(i) The applicable percent for 2015 is 98.5 percent.

(ii) The applicable percent for 2016 and subsequent years is 98.0 percent.

(6) The reporting period for a year is the calendar year from January 1 through December 31 that occurs 2 years prior to the program year in which the payment adjustment is applied.

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

32. The authority citation for part 486 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C 273).

33. Section 486.106 is amended by revising the introductory text and paragraphs (a) and (b) to read as follows:

§ 486.106 Condition for coverage: Referral for service and preservation of records.

All portable X-ray services performed for Medicare beneficiaries are ordered by a physician or a nonphysician practitioner as provided in § 410.32(a) of this chapter or by a nonphysician practitioner as provided in § 410.32(a)(2) and records are properly preserved.

(a) *Standard—referral by a physician or nonphysician practitioners.* Portable X-ray examinations are performed only on the order of a physician licensed to practice in the State or by a nonphysician practitioner acting within the scope of State law. Such nonphysician practitioners may be treated the same as physicians treating beneficiaries for the purpose of this paragraph. The supplier's records show that:

(1) The portable X-ray test was ordered by a licensed physician or a nonphysician practitioner acting within the State scope of law; and

(2) Such physician or nonphysician practitioner's written, signed order specifies the reason a portable X-ray test is required, the area of the body to be exposed, the number of radiographs to be obtained, and the views needed; it also includes a statement concerning the condition of the patient which indicates why portable X-ray services are necessary.

(b) *Standard—records of examinations performed.* The supplier makes for each patient a record of the date of the portable X-ray examination, the name of the patient, a description of the procedures ordered and performed, the referring physician or nonphysician practitioner, the operator(s) of the portable X-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

34. 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).

35. Section 495.8 is amended by revising paragraph (a)(2)(v) to read as follows:

§ 495.8 Demonstration of meaningful use criteria.

(a) * * *

(2) * * *

(v) *Exception for Medicare EPs for PY 2012 and 2013—Participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot.* To satisfy the clinical quality measure reporting requirements of meaningful use, aside from attestation, an EP participating in the Physician Quality Reporting System may also participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot through one of the following methods:

(A) Submission of data extracted from the EP's certified EHR technology through a Physician Quality Reporting System qualified EHR data submission vendor; or

(B) Submission of data extracted from the EP's certified EHR technology, which must also be through a Physician Quality Reporting System qualified EHR.

* * * * *

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 27, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: June 28, 2012.

Kathleen Sebelius,

Secretary.

[FR Doc. 2012–16814 Filed 7–6–12; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS–1589–P]

RIN 0938–AR10

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

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 2013 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, we are proposing updates and refinements to the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program. We also are proposing revisions to the electronic reporting pilot for the Electronic Health Record (EHR) Incentive Program, and the various regulations governing Quality Improvement Organizations (QIOs), including the secure transmittal of electronic medical information, beneficiary complaint resolution and notification processes, and technical changes.

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 4, 2012.

ADDRESSES: In commenting, please refer to file code CMS–1589–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–1589–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–1589–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.

Submission of comments on paperwork requirements: You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section.

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

FOR FURTHER INFORMATION CONTACT: Marjorie Baldo, (401) 786–4617, for issues related to new CPT and Level II HCPCS codes, exceptions to the 2 times rule, and new technology APCs.

Jennifer Bean, (410) 786–4827, for issues related to the Hospital Outpatient Quality Reporting Program.

Anita Bhatia, (410) 786–7236, for issues related to the ASCQR Program.

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

Carrie Bullock, (401) 786–0378, for issues related to device-dependent APCs, blood products, and no cost/full credit and partial credit devices.

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

Caroline Gallaher, (410) 786–8705, for issues related to Inpatient Rehabilitation Facilities Quality Reporting Program.

Alpha-Banu Huq, (410) 786–8687, for issues related to OPPS drugs, radiopharmaceuticals, biologicals, blood clotting factors, and packaged items/services.

Twi Jackson, (410) 786–1159, for issues related to hospital outpatient visits, extended assessment composite APC, and inpatient-only procedures.

Thomas Kessler, (410) 786–1991, for issues related to QIO regulations.

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

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

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

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

John McInnes, (410) 786–0378, for issues related to new technology intraocular lenses (NTIOLs).

Char Thompson, (410) 786–2300, for issues related to OPPS CCRs and ambulatory surgical center (ASC) payments.

Marjorie Baldo, (410) 786–4617, for all other issues related to hospital outpatient and ambulatory surgery 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.

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Addenda Available Only Through the Internet on the CMS Web Site

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

that are posted on the CMS Web site identified above should contact Charles Braver at (410) 786–0378.

Alphabetical List of Acronyms Appearing in This Federal Register Document

AHA American Hospital Association
AMA American Medical Association
APC Ambulatory Payment Classification
ASC Ambulatory surgical center
ASCQR Ambulatory Surgical Center Quality Reporting
ASP Average sales price
AWP Average wholesale price
BBA Balanced Budget Act of 1997, 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
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
CLFS Clinical Laboratory Fee Schedule
CMHC Community mental health center
CMS Centers for Medicare & Medicaid Services
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
CY Calendar year
DFO Designated Federal Official
DRA Deficit Reduction Act of 2005, Public Law 109–171
DSH Disproportionate share hospital
EACH Essential access community hospital
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
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
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
IRF Inpatient rehabilitation facility
IRF–PAI Inpatient Rehabilitation Facility-Patient Assessment Instrument
LDR Low dose rate
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
PCR Payment-to-cost ratio
PE Practice expense
PHP Partial hospitalization program
PHS Public Health Service [Act], Public Law 96–88
PPI Producer Price Index
PPS Prospective payment system
PPV Pneumococcal pneumonia
PQRS Physician Quality Reporting System
PT Physical therapy
QDC Quality data code
QIO Quality Improvement Organization
RAC Recovery Audit Contractor
RFA Regulatory Flexibility Act
RTI Research Triangle Institute, International
RVU Relative value unit
SCH Sole community hospital
SCOD Specified covered outpatient drugs
SI Status indicator
SIR Standardized infection ratio
SLP Speech-language pathology
TOPs Transitional Outpatient Payments
USPSTF United States Preventive Services Task Force
UTI Urinary tract infection
VBP Value-based purchasing
WAC Wholesale acquisition cost

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I. Executive 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 ASCs beginning January 1, 2013. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the relative payment weights and conversion factor for services payable under the 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 to establishing payment rates for CY 2013, we are proposing updates and new requirements under the Hospital OQR Program, the ASCQR Program, and the IRF Quality Reporting Program. We also are proposing certain revisions to the electronic reporting pilot for the EHR Incentive Program and to the regulations governing the Quality Improvement Organizations (QIOs), including the secure transmittal of electronic medical information, beneficiary complaint resolution and notification processes, and technical corrections.

2. Summary of the Major Provisions

- *OPPS Update:* For CY 2013, we are proposing to increase payment rates under the OPPS by an OPD fee schedule increase factor of 2.1 percent. This increase is based on the projected hospital inpatient market basket percentage increase of 3.0 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.8 percentage points, and minus a 0.1 percentage point adjustment required by the Affordable Care Act. Under this proposal, we estimate that total payments, including beneficiary cost-sharing for CY 2013 to the more than 4,000 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers (CMHCs)), would be approximately $48.1 billion, an increase of approximately $4.6 billion compared to CY 2012 payments, or $700 million excluding our estimated changes in enrollment, utilization, and case-mix.

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

- *Geometric Mean-Based Relative Payment Weights:* CMS has discretion under the statute to set OPPS payments based upon either the estimated mean or median costs of services within an Ambulatory Payment Classification

(APC) group, the unit of payment. To improve our cost estimation, for CY 2013, we are proposing to use the geometric mean costs of services within an APC to determine the relative payment weights of services, rather than the median costs that we have used since the inception of the OPPS. Our analysis shows that the proposed change to means would have a limited payment impact on most providers, with a small number experiencing payment gain or loss based on their service-mix.

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

• *Cancer Hospital Payment Adjustment:* For CY 2013, 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 proposed target PCR of 0.91 would be used to determine the CY 2013 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment amount associated with the cancer hospital payment adjustment would be the additional payment needed to result in a proposed PCR equal to 0.91 for each cancer hospital.

• *Payment Adjustment Policy for Radioisotopes Derived from Non-Highly Enriched Uranium Sources:* The Administration has established an agenda to eliminate domestic reliance on reactors outside of the United States that produce highly enriched uranium (HEU), and to promote the conversion of all medical isotope production to non-HEU sources. We are proposing to exercise our statutory authority to make payment adjustments necessary to ensure equitable payments, to provide an adjustment for CY 2013 to cover the marginal cost of hospital conversion to use of non-HEU sources to obtain radioisotopes used in medical imaging. The adjustment would cover the marginal cost of radioisotopes produced from non-HEU sources over the costs of radioisotopes produced by HEU sources.

• *Payment of Drugs, Biologicals, and Radiopharmaceuticals:* For CY 2013, we are proposing to pay for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status at the statutory default of average sales price (ASP) plus 6 percent.

• *Supervision of Hospital Outpatient Therapeutic Services:* We are clarifying the application of the supervision regulations to physical therapy, speech-language pathology, and occupational therapy services that are furnished in OPPS hospitals and critical access hospitals (CAHs). We are proposing to extend the enforcement instruction for CAHs and certain small rural hospitals for one final year through CY 2013.

• *Outpatient Status:* We are concerned about recent increases in the length of time that Medicare beneficiaries spend as outpatients receiving observation services. In addition, hospitals continue to express concern about Medicare Part B rebilling policies when a hospital inpatient claim is denied because the admission was not medically necessary. We are providing an update on the Part A to Part B Rebilling Demonstration that is in effect for CY 2012 through CY 2014, which was designed to assist us in evaluating these issues. In addition, we are soliciting public comments on potential clarifications or changes to our policies regarding patient status that may be appropriate.

• *Ambulatory Surgical Center Payment Update:* For CY 2013, we are proposing to increase payment rates under the ASC payment system by an MFP-adjusted CPI–U update factor of 1.3 percent. This increase is based on a projected CPI–U update of 2.2 percent minus a multifactor productivity adjustment required by the Affordable Care Act that is projected to be 0.9 percent. Based on this update, we estimate that total ASC payments, including beneficiary cost-sharing, for CY 2013 would be approximately $4.103 billion, an increase of approximately $211 million compared to estimated CY 2012 payments.

• *New Technology Intraocular Lenses:* We are proposing significant revisions to the regulations governing payments for new technology intraocular lens (NTIOLs), specifically § 416.195(a)(2) and § 416.195(a)(4). We are proposing to revise § 416.195(a)(2) to require that the IOL's FDA-approved labeling contain a claim of a specific clinical benefit based on a new lens characteristic in comparison to currently available IOLs. We are proposing to revise § 416.195(a)(4) to require that any specific clinical benefit referred to in § 416.195(a)(2) must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved outcome.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are seeking public comment on our approach for future measure selection and development as well as proposing certain measures for future inclusion in the ASCQR Program measure set. For the CY 2015 payment determination and subsequent years payment determinations, we are proposing requirements regarding the dates for submission, payment, and completeness for claims-based measures. We also are proposing how the payment rates would be reduced for ASCs that fail to meet program requirements beginning in CY 2014 and are clarifying our policy on updating measures.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are proposing no new measures for CY 2013. We also are proposing no new targeting criteria to select hospitals for validation of medical records. We are confirming the suspension of data collection for specific measures. We are proposing that the criteria we would consider when determining whether to retire measures for the Hospital Inpatient Quality Reporting (IQR) Program are applicable likewise to the Hospital OQR Program. We are proposing that measures adopted in future rulemaking are automatically adopted for all subsequent year payment determinations unless we propose to remove, suspend, or replace them. We are proposing changes to administrative forms used in the program. We are proposing to extend the deadline for submitting a notice of participation form and to enter structural measures data.

