html*), set-up (*http://www.cdc.gov/nhsn/ambulatory-surgery/setup.html*), and reporting (*https://sdn.cdc.gov*; data certificate required for this site) procedures. We believe that ASCs would know and be comfortable with these procedures because these procedures are already used by many ASCs to fulfill State-mandated reporting of HAI data through the NHSN in at least 17 States.

We are proposing that ASCs would have until August 15, 2015 to submit their 2014–2015 influenza season data to NHSN. We are proposing an August 15, 2015 deadline because this date is the latest date possible for data entry that will provide sufficient time for CMS to make the CY 2016 payment determinations. Further, this date aligns the data entry deadline with the deadline for the measures entered via the CMS online tool. We believe this data submission deadline allows ASCs to have sufficient time to collect and compile the necessary data while taking into account ASCQR Program considerations.

We invite public comment on these proposals.

7. ASCQR Program Validation of Claims-Based and CMS Web-Based Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53641 through 53642), consistent with other CMS quality reporting programs, we did not require validation of claims-based measures (beyond the usual claims validation activities conducted by our administrative contractors) or structural (Web-based) measures for the ASCQR Program. We also do not require validation of claims-based or Web-based measures under the Hospital IQR and OQR Programs.

We noted that with regard to the current ASCQR Program claims-based measures, the number of events expected to be reported is small because most of the measures are for adverse or rare events. In this situation, any random selection of cases would require a burdensome sample size. Further, we expect the accuracy for reported adverse events to be high. We stated that, because we do not believe at this time that any results that could be obtained justify the burden associated with a data validation process which would necessitate an independent validation effort, we also are not requiring a data validation process for our current claims-based measures, and we continue to believe so.

We stated that as we gain more experience with the ASCQR Program, we will reassess whether a data validation process for claims-based and measures where aggregate data is reported via an online tool is needed. At this time, we believe that it would be overly burdensome to validate the reported data given the inexperience that ASCs have with reporting quality data to CMS coupled with the low incidence of cases for the claims-based measures.

8. Extraordinary Circumstances Extensions or Waivers for the CY 2014 Payment Determination and Subsequent Years

a. Background

In our experience, there have been times when facilities have been unable to submit information to meet program requirements due to extraordinary circumstances that are not within their control. It is our goal to not penalize such entities for such circumstances and we do not want to unduly increase their burden during these times. Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53642 through 53643), we established procedures for extraordinary circumstance extension or waiver requests for the submission of information required under the ASCQR Program. We refer readers to that rule for a complete discussion of the process.

b. Proposed Additional Criterion for Extraordinary Circumstance Waivers or Extensions for CY 2014

We are proposing that starting in CY 2014 we may grant a waiver or extension to ASCs for data submission requirements if we determine that a systematic problem with one of our data collection systems directly or indirectly affected the ability of ASCs to submit data. Because we do not anticipate that such systematic errors will happen often, we do not anticipate granting a waiver or extension on this basis frequently. If we make the determination to grant a waiver or extension, we are proposing to communicate this decision through listserv notice and posting via our QualityNet Web site (*https://www.qualitynet.org*) as we have done in the past with CMS-issued waivers where a geographic location was affected by adverse weather.

We invite public comment on this proposal.

9. ASCQR Program Reconsideration Procedures for the CY 2014 Payment Determination and Subsequent Years

We have established similar processes by which participating hospitals can submit requests for reconsideration of quality reporting program payment determinations for the Hospital IQR Program and the Hospital OQR Program. We believe these reconsideration processes have been effective in the hospital quality reporting programs and such a process would be effective for ASC quality reporting. Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 through 56344), we adopted an informal reconsideration process for the ASCQR Program for the CY 2014 payment determination and subsequent years modeled after the reconsideration processes we implemented for the Hospital IQR and Hospital OQR Programs. We refer readers to that rule for a complete discussion of our procedures.

We are not proposing any changes to this informal reconsideration process. However, we want to clarify some aspects of the informal reconsideration review process that we established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 to 53644). As we stated in that rule, we intend to complete any reconsideration reviews and communicate the results of these determinations within 90 days following the deadline for submitting requests for reconsideration. For those ASCs that submit a reconsideration request, the reconsideration determination would be the final ASCQR Program payment determination. For those ASCs that do not submit a reconsideration request or do not submit a reconsideration request as specified in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 through 53644), for example, the request was not submitted by the deadline, the CMS determination would be the final payment determination. There would be no appeal of any final ASCQR Program payment determination.

XVI. Proposed Changes to the Conditions for Coverage (CfCs) for Organ Procurement Organizations (OPOs) (42 CFR Part 486, Subpart G)

A. Background

The Organ Procurement Organization Certification Act of 2000 (section 701 of Pub. L. 106–505) amended section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) and directed the Secretary to establish regulations governing the certification and/or recertification of Organ Procurement Organizations (OPOs). Among other things, section 371(b)(1)(D)(ii) of the Public Health Service Act, as amended by section 701 of Public Law 106–505, requires that regulations be established for the certification and/or recertification process, which (1) ''rely on outcome and process performance measures that are based on empirical evidence obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations,'' and (2) ''use multiple outcome measures as part of the certification process.'' Payment under the Medicare and Medicaid programs for organ procurement costs may only be made if, among other requirements, the OPO is certified or recertified as meeting the standards to be a qualified OPO under section 371(b) of the Public Health Service Act and meets the performance-related standards prescribed by the Secretary, as provided for in section 1138(b) of the Social Security Act.

The final rules implementing these statutory requirements and setting out the Conditions for Coverage (CfCs) for OPOs (OPO CfCs) were published in the **Federal Register** on May 31, 2006 (71 FR 30982). The OPO CfCs are codified at 42 CFR Part 486 and set forth the certification and recertification processes for OPOs. OPOs are required to meet their CfCs, which include both outcome and process performance measures. We refer readers to 42 CFR 486.316 for the compliance requirements for recertification and 42 CFR 486.318 for the three outcome measures.

In general, with the exception of OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, or possessions, the three outcome measures are: (1) A donation rate of eligible donors as a percentage of eligible deaths; (2) an observed donation rate as compared to the expected donation rate; and (3) a yield measure, which requires that two of the following three outcome measures be met: (i) The number of organs transplanted per standard criteria donor, (ii) the number of organs transplanted per expanded criteria donors, and (iii) the number of organs used for research per donor. For OPOs that operate exclusively in noncontiguous States, Commonwealths, Territories, and possessions, the three outcome measures are: (1) A donation rate of eligible donors as a percentage of eligible deaths; (2) an observed donation rate as compared to the expected donation rate; and (3) a yield measure, which requires that two of the following three outcome measures be met: (i) The number of kidneys transplanted per standard criteria donor; (ii) the number of kidneys transplanted per expanded criteria donors; and (iii) the number of organs used for research per donor. All of the yield measures include pancreata used for islet cell transplantation as required by section 371(c) of the Public Health Service Act (42 U.S.C. 273(c)). The first and third outcome measures are compared to a national mean. The second outcome measure is calculated by the Scientific Registry of Transplant Recipients (SRTR).

B. Proposed Regulatory Changes

We are proposing to modify the requirements in § 486.316(a)(1) and (b) and the introductory text of § 486.318(a) and (b) of the regulations so that all of the OPOs must meet two out of the three outcome measures to be recertified. We have become concerned about the requirement to automatically decertify OPOs if they fail to meet all three of the outcome measures. We now believe that the requirement that each OPO meet all three outcome measures as set forth in § 486.318 is unnecessarily stringent. For that reason, we are proposing to modify the outcome measure requirement so that OPOs would be required to meet two of the three outcome measures.

The majority of all of the OPOs are meeting all three of the outcome measures. From our experience with OPOs, we have observed that many of the OPOs that are failing to meet all three outcome measures are meeting two of the three measures and are in compliance with all of the other requirements in the OPO CfCs; that is, the process performance measures set forth at §§ 486.320 through 486.348. We believe these OPOs are performing satisfactorily and should not be decertified based solely on their failure to meet one outcome measure. This belief is based not only on our observation and monitoring of these OPOs' performance, but also on some concerns with the outcome measures.

From the feedback we have received from the OPO community, there may be some variance in how OPOs are determining the ''eligible deaths'' in their donation service area (DSA), which is the denominator in the first outcome measure. Various members of the OPO community have indicated that the same donor could be counted as an eligible donor by one OPO, but not another OPO. This is apparently due to differences in how the definition of ''eligible death'' is being clinically interpreted and implemented. Another reason for this variance could be how the determination is made. One member of the OPO community stated that, in one OPO, that determination may be made by a group of clinical staff, while in another, it is made by the data entry person. Therefore, we are concerned that this apparent variance may be adversely affecting the performance of some OPOs on the outcome measures.

We also are concerned that the current measures may not be accurately allowing for adjustment of various factors. OPOs' DSAs vary substantially in their demographics. For example, the first of the possible three yield outcome measures involves standard criteria donors. However, many individuals in the OPO community have indicated that there is a considerable difference between standard criteria donors (SCDs) around the country and that this could explain at least some of the differences in some of the OPOs' yield measures. Because a SCD is anyone who meets the eligibility criteria for an eligible donor and does not meet the criteria to be an expanded criteria donor or a donor after cardiac death, the demographics of an OPO's DSA could have a significant impact on the organ yield that could reasonably be expected in that DSA. For example, if a particular DSA has an older potential donor population or one that is typically not as healthy, this could significantly impact the organ yield in that DSA as compared to a DSA with a population of generally more healthy individuals.

We also have received anecdotal reports that OPOs may be making clinical decisions based on their assessment of their own performance on the outcome measures. In particular, there may have been cases when OPOs did not pursue certain potential donors with multiple comorbidities because they believed that they would only be able to procure one or two organs from that potential donor. If an OPO is concerned about its performance on the yield measures specified under § 486.318(a)(3) and (b)(3), it may be advantageous to its performance on the yield measures to forgo a potential donor rather than procure only one organ and worsen its performance on the yield measures. This would result in

not only one potentially transplantable organ being averted, but consequently a potential transplant recipient not receiving a transplant. This could have a significant impact on the potential transplant recipient waiting for transplants nationwide. This is especially problematic in the case of extra-renal organs for which there is no viable alternative to an organ transplant.

We are proposing to hold the OPOs accountable for meeting two out of three current outcome measures. We believe this will avoid the automatic decertification of OPOs that are performing satisfactorily. Therefore, we are proposing to revise paragraphs (a)(1) and (b) of § 486.316 and the introductory text of paragraphs (a) and (b) of § 486.318 of the regulations to require that OPOs meet at least two out of the three outcome measures instead of the requirement to meet all three outcome measures.

In addition to soliciting public comments on the proposals we discuss above, we are soliciting public comments on the current outcome measures in the OPO CfCs, as well as public comments on any other potential empirically based outcome measures for OPOs that might be used in the future. We would especially appreciate public comments on the new yield measure that is produced by the SRTR and is being used by the Organ Procurement and Transplantation Network (OPTN). The OPTN recently adopted this new yield measure that calculates the expected number of organs transplanted for each donor based on multiple donor risk factors. The measure uses more extensive risk factors that mitigate the differences in the donor pool of the each DSA. This allows an OPO's performance to be measured in terms of the expected outcomes for the DSA based upon the expected outcomes for individual donors within the DSA and not against a national average.

When comparing OPOs currently identified to be below expected performance levels by the OPTN matrix and the OPOs identified as below expected performance levels by the CMS measures, we have noted that the lists are not the same. If the new OPTN measure is a more accurate reflection of performance as measured by the organs transplanted for each donor in each individual DSA (as is accepted by the HRSA and the OPO community), this could mean that we may take inappropriate enforcement action when using the current yield measure. Therefore, we are specifically soliciting public comments on this new OPTN yield measure. Specific details on the risk adjustment models used for this measure are located on the SRTR Web site at: *http://www.srtr.org/csr/current/Tech_notes.aspx*.

In summary, we are proposing to revise §§ 486.316 and 486.318 of our regulations by modifying the current outcome measures requirement to require that OPOs must meet two out of the three outcome measures instead of all three outcome measures.

XVII. Proposed Revisions of the Quality Improvement Organization (QIO) Regulations

A. Legislative History

The Utilization and Quality Control Peer Review Program was originally established by sections 142 and 143 of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982 (Pub. L. 97–248). The name of the individual organizations covered under the program was ''Peer Review Organizations.'' In a final rule with comment period published in the **Federal Register** on May 24, 2002 (67 FR 36539), we revised the regulatory references to these organizations to ''Quality Improvement Organizations'' (QIOs)—without changing the definition or functions of the QIOs—to reflect the program's shift from a compliance-oriented focus to one emphasizing quality improvement. There have been a number of amendments to the QIO statute over the years, but they have not resulted in any substantial changes in how the program operates. However, in section 261 of the recently enacted Trade Adjustment Assistance Extension Act of 2011 (TAAEA) (Pub. L. 112–40), Congress authorized numerous changes to the original legislation to modernize and improve the QIO Program and included additional flexibility for the Secretary in the administration of the QIO Program. This legislation also updated the nomenclature from the Peer Review Organization Program to the QIO Program and included amendments to update the terminology of the program (replacing ''peer review organization'' and ''utilization and quality control peer review organization'' with ''quality improvement organization'' in relevant provisions of the Act.)

Specifically, section 261 of the TAAEA increased the flexibility available to the Secretary by updating the statutory definition of the organizations that can contract with CMS as QIOs (as described in section 1152 of the Act), changing certain contract terms and processes by which the Secretary contracts with QIOs (as described in section 1153 of the Act), and broadening the Secretary's authority to delineate the scope of work for QIOs (as described in section 1154 of the Act).

The regulations that implement sections 1152 and 1153 of the Act are codified at 42 CFR Part 475; Subpart C of Part 475 includes provisions that specifically govern the types of organizations eligible to become QIOs. The regulations that implement section 1154 of the Act and much of the work performed by QIOs are codified at 42 CFR Part 476. Section 1154 of the Act states that much of the work QIOs will perform is subject to the terms of their contracts with CMS. We note that, consistent with this provision, the contracts and requests for proposals used to contract with QIOs include significant detail on the work performed by the QIOs.

B. Basis for Proposals

Section 261 of the TAAEA eliminated certain limitations specified in sections 1152 and 1153 of the Act that appear in several existing provisions in Part 475. In order to eliminate these limitations in the regulations and fully utilize the flexibility provided as a result of the statutory changes, we are proposing regulatory changes to implement the statutory amendments. These changes involve, among other things, changing the eligibility standards for an entity to be awarded a QIO contract and defining specific terms that will be used to describe QIOs and their quality improvement work. We are proposing to change the terminology related to the geographic area in which a QIO must perform its different functions. As the statute authorizes, the QIO area can now be any geographic area CMS believes will be most effective in accomplishing its goals for the QIO contract. We also are proposing to revise provisions regarding the eligibility of a health care facility association to be a QIO and to eliminate an obsolete provision at § 475.106 regarding the eligibility of payor organizations to be QIOs. The statutory amendments also include a change in the contract period for a QIO, extending it from 3 to 5 years. Although we did not previously update this regulation with a prior statutory change in the QIO contract term from 2 years to 3 years, we are now including the 5-year time period in the proposed rule as a technical correction in order to bring the regulations up to date with the amended statutory timeframe. We believe that these changes would be instrumental in improving aspects of the QIO's review activities and would enable us to improve the program by ensuring that QIOs are better able to meet the needs of Medicare beneficiaries. The specific proposed

changes and corrections are explained in more detail in the following sections.

QIOs work at the grassroots level of American health care delivery systems in all 50 States, the District of Columbia, and most U.S. Territories in order to improve care for Medicare beneficiaries. QIOs originally reviewed Medicare services to determine whether they were reasonable and medically necessary, met professionally recognized standards of care, and were provided in the appropriate setting. However, the QIO contract has evolved over the course of the years as the literature supports the concept that defects in the health care process are rarely related to the performance of one individual but to a system of care with multiple opportunities for failure. Attempts to improve quality through inspection methods, that is, by performing one chart review at a time, are less likely to yield the systemic improvements in care for Medicare beneficiaries that can come from analyzing data in order to identify problems, developing a plan of action, monitoring the result through data driven processes, and making changes as needed based on those results.

The qualifications and expertise required to execute these quality improvement initiatives have evolved to now include expertise from disciplines such as physicians, nurses, other clinicians, health care leaders, experts in statistics and health care system reengineering, and many other kinds of professionals. We intend to interpret our proposed regulation so as not to prohibit the use of professionals in the health care industry that are not licensed physicians or certified practitioners. We recognize/anticipate that these other professionals may offer valuable insight to QIOs on ways to enhance the performance of their QIO functions, as well as provide services designed to help QIOs maximize their impact. We propose to adopt this approach to further our goal that the regulations under 42 CFR Part 475 reflect a multidisciplinary approach to the performance of QIOs. Therefore, the proposed standards here would not be a barrier to the inclusion of any other nonphysician or nonpractitioner professional that CMS or the QIO deems appropriate for the successful performance of QIO functions. Patients and their families also play a critical role in the success of quality improvement initiatives. Amendments to the Act made by the TAAEA would accommodate the evolution of quality improvement and would allow CMS the flexibility to expand the types of organizations eligible to provide multi-disciplinary support in quality improvement. We seek with this proposal to ensure that the regulations governing QIO eligibility reflect the increased flexibility afforded by the TAAEA. This will help us ensure that we can administer the QIO Program in a manner that reflects contemporary practices and allows us to include the appropriate individuals and entities in working toward improving care processes.

As described in section 1154 of the Act, QIOs perform many specific review functions that are necessary to ensure the quality of care provided to Medicare beneficiaries. The addition to section 1154 of subparagraph (a)(18) by the TAAEA explicitly provides the Secretary with the broad authority to require that QIOs perform any additional activities the Secretary determines may be necessary for the purposes of improving the quality of Medicare services. Based on this authority, QIOs will, as a general matter, be required to represent CMS as ''change agents'' that work at local levels in their individual QIO geographic areas. Through the contracting process, different QIOs might now be required to work on one or more different tasks; that is, all QIOs might no longer be required to handle the complete and broad range of QIO activities within their geographic areas but to focus on particular tasks of QIO work. For example, QIOs might be required to offer to a variety of stakeholders the knowledge and resources for improving health quality, efficiency, and value designed to improve the care provided to Medicare beneficiaries. Stakeholders might include providers, practitioners, patients, and others who are interested in improving care.

As under the current program, QIOs will be required to base their work on clinical evidence and some may be required to generate reliable data about clinical performance. QIOs may also serve as independent, objective, and collaborative partners that support CMS' mission to improve health care quality in the Medicare program (which, in turn, has the potential to greatly benefit the broader health care community) by leveraging the best efforts of all health care stakeholders, including patients and their families. While the goal of the QIOs is to benefit Medicare beneficiaries, the work of the QIOs may also, as a secondary matter, benefit other patients and residents who receive medical care. In this context, we are seeking to ensure that the regulations governing QIO eligibility reflect contemporary practices and include those that can help to improve care processes for Medicare beneficiaries. We are proposing to do so by removing restrictions that are no longer statutorily mandated and including requirements that reflect the current goals of the QIO program.

One such contemporary practice is the inclusion of patients and families in health care quality improvement. As a result, we have added to the QIO requirements a new focus on patient and family engagement and patient and family inclusion in quality improvement initiatives.

We believe that the TAAEA legislation allows us a great deal of flexibility in how we restructure the work that QIOs perform and the types of organizations qualified to perform that work. We intend to continually examine methods for providing care to beneficiaries in a way that maximizes efficiency, eliminates waste, decreases harm, lowers costs through improvement, and engages patients more effectively. One way to continue improving the quality, efficacy, and efficiency of care in the Medicare program is to reconsider how QIOs provide services to determine whether the current longstanding contract structure and eligibility requirements best fit the continually evolving science related to driving quality improvement. The changes we are proposing are intended to ensure that we have the flexibility we need to reconsider certain aspects of the QIO program structure in response to experience and changes in research findings and the health care community's approach to quality improvement.

The regulatory proposals here focus on the primary functional responsibilities of a QIO as a basis for determining eligibility. These are case review (which includes the statutory minimum standards) and quality improvement initiatives. We believe that the proposed eligibility and contracting standards for QIOs focus on the necessary minimum requirements for successful operation of the QIO Program.

C. Proposed Changes to the Nomenclature and Regulations Under 42 CFR Parts 475 and 476

In this proposed rule, we set forth proposals for updating the nomenclature and the definition of physician in both 42 CFR Parts 475 and 476 and for the partial deletion and revision of the regulations under 42 CFR Parts 475. Currently, Part 475 includes definitions and standards governing eligibility and the award of contracts to QIOs. We are proposing to replace nomenclature that has been amended by

the TAAEA, revise the existing definition in Part 475, Subpart A and Part 476, Subpart A of the term ''physician'', add new definitions to Part 475, Subpart A as necessary to support proposed new substantive provisions in Part 475, Subpart C, and revise, add, and replace some substantive provisions in Part 475, Subpart C.

1. Proposed Nomenclature Changes

In order to conform the regulations to the nomenclature changes made by section 261 of the TAAEA, we are proposing nomenclature changes where necessary in 42 CFR Part 475. We are, for example, proposing to revise the heading of Subpart C of Part 475 to read ''Subpart C—Quality Improvement Organizations'' and to replace the term ''peer review'' with ''quality improvement.'' In each proposed provision in Part 475, Subpart C, we use the new nomenclature where appropriate.

In addition, Part 476 is currently entitled ''Utilization and Quality Control Review,'' and Subpart C of Part 476 is entitled ''Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations (QIOs),'' both of which reflect the terminology used before enactment of the TAAEA. In order to reflect the nomenclature changes made by the TAAEA, we are proposing to revise the title of Part 476 to read: ''Part 476—Quality Improvement Organization Review'' and the title of Subpart C of Part 476 to read: ''Subpart C—Review Responsibilities of Quality Improvement Organizations (QIOs).''