• *Electronic Health Record (EHR) Incentive Program:* For the EHR Incentive Program, we are proposing to extend the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs through 2013, exactly as finalized for 2012. Other changes to the Medicare and Medicaid EHR Incentive Programs are proposed in a Notice of Proposed Rulemaking published in the **Federal Register** on March 7, 2012.

• *Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP):* We are proposing to: (1) Adopt updates on a previously adopted measure for the IRF QRP that will affect annual prospective payment amounts in FY 2014; (2) adopt a policy that would provide that any measure that has been adopted for use in the IRF QRP will remain in effect until the measure is

actively removed, suspended, or replaced; and (3) adopt policies regarding when notice-and-comment rulemaking will be used to update existing IRF QRP measures.

• *Revisions to the Quality Improvement Organization (QIO) Regulations:* We are proposing to revise the QIO program regulations to: (1) Give QIOs the authority to send and receive secure transmissions of electronic versions of medical information; (2) provide more detailed and improved procedures for QIOs when completing Medicare beneficiary complaint reviews and general quality of care reviews, including procedures related to a new alternative dispute resolution process called ''immediate advocacy''; (3) increase the information beneficiaries receive in response to QIO review activities; (4) convey to Medicare beneficiaries the right to authorize the release of confidential information by QIOs; and (5) make other technical changes that are designed to improve the regulations. The technical changes to the QIO regulations that we are proposing to improve the regulations reflect CMS' commitment to the general principles of the President's Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011).

3. Summary of Costs and Benefits

In sections XXII. and XXIII. of this 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 include the following:

a. Impacts of the OPPS Update

(1) Impacts of All Proposed OPPS Changes

Table 45 in section XXII. of this proposed rule displays the distributional impact to various groups of hospitals and for CMHCs of all the proposed OPPS changes for CY 2013 compared to all estimated OPPS payments in CY 2012. We estimate that the proposals in this proposed rule would result in a 2.1 percent overall increase in OPPS payments to providers. We estimate that the increase in OPPS expenditures, including beneficiary cost-sharing, would be approximately $700 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 $4.6 billion in OPPS expenditures, including beneficiary cost-sharing, for CY 2013 compared to CY 2012 OPPS expenditures. We estimate that total OPPS payments, including beneficiary cost-sharing, would be $48.1 billion for CY 2013.

We estimated the isolated impact of our proposed OPPS policies on CMHCs because CMHCs furnish only partial hospitalization services. Continuing the provider-specific structure that we adopted for CY 2011 and basing payment fully on the data for the type of provider furnishing the service, we estimate a 4.4 percent decrease in CY 2013 payments to CMHCs relative to their CY 2012 payments. This effect is largely attributable to a decline in the relative payment weight for APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs) using the proposed geometric mean-based relative payment weights as opposed to median-based relative payment weights.

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

We estimate that our proposal to base the APC relative payment weights on the geometric mean costs rather than the median costs of services within an APC would not significantly impact most providers. Payments to low volume urban hospitals and to hospitals for which disproportionate share hospital (DSH) data are not available would increase by an estimated 2.1 and 4.0 percent, respectively. The increase to hospitals without available DSH data is largely attributable to payment increases for partial hospitalization and group psychotherapy services furnished in the hospital. These hospitals are largely non-IPPS psychiatric hospitals. In contrast, payments to CMHCs would decrease by an estimated 6.9 percent due primarily to lower payments for APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs).

(3) Impacts of the Updated Wage Indices

We estimate no significant impacts related to updating the wage indices and applying the frontier State wage index. Adjustments to the wage indices other than the frontier State wage adjustment would not significantly affect most hospitals. Overall, urban hospitals would experience no change from CY 2012 to CY 2013, and rural hospitals would experience payment decreases of approximately 0.2 percent. Urban hospitals in the New England and Pacific regions would experience the most significant payment changes with a decrease of 1.2 percent in New England and an increase of 1.6 percent in the Pacific region.

We estimate that all facilities and all hospitals would experience a combined increase of 0.1 percent due to the frontier State wage index, which is not budget neutral. The frontier State wage index would only affect hospitals in the West North Central and Mountain regions, with rural hospitals in those regions experiencing slightly greater percentage payment increases than urban hospitals in those regions.

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

There are no significant impacts of our payment proposals for hospitals that are eligible for the proposed rural adjustment or for the proposed cancer hospital payment adjustment. We are not proposing 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 policies.

(5) Impacts of the OPD Fee Schedule Increase Factor

We estimate that, for most hospitals, the application of the proposed OPD fee schedule increase factor of 2.1 percent to the conversion factor would mitigate the small negative impacts of the budget neutrality adjustments. Certain low volume hospitals and hospitals for which DSH data are not available would experience larger increases ranging from 4.1 percent to 8.3 percent. We estimate that rural and urban hospitals would experience similar increases of approximately 2 percent as a result of the proposed OPD fee schedule increase factor and other budget neutrality adjustments. Classifying hospitals by teaching status or type of ownership suggests that these hospitals would receive similar 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 percentage change in estimated total payments by specialty groups under the proposed CY 2013 payment rates compared to estimated CY 2012 payment rates range between −2 percent for respiratory system procedures, integumentary system procedures, and cardiovascular system procedures to 5 percent for nervous system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our proposals to significantly affect the number of

hospitals that do not receive a full annual payment update.

d. Impacts of the EHR Incentive Program Proposal

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

e. Impacts of the ASCQR Program

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

B. Legislative and Regulatory Authority for the Hospital OPPS

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

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

Under the OPPS, we pay for hospital outpatient services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this 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 hospital services that are furnished to inpatients who are entitled to Part A and have exhausted their Part A benefits, or who are not so entitled.

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

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

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

C. Excluded OPPS Services and Hospitals

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

Under § 419.20(b) of the regulations, we specify the types of hospitals and entities that are excluded from payment under the OPPS. These excluded entities include: Maryland hospitals, but only for services that are paid under a cost containment waiver in accordance

with section 1814(b)(3) of the Act; CAHs; hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

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

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

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel), Formerly Named the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of 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 representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) subject to the OPPS, reviews clinical data and advises CMS about the clinical integrity of the APC groups and their payment weights. The Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). Since its initial chartering, the Secretary has renewed the Panel's charter five times: on November 1, 2002; on November 1, 2004; on November 21, 2006; on November 2, 2008 and November 12, 2010. The current charter specifies, among other requirements, that: the Panel continues to be technical in nature; is governed by the provisions of the FACA; may convene up to three meetings per year; has a Designated Federal Official (DFO); and is chaired by a Federal Official designated by the Secretary. The current charter was amended on November 15, 2011 and the Panel was renamed to reflect expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and 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_Advisory_PanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage*.

3. Panel Meetings and Organizational Structure

The Panel has held multiple meetings, with the last meeting taking place on February 27–29, 2012. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting and, when necessary, to solicit nominations for Panel membership and to announce new members.

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

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

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

Discussions of the other recommendations made by the Panel at the February 2012 Panel meeting are included in the sections of this proposed rule that are specific to each recommendation. For discussions of earlier Panel meetings and recommendations, we refer readers to previously published hospital 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 2012 OPPS/ASC Final Rule With Comment Period

We received approximately 61 timely pieces of correspondence on the CY 2012 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 24, 2011 (76 FR 74122), some of which contained multiple comments on the interim APC assignments and/or status indicators of HCPCS codes identified with comment

indicator ''NI'' in Addendum B to that final rule with comment period. We will present summaries of those public comments on topics open to comment in the CY 2012 OPPS/ASC final rule with comment period and our responses to them under the appropriate headings.

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative 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 2013 OPPS, we are proposing to recalibrate the APC relative payment weights for services furnished on or after January 1, 2013, and before January 1, 2014 (CY 2013), using the same basic methodology that we described in the CY 2012 OPPS/ASC final rule with comment period. That is, we 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 2013, we used approximately 141 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for hospital outpatient department services furnished on or after January 1, 2011, and before January 1, 2012. For 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 141 million final action claims for services provided in hospital outpatient settings used to calculate the proposed CY 2013 OPPS payment rates, approximately 113 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 113 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 108 million claims, we created approximately 110 million single records, of which approximately 74 million were ''pseudo'' single or ''single session'' claims (created from approximately 28 million multiple procedure claims using the process we discuss later in this section). Approximately 959,000 claims were trimmed out on cost or units in excess of +/− 3 standard deviations from the geometric mean, yielding approximately 110 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 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. Ultimately, we were able to use for CY 2013 ratesetting some portion of approximately 95 percent of the CY 2011 claims containing services payable under the OPPS.

The proposed APC relative weights and payments for CY 2013 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 2011 that were processed before January 1, 2012. While we have historically based the payments on median hospital costs for services in the APC groups, we are proposing to establish the cost-based relative payment weights of the CY 2013 OPPS using geometric mean costs, as discussed in section II.A.2.f. of this proposed rule. Therefore, on the CMS Web site, along with Addenda A and B, we are providing a file that presents payment information for the proposed CY 2013 OPPS payments based on geometric mean costs compared to those based on median costs. Under the proposed methodology, we select claims for services paid under the OPPS and match these claims to the most recent cost report filed by the individual hospitals represented in our claims data. We continue to believe that it is appropriate to use the most current full calendar year claims data and the most recently submitted cost reports to calculate the relative costs underpinning the APC relative payment weights and the CY 2013 payment rates.

b. Proposed Use of Single and Multiple Procedure Claims

For CY 2013, in general, we are proposing to continue to use single procedure claims to set the costs on which the APC relative payment weights would be 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 enabled us to create multiple ''pseudo'' single procedure claims from claims that were submitted as multiple procedure claims spanning multiple dates of service, or claims that contained numerous separately paid procedures reported on the same date on one claim. We refer to these newly created single procedure claims as ''pseudo'' single procedure claims. The history of our use of a bypass list to generate ''pseudo'' single procedure claims is well documented, most recently in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74132 through 74134). In addition, for CY 2008, we increased packaging and created the first composite APCs, and continued those policies through CY 2012. Increased packaging and creation of composite APCs also increased the number of bills that we were able to use for ratesetting by enabling us to use claims that contained multiple major

procedures that previously would not have been usable. Further, for CY 2009, we expanded the composite APC model to one additional clinical area, multiple imaging services (73 FR 68559 through 68569), which also increased the number of bills we were able to use in developing the OPPS relative weights on which payments are based. We have continued the composite APCs for multiple imaging services through CY 2012, and are proposing to continue this policy for CY 2013. We refer readers to section II.A.2.e. of this proposed rule for a discussion of the use of claims in modeling the costs for composite APCs.

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 2013 OPPS. This methodology enabled us to create, for this proposed rule, approximately 74 million ''pseudo'' single procedure claims, including multiple imaging composite ''single session'' bills (we refer readers to section II.A.2.e.(5) of this proposed rule for further discussion), to add to the approximately 36 million ''natural'' single procedure claims. For this proposed rule, ''pseudo'' single procedure and ''single session'' procedure bills represented approximately 67 percent of all single procedure bills used for ratesetting purposes.

For CY 2013, we are proposing to bypass 480 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 2013, data available for the February 27, 2012 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) from CY 2011 claims processed through September 30, 2011, and CY 2010 claims data processed through June 30, 2011, used to model the payment rates for CY 2012) to determine whether it would be appropriate to propose to add additional codes to the previous year's bypass list. For CY 2013, we are proposing to continue to bypass all of the HCPCS codes on the CY 2012 OPPS bypass list, with the exception of HCPCS codes that we are proposing to be deleted for CY 2013, 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. We also are proposing to add to the bypass list for CY 2013 HCPCS codes not on the CY 2012 bypass list that, using either the CY 2012 final rule data (CY 2010 claims) or the February 27, 2012 Panel data (first 9 months of CY 2011 claims), met the empirical criteria for the bypass list that are summarized below. Finally, to remain consistent with the CY 2013 proposal to develop OPPS relative payment weights based on geometric mean costs, we are proposing that the median cost of packaging criterion instead be based on the geometric mean cost of packaging. The entire list proposed for CY 2013 (including the codes that remain on the bypass list from prior years) 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 we are proposing to establish the CY 2013 OPPS relative payment weights based on geometric mean costs. To remain consistent in the metric used for identifying cost patterns, we are proposing to use the geometric mean cost of packaging to identify potential codes to add to the bypass list. The proposal to develop the CY 2013 OPPS relative payment weights based on geometric mean costs is discussed in greater detail in section II.A.2.f. of this proposed rule.

In response to comments to 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. We are proposing for CY 2013, based on the same rationale described for the CY 2012 OPPS/ASC final rule with comment period (76 FR 74133), to continue to update the packaged cost threshold by the market basket increase. By applying the final CY 2012 market basket increase of 1.90 percent to the prior non-rounded dollar threshold of $52.76 (76 FR 74133), we determined that the threshold remains for CY 2013 at $55 ($53.76 rounded to $55, the nearest $5 increment). Therefore, we are proposing to set the geometric mean packaged cost threshold on the CY 2011 claims at $55 for a code to be considered for addition to the CY 2013 OPPS bypass list.

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

In addition, we 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 2013 OPPS proposal. Some of these codes were identified by CMS medical advisors and some were identified in prior years by commenters with specialized knowledge of the packaging associated with specific services. We also 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) and the CPT codes for additional hours of drug administration to the bypass list (73 FR 68513 and 71 FR 68117 through 68118).

As a result of the multiple imaging composite APCs that we established in CY 2009, the program logic for creating ''pseudo'' single procedure claims from bypassed codes that are also members of multiple imaging composite APCs changed. When creating the set of ''pseudo'' single procedure claims, claims that contain ''overlap bypass codes'' (those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs) were identified first. These HCPCS codes were then processed to create multiple imaging composite ''single session'' bills, that is, claims containing HCPCS codes from only one imaging family, thus suppressing the initial use of these codes as bypass codes. However, these ''overlap bypass codes'' were retained on the bypass list because, at the end of the ''pseudo'' single processing logic, we reassessed the claims without suppression of the ''overlap bypass codes'' under our longstanding ''pseudo'' single process to determine whether we could convert additional claims to ''pseudo'' single procedure claims. (We refer readers to section II.A.2.b. of this 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 2013. The list of bypass codes contains codes that were reported on claims for services in CY 2011 and, therefore, includes codes that were in effect in 2011 and used for billing but were deleted for CY 2012. We retained these deleted bypass codes on the proposed CY 2013 bypass list because these codes existed in CY 2011 and were covered OPD services in that period, and CY 2011 claims data are used to calculate CY 2013 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that were members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we are proposing to add for CY 2013 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 2013 bypass list because these codes were either deleted from the HCPCS before CY 2011 (and therefore were not covered OPD services in CY 2011) or were not separately payable codes under the proposed CY 2013 OPPS because these codes are not used for ratesetting (and therefore would not need to be bypassed). None of these proposed deleted codes are ''overlap bypass'' codes.

TABLE 1—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2013 BYPASS LIST

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

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

For CY 2013, we are proposing to continue to use the hospital-specific overall ancillary and departmental CCRs to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 2013 APC payment rates are based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2011 claims data from the most recent available hospital cost reports, in most cases, cost reports beginning in CY 2010. For the CY 2013 OPPS proposed rates, we used the set of claims processed during CY 2011. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. That crosswalk is available for review and continuous comment on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2011 (the year of the claims data we used to calculate the proposed CY 2013 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2011 Data Specifications Manual.

In accordance with our longstanding policy, we calculated CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculated CCRs was the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). One longstanding exception to this general methodology for calculation of CCRs used for converting charges to costs on each claim, as detailed in the CY 2007 OPPS/ASC final rule with comment period, is the calculation of blood costs, as discussed in section II.A.2.d.(2) of this 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 for hospitals that filed outpatient claims in CY 2011 before determining whether the CCRs for such hospitals were valid.

We then calculated the CCRs for each cost center and the overall ancillary CCR for each hospital for which we had claims data. We did this using hospital-specific data from the Hospital Cost Report Information System (HCRIS). We used the most recent available cost report data, in most cases, cost reports with cost reporting periods beginning in CY 2010. For 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 2013 OPPS payment rates. If the most recently available cost report was submitted but not settled, we looked at the last settled cost report to determine the ratio of submitted to settled cost

using the overall ancillary CCR, and we then adjusted the most recent available submitted, but not settled, cost report using that ratio. We then calculated both an overall ancillary CCR and cost center-specific CCRs for each hospital. We used the overall ancillary CCR referenced above in this section of this proposed rule 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 2013.

Since the implementation of the OPPS, some commenters have raised concerns about potential bias in the OPPS cost-based weights due to ''charge compression,'' which is the practice of applying a lower charge markup to higher cost services and a higher charge markup to lower cost services. As a result, the cost-based weights may reflect some aggregation bias, undervaluing high-cost items and overvaluing low-cost items when an estimate of average markup, embodied in a single CCR, is applied to items of widely varying costs in the same cost center. This issue was evaluated in a report by Research Triangle Institute, International (RTI). The RTI final report can be found on RTI's Web site at: *http://www.rti.org/reports/cms/HHSM-500-fxsp0;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 order to develop a robust analysis regarding the use of cost data from the ''Implantable Devices Charged to Patients'' cost center, we believe that it is necessary to have a critical mass of cost reports filed with data in this cost center. In preparation for the CY 2013 OPPS/ASC proposed rule, we assessed the availability of data in the ''Implantable Devices Charged to Patients'' cost center using cost reports in the December 31, 2011 quarter ending update of HCRIS, which was the latest upload of the cost report data that we could use for the CY 2013 proposed rule. We determined that 2,063 hospitals, out of approximately 3,800 hospitals, utilized the ''Implantable Devices Charged to Patients'' cost center, and we believe that this is a sufficient amount of data from which to generate a meaningful analysis. Therefore, we are proposing to use data from the ''Implantable Devices Charged to Patients'' cost center to create a distinct CCR for use in calculating the OPPS relative weights for CY 2013. Table 2 below contains a list of APCs that had either a greater than or less than 3.0 percentage point change in cost when the ''Implantable Devices Charged to Patients'' cost center is used to create a distinct CCR compared to a CCR created from the combination of the ''Medical Supplies Charged to Patients'' and the ''Implantable Devices Charged to Patients'' cost centers as was used in the CY 2012 OPPS/ASC final rule with comment period.

TABLE 2—PERCENTAGE CHANGE IN APC COST WHEN THE ''IMPLANTABLE DEVICES CHARGED TO PATIENTS'' COST CENTER IS USED TO CREATE DISTINCT CCR

APC	APC descriptor	Percentage change in cost
0654	Level II Insertion/Replacem of Permanent Pacemaker	6.99
0315	Level II Implantation of Neurostimulator Generator	5.71
0227	Implantation of Drug Infusion Device	5.65
0386	Level II Prosthetic Urological Procedures	4.92
0107	Insertion of Cardioverter-Defibrillator Pulse Generat	4.89
0089	Insertion/Replace of Perm Pacemaker and Electrodes	4.71
0108	Insertion/Replace/Repair of Cardioverter-Defibr Sys	4.42
0039	Level I Implantation of Neurostimulator Generator	4.35
0655	Insert/Replac/Conv of a Perm Dual Cham Pacemaker	4.20
0680	Insertion of Patient Activated Event Recorders	3.77
0090	Level I Insertion/Replacem of Permanent Pacemaker	3.68
0318	Implanta of Neurostimulator Pulse Gen and Electrode	3.64
0106	Insert/Replac of Pacemaker Leads and/or Electrodes	3.10
0387	Level II Hysteroscopy	−3.16
0100	Cardiac Stress Tests	−3.20
0269	Level II Echocardiogram Without Contrast	−3.21
8002	Level I Extended Assess & Management Composite	−3.31
0101	Tilt Table Evaluation	−3.34
0142	Level I Small Intestine Endoscopy	−3.49
0084	Level I Electrophysiologic Procedures	−3.61
8000	Cardiac Electrophysiologic Eval and Ablation Compo	−3.69
0165	Level IV Urinary and Anal Procedures	−3.73
0270	Level III Echocardiogram Without Contrast	−3.73
0679	Level II Resuscitation and Cardioversion	−3.76

TABLE 2—PERCENTAGE CHANGE IN APC COST WHEN THE ''IMPLANTABLE DEVICES CHARGED TO PATIENTS'' COST CENTER IS USED TO CREATE DISTINCT CCR—Continued

APC	APC descriptor	Percentage change in cost
0174	Level IV Laparoscopy	−3.78
0659	Hyperbaric Oxygen	−4.01
0085	Level II Electrophysiologic Procedures	−4.15
0111	Blood Product Exchange	−4.27
0381	Single Allergy Tests	−5.10
0370	Multiple Allergy Tests	−7.46
0012	Level I Debridement & Destruction	−8.15
0251	Level II ENT Procedures	−8.46

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, MRI, 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 weights would better estimate the costs of those services if CMS were to add standard costs centers for CT scans, MRIs, and cardiac catheterization in order for hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the cost from charges on claims data. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a more detailed discussion on the reasons for the creation of standard cost centers for CT scans, MRIs, and cardiac catheterization. The new standard cost centers for CT scans, MRIs, and cardiac catheterization are effective for cost report periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10. However, because cost reports that were filed on the revised cost report Form CMS–2552–10 are not currently accessible in the HCRIS, we were unable to calculate distinct CCRs for CT scans, MRI, and cardiac catheterization using the new standard cost centers for these services. We believe that we will have cost report data available for an analysis of creating distinct CCRs for CT scans, MRIs, and cardiac catheterization for the CY 2014 OPPS rulemaking.

We believe that improved cost report software, the incorporation of new standard and nonstandard cost centers, and the elimination of outdated requirements will improve the accuracy of the cost data contained in the electronic cost report data files and, therefore, the accuracy of our cost estimation processes for the OPPS relative weights. We will continue our standard practice of examining ways in which we can improve the accuracy of our cost estimation processes.

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 OPPS payment rates for CY 2013. The Hospital OPPS page on our 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. Our Web site, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*, includes information about purchasing the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–9–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2011 claims that were used to calculate the proposed payment rates for the CY 2013 OPPS.