2. Proposals To Add and Revise Definitions

We are proposing changes to §§ 475.101 through 475.107 to reflect new eligibility standards for an entity to be awarded a QIO contract and to use specific terms that will be used to describe QIOs and their quality improvement work. In connection with these changes, we are proposing to add definitions of ''case review'', and ''QIO area,'' add cross-references to definitions in § 476.1 of ''practitioner'' and ''quality improvement initiative,'' and revise the definition of ''physician'' under § 475.1 and § 476.1, as discussed below. We are soliciting public comments on our proposed definitions.

We are proposing to define ''case reviews'' to mean ''the different types of reviews that QIOs are authorized to perform. Such reviews include, but are not limited to: (1) Beneficiary complaint reviews; (2) general quality of care reviews; (3) Emergency Medical Treatment and Labor Act (EMTALA) reviews; (4) medical necessity reviews, including appeals and DRG validation reviews; and (5) admission and discharge reviews.'' We are providing this list to illustrate the range and scope of case reviews but note that the Act and other provisions in Chapter IV of Title 42 of the Code of Federal Regulations require additional reviews and that the Secretary, pursuant to section 1154(a)(18) of the Act, may require additional reviews under the contracts awarded to QIOs.

We are proposing to expand the definition of ''physician'' beyond its existing definition under § 475.1 and § 476.1 to reflect the definition in section 1861(r) of the Act, as well as to cover several additional characteristics that are unique to the QIO Program. We are proposing the following definition of physician for both Parts 475 and 476: A physician is ''(1) A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatry, a doctor of optometry, or a chiropractor as described in section 1861(r) of the Act; (2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice as a doctor as described in paragraph (1) above; and (3) An individual licensed to practice as a doctor as described in paragraph (1) above in any Territory or Commonwealth of the United States of America.'' We believe these revisions are necessary to eliminate references in paragraphs (1) and (2) of the definition in § 475.1 to physicians licensed in the State in which the QIO is located, in order to reflect the fact that a QIO's contract area may no longer be limited to one State. In addition, we are proposing to amend paragraph (3) of the definition in § 475.1 so that it no longer applies to just American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands. We are proposing to enlarge this part of the definition to apply to physicians licensed to practice in all U.S. Territories and Commonwealths to more closely align with the Secretary's flexibility in awarding QIO contracts granted by the TAAEA. We are soliciting public comments on whether our proposed definition is sufficiently inclusive and appropriate to achieve these goals. We also are proposing to define the term ''practitioner'' and ''quality improvement initiative'' for purposes of Part 475 by cross-referencing the existing definitions at 42 CFR 476.1.

In connection with our proposal to revise the requirements that an entity must meet to serve as a QIO, we also are proposing to define, in § 475.1, the terminology related to the geographic area in which a QIO must perform its different functions. Currently, the regulations in Part 475 do not define this area, but do refer to a QIO's ''review area'' in a number of places in existing text at §§ 475.102 and 475.103 and ''QIO area'' in §§ 475.1, 475.105(a), and 475.107(a) and (d). The term ''review area'' was used to refer to the geographic area in which each QIO performs its review functions under its contract with CMS while the term ''QIO area'' was used to refer to the geographic area covered by the contract. We are proposing to define and use the term ''QIO area'' to mean ''the defined geographic area, such as the State(s), region(s), or community(ties), in which the CMS contract directs the QIO to perform.'' Our addition of this proposed definition is meant to reflect the flexibility afforded to us by the TAAEA to establish a QIO area as the geographic area we believe will be most effective in accomplishing the goals of a particular QIO contract. In addition, the change in terminology from ''QIO review area'' to ''QIO area'' is intended to emphasize that the term can encompass more than just ''review'' functions. With this change, we intend to not only broaden the scope for choosing an appropriately sized geographic area, but also to identify capability and functionality as the primary way to identify the appropriate organization to perform specific QIO contract functions.

3. Proposals Relating To Scope and Applicability of Subpart C of Part 475

We believe that the scope and applicability provision for 42 CFR Part 475, Subpart C should reflect that the statutory authority for the QIO program was amended by the TAAEA, in particular the definition of a QIO and the eligibility and contracting standards. We are proposing to replace the regulatory language in § 475.100 with new language that explicitly acknowledges that the regulations in Subpart C implement sections 1152 and 1153(b) and (c) of the Act as amended by section 261 of the TAAEA. In addition, we are proposing to include the reference to section 1153(c) of the Act to reflect our proposal, in § 475.107(c), to include the 5-year contract term that now appears in amended section 1153(c)(3) of the Act. The proposed revisions to §§ 475.101 through 475.107 are intended to allow organizations that currently perform QIO work to compete for new QIO contracts, while expanding eligibility to additional entities under the new authority granted by the TAAEA. As the program evolves, we will focus contract determinations on the ability of

organizations to perform QIO functions as stated in the Request for Proposal (RPF). We are soliciting public comments on whether our proposed regulation text for Subpart C of Part 475 sufficiently meets this goal as well as our explained goal to implement the flexibility provided by Congress in the TAAEA amendments.

4. Proposals Relating to Eligibility Requirements for QIOs (§§ 475.101 through 475.106)

Prior to the TAAEA amendments, section 1152 of the Act defined a QIO as an entity that: (1) Is composed of a substantial number of licensed doctors of medicine and osteopathy engaged in the practice of medicine or surgery in the area where the QIO will perform or has available the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the area where the QIO will perform to assure adequate review of the services provided by various medical specialties and subspecialties; (2) is able, in the judgment of the Secretary, to perform review functions in a manner consistent with the efficient and effective administration of the QIO statute and to perform reviews of the pattern of quality of care in an area of medical practice where actual performance is measured against objective criteria which define acceptable and adequate practice; and (3) has at least one individual who is a representative of consumers on its governing body. In section 261 of the TAAEA, Congress replaced the first two of these requirements with requirements that a QIO: (1) Be able, as determined by the Secretary, to perform QIO functions in a manner consistent with the efficient and effective administration of Part B of Title XI and Title XVIII of the Act; and (2) have at least one individual who is a representative of health care providers on its governing body. Congress left unchanged the third requirement in section 1152(3) of the Act that a QIO have at least one individual representing consumers on its governing body. We have interpreted and the regulations in Part 475 implement the statutory definition in section 1152 of the Act as setting minimum eligibility requirements for an entity to hold a QIO contract. Our regulatory proposal in this proposed rule would implement the changes in the QIO eligibility standards made by the TAAEA.

We recognize the vital role of physicians in the work of the QIOs and also believe that some of the functions of the QIOs necessitate a multidisciplinary approach to quality improvement, inclusive of expertise from a wide breadth of disciplines. With the elimination of the requirement that a QIO be sponsored by or have access to physicians in a specific organization structure, we are proposing to delete the eligibility requirements in §§ 475.101 through 476.104 related to the concepts of ''physician-sponsored organization'' and ''physician-access organization.'' In light of the current multidisciplinary approach to QIO activities, we believe that expanding the existing eligibility requirements beyond ''physician-sponsored organizations'' and ''physician-access organizations'' will both better reflect the flexibility Congress provided in the TAAEA amendments to section 1152 of the Act and be inclusive of the multidisciplinary approach that currently exists in contemporary quality improvement.

In addition, to implement the language added by section 261 that a QIO must be able, as determined by the Secretary, to perform the functions under the Act consistent with the purposes of the QIO program and the Medicare program, we are proposing language in §§ 475.101 through 475.103 to distinguish the requirements for QIOs to be able to perform case reviews from the requirements for QIOs to be able to perform quality improvement initiatives. We are soliciting public comments on our focus on these primary QIO functions and how this functional approach will ensure that QIOs are appropriately selected for contract award. We are proposing to vacate and reserve existing §§ 475.104 and 475.106.

a. Eligibility To Be Awarded a QIO Contract (§ 475.101)

As proposed here, revised § 475.101 would no longer reference ''physician-sponsored organizations'' and ''physician-access organizations,'' would retain the requirement that the governing body of the QIO include at least one consumer representative, and would include new eligibility standards for an organization to be awarded a QIO contract based on the TAAEA amendments to section 1152 of the Act. First, in paragraph (a), we are proposing that a QIO must have a governing body that includes at least one representative of health care providers and one representative of consumers as required by section 1152(2) and (3) of the Act as amended by the TAAEA. Second, in paragraph (b), we are proposing to interpret and implement the amended language in section 1152(1) of the Act that an organization awarded a QIO contract must be able, as determined by the Secretary, to perform the functions under the Act consistent with the purposes of the QIO program and the Medicare program by requiring that an organization demonstrate the ability to meet eligibility requirements and perform the functions of a QIO. Our proposal characterizes the functions of a QIO as the contractual requirements for QIOs to perform activities that are built into the request for proposals used to award QIO contracts and the ability to perform case reviews and/or quality improvement initiatives as described in these regulations. In our view, these broad categories encompass the work QIOs are required to perform under section 1154 of the Act. Our proposal reflects a different approach to structuring the QIO requirements than the current rule; we are proposing to focus on the functions the organization performs under the QIO contract instead of the structure of the organization itself. As discussed in more detail below in connection with proposed §§ 475.102 and 475.103, this function-focused approach also reflects both the important role of physicians and a multidisciplinary approach for the two primary functions of the QIO contracts: (1) Case reviews and (2) quality improvement initiatives. These two primary functions are based on the statutory requirements for the functions QIOs must perform and our current approach of using quality improvement initiatives to improve the quality of care provided to Medicare beneficiaries. By referencing the contractual requirements set forth in the requests for proposals, we are proposing to incorporate the flexibility provided in section 1154(a) to require a QIO to perform one or more of the listed QIO functions and section 1154(a)(18) of the Act for the inclusion of additional activities for QIOs to perform when we determine that they are necessary to improve the quality of care for Medicare beneficiaries.

Finally, in paragraph (c), we are proposing that a QIO must demonstration the ability to actively engage beneficiaries, families, and consumers, as applicable, in case reviews and quality improvement initiatives. Although this is not a specifically required qualification for a QIO under sections 1152 and 1153 of the Act, we are proposing this requirement because it reflects the multidisciplinary and multistakeholder approach to QIO functions that we intend to establish. Health care costs have doubled as a share of the economy over the past three decades, causing stress on beneficiaries, families, employers, and government budgets. We believe that motivating beneficiaries to

become involved in their own health care may reduce waste and ultimately improve the quality and efficiency of health care. One important way to accomplish this is by educating beneficiaries, their families, providers, and the public about the importance of identifying and pursuing value in health care. Value represents the best possible quality of health care at the most reasonable cost. A major component of a successful value initiative depends on a QIO's understanding of patient and family goals, expectations, motivations, and aspirations. Our inclusion of the requirement that a QIO have the ability to understand the needs of beneficiaries, families, and consumers and actively engage them in health care decisions emphasizes our commitment to patient and family engagement as an essential component of the QIO program.

We are soliciting public comments on whether our proposal sufficiently incorporates the statutory flexibility, identifies the goals of the QIO eligibility requirements, and provides guidance on how organizations will be determined eligible for QIO contracts.

b. Eligibility Requirements for QIOs to Perform Case Reviews (§ 475.102)

In this proposed rule, we are proposing to list the *type* of factors CMS will use to determine that an organization has demonstrated its ability to perform case reviews. We do not consider this list to be comprehensive, but an indication of what we intend to focus on. The list of factors emphasizes the importance of QIOs having access to qualified physicians and practitioners for this purpose. In paragraph (a) of § 475.102, we are proposing that CMS will determine that an organization has demonstrated the ability to perform case reviews based on factors related to how the QIO work will be performed and the underlying capabilities necessary for performing well. Under our proposal, CMS will consider such factors as (1) the organization's proposed processes, capabilities, quantitative and/or qualitative performance objectives, and case review methodology; (2) the organization's proposed involvement of and access to physicians and practitioners in the QIO area with appropriate expertise and specialization in the areas of health care related to case reviews; (3) the organization's ability to take into consideration urban versus rural and regional characteristics in the health care setting where the care under review was provided; (4) the organization's ability to take into consideration evidence-based national clinical guidelines and professionally recognized standards of care; and (5) the organization's access to qualified information technology (IT) expertise. In this paragraph, we intend to propose these general factors and standards CMS may use to establish the minimum level of resources and skills the organization must have in order to demonstrate that its processes and capabilities are satisfactory and meet the purposes of the QIO program.

In paragraph (b) of § 475.102, we are proposing that CMS may consider characteristics such as the geographic location, size and prior experience of an organization in order to determine whether the organization has the capability to perform case reviews. In terms of prior experience, we are proposing that CMS will gauge the significance of an organization's experience based on how relevant it is to the tasks that CMS intends to include in the QIO contract and the goals CMS intends to accomplish. While we intend to emphasize the importance of prior experience, we do not intend to limit the evidence an organization may present to us to demonstrate its capability to perform case reviews. Therefore, we have included language in proposed § 475.102(b) to indicate that CMS can consider a variety of factors, as indicated in section 1153(b)(4) of the Act.

Finally, we are proposing to include in paragraph (c) of § 475.102 clarifications to the text that reflect the existing regulatory text at § 475.104(d), with some minor modifications. The existing provision states that a State government that operates a Medicaid program will be considered incapable of performing utilization and quality review functions in an effective manner, unless the State demonstrates to CMS' satisfaction that it will act with complete independence and objectivity. As proposed, the provision at § 475.102(c) maintains the substance of the existing rule while making it clear that the scope of its review will be limited to case reviews. In order to do this, we have proposed to replace the term ''utilization and quality review functions'' with the term ''case reviews.'' In addition, we are proposing to revise the language to clarify that the objectivity and independence mentioned in the existing regulation relate to objectivity and independence from the Medicaid program, as we believe there is an inherent conflict of interest that arises from the State's financial interest in the administration of that program.

Our proposal at § 475.102 implements the statutory responsibility for the Secretary to determine whether an organization can perform the QIO function of case reviews in a manner that is consistent with the efficient and effective operation of the QIO Program and the Medicare Program. We are soliciting public comments on whether the regulation text should incorporate the standards for QIOs that we propose to use and the factors we intend to consider when determining whether those standards have been met.

We are proposing to delete and reserve all of § 475.104 in light of our proposed changes to § 475.102. We believe that aspects of § 475.104 that we have not proposed to incorporate into § 475.102 are obsolete due to the revisions in the TAAEA legislation.

c. Eligibility Requirements for QIOs to Conduct Quality Improvement Initiatives (§ 475.103)

Case reviews are concerned with care that was provided, or should be provided, based on the facts of a particular case, concerning a particular episode of care or concerning a particular beneficiary, or both. By contrast, the vast majority of quality improvement initiatives are not initiated in the same manner as case reviews. Rather, quality improvement initiatives are based on patterns of care that reveal problems that are more systematic in nature, such as those that result in inefficiency, waste, or high cost, or that could potentially harm beneficiaries. These patterns of care can reflect problems that might impact large segments of the population, or single episodes of care where the impact might affect fewer people, but the QIO is concerned about the health and safety of the public due to the severity of the quality of care issue. We are proposing under revised § 475.103(a) that CMS will determine if an organization is capable of performing quality improvement initiatives using factors similar to those listed for QIOs that will perform case reviews. In paragraph (a), we are proposing a list of the type of factors CMS will use to determine that an organization has demonstrated its ability to perform quality improvement initiatives. We do not consider this list to be comprehensive, but an indication of what we intend to focus on. Specifically, in revised paragraph § 475.103(a), we are proposing that CMS will determine that an organization has demonstrated the ability to perform quality improvement initiatives based on factors tied to how the QIO work will be performed and the underlying capabilities necessary for performing well. Under our proposal, CMS will consider such factors as (1) The organization's proposed processes,

capabilities, quantitative and/or qualitative performance objectives, and methodology to perform quality improvement initiatives; (2) the organization's proposed involvement of and access to physicians and practitioners in the QIO area with appropriate expertise and specialization in the areas of health care concerning the quality improvement initiative; and (3) the organization's access to professionals with requisite knowledge of quality improvement methodologies and practices as well as qualified information technology and technical expertise. We plan to use these factors, and others as necessary, to determine if an organization has satisfactory capabilities and sufficient resources to initiate, follow up on, and follow through to completion quality improvement initiatives that it agrees to undertake. We consider appropriate quality improvement resources to include a multidisciplinary team that is comprised of appropriate health care professionals to perform quality improvement initiatives as well as the administrative, IT and technical staff necessary to accomplish the quality improvement initiatives.

In paragraph (b), we are proposing that CMS may consider characteristics such as the geographic location, size, and prior experience of an organization in order to determine whether the organization has the capability to perform quality improvement initiatives. In terms of prior experience, we are proposing that CMS will gauge the significance of an organization's experience based on how relevant it is to the tasks that CMS intends to include in the QIO contract and the goals CMS intends to accomplish. While we intend to emphasize the importance of prior experience, we do not intend to limit the evidence an organization may present to us to demonstrate its capability to perform quality improvement initiatives. We are proposing to include language in proposed § 475.103(b) to indicate that CMS can also consider a variety of other factors, as indicated in section 1153(b)(4) of the Act.

Finally, we are proposing to include in paragraph (c) clarifications to the text that reflect the existing regulatory text at § 475.104(d), with some minor modifications. The current provision states that a State government that operates a Medicaid program will be considered incapable of performing utilization and quality review functions in an effective manner, unless the State demonstrates to CMS' satisfaction that it will act with complete independence and objectivity. As proposed, the provision at § 475.103(c) maintains the substance of the existing rule while making it clear that the scope of its review will be limited to quality improvement initiatives. In order to do this, we have proposed to replace the term ''utilization and quality review functions'' with the term ''quality improvement initiatives.'' In addition, we are proposing to revise the language to clarify that the objectivity and independence mentioned in the existing regulation relate to objectivity and independence from the Medicaid program, as we believe there is an inherent conflict of interest that arises from the State's financial interest in the administration of that program.

Our proposal at § 475.103 implements the statutory responsibility for the Secretary to determine whether an organization can perform the QIO function of quality improvement initiatives in a manner that is consistent with the efficient and effective operation of the QIO Program and the Medicare Program. We solicit comment on whether the regulation text should incorporate the standards for QIOs that we propose to use and the factors we intend to consider when determining whether those standards have been met.

d. Prohibitions on Eligibility as a QIO (§ 475.105)

We are proposing revisions to § 475.105(a)(2) to eliminate the prohibition against an association of health care facilities being awarded a QIO contract, to reflect a TAAEA amendment deleting this restriction from section 1153(b)(3) of the Act. We also are proposing to move the existing provision covering the exclusion of health care facility affiliates in paragraph (a)(3) to paragraph (a)(2), and to create a revised paragraph (a)(3) that would include payor organizations as excluded entities unless they meet certain exception requirements identified in section 1153(b)(2)(B) of the Act. Prior to the TAAEA amendment, the statute imposed two prohibitions on CMS contracting with a payor organization to perform QIO functions: A prohibition applicable before November 15, 1984 and a prohibition with exceptions for periods of time after November 15, 1984. After November 15, 1984, a payor organization could perform as a QIO if the Secretary determined that there were no other entities available for a QIO area. These restrictions were implemented in the existing regulations codified at §§ 475.105(b) and 475.106. The TAAEA amendments left unchanged the prohibition in effect for the period of time before November 15, 1984, but revised section 1153(b)(2)(B) of the Act to add exceptions to the prohibition applicable after November 15, 1984. Section 1153(b)(2)(B) of the Act, as amended, permits the award of a QIO contract to a payor organizations not only when the Secretary determines that there is no other entity available for an area, but also when the Secretary determines that there is a more qualified entity to perform one or more of the functions in section 1154(a) of the Act, if the entity meets all other requirements and standards in the QIO statute. We read this provision to mean that when the Secretary determines that a payor organization is more qualified than a nonpayor organization in the QIO area to perform one or more of the functions in section 1154(a) of the Act, that payor entity can qualify as a QIO so long as all other eligibility criteria are met. We have reflected this interpretation in the proposed rule as § 475.105(a)(3).

The existing paragraph (b) prohibits payor organizations from being QIOs prior to November 15, 1984. Since that date has long passed, we believe this paragraph should be eliminated. We are proposing to delete and reserve paragraph (b) of § 475.105 in its entirety. Paragraph (c) would remain largely unchanged except for a minor terminology update to clarify in the regulation text that the term ''facility'' is meant to refer to a ''health care facility'' and to change the term ''conduct any review activities'' to ''perform any case review activities'' to indicate our separation of case review functions from quality improvement initiatives. We do not believe that these changes affect the underlying prohibitions.

As noted above, we are proposing to delete and reserve all of § 475.106 in light of our proposed changes to § 475.105. We believe that aspects of § 475.106 that we have not proposed to incorporate into § 475.105 are obsolete due to the passage of time.

5. Proposals Relating to QIO Contract Awards (§ 475.107)

The existing regulations at 42 CFR Part 475 also include requirements related to the establishment of QIO contracts and the assignment of bonus points. We are proposing to delete the portions of existing § 475.107(c) pertaining to the assignment of up to 10 percent of available bonus points to physician-sponsored organizations, and the assignment of points in connection with the structure of the organization as ''physician-sponsored'' or ''physician-access.'' These provisions are obsolete in light of the changes to section 1152(1) of the Act and our proposals above

relating to the eligibility standards for an organization awarded a QIO contract. We also are proposing to use cross-references in § 475.107(a) and (b) to the revised standards we are proposing in §§ 475.101 through 475.103. We are proposing to retain the regulatory language that requires CMS to identify proposals that meet the requirements of § 475.101 (proposed § 475.107(a)) and to identify those proposals that set forth minimally acceptable plans in accordance with the requirements of § 475.102 or § 475.103, or both as applicable (proposed § 475.107(b)).

The existing § 475.107(d) states that the contract for a given QIO area to the selected organization cannot exceed 2 years, which is inconsistent with the current statutory provision at section 1153(c)(3) of the Act. We are proposing here to redesignate this provision as paragraph (c) and to provide for a 5-year contract term as required by section 1153(c)(3) of the Act, as amended by section 261 of the TAAEA.

XVIII. Medicare Fee-for-Service Electronic Health Record (EHR) Incentive Program

A. Incentive Payments for Eligible Professionals (EPs) Reassigning Benefits to Method II CAHs

Section 1848(o)(1)(A) of the Act, as amended by section 4101(a) of the HITECH Act, establishes the Medicare EHR Incentive Program, which provides for incentive payments to eligible professionals (EPs) who are meaningful users of certified EHR technology during the relevant EHR reporting periods. Section 1848(o)(1)(A)(i) of the Act provides that EPs who are meaningful EHR users during the relevant EHR reporting period are entitled to an incentive payment amount, subject to an annual limit, equal to 75 percent of the Secretary's estimate of the Medicare allowed charges for covered professional services furnished by the EP during the relevant payment year. Under section 1848(o)(1)(B)(ii) of the Act, an EP is entitled to an incentive payment for up to 5 years. In addition, in accordance with section 1848(o)(1)(A)(ii) of the Act, there shall be no incentive payments made with respect to a year after 2016.

1. Background for Definition of EPs and EHR Incentive Payments to EPs

In accordance with section 1848(o)(5)(C) of the Act, in the final rule for Stage 1 of the EHR Incentive Program (75 FR 44442), we established a definition of the term ''eligible professional'' in the regulations at 42 CFR 495.100 to mean a physician as defined under section 1861(r) of the Act. Section 1861(r) of the Act defines the term ''physician'' to mean the following five types of professionals, each of which must be legally authorized to practice their profession under State law: A doctor of medicine or osteopathy; a doctor of dental surgery or dental medicine; a doctor of podiatric medicine; a doctor of optometry; or a chiropractor. As also discussed in that final rule (75 FR 44439), in accordance with section 1848(o)(1)(C) of the Act, hospital-based EPs are not eligible for an EHR incentive payment. The term ''hospital-based EP'' is defined in § 495.4 of the regulations as ''Unless it meets the requirements of § 495.5 of this part, a hospital-based EP means an EP who furnishes 90 percent or more of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting in the year preceding the payment year, or in the case of a payment adjustment year, in either of the 2 years before such payment adjustment year.'' Paragraphs (1)(i) and (1)(ii) of the definition specify how the percentage of covered professional services is calculated for Medicare for purposes of the payment years and payment adjustment years, respectively. We note a discrepancy between the regulation text for this definition and the final policy we established in the preamble of the EHR Incentive Program Stage 2 final rule (77 FR 54102). Under the policy we finalized in that rule, we determine whether an EP is hospital-based for a payment adjustment year using either of the following Federal fiscal year's (FY) data: (1) The fiscal year before the year that is 1 year prior to the payment adjustment year (for example, FY 2013 data for payment adjustment year 2015); or (2) the fiscal year before the year that is 2 years prior to the payment adjustment year (for example, FY 2012 data for payment adjustment year 2015). If the data from either year result in a hospital-based determination, the EP would not be subject to the payment adjustments for the relevant year. In the definition under § 495.4 of the regulations, however, paragraph (1)(ii) incorrectly refers to the fiscal year preceding the payment adjustment year and the fiscal year 2 years before the payment adjustment year. The introductory text of the definition also incorrectly references either of the 2 years before such payment adjustment year. We are taking this opportunity to make a technical correction to paragraph (1)(ii) and the introductory text of the definition of ''hospital-based EP'' at § 495.4 to conform to the policy stated in the preamble of the EHR Incentive Program Stage 2 final rule (77 FR 54102). We are proposing to revise paragraph (1)(ii)(A) of the definition to read ''The Federal fiscal year 2 years before the payment adjustment year; or'' and paragraph (1)(ii)(B) of the definition to read ''The Federal fiscal year 3 years before the payment adjustment year.'' We also are proposing to revise the introductory text of the definition to reference, in the case of a payment adjustment year, either of the 2 years before the year preceding such payment adjustment year. Section 1848(o)(5)(A) of the Act defines covered professional services as having the same meaning as in section 1848(k)(3) of the Act; that is, services furnished by an eligible professional for which payment is made under, or is based on, the Medicare Physician Fee Schedule (MPFS). In accordance with section 1848(a)(1) of the Act, the Medicare allowed charge for covered professional services is the lesser of the actual charge or the MPFS amount established in section 1848 the Act. As specified under section 1848(o)(1)(A)(i) of the Act, the Secretary's estimate of allowed charges for EHR incentive payments is based on claims submitted to Medicare no later than 2 months following the end of the relevant payment year.

Section 1848(o)(1)(B)(i) of the Act sets forth the annual limits on the EHR incentive payments to EPs. Specifically, section 1848(o)(1)(B) of the Act provides that the incentive payment for an EP for a given payment year shall not exceed the following amounts:

- For the EP's first payment year, for such professional, $15,000 (or $18,000, if the EP's first payment year is 2011 or 2012);
- For the EP's second payment year, $12,000;
- For the EP's third payment year, $8,000;
- For the EP's fourth payment year, $4,000;
- For the EP's fifth payment year, $2,000; and
- For any succeeding year, $0.

Under section 1848(o)(1)(B)(iv) of the Act, for EPs who predominantly furnish services in a geographic HPSA (as designated by the Secretary under section 332(a)(1)(A) of the Public Health Service Act), the incentive payment limitation amounts for each payment year are increased by 10 percent. Section 1848(o)(1)(B)(iii) of the Act also provides for a phased reduction in payment limits for EPs who first demonstrate meaningful use of certified EHR technology after 2013. Section 1848(o)(1)(D)(i) of the Act, as amended

by section 4101(a) of the HITECH Act, provides that the incentive payments may be disbursed as a single consolidated payment or in periodic installments as the Secretary may specify. We make a single, consolidated, annual incentive payment to EPs. Payments are made on a rolling basis, as soon as we ascertain that an EP has demonstrated meaningful use for the applicable reporting period (that is, 90 days for the first year or a calendar year for subsequent years), and reached the threshold for maximum payment.

Section 1848(o)(1)(A) of the Act provides that ''with respect to covered professional services provided by an eligible professional,'' the incentive payment ''shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)).'' Section 1842(b)(6)(A) of the Act allows for reassignment of payments to an employer or entity with which the physician has a valid contractual arrangement allowing the entity to bill for the physician's services. Therefore, we provided that EPs would be allowed to reassign their incentive payments to their employer or an entity that they have a valid employment agreement or contract providing for such reassignment, consistent with all rules governing reassignments (75 FR 44445). Section 495.10(f) of the regulations permits EPs to reassign their incentive payments to an employer or to an entity with which they have a contractual arrangement, consistent with all rules governing reassignments, including 42 CFR Part 424, Subpart F. Section 495.10(f) also precludes an EP from reassigning the incentive payment to more than one employer or entity. To implement this requirement, we use the EP's Medicare enrollment information to determine whether an EP belongs to more than one practice (that is, whether the EP's National Provider Identifier (NPI) is associated with more than one practice). In cases where an EP is associated with more than one practice, the EP would select one tax identification number to receive any applicable EHR incentive payment.

2. Special Circumstances of EPs Reassigning Benefits to Method II CAHs

Since we implemented the EHR Incentive Program, we have received many requests from CAHs billing under Method II (Method II CAHs), members of Congress, and hospital associations requesting that we make it possible for EPs who assign their reimbursement and billing to a Method II CAH to participate in the program. Under section 1834(g)(2) of the Act, a CAH may elect to receive a cost-based payment for the facility costs of providing outpatient services, plus 115 percent of the fee schedule amount for professional services included within outpatient CAH services. CAHs that elect to receive both a facility payment and a professional payment for outpatient services are commonly referred to as Method II CAHs. The statute also provides that, as a condition for applying this provision, the Secretary may not require that each physician or other practitioner providing professional services in a CAH must assign billing rights for such services to the CAH. Physicians and other practitioners who do not assign such rights to their Method II CAH continue to receive payment for their professional services directly under the appropriate professional fee schedule.

Since the inception of the EHR Incentive Program, we have been unable to account for the services furnished by EPs in Method II CAH outpatient departments (including emergency departments) due to limitations in our information systems. Specifically, our information systems have not been capable of receiving and storing line-level rendering EP identifying information for these Method II CAH claims for services furnished by EPs in outpatient departments. These claims are billed by the CAH on behalf of the EPs furnishing the services using the institutional claim form UB–04 or its electronic counterpart, the X12 837I format. Until a recent information systems change was implemented, we were unable to identify the NPI of the EP furnishing the service at the service line-level on the claim. While the information systems received and stored NPIs from each claim, the NPIs were not tied to the specific services furnished on the claim. This limitation made it impossible to take into account the services furnished by EPs in Method II CAH outpatient settings when we annually determined the hospital-based status of each EP for each payment year for purposes of the EHR Incentive Program. In addition, for those EPs who were determined to be not hospital-based and who successfully demonstrated meaningful use, we were unable to take into account such services in calculating the amount of an EP's EHR incentive payment for a payment year. Because the limitations in our information systems prevented us from identifying the NPIs of the EPs who furnished the services on the Method II CAH claims, we were unable to include those claims for purposes of the hospital-based determinations and EHR incentive payment calculations. However, it is important to note that these EPs could still participate in the EHR Incentive Program and qualify for an incentive payment based on their non-Method II CAH claims.

We began soon after the implementation of the EHR Incentive Program to develop the requisite changes so that our information systems would be able to receive and store line-level rendering EP identifying information for these Method II CAH claims. We were able to implement these information systems changes effective for claims submitted on or after October 1, 2012 (in other words, on or after the start of FY 2013). Under the existing regulations at § 495.4, we determine an EP's hospital-based status for a payment year based on claims data from the fiscal year preceding the payment year. Thus, for purposes of the 2013 payment year, we determine whether an EP is hospital-based using claims data from FY 2012. However, as noted above, we are unable to take into account Method II CAH claims prior to the start of FY 2013. As a result, under the existing regulations, the hospital-based determinations for EPs for the 2013 payment year are based on FY 2012 claims data that do not include Method II CAH claims. The earliest that we would be able to include such claims under the existing regulations would be for the hospital-based determinations for the 2014 payment year, which are based on FY 2013 claims data.

We want to avoid further delay in taking into account the services furnished by EPs in Method II CAH outpatient settings. Therefore, we are proposing to add a provision to the definition of ''hospital-based EP'' at § 495.4 under new paragraph (3) to provide a special methodology for making hospital-based determinations for the 2013 payment year for EPs with services billed by Method II CAHs. We are making this proposal solely in order to take into account the special circumstances of those EPs as described above. Under this proposal, we would be able to take into account Method II CAH claims when making hospital-based determinations for payment year 2013, one year before we would be able to do so under the existing regulations. Specifically, we are proposing that, for payment year 2013 only, we would use a two-step process to make hospital-based determinations for EPs who furnish covered professional services billed by Method II CAHs. First, after we have accumulated the Method II CAH claims with the line-level furnishing EP identifying information for FY 2013

(October 1, 2012 through September 30, 2013), we would use that data to identify which EPs had Method II CAH service billings during that year, and we would make a special hospital-based determination for that subset of EPs for payment year 2013. Any EP determined to be nonhospital-based on the basis of FY 2013 claims data would be eligible to demonstrate meaningful use for the relevant EHR reporting period and potentially qualify for an EHR incentive payment for payment year 2013. An EP who believes that he or she would be determined to be nonhospital-based under this proposed provision and wishes to qualify for the EHR incentive payment for payment year 2013 should not wait for the determination to implement Certified EHR Technology and begin meaningful use for an EHR reporting period in 2013. To qualify for an EHR incentive payment for payment year 2013, an EP will need to demonstrate meaningful use of Certified EHR Technology for an EHR reporting period in 2013. As is the case with other EPs that reassign their EHR incentive payments to another entity, these EPs may reassign their EHR incentive payments to the Method II CAH that bills on their behalf if the CAH is an employer or they have a contractual arrangement, consistent with the rules governing reassignments. Second, in the case of an EP determined to be hospital-based on the basis of FY 2013 claims data, we would check the hospital-based determination we have already for that EP under the existing regulation using the FY 2012 file. Any EP found to be nonhospital-based on the basis of the FY 2012 claims data (which do not include Method II CAH claims) would be held harmless to the determination made on the basis of FY 2013 claims data and considered nonhospital-based for payment year 2013. We believe that this second step of the proposed methodology is important to protect EPs who were initially determined nonhospital-based at the beginning of payment year 2013 under the existing regulation. We do not believe those EPs who were determined nonhospital-based under the existing regulation should have those determinations reversed by later (although more complete) FY 2013 claims data. This hold-harmless provision would preserve the prospectivity of nonhospital-based determinations for payment year 2013 that were made under the existing regulation and maintain the eligibility of those EPs to receive EHR incentive payments for payment year 2013. At the same time, the first step of our proposal would provide an opportunity for EPs who were determined to be hospital-based for payment year 2013 on the basis of FY 2012 data, which did not include the Method II CAH claims for their services, to establish their nonhospital-based status on the basis of the more complete FY 2013 data. It is important to note that, due to the systems limitations described above, we are unable to propose any special method for making EHR incentive payments and hospital-based determinations for the payment years prior to payment year 2013. We lack the ability to retrieve line-level furnishing EP identifying information for Method II CAH claims during the years prior to FY 2013. We are inviting public comments on this proposal.

B. Cost Reporting Periods for Interim and Final EHR Incentive Payments to Eligible Hospitals

1. Background

In the July 28, 2010 final rule for Stage 1 of the EHR Incentive Program, we established the cost report periods from which we would draw the requisite data (for example, hospital acute care inpatient discharges and Medicare Part A acute care inpatient days) for determining interim and final EHR incentive payments to eligible hospitals (75 FR 44450). We specified in § 495.104(c)(2) of the regulations that we would use discharge and other relevant data from the hospital's most recently submitted 12-month cost report in order to determine preliminary hospital EHR incentive payments. Similarly, we specified in § 495.104(c)(2) that we would make final EHR incentive payments to hospitals based on discharge and other relevant data from the hospital's first 12-month cost reporting period that begins on or after the first day of the payment year. (For purposes of EHR incentive payments for eligible hospitals, a payment year is a Federal fiscal year.) As we noted in the final rule (75 FR 44450 through 44451), section 1886(n)(2)(C) of the Act requires that a ''12-month period selected by the Secretary'' be employed for purposes of determining the discharge related amount. As we also stated in that final rule (77 FR 44452), we believe that the requirement for using 12-month cost reporting periods for purposes of determining preliminary and final payments is important to avoid the use of nonstandard cost reporting periods, which are often quite short (for example, 3 months) and therefore are ''not likely to be truly representative of a hospital's experience, even if methods were to be adopted for extrapolating data over a full cost reporting period.''

2. Special Circumstances

Since the publication of the EHR Incentive Program final rule for Stage 1, we have become aware of circumstances in which the only cost reporting period for an eligible hospital that begins on or after the first day of a payment year is a nonstandard cost reporting period. For example, a hospital may be merging with another hospital under an arrangement in which its CCN, and therefore its existence as an identifiable hospital for Medicare EHR Incentive Program purposes, will not survive the merger. In such circumstances, the last cost reporting period for the hospital after its final payment year and prior to its merger into the surviving hospital may be a short period. In order to accommodate these situations, we are proposing to revise § 495.104(c)(2) of the regulations to provide that, in cases where there is no 12-month cost reporting period that begins on or after the beginning of a payment year, we will use the most recent 12-month cost reporting period available at the time of final settlement in order to determine final EHR incentive payments for the hospital. We understand that, under this proposal, the last available cost reporting period that we would use for the final determination of EHR incentive payments may be the same 12-month cost reporting period that had been used for purposes of determining the hospital's interim EHR incentive payments. We believe that this result is preferable to resorting to a nonstandard cost reporting period because a 12-month period is required by the statute to determine the discharge related amount and such periods tend, for reasons discussed in the EHR Incentive Program Stage 1 final rule, to be unrepresentative of the hospital's experience. We are inviting public comments on this proposal.

XIX. Medicare Program: Provider Reimbursement Determinations and Appeals

A. Matters Not Subject to Administrative or Judicial Review (§ 405.1804)

1. Background

Section 1878(a) of the Act addresses appeals of certain Medicare payment determinations to the Provider Reimbursement Review Board (the ''Board''). Below we briefly discuss the prospective payment system (PPS) under which payments for certain Medicare inpatient hospital services are made.

The Social Security Amendments of 1983 (Pub. L. 98–21) added section

1886(d) to the Act, which changed the method of payment for inpatient hospital services under Medicare Part A for short-term acute care hospitals. The method of payment for these hospitals was changed from a cost-based retrospective reimbursement system to a system based on prospectively set payment rates; that is, a PPS. Under Medicare's hospital inpatient prospective payment system (the hospital IPPS), payment is made at a predetermined rate for each hospital discharge.

The Social Security Amendments of 1983 also added section 1886(e)(1) to the Act, which required that, for cost reporting periods beginning in FYs 1984 and 1985, the IPPS result in aggregate program reimbursement equal to ''what would have been payable'' under the reasonable cost-based reimbursement provisions of prior law; that was, for FYs 1984 and 1985, the IPPS would be ''budget neutral.'' Section 1886(e)(1)(A) of the Act required that the projected aggregate payments for the hospital-specific portion should equal the comparable share of estimated reimbursement under prior law. Section 1886(e)(1)(B) of the Act required that projected aggregate reimbursement for the Federal portion of the prospective payment rates equal the corresponding share of estimated amounts payable prior to the passage of Public Law 98–21. In the 1983 IPPS interim final rule published in the **Federal Register** on September 1, 1983, we explained how the adjustment of the Federal portion of the prospective payment rate was determined, as well as the resulting adjustment factors for FY 1984 (48 FR 39887).

Under section 1878 of the Act and the regulations at Subpart R of 42 CFR Part 405, the Board has the authority to adjudicate certain reimbursement appeals by providers. The Board's decisions are subject to review by the Administrator of CMS under section 1878(f)(1) of the Act, as implemented by § 405.1875 of the regulations. A final decision of the Board, or any reversal, affirmance, or modification of a final Board decision by the Administrator, may be subject to review by a United States District Court.

2. Proposed Technical Conforming Change

Certain matters affecting payment to hospitals under the IPPS are not subject to administrative or judicial review. For example, section 1886(d)(7) of the Act precludes administrative and judicial review of the budget neutrality adjustment effected pursuant to section 1886(e)(1) of the Act. This preclusion of review is also reflected in section 1878(g)(2) of the Act (which states that ''determinations and other decisions described in section 1886(d)(7) shall not be reviewed by the Board or any other court . . . .''). The existing regulatory text at § 405.1804(a) provides that there is no administrative or judicial review of ''any budget neutrality adjustment in the prospective payment rates.''

The language of § 405.1804(a) was promulgated as part of the implementing regulations (48 FR 39785 and 39835) for the hospital IPPS. Section 405.1804(a) was codified pursuant to section 1886(d)(7) of the Act. At the time of promulgation, section 1886(d)(7) of the Act specified only the budget neutrality adjustment in section 1886(e)(1) of the Act. Additional budget neutrality adjustments under the IPPS were added by law and were not precluded from administrative or judicial review. For example, section 4410 of the Balanced Budget Act of 1997 (the BBA), Public Law 105–33, established the rural floor wage index budget neutrality adjustment, and did not preclude administrative or judicial review in the statute for this adjustment.

We recognize that the language of the regulation at § 405.1804(a) is overly broad because it states that there is no administrative or judicial review of ''any'' budget neutrality adjustment in the prospective payment rates, and its terms are not limited to the budget neutrality adjustment specified in section 1886(e)(1) of the Act. We understand that the Board has relied on § 405.1804(a) to deny jurisdiction in appeals relating to budget neutrality adjustments other than the adjustment in section 1886(e)(1) of the Act. To the extent that the existing § 405.1804(a) refers to ''any'' budget neutrality adjustment, we believe that this regulatory text is not consistent with the current statute. Therefore, we are proposing to make a technical conforming change to § 405.1804(a) to conform the regulation to the current statute. This proposed technical conforming change would clarify that there is no administrative or judicial review with respect to the budget neutrality adjustments enumerated in section 1886(e)(1) of the Act, and this preclusion of review does not apply to other budget neutrality adjustments under the IPPS.

B. Clarification of Reopening of Predicate Facts in Intermediary Determinations of Provider Reimbursement (§ 405.1885)

A provider must submit an annual cost report to a fiscal intermediary (currently referred to as a Medicare Administrative Contractor (MAC)), as specified in regulations at §§ 413.20(b) and 413.24(f). Through its review and settlement process, the intermediary determines the total amount of reimbursement due a provider for its cost reporting period. This constitutes an ''intermediary determination,'' as defined in § 405.1801(a). In accordance with § 405.1803, an intermediary determination is set forth in a notice of program reimbursement (NPR), which explains the intermediary's final determination of the total amount of program reimbursement due the provider for the cost reporting period in question.

Section 405.1803(b) requires that the NPR explain any differences between the intermediary determination and the amount of program reimbursement claimed by the provider. Such differences may be attributable to specific provisions of the Medicare statute, regulations, CMS rulings, or program instructions. In addition, the intermediary determination may reflect specific findings of fact by the intermediary that differ from the provider's understanding of the facts.

The factual underpinnings of a specific determination of the amount of reimbursement due a provider sometimes first arise in, or are determined for, the same fiscal period as the cost reporting period under review. For example, the determination of whether a hospital subject to the inpatient prospective payment system (IPPS) should receive a payment adjustment for serving a significantly disproportionate share of low income patients under section 1886(d)(5)(F) of the Act and § 412.106 of the regulations in a given fiscal period depends on the number of the hospital's patient days for the same period.

However, the factual underpinnings of a specific determination of the amount of reimbursement due a provider may first arise in, or be determined for, a different fiscal period than the cost reporting period under review. We refer to these factual determinations as ''predicate facts.'' For example, the determination of an IPPS-exempt hospital's target amount (that is, per-discharge (case) limitation) or rate-of-increase ceiling under section 1886(b) of the Act and regulations at § 413.40 depends on: (1) The hospital's allowable net inpatient operating costs for a base period of at least 12 months before the first cost reporting period subject to the rate-of-increase ceiling; or (2) for later cost reporting periods, the target amount for the preceding 12-month cost reporting period. The hospital's allowable costs for its base period are

''predicate facts'' with respect to the first cost reporting period that is subject to the target amount because such base period costs figure in the determination of the hospital's first target amount. The target amount for each cost reporting period after the base period then becomes a ''predicate fact'' for the next cost reporting period. We refer readers to section 1886(b)(3)(A) of the Act (for the first period, the target amount is calculated using ''allowable operating costs of inpatient hospital services for the preceding 12-month cost reporting period;'' the target amount for later cost reporting periods is calculated using the target amount for the preceding 12-month cost reporting period, increased by an applicable update factor).