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

We used the methodology described in sections II.A.2.a. through II.A.2.e. of this proposed rule to calculate the geometric mean costs we use to establish the proposed relative weights used in calculating the proposed OPPS payment rates for CY 2013 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We note that we are providing a file comparing the CY 2013 proposed payments under the geometric mean cost-based OPPS, relative to what they would be under a CY 2013 median-based OPPS. We are providing this file so that the public can provide meaningful comment on our proposal to base the CY 2013 OPPS relative payment weights on geometric mean costs. We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC geometric mean costs to scaled payment weights.

a. Claims Preparation

For this proposed rule, we used the CY 2011 hospital outpatient claims processed before January 1, 2012, to calculate the geometric mean costs of APCs that underpin the proposed relative weights for CY 2013. To begin the calculation of the proposed relative weights for CY 2013, we pulled all claims for outpatient services furnished in CY 2011 from the national claims

history file. This is not the population of claims paid under the OPPS, but all outpatient claims (including, for example, critical access hospital (CAH) claims and hospital claims for clinical laboratory services for persons who are neither inpatients nor outpatients of the hospital).

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

We divided the remaining claims into the three groups shown below. Groups 2 and 3 comprise the 113 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 and comment on our Web site: *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 nothing but influenza and pneumococcal pneumonia (PPV) vaccines. Influenza and PPV vaccines are paid at reasonable cost and, therefore, these claims are not used to set OPPS rates.

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

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

We then removed line-items that were not paid during claim processing, presumably for a line-item rejection or denial. The number of edits for valid OPPS payment in the Integrated Outpatient Code Editor (I/OCE) and elsewhere has grown significantly in the past few years, especially with the implementation of the full spectrum of National Correct Coding Initiative (NCCI) edits. To ensure that we are using valid claims that represent the cost of payable services to set payment rates, we removed line-items with an OPPS status indicator that were not paid during claims processing in the claim year, but have a status indicator of ''S,'' ''T,'' ''V,'' or ''X'' in the prospective year's payment system. This logic preserves charges for services that would not have been paid in the claim year but for which some estimate of cost is needed for the prospective year, such as services newly proposed to come off the inpatient list for CY 2012 that were assigned status indicator ''C'' in the claim year. It also preserves charges for packaged services so that the costs can be included in the cost of the services with which they are reported, even if the CPT codes for the packaged services were not paid because the service is part of another service that was reported on the same claim or the code otherwise violates claims processing edits.

For CY 2013, we are proposing to continue the policy we implemented for CY 2012 to exclude line-item data for pass-through drugs and biologicals (status indicator ''G'' for CY 2011) and nonpass-through drugs and biologicals (status indicator ''K'' for CY 2011) where the charges reported on the claim for the line were either denied or rejected during claims processing. Removing lines that were eligible for payment but were not paid ensures that we are using appropriate data. The trim avoids using cost data on lines that we believe were defective or invalid because those rejected or denied lines did not meet the Medicare requirements for payment. For example, edits may reject a line for a separately paid drug because the number of units billed exceeded the number of units that would be reasonable and, therefore, is likely a billing error (for example, a line reporting 55 units of a drug for which 5 units is known to be a fatal dose). As with our trimming in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74141) of line-items with a status indicator of ''S,'' ''T,'' ''V,'' or ''X,'' we believe that unpaid line-items represent services that are invalidly reported and, therefore, should not be used for ratesetting. We believe that removing lines with valid status indicators that were edited and not paid during claims processing increases the accuracy of the data used for ratesetting purposes.

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

(1) Splitting Claims

For the CY 2013 OPPS, we then split the remaining claims into five groups: single majors; multiple majors; single minors; multiple minors; and other claims. (Specific definitions of these groups follow below.) For CY 2013, we are proposing to continue our current policy of defining major procedures as any HCPCS code having a status indicator of ''S,'' ''T,'' ''V,'' or ''X;'' defining minor procedures as any code having a status indicator of ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N,'' and classifying ''other'' procedures as any code having a status indicator other than one that we have classified as major or minor. For CY 2013, we are proposing to continue assigning status indicator ''R'' to blood and blood products; status indicator ''U'' to brachytherapy sources; status indicator ''Q1'' to all ''STVX-packaged codes;'' status indicator ''Q2'' to all ''T-packaged codes;'' and status indicator ''Q3'' to all codes that may be paid through a composite APC based on composite-specific criteria or paid separately through single code APCs when the criteria are not met.

As discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68709), we established status indicators ''Q1,'' ''Q2,'' and ''Q3'' to facilitate identification of the different categories of codes. We are proposing to treat these codes in the same manner for data purposes for CY 2013 as we have treated them since CY 2008. Specifically, we are proposing to continue to evaluate whether the criteria for separate payment of codes with status indicator ''Q1'' or ''Q2'' are met in determining whether they are treated as major or minor codes. Codes with status indicator ''Q1'' or ''Q2'' are carried through the data either with status indicator ''N'' as packaged or, if they meet the criteria for separate payment, they are given the status indicator of the APC to which they are assigned and are considered as ''pseudo'' single procedure claims for major codes. Codes assigned status indicator ''Q3'' are paid under individual APCs unless they occur in the combinations that qualify for payment as composite APCs and, therefore, they carry the status indicator of the individual APC to which they are assigned through the data process and are treated as major codes during both the split and ''pseudo'' single creation process. The calculation of the geometric mean costs for composite APCs from multiple procedure major claims is discussed in section II.A.2.e. of this 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,'' ''V,'' or ''X,'' which includes codes with status indicator ''Q3''); claims with one unit of a status indicator ''Q1'' code (''STVX-packaged'') where there was no code with status indicator ''S,'' ''T,'' ''V,'' or ''X'' on the same claim on the same date; or claims with one unit of a status indicator ''Q2'' code (''T-packaged'') where there was no code with a status indicator ''T'' on the same claim on the same date.

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

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

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

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

The claims listed in numbers 1, 2, 3, and 4 above are included in the data file that can be purchased as described above. Claims that contain codes to which we have assigned status indicators ''Q1'' (''STVX-packaged'') and ''Q2'' (''T-packaged'') appear in the data for the single major file, the multiple major file, and the multiple minor file used for ratesetting. Claims that contain codes to which we have assigned status indicator ''Q3''

(composite APC members) appear in both the data of the single and multiple major files used in this 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).

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 2013 ''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. Where 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.e.(5) of this proposed rule, were met. Where 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 proposed CY 2013 OPPS payment would be 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'' (''STVX-packaged'') on the same date of service or contained multiple units of a single code with status indicator ''Q1,'' we selected the status indicator ''Q1'' HCPCS code that had the highest CY 2012 relative weight, set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q1.'' We then packaged all costs for the following into a single cost for the ''Q1'' HCPCS code that had the highest CY 2012 relative weight to create a ''pseudo'' single procedure claim for that code: Additional units of the status indicator ''Q1'' HCPCS code with the highest CY 2012 relative 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, where a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') or multiple units of a single code with status indicator ''Q2,'' we selected the status indicator ''Q2'' HCPCS code that had the highest CY 2012 relative 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 ''Q2.'' We then packaged all costs for the following into a single cost for the ''Q2'' HCPCS code that had the highest CY 2012 relative weight to create a ''pseudo'' single procedure claim for that code: Additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2012 relative 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.

Where a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') and status indicator ''Q1'' (''STVX-packaged''), we selected the T-packaged status indicator ''Q2'' HCPCS code that had the highest relative weight for CY 2012 and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q2.'' We then packaged all costs for the following into a single cost for the selected (''T packaged'') HCPCS code to create a ''pseudo'' single procedure claim for that code: Additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2012 relative weight; other codes with status indicator ''Q2''; codes with status indicator ''Q1'' (''STVX-packaged''); and other packaged HCPCS codes and packaged revenue code costs. We favor status indicator ''Q2'' over ''Q1'' HCPCS codes because ''Q2'' HCPCS codes have higher CY 2012 relative weights. If a status indicator ''Q1'' HCPCS code had a higher CY 2011

relative weight, it would become 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, where they meet the criteria for single procedure claims. Conditionally packaged codes are identified using status indicators ''Q1'' and ''Q2,'' and are described in section XII.A.1. 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 this methodology for the purpose of creating pseudo single procedure claims for the CY 2013 OPPS.

c. Completion of Claim Records and Geometric Mean Cost Calculations

(1) General Process

We then packaged the costs of packaged HCPCS codes (codes with status indicator ''N'' listed in Addendum B to this proposed rule (which is referenced in section XIX. of this proposed rule and 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 3 below that appeared on the claim without a HCPCS code into the cost of the single major procedure remaining on the claim.

As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66606), for the CY 2008 OPPS, we adopted an APC Panel recommendation that CMS should review the final list of packaged revenue codes for consistency with OPPS policy and ensure that future versions of the I/OCE edit accordingly. As we have in the past, we are proposing to continue to compare the final list of packaged revenue codes that we adopt for CY 2013 to the revenue codes that the I/OCE will package for CY 2013 to ensure consistency.

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

For CY 2013, as we did for CY 2012, we reviewed the changes to revenue codes that were effective during CY 2011 for purposes of determining the charges reported with revenue codes but without HCPCS codes that we would propose to package for CY 2013. We believe that the charges reported under the revenue codes listed in Table 3 below continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes. Therefore, for CY 2013, we are proposing to continue to package the costs that we derive from the charges reported without HCPCS code under the revenue codes displayed in Table 3 below for purposes of calculating the geometric mean costs on which the proposed CY 2013 OPPS/ASC payment rates are based.

TABLE 3—PROPOSED CY 2013 PACKAGED REVENUE CODES

Revenue code	Description
0250	Pharmacy; General Classification.
0251	Pharmacy; Generic Drugs.
0252	Pharmacy; Non-Generic Drugs.
0254	Pharmacy; Drugs Incident to Other Diagnostic Services.
0255	Pharmacy; Drugs Incident to Radiology.
0257	Pharmacy; Non-Prescription.
0258	Pharmacy; IV Solutions.
0259	Pharmacy; Other Pharmacy.
0260	IV Therapy; General Classification.
0261	IV Therapy; Infusion Pump.
0262	IV Therapy; IV Therapy/Pharmacy Svcs.
0263	IV Therapy; IV Therapy/Drug/Supply Delivery.
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.

TABLE 3—PROPOSED CY 2013 PACKAGED REVENUE CODES—Continued

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

In accordance with our longstanding policy, we 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 MAC was required to allocate the sum of charges for services with a status indicator equaling ''S'' or ''T'' based on the relative 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 2013 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 108 million claims were left. Using these approximately 108 million claims, we created approximately 110 million single and ''pseudo'' single procedure claims, of which we used slightly more than 110 million single bills (after trimming out approximately 959,000 claims as discussed in section II.A.1.a. of this

proposed rule) in the CY 2013 geometric mean cost development and ratesetting.