A provider may challenge an intermediary determination by filing an appeal within 180 days of the NPR to the Board (under section 1878(a) of the Act and regulations at § 405.1835) or, if the amount in controversy is at least $1,000 but less than $10,000, to the intermediary hearing officer(s) (under § 405.1811). Alternatively, in accordance with § 405.1885, the provider may request that the intermediary reopen its NPR. In addition, the intermediary may reopen the NPR on its own motion. Under § 405.1885(b), reopening must be requested by the provider, or initiated on the intermediary's own motion, within 3 years of the NPR, although there is no time limit for the reopening of an intermediary determination that was procured by fraud or similar fault of a party to such determination.

Appeal and reopening of an intermediary determination are both ''issue-specific.'' In order to meet the jurisdictional requirements for appeal to the Board or to the intermediary hearing officer(s), the provider must establish its dissatisfaction with each specific matter at issue in the intermediary determination. We refer readers to section 1878(a) of the Act and regulations at § 405.1835(a)(1) and (b) (Board appeals) and § 405.1811(a)(1) and (b) (intermediary hearing officer appeals). Similarly, § 405.1885(a)(1) provides that the intermediary determination may be reopened ''for findings on matters at issue in a determination.'' We also refer readers to § 405.1887, which provides that a notice of reopening and any revised intermediary determination must specify the findings on matters at issue to be reopened and the particular findings to be revised through reopening, respectively, and § 405.1889(b), which specifies that a provider's appeal rights after reopening are limited to the specific matters altered in the revised intermediary determination.

In many instances, a factual matter arises in, or is determined for, the same fiscal period as the cost reporting period at issue, and such a factual determination may be appealed or reopened as part of that period's intermediary determination. For example, if an IPPS hospital challenges the patient day count used to determine its DSH payment adjustment for its 2010 cost reporting period, the hospital must appeal its DSH patient day count within 180 days of the NPR for the 2010 cost reporting period (and meet the other jurisdictional requirements for appeal to the Board or to the intermediary hearing officer(s), as applicable). Similarly, the hospital would have to request, or the intermediary would have to initiate on its own motion, the reopening of the hospital's 2010 DSH patient day count within 3 years of the NPR for the 2010 cost reporting period.

When the specific matter at issue is a predicate fact that first arose in, or was determined for, a different fiscal period than the cost reporting period in question, our longstanding interpretation and practice is that the pertinent provisions of the statute and regulations provide for review and potential redetermination of such predicate fact only by a timely appeal or reopening of the NPR for the cost reporting period in which the predicate fact first arose or the NPR for the period for which such predicate fact was first determined by the fiscal intermediary. For example, assuming base period costs calculated for the period consisting of the 12 months prior to the hospital's 2002 cost reporting period, if an IPPS-exempt hospital challenges the determination of its 2008 cost reporting period target amount, the hospital could not appeal the determination of the base period predicate facts unless it was within 180 days of the NPR for the base period. Similarly, the hospital would have to request, or the intermediary would have to initiate on its own motion, the reopening of the determination of the hospital's base period costs within 3 years of the NPR for the base year cost reporting period. In addition, the hospital could appeal the determination of the 2008 cost reporting period target rate within 180 days of the NPR for the 2008 cost reporting period and, similarly, could request the reopening of the determination of its 2008 cost reporting period target amount within 3 years of the NPR for the 2008 cost reporting period. There are no additional periods subject to appeal and reopening of such predicate fact unless the predicate facts are redetermined at a later time through an appeal or reopening. Thus, if the same hospital's allowable base period costs or 2008 cost reporting period's target amount was redetermined on appeal or reopening, the hospital could appeal such redetermination within 180 days of the revised NPR for the redetermination of its base period costs or the revised NPR for the redetermination of the 2008 cost reporting period's target amount, respectively. The reopening of such a redetermination (in this example, of the hospital's base period costs or its 2008 cost reporting period's target amount) also could be available within 3 years of the revised NPR for the base period or the 2008 cost reporting period, respectively.

Many reimbursement formulas require the use of predicate facts, where the factual underpinnings of a specific determination of the amount of provider reimbursement first arise in, or are determined for, a different fiscal period than the cost reporting period under review. As discussed above, we believe that predicate facts should be subject to change only through a timely appeal or reopening for the fiscal period in which the predicate fact first arose or the fiscal period in which such fact was first determined by the intermediary. In some instances, a predicate fact from a prior fiscal period is used in a later period with additional information, which is not found in the original cost report or NPR. We believe this kind of determination may be reviewed and redetermined through a timely appeal or reopening of the NPR for the cost reporting period in which the predicate fact was first used (or applied) by the intermediary to determine the provider's reimbursement. However, we recognize exceptions when a particular legal provision (of the Medicare statute, regulations, or CMS rulings) authorizes, as part of a specific reimbursement rule, the review and revision of a predicate fact after the expiration of the 3-year reopening period. For example, the reaudit regulation in § 413.77(a), promulgated to implement section 1886(h)(2) of the Act (which is related to the determination of the average per-resident amount used to calculate reimbursement for graduate medical education (GME) costs), authorizes intermediaries to modify base-period costs solely for purposes of computing the per-resident amount after the hospital's base-period cost report is no longer subject to reopening under § 405.1885. We refer readers to the decision in *Regions Hospital* v. *Shalala,* 522 U.S. 448 (1998), which sustained

the lawfulness of the reaudit regulation (then designated as § 413.86(e)(1)).

We believe that the above-described interpretation of our rules regarding the appeal or reopening of predicate facts furthers the interests of both providers and the agency in maintaining the finality of intermediary determinations. The alternative, of allowing appeal and reopening of a predicate fact after the expiration of the 3-year reopening period, may result in inconsistent intermediary determinations on a reimbursement matter recurring in different fiscal periods for the same provider. An alternative approach of allowing appeal and reopening of a predicate fact beyond the 3-year reopening period could also result in intermediary determinations that are contrary to Medicare law and policy regarding a specific reimbursement matter. As with the target amount example discussed above, reimbursement for various items is premised on a base period cost determination that could affect reimbursement for a given item for many cost reporting periods thereafter. If a provider disputes such a base period cost determination, it can appeal or request reopening of the NPR for the base period. However, unless such an appeal or reopening results in a different finding as to the predicate fact in question, reimbursement for a given provider cost should not be based on one finding about a predicate fact in the base period and a different finding about the same predicate fact for purposes of determining reimbursement in later fiscal periods.

Under our longstanding interpretation and practice, once the 3-year reopening period has expired, neither the provider nor the intermediary is allowed to revisit a predicate fact that was not changed through the appeal or reopening of the cost report for the fiscal period where such predicate fact first arose or for the fiscal period for which such fact was first determined by the intermediary. Further, the application of such facts is subject to change only through a timely appeal or reopening of the cost report for the fiscal period where the predicate fact was first used (or applied) by the intermediary to determine the reimbursement for the provider cost in question. Accordingly, we are proposing to revise § 405.1885 to clarify that, absent a specific statute, regulation, or other legal provision permitting reauditing, revising, or similar actions changing, predicate facts: (1) A predicate fact is subject to change only through a timely appeal or reopening for the fiscal period in which the predicate fact first arose or the fiscal period for which such fact was first determined by the intermediary; and (2) the application of the predicate fact is subject to change only through a timely appeal or reopening of the cost report for the fiscal period in which it was first used (or applied) by the intermediary to determine the provider's reimbursement.

We note that a recent court decision conflicts with our settled interpretation of the regulations for provider appeals and cost report reopening. In *Kaiser Foundation Hospitals* v. *Sebelius,* 708 F.3d 226 (D.C. Cir. 2013), the court held that providers could appeal predicate facts used to determine their reimbursement in later fiscal periods even though such predicate facts were not timely appealed or reopened for the periods when they first arose or were determined by the intermediary nor was the application of those facts to the periods when those facts were first used by the intermediary to determine the providers' reimbursement. The predicate facts at issue in this case were the teaching hospitals' resident full-time equivalent (FTE) counts for their 1996 cost reporting periods, which, as required by section 1886(h)(4)(F)(i) of the Act, were used to calculate the statutory cap on residents for GME cost reimbursement for the first time in the hospitals' 1998 cost reporting periods. The providers could have challenged their resident FTE counts through timely appeals or reopening of their 1996 fiscal period NPRs, and they could have challenged the calculation of their resident caps through timely appeals or reopening of their 1998 fiscal period NPRs, the first time the caps were applied. Instead, the hospitals appealed their resident caps as applied to later cost reporting periods. The court held that the definition of ''intermediary determination'' under § 405.1801(a)(1), which is incorporated in the reopening rules at § 405.1885(a)(1), did not include factual findings, standing alone, where the providers made no attempt to challenge their GME cost reimbursement for their 1996 or 1998 fiscal periods due to the expiration of the 180-day appeal period and the 3-year period for reopening. Because the providers were not challenging the total amount of program reimbursement paid for their 1996 or 1998 fiscal periods, the court concluded that the intermediary determinations for those periods were not at issue and thus the 3-year limitation on reopening was not applicable.

We disagree with the court's decision, which we believe is contrary to our reopening regulations at § 405.1885(a), and the corresponding appeals regulations (discussed above), and which necessitates our proposed clarification of the regulations. As noted above, we are proposing to revise § 405.1885 to clarify that the specific ''matters at issue in a determination'' that are subject to the reopening rules include factual findings for one fiscal period that are predicate facts for later fiscal periods. The general 3-year reopening period applies to findings about such predicate facts and the reopening period is calculated separately for each finding about a predicate fact. We note that this proposed revision of § 405.1885 would apply to all Medicare reimbursement determinations, and not only to GME payment, which was the particular issue in *Kaiser Foundation Hospitals* v. *Sebelius.* Because this proposed revision clarifies longstanding agency policy, we are proposing that it be effective for any intermediary determination issued on or after the effective date of the final rule, and for any appeals or reopenings (or requests for reopening) that are pending on or after the effective date of the final rule, even if the intermediary determination (at issue in such an appeal or reopening) preceded the effective date of the final rule. We believe the proposed revision is not impermissibly retroactive in effect because the proposal simply clarifies longstanding agency policy and practice, and is procedural in nature. We refer readers, for example, to *Heimmermann* v. *First Union Mortgage Corp.,* 305 F.3d 1257, 1260–61 (11th Cir. 2002) (a rule clarifying the law, especially in an unsettled or confusing area of the law, is not a substantive change in the law, and thus the rule may apply to matters that preceded issuance of the rule). However, if the proposed revision to § 405.1885 were deemed a retroactive application of a substantive change to a regulation, section 1871(e)(1)(A) of the Act permits retroactive application of a substantive change to a regulation if the Secretary determines that such retroactive application is necessary to comply with statutory requirements or that failure to apply the change retroactively would be contrary to the public interest. We have determined that retroactive application of the proposed revision to § 405.1885 is necessary to ensure compliance with the 3-year limit on reopening and with various statutory payment provisions such as the target amount (under section 1886(b) of the Act) and the cap on residents for GME cost reimbursement (under section 1886(h)(4)(F)(i) of the Act). We have further determined that it would be in the public interest to apply

the proposed revision to intermediary determinations, appeals, and reopenings (including requests for reopening) that are pending on or after the effective date of the final rule. Not applying the proposed revisions to pending intermediary determinations, appeals, and reopenings would undermine the 3-year limit on reopening and the interests of both the Medicare program and Medicare providers in the finality of reimbursement determinations, and would be inconsistent with the statutory scheme.

Finally, although we have provided proposed revisions only to § 405.1885, in order to clarify our regulations in accordance with this proposal, we are considering making similar changes regarding predicate facts to the regulations governing intermediary appeals at § 405.1811 and appeals to the Board at § 405.1835. We are requesting public comments with respect to amending the language of these additional regulations for appeals before the intermediary and the Board.

XX. Files Available to the Public via the Internet

We are proposing to create new Addendum P—Proposed OPPS Items and Services That Will be Packaged for CY 2014.

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 proposed rule pertaining to the proposed CY 2014 payments under the OPPS, go to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html* and select ''1601–P'' from the list of regulations. All Addenda for this proposed rule are contained in the zipped folder entitled ''2014 OPPS 1601–P Addenda'' at the bottom of the page.

To view the Addenda of this proposed rule pertaining to the proposed CY 2014 payments under the ASC payment system, go to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html* and select ''1601–P'' from the list of regulations. All Addenda for this proposed rule are contained in the zipped folder entitled ''Addendum AA, BB, DD1 and DD2,'' and ''Addendum EE'' at the bottom of the page.

XXI. Collection of Information Requirements

A. Legislative Requirements for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and to solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comments on each of the issues outlined above for the information collection requirements discussed below.

B. Requirements in Regulation Text

1. Proposed Changes to the Outcome Measure Requirement for OPOs

In section XVI. Of this proposed rule, we discussed our proposal to modify the outcome measures requirement for OPOs set forth at § 486.318. Currently, OPOs are required to meet all three outcome measures in that section or they are automatically decertified. We are proposing to modify that requirement so that OPOs will meet the outcome measures requirement if they meet two out of the three outcome measures.

Based on our experience with OPOs and historical data concerning how many OPOs typically fail to meet one of the outcome measures, we believe that there would be about five OPOs that would fail to meet one of the outcome measures. Our proposal would result in those five OPOs meeting the outcome measures requirement and not being automatically de-certified. Therefore, these five OPOs would not have to perform the ICRs under this section, which would be the time and resources needed to go through the appeals process in an attempt to secure a reversal of the decertification.

The ICRs that an OPO would be required to expend would depend upon how it chose to handle the decertification. An OPO may choose to not engage in the appeals process and merge with another OPO prior to the effective date of the decertification. Other OPOs would likely choose to take advantage of the appeals process, which would begin with reconsideration at the regional administrator level. It is likely that an OPO would expend considerable resources during the reconsideration and, if that was unsuccessful, a hearing before a CMS hearing officer. We believe both would require considerable time and other resources from the OPO's senior staff and legal counsel. We also believe that those OPOs that went onto a hearing would expend considerably more resources than those that received a reversal of their decertification at the reconsideration. While we do not have a reliable estimate on how much these OPOs would save due to the numerous unknown variables, we are confident that these OPOs would sustain a significantly positive effect from not being automatically de-certified as is currently required under the OPO CfCs. In addition, under 5 CFR 1320.3(c), a ''collection of information''' does not include requirements imposed on fewer than 10 entities. Therefore, the requirements of this section are not subject to the PRA.

2. Proposed Changes to the Medicare Fee-for-Service EHR Incentive Program

In section XVIII. of this proposed rule, we are proposing to revise 42 CFR 495.4 to provide a special method for making hospital-based determinations for 2103 only in the cases of those EPs who reassign their benefits to Method II CAHs. We also are proposing a minor clarification to the regulations at § 495.104(c)(2) concerning the cost reporting period to be used in determining final EHR payments for hospitals. We refer readers to the Stage 1 (75 FR 44536 ff) and Stage 2 (77 FR 54126 ff) final rules for the Medicare EHR Incentive Program for the discussions of the burden of the information collection requirements of the Medicare Fee-for-Service EHR Incentive Program. Our proposals in this rule do not modify or increase the information collection requirements of the program in any way.

C. Associated Information Collections Not Specified in Regulatory Text

In this proposed rule, we make reference to proposed associated information collection requirements that are not discussed in the regulation text contained in this proposed rule. The following is a discussion of those requirements.

1. Hospital OQR Program

As we stated in section XIV. of the CY 2012 OPPS/ASC final rule with comment period, the Hospital OQR Program has been generally modeled after the quality data reporting program for the Hospital IQR Program. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72111 through 72114), the CY 2012 OPPS/ASC final rule with comment period (76 FR 74549 through 74554) and the CY 2013 OPPS/ASC final rule with comment period (77 FR 68527 through 68532) for detailed discussions of the Hospital OQR Program information collection requirements we have previously finalized.

a. Hospital OQR Program Requirements for the CY 2015 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68531) for a discussion on the burden of the information collection requirements of the previously adopted Hospital OQR Program measures for the CY 2015 payment determination. We are not proposing to add any additional measures for the CY 2015 payment determination and subsequent years, so there will be no change in our previous burden estimate.

We note that we had previously suspended data collection for the OP–19 measure and deferred data collection for the OP–24 measure.

In addition, we are proposing to codify existing policies related to program participation and withdrawal, data submission, program waivers, data validation, and the reconsideration process. Because we are only codifying existing policies, we do not anticipate any additional burden to hospitals based on this proposal affecting the CY 2015 payment determination or subsequent years.

b. Web-Based Measures for the CY 2016 Payment Determination and Subsequent Years

For the CY 2016 payment determination and subsequent years, we are proposing to add five measures to the program with data collection beginning during CY 2014. We are soliciting public comment on the impact of adding these measures and requiring data submission of aggregate data via a Web-based tool for four chart-abstracted measures. Hospitals will vary greatly as to the number of cases per HOPD due to specialization. However, we estimate based on our past experiences with chart-abstracted measures that each participating hospital will spend 35 minutes per case to collect and submit the data, and that the estimated burden associated with there being one case per hospital would be 1,924 hours (3,300 hospitals × 0.583 hours per hospital).

In addition, HOPDs will incur a financial burden associated with chart abstraction and data submission for these four proposed measures. We estimate the burden associated with there being one case per hospital would be $57,717 (3,300 hospitals × $30.00 per hour × 0.583 hours).

For the CY 2016 payment determination, the burden associated with Hospital OQR Program procedures is the time and effort associated with collecting and submitting the data on the measures. For the chart-abstracted measures where patient-level data is submitted directly to CMS, we estimate that there will be approximately 3,300 respondents per year. For hospitals to collect and submit this information, we estimate it will take 35 minutes per submitted case. Based upon the data submitted for the CY 2012 and CY 2013 payment determinations, we estimate there will be a total of 1,679,700 cases per year, approximately 509 cases per year per hospital. Therefore, the estimated annual hourly burden associated with the aforementioned data submission requirements for the chart-abstracted data is 979,265 hours (1,679,700 cases per year × 0.583 hours per case).

In addition, HOPDs will incur a financial burden associated with chart abstraction and data submission where patient-level data are submitted directly to CMS. We estimate the burden associated with these measures is $29,377,953 (1,679,700 cases per year × $30.00 per hour × 0.583 hours per case).

For the measures where data is submitted to CMS via a Web-based online tool (OP–12, 17, 22, 25, 26, 28, 29, 30, 31) located on a CMS Web site, we estimate that each participating hospital would spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with these measures 4,960 hours (3,300 hospitals × 0.167 hours per measure × 9 measures per hospital) in CY 2015.

In addition, HOPDs will incur a financial burden associated with chart abstraction and data submission for these 9 measures. We estimate that the financial burden associated with these measures would be $148,797 (3,300 hospitals × $30.00 per hour × 0.167 hours per measure x 9 measures).

For the NHSN HAI measure: Influenza Vaccination Coverage among Healthcare Personnel, we estimate that the total annual burden associated with this measure for an HOPD for data submission would be 27,555 hours (3,300 hospitals × 0.167 hour per response for 50 workers per hospital).

In addition, HOPDs will incur a financial burden associated with data submission for this measure. We estimate that the financial burden associated with these measures would be $826,650 ($30.00 per hour × 27,555 hours).

We invite public comment on the burden associated with these information collection requirements.

c. Hospital OQR Program Validation Requirements for the CY 2015 Payment Determination and Subsequent Years

We are not proposing to make any changes to our validation procedures. As a result, the burden associated with the validation procedures for the CY 2015 payment determination as proposed is the same as previously finalized for CY 2014 in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68531) and is the time and effort necessary to submit validation data to a CMS contractor. We estimate 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 estimate each hospital would submit up to 48 cases for the affected year for review. All selected hospitals must comply with these requirements each year, which would result in a total of up to 24,000 charts being submitted by the sampled hospitals (500 selected hospitals x 48 cases per hospital). The estimated annual burden associated with the data validation process for the CY 2015 payment determination is approximately 6,000 hours.

In addition, HOPDs will incur a financial burden associated with the required data abstraction and data submission for this measure. We estimate that the financial burden associated with this measure would be $180,000 ($30.00 per hour × 6,000 hours).

These requirements are currently approved under OCN: 0938–1109. This approval expires on October 31, 2013.

We invite public comment on the burden associated with data validation information collection procedures.

d. Hospital OQR Program Reconsideration and Appeals Procedures

In section XIII.I. of this proposed rule, for the CY 2015 payment determination and subsequent years, we are proposing a minor change to the reconsideration request process to ensure our deadline

for these requests will always fall on a business day. We also are proposing to codify our reconsideration request process at 42 CFR 419.46(h).

While there is burden associated with filing a reconsideration request, 5 CFR 1320.4 of the Paperwork Reduction Act of 1995 regulations excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, or appeals or all of these actions.

2. ASCQR Program Requirements

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

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532), we discussed the information collection requirements for the five claims-based measures (four outcome measures and one process measure) to be used for the CY 2014 payment determination. The five measures are: (1) Patient Burn (NQF #0263); (2) Patient Fall (NQF #0266); (3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267); (4) Hospital Transfer/Admission (NQF #0265); and (5) Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264). We collected quality measure data for the five claims-based measures using QDCs placed on submitted claims for services furnished from October 1, 2012 through December 31, 2012 that were paid by the contractor by April 30, 2013.

Approximately 71 percent of ASCs participated in Medical Event Reporting, which included reporting on the first four claims-based measures, which are outcome measures. Between January 1995 and December 2007, ASCs reported 126 events, an average of 8.4 events per year (Florida Medical Quality Assurance, Inc. and Health Services Advisory Group: Ambulatory Surgical Center Environmental Scan (July 2008) (Contract No. GS–10F–0096T)). We estimated the burden to report QDCs for these 4 claims-based outcome measures to be nominal due to the small number of cases. Based on the data above, extrapolating from 71 percent to 100 percent of ASCs reporting, there would be an average of 11.8 events per year or less than 1 case per month per ASC.