As discussed above, the OPPS has historically developed the relative weights on which APC payments are based using APC median costs. For the CY 2013 OPPS, we are proposing to calculate the APC relative weights using geometric mean costs, and therefore the following discussion of the two times rule and relative weight development refers to geometric means. For more detail about the CY 2013 OPPS/ASC proposal 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 proposed CY 2013 geometric mean costs for each separately payable HCPCS code and each APC. The comparison of HCPCS code-specific and APC geometric mean costs determines the applicability of the 2 times rule. Section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group shall not be treated as comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the same group (the 2 times rule). While we have historically applied the 2 times rule based on median costs, as part of the CY 2013 proposal to develop the OPPS relative payment weights based on geometric mean costs, we also are proposing to apply the 2 times rule based on geometric mean costs. For a detailed discussion of the CY 2013 proposal to develop the APC relative payment weights based on geometric mean costs, we refer readers to section II.A.2.f. of this proposed rule.

We note that, for purposes of identifying significant HCPCS for examination in the 2 times rule, we consider codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC geometric mean cost to be significant. This longstanding definition of when a HCPCS code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing geometric mean costs. Similarly, a HCPCS code for which there are fewer than 99 single bills and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC geometric mean. We note that this method of identifying significant HCPCS codes within an APC for purposes of the 2 times rule was used in prior years under the median-based cost methodology. Under our CY 2013 proposal 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 system. 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. Section III. of this proposed rule includes a discussion of many of the HCPCS code assignment changes that resulted from examination of the geometric mean costs and for other reasons. The APC geometric means were recalculated after we reassigned the affected HCPCS codes. Both the HCPCS code-specific geometric means and the APC geometric means were weighted to account for the inclusion of multiple units of the bypass codes in the creation of ''pseudo'' single procedure claims.

As we discuss in sections II.A.2.d. and II.A.2.e. 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 calculation of single APC criteria-based geometric mean costs. Section II.A.2.e. of this proposed rule discusses the calculation of composite APC criteria-based geometric mean costs. Section VIII.B. of this proposed rule addresses the methodology for calculating the geometric mean costs for partial hospitalization services.

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

At the February 27–28, 2012 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel), we provided the Data Subcommittee with a list of all APCs fluctuating by greater than 10 percent when comparing the CY 2012 OPPS final rule median costs based on CY 2010 claims processed through June 30, 2011, to those based on CY 2011 OPPS/ASC final rule data (CY 2009 claims processed through June 30, 2010). The Data Subcommittee reviewed the fluctuations in the APC median costs but did not express particular concerns with the median cost changes.

At the February 27–28, 2012 Panel meeting, the Panel made a number of recommendations related to the data process. The Panel's recommendations and our responses follow.

Recommendation 1: The Panel recommends that the work of the Data Subcommittee continue.

CMS Response to Recommendation 1: We are accepting this recommendation.

Recommendation 2: The Panel recommends that Kari S. Cornicelli, C.P.A., FHFMA, serve as acting chairperson for the winter 2012 meeting of the Data Subcommittee.

CMS Response to Recommendation 2: We are accepting this recommendation.

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

(1) Device-Dependent APCs

Device-dependent APCs are populated by HCPCS codes that usually, but not always, require that a device be implanted or used to perform the procedure. For a full history of how we have calculated payment rates for device-dependent APCs in previous years and a detailed discussion of how we developed the standard device-dependent APC ratesetting methodology, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66739 through 66742). Overviews of the procedure-to-device edits and device-to-procedure edits used in ratesetting for device-dependent APCs are available in the CY 2005 OPPS final rule with comment period (69 FR 65761 through 65763) and the CY 2007 OPPS/ASC final rule with comment period (71 FR 68070 through 68071).

For CY 2013, we are proposing to use the standard methodology for calculating costs for device-dependent APCs that was finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74148 through 74151). This methodology utilizes claims data that generally represent the full cost of the required device and the most recent cost report data. Specifically, we are proposing to calculate the costs for device-dependent APCs for CY 2013 using only the subset of single procedure claims from CY 2011 claims data that pass the procedure-to-device and device-to-procedure edits; do not contain token charges (less than $1.01) for devices; do not contain the ''FB'' modifier signifying that the device was

furnished without cost to the provider, or where a full credit was received; and do not contain the ''FC'' modifier signifying that the hospital received partial credit for the device. The procedure-to-device edits require that when a particular procedural HCPCS code is billed, the claim must also contain an appropriate device code, while the device-to-procedure edits require that a claim that contains one of a specified set of device codes also contain an appropriate procedure code. We continue to believe the standard methodology for calculating costs for device-dependent APCs gives us the most appropriate costs for device-dependent APCs in which the hospital incurs the full cost of the device.

Table 4A below lists the APCs for which we are proposing to use our standard device-dependent APC ratesetting methodology for CY 2013. We refer readers to Addendum A to this proposed rule (which is available via the Internet on the CMS Web site) for the proposed payment rates for these device-dependent APCs for CY 2013.

TABLE 4A—PROPOSED CY 2013 DEVICE-DEPENDENT APCS

Proposed CY 2013 APC	Proposed CY 2013 status indicator	Proposed CY 2013 APC title
0039	S	Level I Implantation of Neurostimulator Generator.
0040	S	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes.
0061	S	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes.
0082	T	Coronary or Non-Coronary Atherectomy.
0083	T	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization of the Lower Extremity.
0084	S	Level I Electrophysiologic Procedures.
0085	T	Level II Electrophysiologic Procedures.
0086	T	Level III Electrophysiologic Procedures.
0089	T	Insertion/Replacement of Permanent Pacemaker and Electrodes.
0090	T	Insertion/Replacement of Pacemaker Pulse Generator.
0104	T	Transcatheter Placement of Intracoronary Stents.
0106	T	Insertion/Replacement of Pacemaker Leads and/or Electrodes.
0107	T	Insertion of Cardioverter-Defibrillator.
0108	T	Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes.
0115	T	Cannula/Access Device Procedures.
0202	T	Level VII Female Reproductive Procedures.
0227	T	Implantation of Drug Infusion Device.
0229	T	Level II Endovascular Revascularization of the Lower Extremity.
0259	T	Level VII ENT Procedures.
0293	T	Level V Anterior Segment Eye Procedures.
0315	S	Level II Implantation of Neurostimulator Generator.
0318	S	Implantation of Cranial Neurostimulator Pulse Generator and Electrode.
0319	T	Level III Endovascular Revascularization of the Lower Extremity.
0384	T	GI Procedures with Stents.
0385	S	Level I Prosthetic Urological Procedures.
0386	S	Level II Prosthetic Urological Procedures.
0425	T	Level II Arthroplasty or Implantation with Prosthesis.
0427	T	Level II Tube or Catheter Changes or Repositioning.
0622	T	Level II Vascular Access Procedures.
0623	T	Level III Vascular Access Procedures.
0648	T	Level IV Breast Surgery.
0652	T	Insertion of Intraperitoneal and Pleural Catheters.
0653	T	Vascular Reconstruction/Fistula Repair with Device.
0654	T	Insertion/Replacement of a Permanent Dual Chamber Pacemaker.
0655	T	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode.
0656	T	Transcatheter Placement of Intracoronary Drug-Eluting Stents.
0674	T	Prostate Cryoablation.
0680	S	Insertion of Patient Activated Event Recorders.

(2) Blood and Blood Products

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

For CY 2013, 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 2013 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 note that we used geometric mean unit costs for each blood and blood product to calculate the proposed payment rates, consistent with the methodology proposed for other items and services, discussed in section II.A.2.f. of this proposed rule.

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

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

For the CY 2011 update, the AMA's CPT Editorial Panel created 16 new CPT codes in the Endovascular Revascularization section of the 2011 CPT codebook to describe endovascular revascularization procedures of the lower extremity performed for occlusive disease. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71841 through 71845), we discussed the process and methodology by which we assigned the CY 2011 endovascular revascularization CPT codes to APCs that we believe are comparable with respect to clinical characteristics and resources required to furnish the services. Specifically, we were able to use the existing CY 2009 hospital outpatient claims data and the most recent cost report data to create simulated costs for 12 of the 16 new separately payable codes for CY 2011. Because the endovascular revascularization CPT codes were new for CY 2011, we used our CY 2009 single and ''pseudo'' single claims data to simulate the new CY 2011 CPT code definitions. As shown in Table 7 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71844), many of the new endovascular revascularization CPT codes were previously reported using a combination of CY 2009 CPT codes. In order to simulate costs, we selected claims that we believe met the definition for each of the new endovascular revascularization CPT codes. Table 7 showed the criteria we applied to select a claim to be used in the calculation of the costs for the new codes (shown in Column A). As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71842), we developed these criteria based on our clinicians' understanding of services that were reported by the CY 2009 CPT codes that, in various combinations, reflect the services provided that are described by the new CPT codes for CY 2011.

After determining the simulated costs for the procedures, we assigned each CPT code to appropriate APCs based on their clinical homogeneity and resource use. Of the 16 new codes, we assigned 9 CPT codes to APC 0083 (Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty) and 5 CPT codes to APC 0229 (Transcatheter Placement of Intravascular Shunts), and created new APC 0319 (Endovascular Revascularization of the Lower Extremity) for 2 CPT codes. Table 8 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71845) displayed their final CY 2011 APC assignments and CPT costs. We noted that, because these CPT codes were new for CY 2011, they were identified with comment indicator ''NI'' in Addendum B to the CY 2011 OPPS/ASC final rule with comment period to identify them as a new interim APC assignment for CY 2011 and subject to public comment. We specifically requested public comment on our methodology for simulating the costs for these new CY 2011 CPT codes in addition to public comments on the payment rates themselves (75 FR 71845).

As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74156), for CY 2012, we continued to use the CY 2011 methodology in determining the APC assignments for the CPT codes that describe endovascular revascularization of the lower extremity. Because previous endovascular revascularization CPT codes were in existence prior to CY 2011 and assigned to designated APCs, we continued to use existing hospital outpatient claims and cost report data from established codes to simulate estimated costs for the endovascular revascularization CPT codes in determining the appropriate APC assignments for CY 2012, as we did for CY 2011. In the CY 2012 OPPS/ASC final rule with comment period, we also revised the title of APC 0083 from ''Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty'' to ''Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization of the Lower Extremity''; the title of APC 0229 from ''Transcatheter Placement of Intravascular Shunts and Stents'' to ''Level II Endovascular Revascularization of the Lower Extremity''; and the title of APC 0319 from ''Endovascular Revascularization of the Lower Extremity'' to ''Level III Endovascular Revascularization of the Lower Extremity''.

Because the endovascular revascularization of the lower extremity CPT codes were new for CY 2011, CY 2013 is the first year of claims data that are available for ratesetting for these specific CPT codes. For CY 2013, review of the procedures with significant claims data in APCs 0083, 0229, and 0319 shows no 2 times rule violation in these APCs. We believe that the endovascular revascularization CPT codes in APCs 0083, 0229, and 0319 continue to be appropriately placed based on clinical homogeneity and resource costs. Therefore, for CY 2013, we are proposing to continue to assign the endovascular revascularization CPT codes to APCs 0083, 0229, and 0319, as listed in Table 4B below.

TABLE 4B—PROPOSED APCS TO WHICH ENDOVASCULAR REVASCULARIZATION OF THE LOWER EXTREMITY CPT CODES WOULD BE ASSIGNED FOR CY 2013

CY 2012 CPT Code	CY 2012 short descriptor	CY 2012 SI	CY 2012 APC	Proposed CY 2013 SI	Proposed CY 2013 APC
37220	Iliac revasc	T	0083	T	0083
37221	Iliac revasc w/stent	T	0229	T	0229
37222	Iliac revasc add-on	T	0083	T	0083
37223	Iliac revasc w/stent add-on	T	0083	T	0083
37224	Fem/popl revas w/tla	T	0083	T	0083
37225	Fem/popl revas w/ather	T	0229	T	0229
37226	Fem/popl revasc w/stent	T	0229	T	0229
37227	Fem/popl revasc stnt & ather	T	0319	T	0319
37228	Tib/per revasc w/tla	T	0083	T	0083
37229	Tib/per revasc w/ather	T	0229	T	0229
37230	Tib/per revasc w/stent	T	0229	T	0229
37231	Tib/per revasc stent & ather	T	0319	T	0319
37232	Tib/per revasc add-on	T	0083	T	0083
37233	Tib/per revasc w/ather add-on	T	0229	T	0229
37234	Revsc opn/prq tib/pero stent	T	0083	T	0083
37235	Tib/per revasc stnt & ather	T	0083	T	0083

(4) Non-Congenital Cardiac Catheterization (APC 0080)

For CY 2011, the AMA's CPT Editorial Panel restructured the Cardiac Catheterization section of the CPT codebook so that combinations of services that were previously reported using multiple codes are now reported with one CPT code. This revision deleted several non-congenital cardiac catheterization-related CPT codes from the 93500 series and created new CPT codes in the 93400 series and in the 93500 series. We discussed these coding changes in detail in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71846 through 71849), along with the process by which we assigned the new CPT codes to APCs that we believe are comparable with respect to clinical characteristics and resources required to furnish the cardiac catheterization services described by the new CPT codes. As discussed in that final rule with comment period, we were able to use the existing CY 2009 hospital outpatient claims data and the most recent cost report data to create simulated costs for the new separately payable CPT codes for CY 2011. Specifically, to estimate the hospital costs associated with the 20 new non-congenital cardiac catheterization-related CPT codes based on their CY 2011 descriptors, we used claims and cost report data from CY 2009. Because of the substantive coding changes associated with the new non-congenital cardiac catheterization-related CPT codes for CY 2011, we used our CY 2009 single and ''pseudo'' single claims data to simulate the new CY 2011 CPT code definitions. We stated that many of the new CPT codes were previously reported using multiple CY 2009 CPT codes, and we provided a crosswalk of the new CY 2011 cardiac catheterization CPT codes mapped to the CY 2009 cardiac catheterization CPT codes in Table 11 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71849). Table 11 showed the criteria we applied to select a claim to be used in the calculation of the cost for the new codes (shown in Column A). As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71847 through 71848), we developed these criteria based on our clinicians' understanding of services that were reported by the CY 2009 CPT codes that, in various combinations, reflect the services provided that are described in the new CPT codes. We used approximately 175,000 claims for the new non-congenital catheterization-related CPT codes, together with the single and ''pseudo'' single procedure claims for the remaining non-congenital catheterization-related CPT codes in APC 0080 (Diagnostic Cardiac Catheterization), to calculate CPT level costs and the cost for APC 0080 of approximately $2,698. We noted that, because the CPT codes listed in Table 11 were new for CY 2011, they were identified with comment indicator ''NI'' in Addendum B to that final rule with comment period to identify them as subject to public comment. We specifically requested public comment on our methodology for simulating the costs for these new CY 2011 CPT codes, in addition to public comments on the payment rates themselves (75 FR 71848).

For CY 2012, we continued to use the CY 2011 methodology in determining the APC assignments for the new cardiac catheterization CPT codes. That is, we continued to use the CY 2011 methodology in determining the APC assignments for the cardiac catheterization CPT codes by using the existing hospital outpatient claims and the cost report data from the predecessor cardiac catheterization CPT codes to simulate an estimated cost for the new cardiac catheterization CPT codes in determining the appropriate APC assignments. Specifically, we used the CY 2010 hospital outpatient claims data and the most recent cost report data to create simulated costs for the new separately payable CPT codes for CY 2012 to determine the payment rates for the cardiac catheterization CPT codes. For CY 2012, we did not make any changes to the CY 2011 APC assignments of any of the codes assigned to APC 0080 because the claims data supported continuation of these APC assignments.

Because the cardiac catheterization CPT codes were new for CY 2011, CY 2013 is the first year of claims data that are available for ratesetting for these specific CPT codes. For CY 2013, our analysis of the CY 2011 claims data available for this proposed rule shows no violation in the 2 times rule for the cardiac catheterization CPT codes because the lowest cost of a CPT code with significant claims data in APC 0080 is approximately $1,716 (for CPT code 93451), while the highest cost of a CPT code with significant claims data is approximately $3,308 (for CPT code 93461). We believe that the cardiac catheterization CPT codes continue to be appropriately placed in APC 0080 based on clinical homogeneity and resource costs. Therefore, for CY 2013, we are proposing to continue to assign the cardiac catheterization CPT codes to APC 0080 as listed below in Table 5.

TABLE 5—PROPOSED APCS TO WHICH NON-CONGENITAL CARDIAC CATHETERIZATION CPT CODES WOULD BE ASSIGNED FOR CY 2013

CY 2012 HCPCS code	CY 2012 short descriptor	CY 2012 SI	CY 2012 APC	Proposed CY 2013 SI	Proposed CY 2013 APC
93451	Right heart cath	T	0080	T	0080
93452	Left hrt cath w/ventrclgrphy	T	0080	T	0080
93453	R&I hrt cath w/ventriclgrphy	T	0080	T	0080
93454	Coronary artery angio s&i	T	0080	T	0080
93455	Coronary art/grft angio s&i	T	0080	T	0080
93456	R hrt coronary artery angio	T	0080	T	0080
93457	R hrt art/grft angio	T	0080	T	0080
93458	L hrt artery/ventricle angio	T	0080	T	0080
93459	L hrt art/grft angio	T	0080	T	0080
93460	R&I hrt art/ventricle angio	T	0080	T	0080
93461	R&I hrt art/ventricle angio	T	0080	T	0080
93462	L hrt cath trnsptl puncture	T	0080	T	0080
93463	Drug admin & hemodynamic meas	N	NA	N	NA
93464	Exercise w/hemodynamic meas	N	NA	N	NA
93565	Inject l ventr/atrial angio	N	NA	N	NA
93566	Inject r ventr/atrial angio	N	NA	N	NA
93567	Inject suprvlv aortography	N	NA	N	NA
93568	Inject pulm art hrt cath	N	NA	N	NA

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

For CY 2011, the AMA's CPT Editorial Panel established three new codes to describe computed tomography of the abdomen and pelvis. CPT codes 74176 (Computed tomography, abdomen and pelvis; without contrast material), 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)), and 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions) were effective January 1, 2011. As shown in Table 6, for CY 2011, these services were paid in one of two methods under the hospital OPPS. They were either paid separately through a single APC or through a composite APC. We assigned CPT code 74176 to APC 0332 (Computed Tomography Without Contrast), CPT code 74177 to APC 0283 (Computed Tomography With Contrast), and CPT code 74178 to APC 0333 (Computed Tomography Without Contrast Followed By Contrast). We also assigned CPT code 74176 to composite APC 8005 (CT and CTA Without Contrast Composite), and CPT codes 74177 and 74178 to composite 8006 (CT and CTA With Contrast Composite). We assigned the codes to status indicator ''Q3'' to indicate that the codes were eligible for composite payment under the multiple imaging composite APC methodology when they are furnished with other computed tomography procedures to the same patient on the same day.

Consistent with our longstanding policy for new codes, we assigned these codes to interim APCs for CY 2011, with comment indicator ''NI'' in Addendum B of the CY 2011 OPPS/ASC final rule with comment period denoting that the codes were new with an interim APC assignment on which comments would be accepted. In accordance with our longstanding policy to provide codes to enable payment to be made for new services as soon as the code is effective, our interim APC assignments for each code were based on our understanding of the resources required to furnish the services and their clinical characteristics as defined in the code descriptors.

TABLE 6—CY 2011 OPPS APC ASSIGNMENTS FOR THE COMPUTED TOMOGRAPHY OF ABDOMEN AND PELVIS CPT CODES

CY 2011 CPT Code	CY 2011 short descriptor	CY 2011 SI	CY 2011 single code APC	CY 2011 single code APC payment rate	CY 2011 composite APC	CY 2011 composite APC payment rate
74176	Ct abd & pelvis	Q3	0332	$193.85	8005	$420.85
74177	Ct abd & pelv w/contrast	Q3	0283	299.81	8006	628.61
74178	Ct abd & pelv 1/< regns	Q3	0333	334.24	8006	628.61

As we described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74259), in general, stakeholders who provided comments on the interim assignments of these codes for CY 2011 stated that the most appropriate approach to establishing payment for these new codes was to assign these procedures to APCs that recognize that each of the new codes reflects the reporting under a single code of two services that were previously reported under two separate codes and that, therefore, payments would be more accurate and better reflective of the services under the OPPS if we were to establish payment rates for the codes for CY 2012 using claims data that reflect the combined cost of the two predecessor codes. In addition, at the February 28–March 1, 2011 Panel meeting, several presenters reported their concern and disagreement with our single APC assignments for these new codes. The presenters stated that the payment rates for the single APC assignments reflected only half of the true costs of these services based on their internal calculated costs. Similar to the public commenters, the

presenters indicated that, prior to CY 2011, these services were reported using a combination of codes, and suggested that CMS revise the methodology to include these combinations of codes to determine accurate payment rates for these services. Specifically, the presenters indicated that simulating the costs for CPT codes 74176, 74177, and 74178 using historical claims data from the predecessor codes would result in the best estimates of costs for these codes and, therefore, the most accurate payment rates.

After examination of our claims data for the predecessor codes, and after considering the various concerns and recommendations that we received on this issue (specifically, the views of the stakeholders who met with us to discuss this issue, the comments received in response to the CY 2011 OPPS/ASC final rule with public comment period, and input from the Panel at its February 28–March 1, 2011 meeting), we proposed to revise our payment methodology for CPT codes 74176, 74177, and 74178 for CY 2012 (76 FR 42235). That is, we proposed to simulate the costs for CPT codes 74176, 74177, and 74178 using historical claims data from the predecessor codes to determine the most accurate payment rates for these codes. This new proposed payment methodology necessitated establishing two new APCs, specifically, APC 0331 (Combined Abdominal and Pelvis CT Without Contrast) to which CPT code 74176 would be assigned, and APC 0334 (Combined Abdominal and Pelvis CT With Contrast) to which CPT codes 74177 and 74178 would be assigned. In addition, we proposed to continue to assign CPT code 74176 to composite APC 8005 and CPT codes 74177 and 74178 to composite APC 8006 for CY 2012.

Based on the feedback that we received from the Panel at its August 10–11, 2011 meeting, and the public comments received on the CY 2012 OPPS/ASC proposed rule in support of the proposed revised payment methodology for CPT codes 74176, 74177, and 74178, we finalized our proposals in the CY 2012 OPPS/ASC final rule with comment period. Specifically, we reassigned CPT code 74176 from APC 0332 to APC 0331, CPT code 74177 from APC 0283 to APC 0334, and CPT code 74178 from APC 0333 to APC 0334. (We refer readers to the CY 2012 OPPS/ASC final rule with comment period for a detailed description of the methodology we used to simulate the costs of these procedures using claims data for the predecessor CPT codes (76 FR 74259 through 74262).) We also continued with our composite APC assignments for these codes. Specifically, we continued to assign CPT code 74176 to composite APC 8005 and CPT codes 74177 and 74178 to composite APC 8006. Table 7 below shows the payment rates for these codes for the CY 2012 update.