For the claims-based process measure, Prophylactic IV Antibiotic Timing, we also estimated the burden associated with submitting QDCs to be nominal because few procedures performed by ASCs will require prophylactic antibiotic administration.

We invite public comment on the burden associated with these information collection requirements.

b. Claims-Based and Web-Based Measures for the CY 2015 and CY 2016 Payment Determinations

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532), we discussed the information collection requirements for the measures to be used for the CY 2015 and CY 2016 payment determinations. For the CY 2015 payment determination, we finalized the retention of the five measures we adopted for the CY 2014 payment determination, and we added two structural, Web-based, measures: Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures (76 FR 74504 through 74509). For the CY 2016 payment determination, we 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).

Based on our data for CY 2014 payment determinations above for claims-based measures, extrapolating to 100 percent of ASCs reporting, there would be an average of 11.8 events per year. Thus, we estimated the burden to report QDCs on this number of claims per year for the first four claims-based outcome measures to be nominal due to the small number of cases (approximately one case per month per ASC) for the CY 2015 and CY 2016 payment determinations. We estimated the burden associated with submitting QDCs for the fifth measure to be nominal as well, as discussed above.

For the CY 2015 payment determination, for the Web-based measures, ASCs will enter required information using a Web-based collection tool between July 1, 2013 and August 15, 2013. For the Safe Surgery Checklist Use measure, we estimated that each participating ASC will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 878 hours (5,260 ASCs × 1 measure × 0.167 hours per ASC). For the CY 2015 payment determination, we estimate that, for the ASC Facility Volume Data on Selected ASC Surgical Procedures measure, each participating ASC would spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 878 hours (5,260 ASCs × 1 measure 0.167 hours per ASC).

For the CY 2016 payment determination, in this proposed rule we are proposing that ASCs would report data for the Safe Surgery Checklist measure and the ASC Volume Data on Selected ASC Surgical Procedures measure between January 1, 2015 and August 15, 2015 for services furnished between January 1, 2014 and December 31, 2014. For the Safe Surgery Checklist measure for the CY 2016 payment determination, we estimate that each participating ASC would spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 878 hours (5,260 ASCs × 1 measure × 0.167 hours per ASC). For the CY 2016 payment determination, for the ASC Volume Data on Selected ASC Surgical Procedures measure, we estimate that each participating ASC would spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 878 hours (5,260 ASCs × 1 measure × 0.167 hours per ASC).

For the CY 2016 payment determination, for the NHSN HAI measure: Influenza Vaccination Coverage among Healthcare Personnel, we estimate that the total annual burden associated with this measure for ASCs, including NHSN registration (5,260 ASCs × 0.083 hour per facility = 437 hours) and data submission (5,260 ASCs × 0.167 hour per response for 20 workers per facility = 17,568), will be 18,005 hours. This estimate is based upon burden estimates from the CDC (OMB No. 0920–0666) and reported numbers for the average number of workers per ASC.

For the CY 2016 payment determination, in this proposed rule, we are proposing to add four measures to the program with data collection to begin during CY 2014 and submission to be via a Web-based tool. As chart-abstracted measures, we estimate that each participating ASC would spend 35 minutes per case to collect and submit the data, making the total estimated burden for ASCs with a single case per ASC would be 3,067 hours (5,260 ASCs × 0.583 hours per case per ASC). We expect that ASCs would vary greatly as to the number of cases per ASC due to ASC specialization.

In addition, ASCs would incur a financial burden associated with chart abstraction and data submission for these four proposed measures. We estimate that, for a per chart abstracted case, an ASC would incur a cost of $91,997 (5,260 ASCs × $30.00 per hour × 0.583 hours). We are soliciting public comment on the impact of adding these measures and requiring data submission.

We invite public comment on the burden associated with these information collection requirements.

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 years, that once an ASC submits any quality measure data, it would be considered to be participating in the ASCQR Program. Once an ASC submits quality measure data indicating its participation in the ASCQR Program, in order to withdraw, an ASC must complete and submit an online form indicating that it is withdrawing from the program.

For the CY 2015 payment determination and subsequent years, if the ASC submits quality measure data, there is no additional action required by the ASC to indicate participation in the program. The burden associated with the requirements to withdraw from the program is the time and effort associated with accessing, completing, and submitting the online form. Based on the number of hospitals that have withdrawn from the Hospital OQR Program over the past 4 years, we estimated that 2 ASCs would withdraw per year and that an ASC would expend 30 minutes to access and complete the form, for a total burden of 1 hour per year.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53638 through 53639), we finalized for the CY 2015 payment determination the requirement that ASCs 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 52,600 hours (10 hours × 5,260 ASCs). The financial burden associated with these requirements is estimated to be $1,578,000 ($30.00 per hour × 52,600 hours).

In the FY 2013 IPPS/LTCH PPS final rule, we adopted a process for an extension or waiver for submitting information required under the program due to extraordinary circumstances that are not within the ASC's control. We are requiring that an ASC would complete a request form that would be available on the QualityNet Web site, supply requested information, and submit the request. The burden associated with these requirements is the time and effort associated with gathering required information as well as accessing, completing, and submitting the form. Based on the number of ASCs that have submitted a request for an extension or waiver from the ASCQR Program over the past year, we estimate that 200 ASCs per year would request an extension or waiver and that an ASC would expend 2 hours to gather required information as well as access, complete, and submit the form, for a total burden of 400 hours per year. This estimate takes into account continued billing and claims processing issues.

We also adopted a reconsideration process that would apply to the CY 2014 payment determination and subsequent payment determination years under the ASCQR Program. While there is burden associated with an ASC filing a reconsideration request, the regulations at 5 CFR 1320.4 for the Paperwork Reduction Act of 1995 exclude data collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, or appeals or all of these actions.

We invite public comment on the burden associated with these information collection requirements.

3. Hospital VBP Program Requirements

In section XIV. of this proposed rule, for the Hospital VBP Program, we are proposing to allow hospitals to request an independent CMS review that would be an additional appeal process beyond the existing review and corrections process (77 FR 53578 through 53581 and 76 FR 74544 through 74547) and appeal process codified at 42 CFR 412.167.

While there is burden associated with a hospital requesting an independent CMS review, the regulations at 5 CFR 1320.4 for the Paperwork Reduction Act of 1995 exclude collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, or appeals or all of these actions.

We invite public comment on the burden associated with these information collection requirements.

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–1601–P; Fax: (202) 395–6974; or Email: *OIRAsubmissions_@omb.eop.gov*

XXII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XXIII. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Contract with America Advancement Act of 1996 (Pub. L. 104–121) (5 U.S.C. 804(2)). This section of the proposed rule contains the impact and other economic analyses for the provisions that we are proposing.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated as an ''economically'' significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Contract with America Advancement Act of 1996 (Pub. L. 104–121). Accordingly, the proposed rule has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this proposed rule. In this proposed rule, we

are soliciting public comments on the regulatory impact analysis provided.

2. Statement of Need

This proposed rule is necessary to update the Medicare hospital OPPS rates. It is necessary to propose to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2014. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are proposing to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2012, through and including December 31, 2012, and updated cost report information.

For CY 2014, we are proposing to continue 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 proposed rule, we are proposing to implement these payment provisions. Also, we list the 15 drugs and biologicals in Table 19 that we are proposing to remove from pass-through payment status for CY 2014.

This proposed rule is also necessary to update the ASC payment rates for CY 2014, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC in CY 2014. Because the ASC payment rates are based on the OPPS relative payment weights for the majority of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, because the services provided in ASCs are identified by HCPCS codes that are reviewed and revised either quarterly or annually, depending on the type of code, it is necessary to update the ASC payment rates annually to reflect these changes to HCPCS codes. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC not less frequently than every 2 years. Sections 1833(i)(2)(D)(iv) and 1833(i)(7) of the Act authorize the Secretary to implement a quality reporting system for ASCs in a manner so as to provide for a reduction of 2.0 percentage points in any annual update with respect to the year involved for ASCs that fail to meet the quality reporting requirements. For CY 2014, we discuss the impacts associated with this payment reduction in section XV.C. of this proposed rule.

3. Overall Impacts for the Proposed OPPS and ASC Payment Provisions

We estimate that the effects of the proposed OPPS payment provisions would result in expenditures exceeding $100 million in any 1 year. We estimate that the total increase from the proposed changes in this proposed rule in Federal government expenditures under the OPPS for CY 2014 compared to CY 2013 would be approximately $600 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate that the proposed OPPS expenditures for CY 2014 would be approximately $4.372 billion higher, relative to expenditures in CY 2013. Because this proposed rule 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 39 displays the redistributional impact of the proposed CY 2014 changes in OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the proposed update to the conversion factor and other adjustments (not including the effects of outlier payments, the pass-through estimates, and the application of the frontier State wage adjustment for CY 2014) would increase total OPPS payments by 1.8 percent in CY 2014. The proposed changes to the APC weights, the proposed changes to the wage indices, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, and the proposed payment adjustment for cancer hospitals would not increase OPPS payments because these proposed changes to the OPPS would be budget neutral. However, these proposed updates would change the distribution of payments within the budget neutral system. We estimate that the proposed total change in payments between CY 2013 and CY 2014, considering all proposed payments, including proposed changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment outside of budget neutrality, in addition to the application of the proposed OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G) and 1833(t)(17) of the Act, would increase total estimated OPPS payments by 1.8 percent.

We estimate the total increase (from proposed changes to the ASC provisions in this proposed rule as well as from enrollment, utilization, and case-mix changes) in expenditures under the ASC payment system for CY 2014 compared to CY 2013 to be approximately $133 million. Because the provisions for the ASC payment system are part of a proposed rule that is ''economically significant'' as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the proposed changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of the proposed rule. Tables 40 and Table 41 of this proposed rule display the redistributional impact of the proposed CY 2014 changes on ASC payment, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Detailed Economic Analyses

a. Estimated Effects of Proposed OPPS Changes in This Proposed Rule

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2014 policy changes on various hospital groups. We post on the CMS Web site our proposed hospital-specific estimated payments for CY 2014 with the other supporting documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* At the Web site, select ''regulations and notices'' from the left side of the page and then select ''CMS–1601–P'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 39 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this proposed rule for a discussion of the hospitals whose

claims we do not use for ratesetting and impact purposes.

We estimate the effects of the proposed individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our proposed 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 this proposed rule, we are soliciting public comment and information about the anticipated effects of our proposed changes on providers and our methodology for estimating them. Any public comments that we receive will be addressed in the applicable sections of the final rule with comment period that discuss the specific policies.

(2) Estimated Effects of Proposed OPPS Changes on Hospitals

Table 39 below shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the proposed change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers because we include CMHCs in our weight scaler estimate. We now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 39 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 2013, 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). We display separately the impact of our proposed updates on CMHCs, and we discuss its impact on hospitals as part of our discussion of the hospital impacts.

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor as discussed in detail in section II.B. of this proposed rule. Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The proposed IPPS market basket percentage increase for FY 2014 is 2.5 percent (78 FR 27497). Section 1833(t)(3)(F)(i) of the Act reduces that 2.5 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is proposed to be 0.4 percentage points for FY 2014 (which is also the proposed MFP adjustment for FY 2014 in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27786); and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act further reduce the market basket percentage increase by 0.3 percentage points, resulting in the proposed OPD fee schedule increase factor of 1.8 percent, which we are proposing to use in the calculation of the proposed CY 2014 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.00. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2014 estimates in Table 39.

To illustrate the impact of the proposed CY 2014 changes, our analysis begins with a baseline simulation model that uses the CY 2013 relative payment weights, the FY 2013 final IPPS wage indices that include reclassifications, and the final CY 2013 conversion factor. Table 39 shows the estimated redistribution of the proposed increase in payments for CY 2014 over CY 2013 payments to hospitals and CMHCs as a result of the following factors: APC reconfiguration and recalibration for CY 2014 compared to CY 2013 payments (Column 2); the marginal impact of our packaging proposals other than packaging for clinical laboratory tests (Column 3); the marginal impact of our proposal to package clinical laboratory services (Column 4); the combined impact of all of our packaging proposals and proposed APC reconfiguration and recalibration for CY 2014, compared to CY 2013 payments (Column 5: the combined effect of columns 2, 3 and 4); the proposed wage indices and the rural adjustment (Column 6); the combined impact of proposed APC recalibration, the proposed wage indices and rural adjustment, and the proposed OPD fee schedule increase factor update to the conversion factor (Column 7); the combined impact of proposed APC recalibration, the proposed wage indices and rural adjustment, the proposed conversion factor update, and the proposed CY 2014 frontier State wage index adjustment (Column 8); and the estimated impact taking into account all proposed payments for CY 2014 relative to all payments for CY 2013 (Column 9), including the impact of proposed changes in estimated outlier payments and proposed changes to the pass-through payment estimate.

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are not proposing to make any changes to the policy for CY 2014. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2014 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule would redistribute money during implementation also would depend on changes in volume, practice patterns, and the mix of services billed between CY 2013 and CY 2014 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed OPPS rates for CY 2014 would have a positive effect for providers paid under the OPPS, resulting in a 1.8 percent estimated increase in Medicare payments. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs suggest that these proposed changes would result in a 1.8 percent estimated increase in Medicare payments to all other hospitals. Those estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 39 shows the total number of facilities (3,953), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2012

hospital outpatient and CMHC claims data to model CY 2013 and CY 2014 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2013 or CY 2014 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this proposed rule. 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 (3,791) 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 100 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration

Column 2 shows the estimated effect of the reconfiguration and recalibration of the APCs from CY 2013 to CY 2014 excluding the CY 2014 OPPS packaging proposals. Outpatient laboratory services paid at CLFS rates are included on both sides of the comparison. We estimate that most hospitals would not experience significant changes in payment rates from the APC recalibration alone, though we estimate that Puerto Rico would experience a 4.3 percent increase in payments and that low volume rural hospitals (measured by lines of services) would experience a 1.8 percent payment decrease.

Column 3: APC Recalibration With CY 2014 Packaging Proposals Other than Outpatient Laboratory Services

Column 3 shows the estimated impact of the APC recalibration from CY 2013–2014 with our proposed packaging policies other than packaging for outpatient laboratory services currently paid at CLFS rates. Outpatient laboratory services paid at CLFS rates are included on both sides of the comparison. Hospitals that specialize in a limited set of services would experience the most significant changes in payment. Urban hospitals with less than 21,000 service lines would experience estimated payment decreases ranging from 0.4 to 1.9 percent. Hospitals where DSH data are not available (specialized hospitals not paid under the IPPS) would experience estimated payment decreases of 1.4 percent.

Column 4: APC Recalibration With CY 2014 Outpatient Laboratory Services Packaging Proposal

Column 4 shows the estimated effect of APC recalibration plus our proposed policy for packaging outpatient laboratory services paid at CLFS rates. Outpatient laboratory services paid at CLFS rates are included in the comparison. It does not include estimated effects for other packaging proposals. We estimate that smaller rural hospitals, particularly in the mid-Atlantic region, would experience the most significant payment changes related to the laboratory packaging policy proposal, as they likely furnish more ancillary laboratory services relative to other services than larger hospitals. We estimate that rural hospitals overall would experience a 1.3 percent decrease in payment, and rural hospitals with 100 or fewer beds would experience payment decreases between 1.9 and 3.5 percent. Urban hospitals overall would experience limited estimated payment increases ranging from 0.1 to 0.3 percent.

Column 5: APC Recalibration With All Proposed Changes

Column 5 shows the combined effects of the proposed reconfiguration, recalibration, and other policies (such as proposing to set payment for separately payable drugs and biologicals at the statutory default of ASP+6), plus our proposals to package outpatient laboratory services and other services for CY 2014. We modeled the effect of the APC recalibration changes by varying only the relative payment weights (the final CY 2013 relative weights versus the proposed CY 2014 relative weights calculated using the service-mix and volume in the CY 2012 claims used for this proposed rule) and calculating the percent difference in the relative weight. Column 5 also reflects any proposed changes in multiple procedure discount patterns or conditional packaging that occur as a result of the proposed changes in the relative magnitude of payment weights.

Overall, we estimate that proposed changes in APC reassignment and recalibration across all services paid under the OPPS, together with our proposed packaging policies, would slightly increase payments to urban hospitals by 0.1 percent. We estimate that rural hospitals would experience a decrease in payments of 0.7 percent.

Classifying hospitals according to teaching status, we estimate that the APC recalibration together with our proposed packaging policies would lead to a payment increase of 1.2 percent for major teaching hospitals. We estimate that nonteaching hospitals would experience a decrease of 0.6 percent. Classifying hospitals by type of ownership suggests that voluntary, proprietary, and governmental hospitals would experience changes ranging from a decrease of 0.6 percent to an increase of 0.2 percent as a result of the APC recalibration and proposed packaging policies.

Column 6: New Wage Indices and the Effect of the Rural and Cancer Hospital Adjustments

Column 6 demonstrates the combined budget neutral impact of proposed APC recalibration; the proposed wage index update; the proposed rural adjustment; and the proposed cancer hospital payment adjustment. We modeled the independent effect of the proposed budget neutrality adjustments and the proposed OPD fee schedule increase factor by using the relative payment weights and wage indices for each year, and using a CY 2013 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indices.

Column 6 reflects the independent effects of the proposed 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 proposed frontier State wage index adjustment, which is not budget neutral and is included in Column 8. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are not proposing to make any changes to the policy for CY 2014. The differential impact between the CY 2013 cancer hospital payment adjustment and the proposed CY 2014 cancer hospital payment adjustment would have a minimal 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 proposed CY 2014 scaled weights and a

CY 2013 conversion factor that included a budget neutrality adjustment for the effect of changing the wage indices between CY 2013 and CY 2014. This column estimates the impact of applying the proposed FY 2014 IPPS wage indices for the proposed CY 2014 OPPS without the influence of the frontier State wage index adjustment, which is not budget neutral. The proposed frontier State wage index adjustment is reflected in the combined impact shown in Column 8. We are proposing to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2014, as described in section II.E. of this proposed rule. We estimate that the combination of updated wage data and nationwide application of rural floor budget neutrality would redistribute payment among regions. We also are proposing to update the list of counties qualifying for the section 505 out-migration adjustments.

Overall, we estimate that as a result of the proposed updated wage indices and the proposed rural adjustment, urban hospitals would experience no change from CY 2013 to CY 2014. However, rural hospitals would experience an estimated decrease of 0.3 percent. Urban hospitals in the New England, Mid Atlantic, and Pacific regions and in Puerto Rico would experience the most significant payment changes of 0.6 to 0.7 percent increases. Regionally, the proposed changes would range from a decrease of 0.6 in the rural East South Central region to an increase of 0.7 percent in the rural Pacific region.

Column 7: All Proposed Budget Neutrality Changes Combined With the Proposed OPD Fee Schedule Increase

Column 7 demonstrates the cumulative impact of the proposed budget neutral adjustments from Columns 5 and 6 and the proposed OPD fee schedule increase factor of 1.8 percent. We estimate that, for some hospitals, the addition of the proposed OPD fee schedule increase factor of 1.8 percent would mitigate the impacts created by the proposed budget neutrality adjustments made in Columns 5 and 6.

Most classes of hospitals would receive an increase that is in line with the proposed 1.8 percent overall increase after the update is applied to the budget neutrality adjustments. The largest rural hospitals by number of beds (200+ beds) would experience payment increases of 1.4 percent. Proprietary, voluntary, and government hospitals would experience payment increases ranging from 1.0 to 2.0 percent. Hospitals in Puerto Rico would receive an estimated payment increase of 6.3 percent. The rural Mid-Atlantic region would experience a 0.4 percent payment decrease, while the urban Mid-Atlantic region would experience a 2.8 percent payment increase. Classified by teaching status, nonteaching hospitals would experience a small payment increase of 1.1 percent, with minor and major teaching hospitals experiencing increases ranging from 1.8 to 3.2 percent, respectively.

Column 8: All Proposed Adjustments With the Proposed Frontier State Wage Index Adjustment

This column shows the impact of all proposed budget neutrality adjustments, application of the proposed 1.8 percent OPD fee schedule increase factor, and the nonbudget neutral impact of applying the proposed frontier State wage adjustment (that is, the proposed frontier State wage index change in addition to all proposed changes reflected in Column 7). This column differs from Column 7 solely based on application of the proposed nonbudget neutral frontier State wage index adjustment.

In general, we estimate that all facilities and all hospitals would experience a combined increase of 1.9 percent due to the proposed nonbudget neutral frontier State wage index adjustment. The index would only affect urban hospitals in the West North Central and Mountain regions. Urban hospital in those regions would experience estimated increases of 4.5 percent (West North Central) and 2.3 percent (Mountain) that are attributable to the proposed frontier State wage index and the OPD fee schedule increase factor, and rural hospitals would experience estimated increases of 3.5 percent (West North Central) and 3.4 percent (Mountain) that are attributable to the proposed frontier State wage index and the OPD fee schedule increase factor.

Column 9: All Proposed Changes for CY 2014

Column 9 depicts the full impact of the proposed CY 2014 policies on each hospital group by including the effect of all of the proposed changes for CY 2014 and comparing them to all estimated payments in CY 2013. Column 9 shows the combined budget neutral effects of Column 5 and 6; the proposed OPD fee schedule increase; the impact of the proposed frontier State wage index adjustment; the impact of estimated OPPS outlier payments as discussed in section II.G. of this proposed rule; the proposed change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIII. of this proposed rule); and the impact of decreasing the estimate of the percentage of total OPPS payments dedicated to transitional pass-through payments. Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2013 update (and assumed, for modeling purposes, to be the same number for CY 2014), we included 34 hospitals in our model because they had both CY 2012 claims data and recent cost report data. We estimate that the cumulative effect of all proposed changes for CY 2014 would increase payments to all providers by 1.8 percent for CY 2014. We modeled the independent effect of all proposed changes in Column 9 using the final relative payment weights for CY 2013 and the proposed relative payment weights for CY 2014. We used the final conversion factor for CY 2013 of $71.313 and the proposed CY 2014 conversion factor of $72.728 discussed in section II.B. of this proposed rule.

Column 9 contains simulated outlier payments for each year. We used the one year proposed charge inflation factor used in the proposed FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27767) of 4.85 percent (1.0485) to increase individual costs on the CY 2012 claims, and we used the most recent overall CCR in the April 2013 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2013. Using the CY 2012 claims and a 4.85 percent charge inflation factor, we currently estimate that outlier payments for CY 2013, using a multiple threshold of 1.75 and a proposed fixed-dollar threshold of $2,025 should be approximately 1.2 percent of total payments. The estimated current outlier payments of 1.2 percent are incorporated in the comparison in Column 9. We used the same set of claims and a proposed charge inflation factor of 9.93 percent (1.0993) and the CCRs in the April 2013 OPSF, with an adjustment of 0.9732, to reflect relative changes in cost and charge inflation between CY 2012 and CY 2014, to model the proposed CY 2014 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a proposed fixed-dollar threshold of $2,775.

We estimate that the anticipated change in payment between CY 2013 and CY 2014 for the hospitals failing to meet the Hospital OQR Program requirements would be negligible. Overall, we estimate that facilities would experience an increase of 1.8 percent under this proposed rule in CY

2014 relative to total spending in CY 2013. This projected increase (shown in Column 9) of Table 39 reflects the proposed 1.8 percent OPD fee schedule increase factor, with 0.13 percent for the proposed change in the pass-through estimate between CY 2013 and CY 2014, less 0.2 percent for the difference in estimated outlier payments between CY 2013 (1.2 percent) and CY 2014 (1.0 percent), less 0.1 percent due to the frontier adjustment in CY 2013, plus 0.1 percent due to the proposed frontier State wage index adjustment in CY 2014. When we exclude cancer and children's hospitals (which are held harmless to their pre-BBA amount) and CMHCs, the estimated update increases to 1.8 percent after rounding. We estimate that the combined effect of all proposed changes for CY 2014 would increase payments to urban hospitals by 2.0 percent.

Overall, we estimate that rural hospitals would experience a 0.9 percent increase as a result of the combined effects of all proposed changes for CY 2014. We estimate that rural hospitals that bill less than 5,000 lines of OPPS services would experience an increase of 2.2 percent and rural hospitals that bill 5,000 or more lines of OPPS services would experience increases ranging from 0.9 to 2.4 percent.

Among teaching hospitals, we estimate that the impacts resulting from the combined effects of all proposed changes would include an increase of 3.1 percent for major teaching hospitals and 1.2 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 1.8 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 2.1 percent, proprietary hospitals would experience an increase of 1.3 percent, and governmental hospitals would experience an increase of 1.0 percent.

TABLE 39—ESTIMATED IMPACT OF THE PROPOSED CY 2014 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM

	Number of hospitals	APC Recalibration (CY 2013–2014) (%)	Impact of packaging proposals other than outpatient laboratory services (%)	Impact of outpatient laboratory services packaging proposal (%)	APC Recalibration (all changes) (%)	New wage index and provider adjustments (%)	Combined cols 5, 6 with market basket update (%)	Column 7 with frontier wage index adjustment (%)	All proposed changes (%)
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
ALL FACILITIES *	3,953	0.0	0.0	0.0	0.0	0.0	1.8	1.9	1.8
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,791	0.1	−0.1	0.0	0.0	0.0	1.8	1.9	1.8
URBAN HOSPITALS	2,859	0.1	−0.2	0.2	0.1	0.0	1.9	2.0	2.0
LARGE URBAN (GT 1 MILL.).	1,566	0.1	0.0	0.3	0.4	0.2	2.3	2.3	2.3
OTHER URBAN (LE 1 MILL.).	1,293	0.0	−0.3	0.1	−0.2	−0.1	1.5	1.7	1.5
RURAL HOSPITALS	932	0.0	0.6	−1.3	−0.7	−0.3	0.9	1.1	0.9
SOLE COMMUNITY	389	0.1	0.8	−1.0	−0.1	−0.3	1.4	1.8	1.5
OTHER RURAL	543	0.0	0.4	−1.6	−1.2	−0.2	0.3	0.4	0.4
BEDS (URBAN)									
0–99 BEDS	959	0.0	−0.3	0.3	0.0	0.1	1.8	2.0	1.9
100–199 BEDS	831	0.1	−0.3	−0.2	−0.4	−0.1	1.3	1.4	1.4
200–299 BEDS	454	0.1	−0.6	0.1	−0.4	0.0	1.4	1.6	1.4
300–499 BEDS	407	0.3	−0.4	0.5	0.3	0.0	2.1	2.2	2.1
500 + BEDS	208	−0.1	0.6	0.2	0.7	0.2	2.6	2.6	2.6
BEDS (RURAL)									
0–49 BEDS	352	0.7	1.3	−3.5	−1.5	−0.6	−0.3	−0.1	−0.3
50–100 BEDS	342	0.2	1.5	−1.9	−0.3	−0.1	1.4	1.6	1.4
101–149 BEDS	133	−0.3	0.1	−0.6	−0.8	−0.5	0.5	0.7	0.6
150–199 BEDS	61	−0.5	0.2	−0.8	−1.1	−0.1	0.5	1.0	0.5
200 + BEDS	44	0.1	−0.6	0.3	−0.2	−0.2	1.4	1.4	1.6
VOLUME (URBAN)									
LT 5,000 Lines	485	−1.4	−0.4	2.4	0.5	0.2	2.5	2.7	2.6
5,000—10,999 Lines	109	−1.4	−0.5	3.2	1.3	−0.1	3.0	3.5	2.4
11,000–20,999 Lines	132	0.1	−1.9	2.4	0.6	0.0	2.5	2.6	2.5
21,000–42,999 Lines	262	0.4	−1.8	1.2	−0.2	−0.2	1.4	1.4	1.4
42,999—89,999 Lines	517	0.2	−0.9	0.7	−0.1	0.1	1.8	1.8	1.8
GT 89,999 Lines	1,354	0.1	0.0	0.1	0.1	0.0	2.0	2.1	2.0
VOLUME (RURAL)									
LT 5,000 Lines	31	−1.8	0.3	2.2	0.6	−0.4	2.1	6.7	2.2
5,000–10,999 Lines	34	5.8	−0.1	−4.4	1.0	−0.5	2.3	2.3	2.4
11,000–20,999 Lines	67	3.0	0.2	−2.6	0.5	−0.7	1.6	1.7	1.5
21,000–42,999 Lines	182	1.0	1.2	−2.4	−0.3	−0.3	1.2	1.8	1.1
GT 42,999 Lines	618	−0.1	0.6	−1.2	−0.7	−0.2	0.8	1.0	0.9
REGION (URBAN)									
NEW ENGLAND	150	0.0	2.2	−1.4	0.7	0.6	3.1	3.1	3.0
MIDDLE ATLANTIC	342	0.0	0.8	−0.5	0.3	0.7	2.8	2.8	2.8
SOUTH ATLANTIC	432	−0.3	−0.6	0.5	−0.4	−0.3	1.1	1.1	1.2
EAST NORTH CENT.	459	0.2	0.1	−0.3	0.0	−0.2	1.5	1.5	1.6
EAST SOUTH CENT.	172	−0.2	−0.8	0.9	−0.1	−0.3	1.4	1.4	1.5
WEST NORTH CENT.	193	0.0	0.5	1.5	2.0	−0.3	3.5	4.5	3.5
WEST SOUTH CENT.	487	0.7	−2.1	0.5	−0.9	−0.2	0.8	0.8	0.9
MOUNTAIN	194	−0.6	0.4	0.8	0.5	−0.3	2.0	2.3	2.0
PACIFIC	385	0.5	−0.9	0.6	0.2	0.6	2.6	2.6	2.5
PUERTO RICO	45	4.3	−0.5	0.0	3.9	0.6	6.3	6.3	6.6
REGION (RURAL)									
NEW ENGLAND	25	−0.3	3.5	−1.6	1.6	0.6	3.9	3.9	3.8

TABLE 39—ESTIMATED IMPACT OF THE PROPOSED CY 2014 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM—Continued

	Number of hospitals	APC Recalibration (CY 2013–2014) (%)	Impact of packaging proposals other than outpatient laboratory services (%)	Impact of outpatient laboratory services packaging proposal (%)	APC Recalibration (all changes) (%)	New wage index and provider adjustments (%)	Combined cols 5, 6 with market basket update (%)	Column 7 with frontier wage index adjustment (%)	All proposed changes (%)
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
MIDDLE ATLANTIC	68	0.3	1.7	−3.9	−2.0	−0.3	−0.4	−0.4	−0.4
SOUTH ATLANTIC	158	−0.3	−0.2	−0.9	−1.4	−0.4	0.0	0.0	0.1
EAST NORTH CENT.	124	0.0	0.8	−1.8	−1.1	−0.4	0.4	0.4	0.4
EAST SOUTH CENT.	170	0.0	−0.3	−0.8	−1.1	−0.6	0.1	0.1	0.2
WEST NORTH CENT.	99	−0.1	0.8	0.0	0.7	−0.1	2.3	3.5	2.5
WEST SOUTH CENT.	196	0.6	−0.4	−1.3	−1.1	−0.4	0.3	0.3	0.4
MOUNTAIN	63	−0.1	1.6	−1.6	−0.2	0.2	1.9	3.4	1.4
PACIFIC	29	0.2	1.9	−0.2	1.8	0.7	4.3	4.3	4.3
TEACHING STATUS									
NON-TEACHING	2,792	0.0	−0.4	−0.2	−0.6	−0.1	1.1	1.2	1.2
MINOR	686	0.0	−0.5	0.5	0.0	0.0	1.8	2.0	1.8
MAJOR	313	0.2	1.2	−0.2	1.2	0.2	3.2	3.2	3.1
DSH PATIENT PERCENT									
0	12	1.8	−5.4	3.5	−0.3	−0.1	1.5	1.5	1.4
GT 0–0.10	349	−0.4	0.2	0.6	0.4	0.1	2.3	2.4	2.3
0.10–0.16	334	−0.2	0.3	0.1	0.2	0.1	2.1	2.2	2.2
0.16–0.23	680	−0.1	0.3	−0.2	0.1	0.0	1.8	2.0	1.9
0.23–0.35	1,045	−0.2	0.1	0.1	0.0	0.0	1.7	1.9	1.8
GE 0.35	831	0.7	−0.8	−0.2	−0.3	0.0	1.5	1.5	1.5
DSH NOT AVAILABLE **	540	2.3	−1.4	1.6	2.4	0.0	4.2	4.2	3.9
URBAN TEACHING/DSH									
TEACHING & DSH	909	0.1	0.2	0.2	0.5	0.1	2.4	2.5	2.4
NO TEACHING/DSH	1,429	0.0	−0.8	0.2	−0.5	0.0	1.2	1.3	1.3
NO TEACHING/NO DSH	12	1.8	−5.4	3.5	−0.3	−0.1	1.5	1.5	1.4
DSH NOT AVAILABLE**	509	2.0	−1.2	1.5	2.3	0.1	4.2	4.2	3.9
TYPE OF OWNERSHIP									
VOLUNTARY	2,004	0.0	0.2	0.0	0.2	0.1	2.0	2.2	2.1
PROPRIETARY	1,250	0.3	−1.5	0.9	−0.4	−0.1	1.3	1.4	1.3
GOVERNMENT	537	0.3	0.1	−1.0	−0.6	−0.2	1.0	1.0	1.0
CMHCs	100	−5.4	−3.6	3.5	−5.7	−0.2	−4.1	−4.1	−3.8

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 and the proposed recalibration of APC weights based on CY 2012 hospital claims data. Changes in this column do not include reconfigurations and data changes from the 2014 packaging proposal.

Column (3) shows the additional impact of changes resulting from the reclassification of HCPCS codes among APC groups and other data changes as a result of including the 2014 OPPS packaging proposal (but excluding the proposed packaging of outpatient laboratory services currently paid at CLFS rates).

Column (4) shows the additional impact of changes resulting from the reclassification of HCPCS codes among APC groups and other data changes as a result of including the 2014 OPPS proposal to package outpatient laboratory services currently paid at CLFS rates.

Column (5) includes all CY 2014 OPPS proposals and compares those to the CY 2013 OPPS (which includes outpatient laboratory services previously paid at CLFS rates).

Column (6) shows the budget neutral impact of updating the wage index by applying the FY 2014 hospital inpatient wage index. The proposed rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. Similarly, the differential in estimated cancer hospital payments for the proposed adjustment is minimal and thus results in a budget neutrality factor of 1.0001.

Column (7) shows the impact of all budget neutrality adjustments and the proposed addition of the 1.8 percent OPD fee schedule update factor (2.5 percent reduced by 0.4 percentage points for the proposed productivity adjustment and further reduced by 0.3 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).

Column (8) shows the non-budget neutral impact of applying the frontier State wage adjustment.

Column (9) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, adding estimated outlier payments, and applying payment wage indexes.

*These 3,953 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs. Payments for laboratory services at CLFS rates, which we are proposing to package in the CY 2014 OPPS, are included in the columns where appropriate.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

(3) Estimated Effects of Proposed OPPS Changes on CMHCs

The last line of Table 39 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization (PHP) services under the OPPS. In CY 2013, CMHCs are paid under two APCs for these services: APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) and APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs). In contrast, hospitals are paid for partial hospitalization services under APC 0175 (Level I Partial Hospitalization (3 services) for hospital-based PHPs) and APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). We use our standard rate-setting methodology to derive the payment rates for each APC based on the cost data derived from claims and cost reports for the provider type to which the APC is specific. For CY 2014, we are proposing to continue the provider-specific APC structure that we adopted in CY 2011. We modeled the impact of this proposed APC policy assuming that CMHCs will continue to provide the same number of days of PHP care, with each day having either 3 services or 4 or more services, as seen in the CY 2012 claims data used for this proposed. 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 proposed relative payment weights for APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs) decline in CY 2014, we estimate that there would be an overall 3.8 percent decrease in payments to CMHCs (shown in Column 9).

Column 6 shows that the estimated impact of adopting the proposed FY 2014 wage index values would result in

a small decrease of 0.2 percent to CMHCs. We note that all providers paid under the OPPS, including CMHCs, would receive a 1.8 percent OPD fee schedule increase factor. Column 7 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2014 and the proposed FY 2014 wage index updates, would result in an estimated decrease of 4.1 percent. Column 8 shows that adding the proposed frontier State wage adjustment would result in no change to the cumulative 4.1 percent decrease. Column 9 shows that adding the proposed changes in outlier and pass-though payments would result in a 3.8 percent decrease in payment for CMHCs. This reflects all proposed changes to CMHCs for CY 2014.

(4) Estimated Effect of Proposed OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary share of payment would increase for services for which the OPPS payments will rise and would decrease for services for which the OPPS payments will fall. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this proposed rule. In all cases, the statute limits beneficiary liability for copayment for a procedure to the hospital inpatient deductible for the applicable year. The CY 2013 hospital inpatient deductible is $1,184. The amount of the CY 2014 hospital inpatient deductible is not available at the time of publication of this proposed rule.

In order to better understand the impact of proposed changes in copayment on beneficiaries, we modeled the percent change in total copayment liability using CY 2012 claims. We estimate, using the claims of the 3,791 hospitals and CMHCs on which our modeling is based, that total beneficiary liability for copayments would remain approximately the same as an overall percentage of total payments, being 20.4 percent in CY 2013 and 20.2 percent in CY 2014.

(5) Estimated Effects of Proposed OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs as discussed in section XII. of this proposed rule. No types of providers or suppliers other than hospitals, CMHCs and ASCs would be affected by the proposed changes in this proposed rule.

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

The effect on the Medicare program is expected to be $600 million in additional program payments for OPPS services furnished in CY 2014. The effect on the Medicaid program is expected to be limited to increased copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We refer readers to our discussion of the impact on beneficiaries in section XXIII.A. of this proposed rule.

(7) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are proposing to make and the reasons for our selected alternatives are discussed throughout this proposed rule. In this section, we discuss some of the major issues and the alternatives considered.

• Alternatives Considered for the Establishment of Comprehensive APCs

We are proposing in section II.A.2.e. of this proposed rule to create 29 comprehensive APCs for CY 2014 to prospectively pay for device-dependent services associated with 121 HCPCS codes. We are proposing to define a comprehensive APC as a classification for the provision of a primary service and all adjunct services provided to support the delivery of the primary service. The comprehensive APC would treat all individually reported codes as representing components of the comprehensive service, resulting in a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service as well as all adjunct services provided to support that delivery of the primary service. For these APCs, we are proposing to treat all previously individually reported codes as representing components of the comprehensive service, making a single payment for the comprehensive service based on all charges on the claim, excluding only charges for services that cannot be covered by Medicare Part B or that are not payable under the OPPS. This would create a single all-inclusive payment for the claim that is subject to a single beneficiary copayment, up to the cap set at the level of the inpatient hospital deductible.

We are proposing this as a step that we believe will further improve the accuracy of our payments for these services where there is a substantial cost for a device that is large compared to the other costs that contribute to the cost of the procedure, and where the cost of the procedure is large compared to the adjunctive and supportive services delivered along with that procedure. We also believe our proposal will enhance beneficiary understanding and transparency for the beneficiary, for physicians, and for hospitals by creating a common reference point with a similar meaning for all three groups by using the comprehensive service concept that already identifies these same services when they are performed in an inpatient environment.

In proposing to package into the comprehensive APCs all other services and supplies, we are including the diagnostic procedures, tests and treatments that assist in the delivery of the primary procedure, visits and evaluations performed in association with the procedure, uncoded services and supplies used during the service, outpatient department services delivered by therapists as part of the comprehensive service, durable medical equipment as well as the supplies to support that equipment, and any other components reported by HCPCS codes that are provided during the comprehensive service, except for mammography services and ambulance services, which are never payable as OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act.

We also considered several ranges of alternatives. First, we considered but are not proposing a limitation of the services that we considered to be ancillary and supportive to the primary service. We did not propose to limit the comprehensive APCs to only HCPCS codes that are currently paid using OPPS payment calculations because we could not identify a unique clinical characteristic that set these services apart from other services reported on the claim. We determined that services currently excluded by the Secretary from OPPS calculations, including, for example, such services as laboratory tests and certain orthotics and supplies, were adjunctive and supportive to the primary procedure in the same manner as the other services currently paid using our OPPS methodology were adjunctive and supportive. We also noted that these services that are currently priced using other payment systems represented a very small fraction of the costs reported on these device dependent claims, typically on the order of 1 percent of the total reported costs. This was consistent with our determination that these services were adjunctive and supportive and should be included in our definition of a comprehensive APC.

Second, we considered but did not propose creating comprehensive APCs

for a different cohort of device dependent procedures. We did not propose a more limited list because we determined that the 29 APCs we proposed all consistently identified truly device dependent services where the other services that are currently assigned to the other device dependent APCs that are not being proposed as comprehensive APCs were clearly provided in support of a primary procedure. We considered limiting our proposal to the five or ten procedures with the most expensive devices but believed that such a division would be arbitrary and would ignore the natural division that occurred when the costs and clinical characteristics of these services were compared to similar procedures delivered as comprehensive services to inpatients. Alternatively, we considered limiting the proposal to those comprehensive services where the procedure itself, without consideration of the device, was responsible for the most significant portion of the cost and was also responsible for the need to deliver the majority of the additional services provided during the encounter. However, although we considered that this last consideration did in fact identify services that were consistent with our proposal to define comprehensive services, we did not propose this alternative as we believe our proposal to create comprehensive APCs for only the 29 most costly device dependent APCs is most consistent with our past practices of iteratively improving the OPPS in small and well-defined increments.

Third, we considered proposing payment adjustments for instances when multiple procedures assigned to comprehensive APCs were reported on the same claim. However, we did not propose this. In examining our claims data, we determined that multiple procedures assigned to comprehensive APCs were reported in only 25 percent of the claims, and that these multiple procedures were almost always reporting components of the same service, such as cardiac stenting, and were assigned to the same APC. In our claims data it was very uncommon to find multiple unrelated device dependent procedures being delivered at the same time. Therefore, we decided to propose that the primary procedure would determine the comprehensive APC and that, in the rare event that procedures were reported that mapped to two different comprehensive APCs on the same claim, the most expensive procedure according to our traditional OPPS accounting methodology would determine the comprehensive APC assignment. We believe that this is consistent with the methodology for assigning payments for those inpatient claims that represent the same or similar comprehensive procedures and that it most accurately reflects the comprehensive service on those occasions in which two or more device dependent HCPCS codes are used to report the single comprehensive service.

Finally, we considered retaining the device-to-procedure edits and procedure-to-device edits that were characteristic of our device-dependent APCs but we instead proposed the elimination of the edits along with the elimination of the status of device dependent APC. We noted that the device-dependent APC was created in response to concerns that hospitals were not coding for the device and that our relative cost estimations were consequently incorrect. In the intervening years we have noticed a significant improvement and stabilization in the reporting of costs, to the extent that we believe that hospitals are now fully accustomed to appropriate cost reporting under the OPPS such that special billing constraints are unnecessary. We further believe that, under our proposal to create comprehensive APCs, there would now be an additional mechanism to ensure accurate cost estimation for the most expensive devices for which an inadvertent omission of costs would be most significant. In the calculations of relative cost for the comprehensive APCs, costs for the device would be correctly assigned to the procedure as long as the hospital reports covered costs anywhere on the claim. Specific device reporting would still be expected and required, but variations in accounting practices would be less likely to influence the final cost accounting.

In summary, we determined to propose to make an all-inclusive comprehensive payment for the procedures in the 29 most costly device dependent APCs because we believe that this identified a consistent set of procedures that were typically provided as a primary procedure supported by a set of adjunctive services, and that this set of services represented an incremental improvement in our prospective payments similar to other prior incremental improvements through which we have established our approach to updating and improving the OPPS.