TABLE 7—CY 2012 OPPS APC ASSIGNMENTS FOR THE COMPUTED TOMOGRAPHY OF ABDOMEN AND PELVIS CPT CODES

CY 2012 CPT Code	CY 2012 short descriptor	CY 2012 SI	CY 2012 single code APC	CY 2012 single code APC payment rate	CY 2012 composite APC	CY 2012 composite APC payment rate
74176	Ct abd & pelvis	Q3	0331	$405.17	8005	$431.60
74177	Ct abd & pelv w/contrast	Q3	0334	580.54	8006	721.12
74178	Ct abd & pelv 1/< regns	Q3	0334	580.54	8006	721.12

We stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74262) that we would reassess whether there is a continued need for these APCs for the CY 2013 OPPS/ASC update once we have actual charges for these services. Because CPT codes 74176, 74177, and 74178 became effective on January 1, 2011, we have hospital claims data available for these codes that we can use for ratesetting for the first time. Analysis of the latest CY 2011 hospital outpatient claims data for the CY 2013 OPPS/ASC proposed rulemaking update, which is based on claims processed with dates of service from January 1, 2011 through December 31, 2011, reveals a decrease in costs for the three procedures, compared to the costs simulated using predecessor CPT codes for CY 2012. CPT code 74176 shows a cost of approximately $314 based on 312,493 single claims (out of 713,662 total claims), while CPT code 74177 reveals a cost of approximately $476 based on 367,002 single claims (out of 951,296 total claims). In addition, CPT code 74178 shows a cost of approximately $537 based on 184,580 single claims (out of 267,401 total claims). Because we used hospital claims data specific to CPT codes 74176, 74177, and 74178, we believe these costs accurately reflect the resources associated with providing computed tomography of the abdomen and pelvis as described by these CPT codes in the HOPD.

Furthermore, our analysis of the CY 2011 claims data available for this proposed rule shows no 2 times rule violation for either APC 0331 or APC 0334. Therefore, for CY 2013, we are proposing to continue to assign CPT code 74176 to APC 0331 and CPT codes 74177 and 74178 to APC 0334. (Because we have claims data available for these three CPT codes, we will no longer simulate their costs using predecessor codes as we did in CY 2012.) In addition, we are proposing to continue to assign these codes to their existing composite APCs for CY 2013. Specifically, we are proposing to continue to assign CPT code 74176 to composite APC 8005, and to assign CPT codes 74177 and 74178 to composite APC 8006. Table 8 below lists the computed tomography of the abdomen and pelvis CPT codes along with their proposed status indicators, and single and composite APC assignments for CY 2013.

TABLE 8—PROPOSED APC ASSIGNMENTS FOR THE COMPUTED TOMOGRAPHY OF ABDOMEN AND PELVIS CPT CODES FOR CY 2013

CY 2012 CPT Code	CY 2012 short descriptor	Proposed CY 2013 SI	Proposed CY 2013 single code APC	Proposed CY 2013 composite APC
74176	Ct abd & pelvis	Q3	0331	8005
74177	Ct abd & pelv w/contrast	Q3	0334	8006
74178	Ct abd & pelv 1/> regns	Q3	0334	8006

(6) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act, as added by section 621(b)(2)(C) of Public Law 108–173 (MMA), mandated the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) (''brachytherapy sources'') separately from other services or groups of services. The additional groups must reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished and include separate groups for palladium-103 and iodine-125 sources. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS proposed and final rules. As we have stated previously (72 FR 66780, 73 FR 41502, 74 FR 60533 through 60534, 75 FR 71978, and 76 FR 74160), we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons. The general OPPS payment methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to cost. We believe that the OPPS prospective payment methodology, as opposed to payment based on hospitals' charges adjusted to cost, would also provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS.

Therefore, for CY 2013, we are proposing to use the costs from CY 2011 claims data for setting the proposed CY 2013 payment rates for brachytherapy sources, as we are proposing for most other items and services that would be paid under the CY 2013 OPPS. We based the proposed rates for brachytherapy sources using geometric mean unit costs for each source, consistent with the methodology proposed for other items and services, discussed in section II.A.2.f. of this proposed rule. We are proposing to continue the other payment policies for brachytherapy sources we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We are proposing to pay for the stranded and non-stranded NOS codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or non-stranded prospective payment rate for such sources, respectively, on a per source basis (as opposed, for example, to a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). We also are proposing to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was superseded for a period of time by section 142 of Pub. L. 110–275). That policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals.

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

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 2013 payment rates for brachytherapy sources, identified with status indicator ''U''. We are inviting public comment on this proposed policy and also requesting recommendations for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources. Such recommendations should be directed to the Division of Outpatient Care, Mail Stop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

e. 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 only necessary, high quality care and to provide that care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims

which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for extended assessment and management services, low dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, multiple imaging services, and cardiac resynchronization therapy services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for a full discussion of the development of the composite APC methodology (72 FR 66611 through 66614 and 66650 through 66652) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) for more recent background.

For CY 2013, 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, multiple imaging services, and cardiac resynchronization therapy services, as discussed in sections II.A.2.e.(1), II.A.2.e.(2), II.A.2.e.(3), II.A.2.e.(4), II.A.2.e.(5), and II.A.2.e.(6), respectively, of this proposed rule.

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

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

For CY 2013, we are proposing to continue the extended assessment and management composite APC payment methodology and criteria for APCs 8002 and 8003 that we finalized for CYs 2009 through 2012. We continue to believe that the composite APCs 8002 and 8003 and related policies provide the most appropriate means of paying for these services. We also are proposing to calculate the costs for APCs 8002 and 8003 using the same methodology that we used to calculate the costs for composite APCs 8002 and 8003 for the CY 2008 OPPS (72 FR 66649). That is, we are proposing to use all single and ''pseudo'' single procedure claims from CY 2011 that met the criteria for payment of each composite APC and apply the standard packaging and trimming rules to the claims before calculating the proposed CY 2013 costs. The proposed CY 2013 cost resulting from this methodology for composite APC 8002 is approximately $446, which was calculated from 17,072 single and ''pseudo'' single bills that met the required criteria. The proposed CY 2013 cost for composite APC 8003 is approximately $813, which was calculated from 255,231 single and ''pseudo'' single bills that met the required criteria.

At its February 2012 meeting, the Advisory Panel on Hospital Outpatient Payment (the Panel) recommended that CMS continue to report clinic/emergency department visit and observation claims data and, if CMS identifies changes in patterns of utilization or cost, that CMS bring those issues to the Visits and Observation Subcommittee. Additionally, the Panel recommended that CMS examine data for discharge status, point of entry, age, primary and secondary diagnoses, and type of hospital (teaching, nonteaching, rural, urban) for patients receiving greater than 48 hours of observation services, if available, and report the findings to the Visits and Observation Subcommittee. The Panel recommended that the Visits and Observation Subcommittee review claims data for HCPCS code G0379 (Direct referral of patient for hospital observation care), and consider the appropriate APC group for the code. The Panel also recommended that the results of CMS' study on unconditionally packaged HCPCS code G0378 (Hospital observation service, per hour) be presented to the Visits and Observation Subcommittee. The Panel recommended that the work of the Visits and Observation Subcommittee continue. We are accepting these recommendations and will provide the requested data to the Panel at a future meeting.

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

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

For CY 2013, 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 2012. That is, we are proposing to use CY 2011 claims on which both CPT codes 55875 and 77778 were billed on the same date of service with no other separately paid procedure codes (other than those on the bypass list) to calculate the payment rate for composite APC 8001. Consistent with our CY 2008 through CY 2012 practice, we are proposing not to use the claims that meet these criteria in the calculation of the costs for APCs 0163 (Level IV Cystourethroscopy and Other Genitourinary Procedures) and 0651 (Complex Interstitial Radiation Source Application), the APCs to which CPT codes 55875 and 77778 are assigned, respectively. We are proposing that the costs for APCs 0163 and 0651 continue

to be calculated 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 2011 claims data available for this CY 2013 proposed rule, we were able to use 650 claims that contained both CPT codes 55875 and 77778 to calculate the cost upon which the proposed CY 2013 payment for composite APC 8001 is based. The proposed cost for composite APC 8001 for CY 2013 is approximately $3,362.

(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 code in Group B for the same beneficiary, payments are made under the appropriate single procedure APCs and the composite APC does not apply.

For CY 2013, 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 2012. We continue to believe that the cost for these services calculated from a high volume of correctly coded multiple procedure claims would result in an accurate and appropriate proposed payment for cardiac electrophysiologic evaluation and ablation services when at least one evaluation service is furnished during the same clinical encounter as at least one ablation service. Consistent with our CY 2008 through CY 2012 practice, we are proposing not to use the claims that meet the composite payment criteria in the calculation of the costs for APCs 0085 and 0086, to which the CPT codes in both Groups A and B for composite APC 8000 are otherwise assigned. The costs for APCs 0085 and 0086 would continue to be calculated using single procedure claims.

For CY 2013, using a partial year of CY 2011 claims data available for this proposed rule, we were able to use 11,358 claims containing a combination of Group A and Group B codes to calculate a proposed cost of approximately $11,458 for composite APC 8000.

Table 9 below lists the proposed groups of procedures upon which we would base composite APC 8000 for CY 2013.

TABLE 9—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	CY 2012 CPT Code	Proposed single code CY 2013 APC	Proposed CY 2013 SI (composite)
Group A			
Comprehensive electrophysiologic evaluation with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording, including insertion and repositioning of multiple electrode catheters, without induction or attempted induction of arrhythmia.	93619	0085	Q3
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording.	93620	0085	Q3
Group B			
Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement.	93650	0085	Q3
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.	93651	0086	Q3
Intracardiac catheter ablation of arrhythmogenic focus; for treatment of ventricular tachycardia	93652	0086	Q3

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

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

Specifically, we 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 partial hospitalization payment, those specified mental health services would be assigned to APC 0034 (Mental Health Services Composite). We are proposing to continue to set the payment rate for APC 0034 at the same rate as we are proposing to pay for APC 0176 (Level II Partial Hospitalization (4 or more services) for Hospital-Based PHPs), which is the maximum partial hospitalization per diem payment, and that the hospital would continue to be paid one unit of APC 0034. Under this proposal, the I/OCE would continue to determine whether to pay for these specified mental health services individually or make a single payment at the same rate as the APC 0176 per diem rate for partial hospitalization for all of the specified mental health services furnished by the hospital on that single date of service. We 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 services under the OPPS than the partial hospitalization per diem rate.

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

Effective January 1, 2009, we provide a single payment each time a hospital bills more than one imaging procedure within an imaging family on the same date of service, in order to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) Ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 8 of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74171 through 74175).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement at 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 2013, 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 payment methodology. We continue to believe that this policy would continue to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session. The proposed CY 2013 payment rates for the five multiple imaging composite APCs (APC 8004, APC 8005, APC 8006, APC 8007, and APC 8008) are based on costs calculated from a partial year of CY 2011 claims available for this CY 2013 OPPS/ASC proposed rule that qualified for composite payment under the current policy (that is, those claims with more than one procedure within the same family on a single date of service). To calculate the proposed costs, we used the same methodology that we used to calculate the final CY 2012 costs for these composite APCs, as described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74169). The imaging HCPCS codes that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC costs, pursuant to our established methodology (76 FR 74169), appear in Table 11 of this proposed rule.