• Alternatives Considered for Payment of Hospital Outpatient Visits

As described in section VII. of this proposed rule, we are proposing to replace the current five levels of visit codes for each clinic, Type A ED, and Type B ED visits with three new alphanumeric Level II HCPCS codes representing a single level of payment for the three types of visits, respectively. We are proposing to assign the new alphanumeric Level II HCPCS to newly created APCs with CY 2014 OPPS payment rates based on the total mean costs of Level 1 through Level 5 visit codes obtained from CY 2012 OPPS claims data for each visit type.

In developing this policy, we considered another alternative, which was to replace the current five levels of visit codes for each clinic, Type A ED, and Type B ED visit with 6 new alphanumeric Level II HCPCS codes representing two levels (lower level and higher level) of payment for each of the three types of visits. The lower-level alphanumeric codes for clinic, Type A ED, and Type B ED visits would replace the current Level 1 and Level 2 visit codes, respectively, and would be assigned to newly created or reconfigured APCs with CY 2014 OPPS payment rates based on the total mean costs of Level 1 and 2 visit codes obtained from CY 2012 OPPS claims data for each visit type. The higher-level alphanumeric codes for clinic, Type A ED, and Type B ED visits would replace the current Level 3 through Level 5 visit codes, respectively, and would be assigned to newly created or reconfigured APCs with CY 2014 OPPS payment rates based on the total mean costs of Level 3 through Level 5 visit codes obtained from CY 2012 OPPS claims data for each visit type.

While we believe that this alternative could offer advantages over the current CY 2013 OPPS visit payment policy, we did not choose this alternative because as we describe in section VII. of this proposed rule we believed that a single level of payment for each type of clinic and ED visit was the best policy option as this proposal would be easily implemented by hospitals; reduces administrative burden relative to the existing five-level visit payment structure; and maximizes hospitals' incentives to provide care in the most efficient manner as there would be no incentive to provide unnecessary care to achieve a higher level visit threshold. A two-level visit payment structure would not be as easily implemented by hospitals as a single-level visit payment structure, and the need for hospitals to develop and implement guidelines to differentiate the levels of service would continue to exist. Also, while the two-level visit payment structure may provide incentives for hospitals to be efficient, the incentives may not be so great as under a single-level visit

payment structure. Therefore, we are proposing to create three new alphanumeric Level II HCPCS codes to describe all levels of each type of clinic and ED visit rather than continue to recognize five levels each of clinic and ED visits.

b. Estimated Effects of ASC Payment System Proposed Policies

ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XII. of this proposed rule, we are proposing to set the CY 2014 ASC relative payment weights by scaling the proposed CY 2014 OPPS relative payment weights by the proposed ASC scaler of 0.8961. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 40 and 41 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which currently is the CPI–U) after application of any quality reporting reduction be reduced by a productivity adjustment. The Affordable Care Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, the CY 2014 payment determinations will be based on the application of a 2.0 percentage point reduction to the annual update factor, which currently is the CPI–U. We calculated the proposed CY 2014 ASC conversion factor by adjusting the CY 2013 ASC conversion factor by 1.0004 to account for changes in the pre-floor and pre-reclassified hospital wage indices between CY 2013 and CY 2014 and by applying the proposed CY 2014 MFP-adjusted CPI–U update factor of 0.9 percent (projected CPI–U update of 1.4 percent minus a projected productivity adjustment of 0.5. percent). The proposed CY 2014 ASC conversion factor is $43.321.

(1) Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2014 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2012 and CY 2014 with precision. We believe that the net effect on Medicare expenditures resulting from the proposed CY 2014 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 Proposed Policies on ASCs

Some ASCs are multispecialty facilities that perform the gamut of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the proposed update to the CY 2014 payments would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the proposed CY 2014 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2012 claims data. Table 40 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2013 payments to estimated CY 2014 payments, and Table 41 shows a comparison of estimated CY 2013 payments to estimated CY 2014 payments for procedures that we estimate would receive the most Medicare payment in CY 2014.

Table 40 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 40.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—Estimated CY 2013 ASC Payments were calculated using CY 2012 ASC utilization (the most recent full year of ASC utilization) and CY 2013 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2013 ASC payments.
- Column 3—Estimated CY 2014 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that would be attributable to proposed updates to ASC payment rates for CY 2014 compared to CY 2013.

As seen in Table 40, we estimate that the proposed update to ASC rates for CY 2014 would result in a 3 percent decrease in aggregate payment amounts for eye and ocular adnexa procedures, an 8 percent increase in aggregate payment amounts for digestive system procedures, and a 1 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 proposed CY 2014 update are variable. For instance, we estimate that, in the aggregate, payment for musculoskeletal system procedures would decrease by 1 percent, whereas payment for genitourinary system procedures, integumentary system procedures and respiratory system procedures would increase by 5 to 7 percent under the proposed CY 2014 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 2014 for digestive system procedures is likely due to an increase in the ASC payment weight for some of the high volume procedures, such as CPT code 43239 (Upper GI endoscopy biopsy) where estimated payment would increase by 13 percent for CY 2014.

Also displayed in Table 40 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 decrease by 12 percent for CY 2014.

TABLE 40—ESTIMATED IMPACT OF THE PROPOSED CY 2014 UPDATE OF THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2014 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical specialty group (1)	Estimated CY 2013 ASC Payments (in millions) (2)	Estimated CY 2014 percent change (3)
Total	$3,625	1
Eye and ocular adnexa	1,496	−3
Digestive system	743	8
Nervous system	540	1
Musculoskeletal system	441	−1
Genitourinary system	159	5
Integumentary system	130	7
Respiratory system	46	7
Cardiovascular system	32	−2
Ancillary items and services	20	−12
Auditory system	12	4
Hematologic & lymphatic systems	5	17

Table 41 below shows the estimated impact of the proposed updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2014. The table displays 30 of the procedures receiving the greatest estimated CY 2014 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2014 program payment.

- Column 1–CPT/HCPCS code.
- Column 2–Short Descriptor of the HCPCS code.
- Column 3–Estimated CY 2013 ASC Payments were calculated using CY 2012 ASC utilization (the most recent full year of ASC utilization) and the proposed CY 2014 ASC payment rates. The estimated CY 2014 payments are expressed in millions of dollars.
- Column 4–Estimated CY 2014 Percent Change reflects the percent differences between the estimated ASC payment for CY 2013 and the estimated payment for CY 2014 based on the proposed update.

TABLE 41—ESTIMATED IMPACT OF THE PROPOSED CY 2014 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/ HCPCS code* (1)	Short descriptor (2)	Estimated CY 2013 ASC payments (in millions) (3)	Estimated CY 2014 percent change (4)
66984	Cataract surg w/iol, 1 stage	$1,107	−3
43239	Upper GI endoscopy, biopsy	163	13
45380	Colonoscopy and biopsy	154	7
45385	Lesion removal colonoscopy	98	7
66982	Cataract surgery, complex	89	−3
45378	Diagnostic colonoscopy	80	7
64483	Inj foramen epidural l/s	79	14
62311	Inject spine l/s (cd)	71	14
66821	After cataract laser surgery	59	−1
G0105	Colorectal scrn; hi risk ind	42	0
15823	Revision of upper eyelid	40	2
64493	Inj paravert f jnt l/s 1 lev	40	14
63650	Implant neuroelectrodes	39	4
G0121	Colon ca scrn not hi rsk ind	36	0
29827	Arthroscop rotator cuff repr	34	5
64590	Insrt/redo pn/gastr stimul	33	6
64721	Carpal tunnel surgery	31	−1
63685	Insrt/redo spine n generator	31	6
64636**	Destroy l/s facet jnt addl	31	−100
29881	Knee arthroscopy/surgery	30	−3
64635	Destroy lumb/sac facet jnt	26	73
29880	Knee arthroscopy/surgery	25	−3
43235	Uppr gi endoscopy diagnosis	23	13
45384	Lesion remove colonoscopy	22	7
52000	Cystoscopy	21	5
62310	Inject spine c/t	20	14

TABLE 41—ESTIMATED IMPACT OF THE PROPOSED CY 2014 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES—Continued

CPT/ HCPCS code* (1)	Short descriptor (2)	Estimated CY 2013 ASC payments (in millions) (3)	Estimated CY 2014 percent change (4)
29823	Shoulder arthroscopy/surgery	19	5
67042	Vit for macular hole	19	0
28285	Repair of hammertoe	18	5
50590	Fragmenting of kidney stone	18	2

*Note that HCPCS codes we are proposing to delete for CY 2014 are not displayed in this table.
** The 100 percent decrease in estimated payment reflects our CY 2014 proposal to package the payment for CPT code 64636.

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

We estimate that the proposed CY 2014 update to the ASC payment system would be generally positive for beneficiaries with respect to the new procedures that we are proposing to add to the ASC list of covered surgical procedures and for those that we are proposing to designate as office-based for CY 2014. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions would be if the ASC coinsurance amount exceeds the inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the inpatient deductible.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the revised ASC payment system, depending on the particular service and the relative payment amounts for that service in the physician's office compared to the ASC. However, for those additional procedures that we are proposing to designate as office-based in CY 2014, 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 minor changes that we are proposing to make to the ASC payment system and the reasons that we have chosen specific options are discussed throughout this proposed rule. There are no proposed major changes to ASC policies for CY 2014.

c. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget Web site at: *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf),* we have prepared two accounting statements to illustrate the impacts of this proposed rule. The first accounting statement, Table 42 (below) illustrates the classification of expenditures for the CY 2014 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2014 OPD fee schedule increase, based on the 2013 Trustee's Report. The second accounting statement, Table 43 (below) illustrates the classification of expenditures associated with the proposed 0.9 percent CY 2014 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs in the 2013 Trustee's Report. The third accounting statement, Table 44 (below), illustrates the classification of expenditures associated with the proposed revision to the definition of hospital-based EP in payment year 2013 for EPs reassigning benefits to Method II CAHs. Lastly, the tables classify most estimated impacts as transfers.

TABLE 42—ACCOUNTING STATEMENT: CY 2014 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2013 TO CY 2014 ASSOCIATED WITH THE PROPOSED CY 2014 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$600 million.
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS.
Total	$600 million.

TABLE 43—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2013 TO CY 2014 AS A RESULT OF THE PROPOSED CY 2014 UPDATE TO THE REVISED ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$27 million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.

TABLE 43—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2013 TO CY 2014 AS A RESULT OF THE PROPOSED CY 2014 UPDATE TO THE REVISED ASC PAYMENT SYSTEM—Continued

Category	Transfers
Total	$27 million.

TABLE 44—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2013 TO CY 2014 AS A RESULT OF THE PROPOSED REVISIONS TO THE DEFINITION OF PROVIDER–BASED EP UNDER THE EHR INCENTIVE PROGRAM

Category	Transfers
Annualized Monetized Transfers	$17,985,000 to $35,970,000.
From Whom to Whom	Federal Government to Medicare Providers.
Total	$17,985,000 to $35,970,000.

d. Effects of Proposed Requirements for the Hospital OQR Program

In section XIII. of this proposed rule, we are proposing to adopt 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 2013. 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 and that 106 hospitals may not receive the full OPD fee schedule increase factor in CY 2015. We are unable at this time to estimate the number of hospitals that may not receive the full OPD fee schedule increase factor in CY 2016.

In section XVI.E.3.a. of the CY 2010 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 IQR Program (75 FR 50225 through 50229). As a result, we believed that the effect of our validation process for CY 2012 would be minimal in terms of the number of hospitals that would not meet all program requirements.

In the CY 2012 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 the CY 2013 OPPS/ASC final rule with comment period, for the CY 2014 payment determination and subsequent years, we made some modifications to administrative requirements in extending a deadline to submit a Notice of Participation as well as to extraordinary circumstance waiver or extension and reconsideration processes to broaden the scope of personnel who can sign these requests. However, we did not make any modifications to our validation requirements. We expect these policies to have minimal impact on the program.

In this proposed rule, for CY 2016 payment determination and subsequent years, we are proposing to add five quality measures with data collection to begin in CY 2014. For four of these measures, data would be submitted via an online tool located on a CMS Web site and one would be submitted via CDC's NHSN. We are proposing to remove two measures from the Hospital OQR Program.

As stated above, we are unable to estimate the number of hospitals that may not receive the full OPD fee schedule increase factor in CY 2016. We also are unable to estimate the number of hospitals that would fail the validation documentation submission requirement for the CY 2016 payment update.

The validation requirements for CY 2014 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 6,000 total cases per quarter for up to 500 hospitals for CY 2014 represents a minimal burden to Hospital OQR Program participating hospitals.

e. Effects of Proposals for the ASCQR Program

In section XV. of this proposed rule, for the ASCQR Program, we are proposing four additional quality

measures for the CY 2016 payment determination and subsequent years. Data collection for these proposed measures would begin in CY 2014. We are proposing to collect aggregate data (numerators, denominators, and exclusions) on all ASC patients for these four proposed chart-abstracted measures via an online Web-based tool located on a CMS Web page. We are also proposing for the CY 2016 payment determination and subsequent years requirements for facility participation, data collection, and submission for claims-based, CMS Web-based, and NHSN measures.

We are unable at this time to estimate the number of ASCs that may not receive the full ASC annual payment update in CYs 2014, 2015, and 2016. However, we do expect our new policies to significantly affect the number of ASCs that do not receive a full annual payment update in CY 2016, though we are not able to estimate the level of this impact at this time.

f. Effects of Proposed Changes to the CfCs for OPOs Relating to the Outcome Measures Requirement for Recertification

In section XVI. of this proposed rule, we discussed our proposal to modify the current outcome measures requirement that OPOs meet all three outcome measures set forth in § 486.318 to a requirement that they meet two out of the three outcome measures. Our proposal would result in those OPOs that fail only one outcome measures avoiding automatic decertification based upon the current outcome measures requirement.

While we are confident that our proposal would have a significantly positive effect on the OPOs that avoided automatic decertification, it is very difficult to quantify the impact of this change. As discussed under section XXI.C. of this proposed rule relating to the ICR requirements, we anticipate that most OPOs that are decertified would engage in the appeals process as set forth in § 486.314. However, we have no reliable way of estimating how many OPOs would likely obtain reversals of their decertifications during reconsideration or how many continue on to a hearing before a CMS hearing officer. Therefore, although we believe there would be a considerably large positive effect as a result of our proposed change to the outcome measures requirement, we are unable to provide a specific estimate of that cost savings.

g. Effects of Proposed Revisions of the QIO Regulations

In section XVII. of this proposed rule, we are proposing to update the regulations at 42 CFR parts 475 and 476 based on the recently enacted Trade Adjustment Assistance Extension Act of 2011 (TAAEA) (Pub. L. 112–40, Section 261) whereby Congress authorized numerous changes to the original legislation and included additional flexibility for the Secretary in the administration of the QIO program. Currently, 42 CFR Part 475 includes definitions and standards governing eligibility and the award of contracts to QIOs. In this proposed rule, we set forth proposals for the partial deletion and revision of the regulations under 42 CFR Parts 475 and 476, which relate to the QIO program, including the following: (1) Replace nomenclature that has been amended by the TAAEA; (2) revise the existing definition for the term ''physician'' in Parts 475 and 476; (3) add new definitions as necessary to support the new substantive provisions in Subpart C; and (4) revise, add, and replace some of the substantive provisions in Subpart C to fully exercise the Secretary's authority for the program and update the contracting requirements to align with contemporary quality improvement.

We estimate the effects of the proposed QIO Program changes to be consistent with the Congressional Budget Office's 2011 Cost Estimate of the Trade Bill (H.R. 2832) which included a reduction in spending of $330 million over the 2012–2021 period. According to the CBO Estimate, the Act and subsequently the proposed regulatory changes ''would modify the provisions under which CMS contracts with independent entities called ['']Quality Improvement Organizations [(QIOs)''] in Medicare. QIOs, generally staffed by health care professionals, review medical care, help beneficiaries with complaints about the quality of care, and implement care improvements. H.R. 2832 would make several changes to the composition and operation of QIOs, and would harmonize QIO contracts with requirements of the Federal Acquisition Regulation. Among those changes are a modification to expand the geographic scope of QIO contracts and a lengthening of the contract period. CBO estimates that those provisions would reduce spending by $330 million over the 2012–2021 period.''

h. Effects of Proposals Regarding Medicare-Fee-for-Service EHR Incentive Program

(1) Incentive Payments for Eligible Professionals (EPs) Reassigning Benefits to Method II CAHs

As discussed in section XVIII.A. of this proposed rule, we are proposing to revise the regulations to provide, during payment year 2013 alone, a special method for determining the hospital-based status of EPs who reassign their benefits to Method II CAHs. It is difficult to determine with precision the cost impact of this proposal. We lack specific information on key factors affecting this impact, including the number of EPs who reassign their benefits to Method II CAHs, the proportion of those EPs who would be determined to be nonhospital-based for 2013 under our proposal, the proportion of those EPs who will qualify for Medicaid incentive payments and choose to accept those payments because they are higher, and the proportion of the remaining EPs who will successfully demonstrate meaningful use in order to qualify for Medicare incentive payments. It is therefore necessary to rely on estimates for each of these factors. As much as possible we will employ the methods of cost estimation that we used to determine the estimated costs of the Medicare incentives for EPs in our Stage 1 final rule (75 FR 44549) and Stage 2 final rule (77 FR 54139) for the Medicare Electronic Health Record Incentive Program, as well as the estimates that we have previously employed for specific factors.

Of the approximately 1,200 CAHs, about three-quarters, or 900, elect under section 1834(g)(2) of the Act to receive a cost-based payment for the facility costs of providing outpatient services, plus 115 percent of the fee schedule amount for professional services included within outpatient CAH services. As we have indicated, we lack specific information on the numbers of EPs who reassign their benefits to these Method II CAHs. While CAHs are relatively small inpatient facilities, we understand that many of them have fairly substantial outpatient clinics. At the same time, we have also been informed that they rely largely on nonphysician practitioners (nurses and nurse practitioners) to staff these outpatient clinics. Therefore, we will assume that the typical outpatient department in a Method II CAH has a relatively small number of physicians, between 5 and 10, on staff and billing for professional services that are reassigned to the CAH. We will also use

this estimate of 5 to 10 physicians per Method II CAH to establish an upper and lower range to our impact estimate. The number of EPs reassigning benefits for outpatient services to Method II CAHs is therefore between 4,500 and 9,000.

In our Stage 2 final rule (77 FR 54139) for the Medicare Electronic Health Record Incentive Program, we determined that about 14 percent of EPs with Medicare claims were hospital-based, and thus ineligible to receive Medicare EHR incentive payments. For purposes of this impact statement, we will assume that 10 percent of EPs reassigning benefits to Method II CAHs are hospital-based. Because CAHs have relatively small inpatient hospital facilities, we believe that the physicians practicing in these facilities will bill for somewhat fewer inpatient services than EPs generally. Using this assumption, the estimate of nonhospital-based EPs reassigning benefits to Method II CAHs is therefore between 4,050 and 8,100. Of these nonhospital-based EPs reassigning benefits to Method II CAHs, some proportion will qualify for Medicaid incentive payments and will choose to receive payments under that program because the payments are higher. For these purposes we will employ the same estimate (20 percent) that we have employed for developing cost estimate in our Stage 2 final rule (77 FR 54140). Thus, we estimate that between 3,240 and 6,480 non-hospital-based EPs reassigning benefits to Method II CAHs do not choose to receive Medicaid incentive payments.

As we have discussed in prior rules (77 FR 54140) our estimates for the number of EPs that will successfully demonstrate meaningful use of CEHRT are uncertain. The percentage of Medicare EPs who will satisfy the criteria for demonstrating meaningful use of CEHRT and will qualify for incentive payments is a key, but highly uncertain factor in developing cost estimates for the EHR incentive program in general and for the present purposes in particular. Consistent with the estimates that we have employed for EPs generally in developing cost estimates in the Stage II final rule, we will assume that 37 percent of the nonhospital-based EPs reassigning benefits to Method II CAHs will satisfy the criteria for demonstrating meaningful use of CEHRT and will qualify for incentive payments in payment years 2013. Thus, we estimate that between 1,199 and 2,398 EPs reassigning benefits to Method II CAHs will actually qualify to receive Medicare EHR incentive payments in 2013. As we have previously discussed, section 1848(o)(1)(B) of the Act provides that the incentive payment for an EP for a given payment year shall not exceed the following amounts:

- For the EP's first payment year, for such professional, $15,000 (or $18,000, if the EP's first payment year is 2011 or 2012);
- For the EP's second payment year, $12,000;
- For the EP's third payment year, $8,000;
- For the EP's fourth payment year, $4,000;
- For the EP's fifth payment year, $2,000; and
- For any succeeding year, $0.

We lack any information on how many of the EPs reassigning benefits to Method II CAHs will qualify for incentive payments for the first time in 2013. However, if we assume for purposes of setting upper limits on our estimates, that all of the 1,199 to 2,398 EPs we have estimated will receive qualify for the first time and receive the maximum incentive payment, our proposal will cost between $17,985,000 and $35,970,000 in payments that we have not previously been making in 2013. Despite the uncertainties of the assumptions that we have employed in developing these estimates, we can state with reasonable confidence that our proposal will result in considerably less than $50,000,000 in payments over and above the payments we would make in the absence of this proposal for 2013.

(2) Cost Reporting Periods for Interim and Final EHR Incentive Payments to Eligible Hospitals

As we discussed in section XVIII.B. of this proposed rule, we are proposing to revise the regulations to provide that, in cases where there is no 12-month cost reporting period that begins on or after the beginning of a payment year, we will use the most recent 12-month cost reporting period available at the time of final settlement in order to determine final EHR incentive payments for the hospital. We are making this proposal solely to address situations in which hospitals have been receiving interim EHR payments but the contractors have not been able to make a determination of final payments because there is no hospital cost report that meets the existing requirements of the regulations. Therefore, we do not expect this to have any financial impact. This proposal would merely allow us to make final settlements in cases that the current regulations do not cover.

B. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals, ASCs and CMHCs are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of $35.5 million or less in any single year. Most ASCs and most CMHCs are considered small businesses with total revenues of $10 million or less in any single year. We estimate that this proposed rule may have a significant impact on approximately 2,004 hospitals with voluntary ownership. For details, see the Small Business Administration's ''Table of Small Business Size Standards'' at *http://www.sba.gov/content/table-small-business-size-standards.*

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule may have a significant impact on approximately 694 small rural hospitals.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $141 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

D. Conclusion

The changes we are proposing to make in this proposed rule would affect all classes of hospitals paid under the OPPS and will affect both CMHCs and

ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2013. Table 39 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 1.8 percent increase in payments for all services paid under the OPPS in CY 2014, after considering all of the proposed changes to APC reconfiguration and recalibration, as well as the proposed OPD fee schedule increase factor, proposed wage index changes, including the proposed frontier State wage index adjustment, estimated payment for outliers, and proposed changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience more significant gains and others would experience modest losses in OPPS payments in CY 2014. We estimate that rural hospitals with 100 or fewer beds would experience a decrease of 3.9 percent. CMHCs would see an overall decrease in payment of 7.7 percent as a result of a decrease in their estimated costs. However, urban hospitals in Puerto Rico would experience an estimated 7.9 percent increase in payment, and non-teaching hospitals for whom DSH data are not available (non-IPPS hospitals) would experience a 5.3 percent increase in payment.

The proposed updates to the ASC payment system for CY 2014 would affect each of the approximately 5,300 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would 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 proposed to be changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 40 demonstrates the estimated distributional impact among ASC surgical specialties of the proposed MFP-adjusted CPI–U update factor of 0.9 percent for CY 2014.

XXIIV. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 39 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 0.5 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 475

Grant programs-health, Health care, Health professions, Quality Improvement Organization (QIO)

42 CFR Part 476

Health care, Health professional, Health record, Quality Improvement Organization (QIO), Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs-health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 495

Computer technology, Electronic health records, Electronic transactions, Health, Health care. Health information technology, Health insurance, Health records, Hospitals, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR Chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405, Subpart R continues to read as follows:

Authority: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

■ 2. Section 405.1804 is amended by revising paragraph (a) to read as follows:

§ 405.1804 Matters not subject to administrative and judicial review under prospective payment system.

* * * * *

(a) The determination of the requirement, or the proportional amount, of the budget neutrality adjustment in the prospective payment rates required under section 1886(e)(1) of the Social Security Act.

* * * * *

■ 3. Section 405.1885 is amended by revising paragraph (a)(1) and adding paragraph (b)(2)(iv) to read as follows:

§ 405.1885 Reopening an intermediary determination or reviewing entity decision.

(a) * * *

(1) A Secretary determination, an intermediary determination, or a decision by a reviewing entity (as described in § 405.1801(a)) may be reopened, with respect to specific findings on matters at issue in a determination or decision, by CMS (with respect to Secretary determinations), by the intermediary (with respect to intermediary determinations), or by the reviewing entity that made the decision (as described in paragraph (c) of this section).

(i) A specific finding on a matter at issue may be legal or factual in nature or a mixed matter of both law and fact.

(ii) A specific finding on a matter at issue may include a factual matter that arose in or was determined for the same cost reporting period as the period at issue in an appeal filed, or a reopening requested by a provider or initiated by an intermediary, under this subpart.

(iii) A specific finding on a matter at issue may include a predicate fact, which is a factual matter that arose in or was determined for a cost reporting period that predates the period at issue (in an appeal filed, or a reopening requested by a provider or initiated by an intermediary, under this subpart), and such factual matter was used in determining an aspect of the provider's reimbursement for a later cost reporting period.

(iv) A specific finding on a matter at issue may not be reopened, and if reopened, revised, except as provided for by this section, § 405.1887, and § 405.1889.

* * * * *

(b) * * *

(2) * * *

(iv) The 3-year period described in paragraphs (b)(2)(i) through (b)(2)(iii) of this section applies to, and is calculated separately for, each specific finding on a matter at issue (as described in paragraphs (a)(1)(i) through (iv) of this section.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 4. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 5. Section 410.27 is amended by—

■ a. Revising paragraph (a) introductory text.

■ b. Removing the word ''and'' at the end of paragraph (a)(1)(iii).

■ c. Removing the period at the end of paragraph (a)(1)(iv)(E) and adding in its place ''; and''.

■ d. Adding paragraph (a)(1)(v).

The revisions and addition read as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service, which are defined as all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals which are not usually self-administered, if—

(1) * * *

(v) In accordance with applicable State law.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 6. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and sec. 124 of Public Law 106–113 (113 Stat. 1501A–332).

■ 7. Section 412.167 is amended by redesignating paragraph (c) as paragraph (d) and adding a new paragraph (c) to read as follows:

§ 412.167 Appeals under the Hospital Value-Based Purchasing (VBP) Program.

* * * * *

(c) If a hospital is dissatisfied with CMS' decision on an appeal request submitted under paragraph (b) of this section, the hospital may request an independent CMS review of that decision.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 8. 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).

■ 9. Section 416.171 is amended by revising paragraph (b)(2) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) * * *

(2) Device-intensive procedures assigned to any APC under the OPPS with device costs greater than 50 percent of the APC costs based on the standard OPPS APC ratesetting methodology.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 10. The authority citation for part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395(t), and 1395hh).

■ 11. Section 419.2 is amended by revising paragraphs (b) introductory text, (b)(3), (b)(4), (b)(7), (b)(11), and (b)(12) and adding paragraphs (b)(13) through (17) to read as follows:

§ 419.2 Basis of payment.

* * * * *

(b) *Determination of hospital outpatient prospective payment rates: Packaged costs.* The prospective payment system establishes a national payment rate, standardized for geographic wage differences, that includes operating and capital-related costs that are integral, ancillary, supportive, dependent, or adjunctive to performing a procedure or furnishing a service on an outpatient basis. In general, these packaged costs may include, but are not limited to, the following items and services, the payment for which are packaged or conditionally packaged into the payment for the related procedures or services.

* * * * *

(3) Observation services;

(4) Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies (including, for example, but not limited to, implantable or certain nonimplantable medical devices, certain drugs and biologicals, implantable biologicals, and skin substitutes or similar wound treatment products) and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations;

* * * * *

(7) Ancillary services;

* * * * *

(11) Implantable and insertable medical items and devices, including, but not limited to, prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of these devices;

(12) Costs incurred to procure donor tissue other than corneal tissue;

(13) Image guidance, processing, supervision, and interpretation services;

(14) Intraoperative items and services;

(15) Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents;

(16) Certain clinical diagnostic laboratory tests; and

(17) Procedures described by add-on codes.

* * * * *

■ 12. Section 419.22 is amended by revising the introductory text and paragraphs (j) and (l) to read as follows:

§ 419.22 Hospital outpatient services excluded from payment under the hospital outpatient prospective payment system.

The following services are not paid for under the hospital outpatient prospective payment system (except when packaged as a part of a bundled payment):

* * * * *

(j) Except as provided in § 419.2(b)(4) and (11), prosthetic devices,-prosthetic supplies, and orthotic devices.

* * * * *

(l) Except as provided in § 419.2(b)(16), clinical diagnostic laboratory tests.

* * * * *

■ 13. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(*5*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*5*) For calendar year 2014, a multifactor productivity adjustment (as determined by CMS) and 0.3 percentage point.

* * * * *

■ 14. Section 419.46 is added to Subpart D to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

(a) *Participation in the Hospital OQR Program.* To participate in the Hospital OQR Program, a hospital as defined in section 1886(d)(1)(B) of the Act and is paid under the OPPS must—

(1) Register on the QualityNet Web site before beginning to report data;

(2) Identify and register a QualityNet security administrator as part of the registration process under paragraph (a)(1) of this section; and

(3) Complete and submit an online participation form available at the QualityNet.org Web site if this form has not been previously completed, if a hospital has previously withdrawn, or if the hospital acquires a new CMS Certification Number (CCN). For Hospital OQR Program purposes, hospitals that share the same CCN are required to complete a single online participation form. Once a hospital has submitted a participation form, it is considered to be an active Hospital OQR Program participant until such time as it submits a withdrawal form to CMS or no longer has an effective Medicare provider agreement. Deadlines for the participation form are described in paragraphs (a)(3)(i) and (ii) of this section, and are based on the date identified as a hospital's Medicare acceptance date.

(i) If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must complete and submit to CMS a completed Hospital OQR Notice of Participation Form by July 31 of the calendar year prior to the affected annual payment update.

(ii) If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must submit a completed participation form no later than 180 days from the date identified as its Medicare acceptance date.

(b) *Withdrawal from the Hospital OQR Program.* A participating hospital may withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet Web site. The hospital may withdraw any time from January 1 to November 1 of the year prior to the affected annual payment updates. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under § 419.43(h), and is required to submit a new participation form in order to participate in any future year of the Hospital OQR Program.

(c) *Submission of Hospital OQR Program data*—(1) *General rule.* Except as provided in paragraph (d) of this section, hospitals that participate in the Hospital OQR Program must submit to CMS data on measures selected under section 1833(17)(C) of the Act in a form and manner, and at a time, specified by CMS.

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on the QualityNet Web site.

(3) *Initial submission deadlines for a hospital that did not participate in the previous year's Hospital OQR Program.* (i) If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update, in addition to submitting a completed Hospital OQR Notice of Participation Form under paragraph (a)(3)(i) of this section.

(ii) If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must submit data for encounters beginning with the first full quarter following submission of the completed Hospital OQR Notice of Participation Form under paragraph (a)(3)(ii) of this section.

(iii) Hospitals with a Medicare acceptance date before or after January 1 of the year prior to an affected annual payment update must follow data submission deadlines as specified in paragraph (c)(2) of this section.

(d) *Exception.* CMS may grant an extension or waiver of one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an extension or waiver as follows:

(1) Upon request by the hospital. Specific requirements for submission of a request for an extension or waiver are available on the QualityNet Web site.

(2) At the discretion of CMS. CMS may grant waivers or extensions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

(e) *Validation of Hospital OQR Program data.* CMS may validate one or more measures selected under section 1833(17)(C) of the Act by reviewing documentation of patient encounters submitted by selected participating hospitals.

(1) Upon written request by CMS or its contractor, a hospital must submit to CMS supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 45 days of the date identified on the written request, in the form and manner specified in the written request.

(2) A hospital meets the validation requirement with respect to a fiscal year if it achieves at least a 75-percent reliability score, as determined by CMS.

(f) *Reconsiderations and appeals of Hospital OQR Program decisions.* (1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital

OQR Program for a particular fiscal year. Except as provided in paragraph (d) of this section, a hospital must submit a reconsideration request to CMS via the QualityNet Web site, no later than the first business day of the month of February of the affected payment year.

(2) A reconsideration request must contain the following information:

(i) The hospital's CMS Certification Number (CCN);

(ii) The name of the hospital;

(iii) The CMS-identified reason for not meeting the requirements of the affected payment year's Hospital OQR Program as provided in any CMS notification to the hospital;

(iv) The hospital's basis for requesting reconsideration. The hospital must identify its specific reason(s) for believing it should not be subject to the reduced annual payment update;

(v) The hospital-designated personnel contact information, including name, email address, telephone number, and mailing address (must include physical mailing address, not just a post office box);

(vi) The hospital-designated personnel's signature;

(vii) A copy of all materials that the hospital submitted to comply with the requirements of the affected Hospital OQR Program payment determination year; and

(viii) If the hospital is requesting reconsideration on the basis that CMS determined it did not meet the affected payment determination year's validation requirement set forth in paragraph (e)(1) of this section, the hospital must provide a written justification for each appealed data element classified during the validation process as a mismatch. Only data elements that affect a hospital's validation score are eligible to be reconsidered.

(3) A hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under part 405, subpart R, of this chapter.

■ 15. Section 419.66 is amended by revising paragraph (b)(3) to read as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(b) * * *

(3) The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, whether or not is remains with the patient when the patient is released from the hospital.

* * * * *

PART 475—QUALITY IMPROVEMENT ORGANIZATIONS

■ 16. The authority citation for part 475 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 17. Section 475.1 is amended by—

■ a. Redesignating paragraphs (a) through (d) in the definition of ''Five percent or more owner'' as paragraphs (1) through (4).

■ b. Adding, in alphabetical order, the definitions of ''Case reviews'', ''Practitioner'', ''QIO area'', and Quality improvement initiative''.

■ c. Revising the definition of ''Physician''.

The additions and revision read as follows:

§ 475.1 Definitions.

* * * * *

Case reviews means the different types of reviews that QIOs are authorized to perform. Such reviews include, but are not limited to—

(1) Beneficiary complaint reviews;

(2) General quality of care reviews;

(3) Emergency Medical Treatment and Labor Act (EMTALA) reviews;

(4) Medical necessity reviews, including appeals and DRG validation reviews; and

(5) Admission and discharge reviews.

* * * * *

Physician means:

(1) A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatry, a doctor of optometry, or a chiropractor as described in section 1861(r) of the Act;

(2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice as a doctor as described in paragraph (1) of this definition; and

(3) An individual licensed to practice as a doctor as described in paragraph (1) of this definition in any Territory or Commonwealth of the United States of America.

Practitioner has the same meaning as provided in § 476.1 of this chapter.

QIO area means the defined geographic area, such as the State(s), region(s), or community(ies), in which the CMS contract directs the QIO to perform.

Quality improvement initiative has the same meaning as provided in § 476.1 of this chapter.

■ 18. Subpart C is revised to read as follows:

Subpart C—Quality Improvement Organizations

Sec.

475.100 Scope and applicability.
475.101 Eligibility requirements for QIO contracts.
475.102 Requirements for performing case reviews.
475.103 Requirements for performing quality improvement initiatives.
475.104 [Reserved]
475.105 Prohibition against contracting with health care facilities, affiliates, and payor organizations.
475.106 [Reserved]
475.107 QIO contract awards.

Subpart C—Quality Improvement Organizations

§ 475.100 Scope and applicability.

This subpart implements sections 1152 and 1153(b) and (c) of the Social Security Act as amended by section 261 of the Trade Adjustment Assistance Extension Act of 2011. This subpart defines the types of organizations that are eligible to become Quality Improvement Organizations (QIOs) and describes certain steps CMS will take in selecting QIOs.

§ 475.101 Eligibility requirements for QIO contracts.

In order to be eligible for a QIO contract, an organization must meet the following requirements:

(a) Have a governing body that includes at least one individual who is a representative of health care providers and at least one individual who is a representative of consumers.

(b) Demonstrate the ability to perform the functions of a QIO, including—

(1) The ability to meet the eligibility requirements and perform activities as set forth in the QIO Request for Proposal; and

(2) The ability to—

(i) Perform case reviews as described in § 475.102; and/or

(ii) Perform quality improvement initiatives as set forth in § 475.103.

(c) Demonstrate the ability to actively engage beneficiaries, families, and consumers, as applicable, in case reviews as set forth in § 475.102, or quality improvement initiatives as set forth in § 475.103.

§ 475.102 Requirements for performing case reviews.

(a) In determining whether or not an organization has demonstrated the ability to perform case review, CMS will take into consideration factors such as:

(1) The organization's proposed processes, capabilities, quantitative, and/or qualitative performance objectives and methodology to perform case reviews;

(2) The organization's proposed involvement of and access to physicians and practitioners in the QIO area with

the appropriate expertise and specialization in the areas of health care related to case reviews;

(3) The organization's ability to take into consideration urban versus rural, and regional characteristics in the health care setting where the care under review was provided;

(4) The organization's ability to take into consideration evidence-based national clinical guidelines and professionally recognized standards of care; and

(5) The organization's access to qualified information technology (IT) expertise.

(b) In making determinations under this section, CMS may consider characteristics such as the organization's geographic location and size. CMS may also consider prior experience in health care quality improvement that CMS considers relevant to performing case reviews; such prior experience may include prior similar case review experience.

(c) A State government that administers a Medicaid program will be considered incapable of performing case review in an effective manner, unless the State demonstrates to the satisfaction of CMS that the State agency performing the case review will act with complete objectivity and independence from the Medicaid program.

§ 475.103 Requirements for performing quality improvement initiatives.

(a) In determining whether or not an organization has demonstrated the ability to perform quality improvement initiatives, CMS will take into consideration factors such as:

(1) The organization's proposed processes, capabilities, quantitative, and/or qualitative performance objectives, and methodology to perform quality improvement initiatives;

(2) The organization's proposed involvement of and access to physicians and practitioners in the QIO area that have the requisite expertise and specialization in the areas of health care concerning the quality improvement initiative; and

(3) The organization's access to professionals with requisite knowledge of quality improvement methodologies and practices, as well as qualified information technology and technical expertise.

(b) In making determinations under this section, CMS may consider characteristics such as the organization's geographic location and size. CMS may also consider prior experience in health care quality improvement that CMS considers relevant to performing quality improvement initiatives; such prior experience may include prior similar quality improvement initiative experience.

(c) A State government that administers a Medicaid program will be considered incapable of performing quality improvement initiative functions in an effective manner, unless the State demonstrates to the satisfaction of CMS that the State agency performing the quality improvement initiatives will act with complete objectivity and independence from the Medicaid program.

§ 475.104 [Reserved]

§ 475.105 Prohibition against contracting with health care facilities, affiliates, and payor organizations.

(a) *Basic rule.* Except as permitted under paragraph (a)(3) of this section, the following are not eligible for QIO contracts:

(1) A health care facility in the QIO area.

(2) A health care facility affiliate; that is, an organization in which more than 20 percent of the members of the governing body are also either a governing body member, officer, partner, five percent or more owner, or managing employee in a health care facility in the QIO area.

(3) A payor organization, unless the Secretary determines that there is no other entity available for an area with which the Secretary can enter into a contract under this part or the Secretary determines that a payor organization is a more qualified entity to perform one or more of the functions of a QIO described in § 475.101(b) and this more qualified entity meets all other requirements and standards of this part.

(b) [Reserved]

(c) *Subcontracting.* A QIO must not subcontract with a health care facility to perform any case review activities except for the review of the quality of care.

§ 475.106 [Reserved]

§ 475.107 QIO contract awards.

Subject to the provisions of § 475.105, CMS will take the following actions in awarding QIO contracts:

(a) Identify, from among all proposals submitted in response to a Request for Proposal, all proposals submitted by organizations that meet the requirements of § 475.101;

(b) Identify, from among all proposals identified in paragraph (a) of this section, all proposals that set forth minimally acceptable plans in accordance with the requirements of § 475.102 or § 475.103, as applicable; and

(c) Award the contract to the selected organization for a specific QIO area for a period of 5 years.

PART 476—QUALITY IMPROVEMENT ORGANIZATION REVIEW

■ 19. 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).

■ 20. The heading of part 476 is revised to read as set forth above.

■ 21. In § 461.1, paragraphs (a) through (d) in the definition of ''Five percent or more owner'' are redesignated as paragraphs (1) though (4) and the definition of ''Physician'' is revised to read as follows:

§ 476.1 Definitions.

* * * * *

Physician means:

(1) A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatry, a doctor of optometry, or a chiropractor, as described in section 1861(r) of the Act;

(2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice as a doctor as described in paragraph (1) of this definition; and

(3) An individual licensed to practice as a doctor as described in paragraph (1) of this definition in any Territory or Commonwealth of the United States of America.

■ 22. The heading of Subpart C is revised to read as follows:

Subpart C—Review Responsibilities of Quality Improvement Organizations (QIOs)

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 23. The authority citation of part 486 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1302b-8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

■ 24. Section 486.316 is amended by revising paragraphs (a)(1) and (b) to read as follows:

§ 486.316 Re-certification and competition processes.

(a) * * *

(1) Meets two out of the three outcome measures requirements at § 486.318; and * * *

(b) *Decertification and competition.* If an OPO does not meet two out of the

three outcome measures as described in paragraph (a)(1) of this section or the requirements described in paragraph (a)(2) of this section, the OPO is decertified. If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the decertification, the OPO's service area is opened for competition from other OPOs. The decertified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

* * * * *

■ 25. Section 486.318 is amended by revising paragraph (a) introductory text and paragraph (b) introductory text to read as follows:

§ 486.318 Condition: Outcome measures.

(a) With the exception of OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, or possessions, an OPO must meet two out of the three following outcome measures:

* * * * *

(b) For OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, and possessions, an OPO must meet two out of the three following outcome measures:

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 26. 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).

■ 27. Section 495.4 is amended by revising the definition of ''Hospital-based EP'' to read as follows:

§ 495.4 Definitions.

* * * * *

Hospital-based EP. Unless it meets the requirements of § 495.5, a hospital-based EP means an EP who furnishes 90 percent or more of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting in the year preceding the payment year, or in the case of a payment adjustment year, in either of the 2 years before the year preceding such payment adjustment year.

(1) For Medicare, this is calculated based on—

(i) The Federal fiscal year preceding the payment year; and

(ii) For the payment adjustments, based on—

(A) The Federal fiscal year 2 years before the payment adjustment year; or

(B) The Federal fiscal year 3 years before the payment adjustment year.

(2) For Medicaid, it is at the State's discretion if the data are gathered on the Federal fiscal year or calendar year preceding the payment year.

(3) For the CY 2013 payment year only, an EP who furnishes services billed by a CAH receiving payment under Method II (as described in § 413.70(b)(3) of this chapter) is considered to be hospital-based if 90 percent or more of his or her covered professional services are furnished in sites of service identified by the codes used in the HIPPA standard transaction as an inpatient hospital or emergency room setting in each of the Federal fiscal years 2012 and 2013.

* * * * *

■ 28. Section 495.104 is amended by revising paragraph (c)(2) to read as follows:

§ 495.104 Incentive payments to eligible hospitals.

* * * * *

(c) * * *

(2) *Interim and final payments.* CMS uses data on hospital acute care inpatient discharges, Medicare Part A acute care inpatient bed-days, Medicare Part C acute care inpatient bed-days, and total acute care inpatient bed-days from the latest submitted 12-month hospital cost report as the basis for making preliminary incentive payments. Final payments are determined at the time of settling the first 12-month hospital cost report for the hospital fiscal year that begins on or after the first day of the payment year, and settled on the basis of data from that cost reporting period. In cases where there is no 12-month hospital cost report period beginning on or after the first day of the payment year, final payments may be determined and settled on the basis of data from the most recently submitted 12-month hospital cost report.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Program No. 93.778 (Medical Assistance)

Dated: June 18, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 26, 2013.

Kathleen Sebelius,

Secretary.

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