We were able to identify approximately 1.0 million ''single session'' claims out of an estimated 1.5 million potential composite cases from our ratesetting claims data, more than half of all eligible claims, to calculate the proposed CY 2013 costs for the multiple imaging composite APCs.

Table 10 below lists the proposed HCPCS codes that would be subject to the multiple imaging composite policy and their respective families and approximate proposed composite APC costs for CY 2013. Table 11 below lists the OPPS imaging family services that overlap with HCPCS codes on the proposed CY 2013 bypass list.

TABLE 10—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1—Ultrasound

Proposed CY 2013 APC 8004 (Ultrasound Composite)	Proposed CY 2013 Approximate APC Cost = $201
76604	Us exam, chest.
76700	Us exam, abdom, complete.
76705	Echo exam of abdomen.
76770	Us exam abdo back wall, comp.
76775	Us exam abdo back wall, lim.
76776	Us exam k transpl w/Doppler.
76831	Echo exam, uterus.
76856	Us exam, pelvic, complete.
76870	Us exam, scrotum.
76857	Us exam, pelvic, limited.

Family 2—CT and CTA with and without Contrast

Proposed CY 2013 APC 8005 (CT and CTA without Contrast Composite)*	Proposed CY 2013 Approximate APC Cost = $412
70450	Ct head/brain w/o dye.
70480	Ct orbit/ear/fossa w/o dye.
70486	Ct maxillofacial w/o dye.
70490	Ct soft tissue neck w/o dye.
71250	Ct thorax w/o dye.
72125	Ct neck spine w/o dye.
72128	Ct chest spine w/o dye.
72131	Ct lumbar spine w/o dye.
72192	Ct pelvis w/o dye.
73200	Ct upper extremity w/o dye.
73700	Ct lower extremity w/o dye.
74150	Ct abdomen w/o dye.
74261	Ct colonography, w/o dye.
74176	Ct angio abd & pelvis.

Proposed CY 2013 APC 8006 (CT and CTA with Contrast Composite)	Proposed CY 2013 Approximate APC Cost = $700
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.

TABLE 10—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

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

Family 3—MRI and MRA with and without Contrast

Proposed CY 2013 APC 8007 (MRI and MRA without Contrast Composite)*	Proposed CY 2013 Approximate APC Cost = $725
70336	Magnetic image, jaw joint.
70540	Mri orbit/face/neck w/o dye.
70544	Mr angiography head w/o dye.
70547	Mr angiography neck w/o dye.
70551	Mri brain w/o dye.
70554	Fmri brain by tech.
71550	Mri chest w/o dye.
72141	Mri neck spine w/o dye.
72146	Mri chest spine w/o dye.
72148	Mri lumbar spine w/o dye.
72195	Mri pelvis w/o dye.
73218	Mri upper extremity w/o dye.
73221	Mri joint upr extrem w/o dye.
73718	Mri lower extremity w/o dye.
73721	Mri jnt of lwr extre w/o dye.
74181	Mri abdomen w/o dye.
75557	Cardiac mri for morph.
75559	Cardiac mri w/stress img.
C8901	MRA w/o cont, abd.
C8904	MRI w/o cont, breast, uni.
C8907	MRI w/o cont, breast, bi.
C8910	MRA w/o cont, chest.
C8913	MRA w/o cont, lwr ext.
C8919	MRA w/o cont, pelvis.
C8932	MRA, w/o dye, spinal canal.
C8935	MRA, w/o dye, upper extr.
Proposed CY 2013 APC 8008 (MRI and MRA with Contrast Composite)	**Proposed CY 2013 Approximate APC Cost = $1,066**
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.
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.

TABLE 10—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

C8911	MRA w/o fol w/cont, chest.
C8912	MRA w/cont, lwr ext.
C8914	MRA w/o fol w/cont, lwr ext.
C8918	MRA w/cont, pelvis.
C8920	MRA w/o fol w/cont, pelvis.
C8931	MRA, w/dye, spinal canal.
C8933	MRA, w/o&w/dye, spinal canal.
C8934	MRA, w/dye, upper extremity.
C8936	MRA, w/o&w/dye, upper extr.

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

TABLE 11—PROPOSED OPPS IMAGING FAMILY SERVICES OVERLAPPING WITH HCPCS CODES ON THE CY 2013 BYPASS LIST

Family 1—Ultrasound	
76700	Us exam, abdom, complete.
76705	Echo exam of abdomen.
76770	Us exam abdo back wall, comp.
76775	Us exam abdo back wall, lim.
76776	Us exam k transpl w/Doppler.
76856	Us exam, pelvic, complete.
76870	Us exam, scrotum.
76857	Us exam, pelvic, limited.

Family 2—CT and CTA with and without Contrast	
70450	Ct head/brain w/o dye.
70480	Ct orbit/ear/fossa w/o dye.
70486	Ct maxillofacial w/o dye.
70490	Ct soft tissue neck w/o dye.
71250	Ct thorax w/o dye.
72125	Ct neck spine w/o dye.
72128	Ct chest spine w/o dye.
72131	Ct lumbar spine w/o dye.
72192	Ct pelvis w/o dye.
73200	Ct upper extremity w/o dye.
73700	Ct lower extremity w/o dye.
74150	Ct abdomen w/o dye.

Family 3—MRI and MRA with and without Contrast	
70336	Magnetic image, jaw joint.
70544	Mri angiography head w/o dye.
70551	Mri brain w/o dye.
71550	Mri chest w/o dye.
72141	Mri neck spine w/o dye.
72146	Mri chest spine w/o dye.
72148	Mri lumbar spine w/o dye.
73218	Mri upper extremity w/o dye.
73221	Mri joint upr extrem w/o dye.
73718	Mri lower extremity w/o dye.
73721	Mri jnt of lwr extre w/o dye.

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

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

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

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74176 through 74182) for a full description of how we developed this policy.

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

- 33206 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial);
- 33207 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); ventricular);
- 33208 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular);
- 33212 (Insertion or replacement of pacemaker pulse generator only; single chamber, atrial or ventricular);
- 33213 (Insertion or replacement of pacemaker pulse generator only; dual chamber, atrial or ventricular);
- 33214 (Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator));
- 33216 (Insertion of a single transvenous electrode, permanent pacemaker or cardioverter-defibrillator);
- 33217 (Insertion of 2 transvenous electrodes, permanent pacemaker or cardioverter-defibrillator);
- 33222 (Revision or relocation of skin pocket for pacemaker);
- 33233 (Removal of permanent pacemaker pulse generator);

- 33234 (Removal of transvenous pacemaker electrode(s); single lead system, atrial or ventricular);
- 33235 (Removal of transvenous pacemaker electrode(s); dual lead system, atrial or ventricular);
- 33240 (Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator); or
- 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator).

For CY 2013, we are proposing to continue to recognize CRT–D as a single, composite service as described above and finalized in the CY 2012 OPPS/ASC final rule with comment period. By continuing to recognize these procedures as a single, composite service, we are able to use a higher volume of correctly coded claims for CPT code 33225, which, because of its add-on code status, is always performed in conjunction with another procedure and, therefore, to address the inherent ratesetting challenges associated with CPT code 33225. We also note that this policy is consistent with the principles of a prospective payment system, specifically to place similar services that utilize technologies with varying costs in the same APC in order to promote efficiency and decision making based on individual patient's clinical needs rather than financial considerations. In calculating the costs upon which the payment rate for APC 0108 is based for CY 2013, for this proposed rule, we included single procedure claims for the individual services assigned to APC 0108, as well as single procedure claims that contain the composite CRT–D service, defined as the combination of CPT codes 33225 and 33249 with the same date of service. We were able to use 9,790 single bills from the CY 2013 proposed rule claims data to calculate a proposed cost of approximately $31,491 for APC 0108. Because CPT codes 33225 and 33249 may be treated as a composite service for payment purposes, we are proposing to continue to assign them status indicator ''Q3'' (Codes that may be paid through a composite APC) in Addendum B to this proposed rule. The assignment of CPT codes 33225 and 33249 to APC 0108 when treated as a composite service is also reflected in Addendum M to this proposed rule (which is available via the Internet on the CMS Web site).

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

f. Proposed Geometric Mean-Based Relative Payment Weights

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

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

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

Section 1833 of the Act set forth the methodological requirements for developing the PPS for hospital outpatient services (the OPPS). At the onset of the OPPS, there was significant concern over observed increases in the volume of outpatient services, and corresponding rapidly growing beneficiary coinsurance. Accordingly, much of the focus was on finding ways to address those issues. The OPPS statute, section 1833(t)(2)(C) of the Act, initially provided that relative payment weights for covered outpatient department services be established based on median costs under section 4523(a) of the BBA of 1997. Later, section 201(f) of the BBRA of 1999 amended section 1833(t)(2)(C) of the Act to allow the Secretary the discretion to base the establishment of relative payment weights on either median or mean hospital costs. Since the OPPS was initially implemented, we have established relative payment weights based on the median hospital costs for both statistical reasons and timely implementation concerns. The proposed

rule for the OPPS was published prior to the passage of the BBRA of 1999, which amended the Act to permit the use of mean costs. At that time, we noted that making payment for hospital outpatient services based on the median cost of each APC was a way of discouraging upcoding that occurs when individual services that are similar have disparate median costs, as well as associating services for which there are low claims volume into the appropriate classifications based on clinical patterns and their resource consumption (63 FR 47562).

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

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

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

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

In our experience in working with the OPPS, we also have implemented many processes to ensure that the cost information we derive from cost reports and claims data is accurate. In the beginning of the OPPS, we implemented a cost trim of three standard deviations outside the geometric mean cost, similar to the cost data trim in the IPPS, because it would ensure that the most aberrant data were removed from ratesetting (65 FR 18484). We also have implemented similar trims to the hospital departmental CCR and claims based unit data related to the services (71 FR 67985 through 67987).

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

In CY 2010, we incorporated a line item trim into our data process that removed lines that were eligible for OPPS payment in the claim year but received no payment, presumably because of a line item rejection or denial due to claims processing edits (74 FR 60359). This line item trim was developed with the goal of using additional lines to model prospective payment.

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

While we have already implemented numerous changes to the data process in order to obtain accurate resource cost estimates associated with providing a procedure, we continue to examine possible areas of improvement. In the past, commenters have expressed

concern over the degree to which payment rates reflect the costs associated with providing a service, believing that, in some cases, high cost items or services that might be packaged are not accordingly reflected in the payment weights (72 FR 66629 through 66630 and 66767). As mentioned above, in the CY 2008 OPPS/ASC final rule with comment period, we developed a packaging policy that identified a number of clinical areas where services would be commonly performed in a manner that was typically ancillary and supportive to other primary procedures. Packaging for appropriate clinical areas provides an incentive for efficient and cost-effective delivery of services. In that final rule with comment period, we recognized that there were strengths and weaknesses associated with using median costs as the metric for developing the OPPS payment weights (72 FR 66615). Medians are generally more stable than means because they are less sensitive to extreme observations, but they also do not reflect subtle changes in cost distributions. As a result, the use of medians rather than means under the OPPS usually results in relative weight estimates being less sensitive to packaging decisions, as well as changes in the cost model due to factors such as the additional claims processed between the proposed rule and the final rule.

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

We recognize that median costs have historically served and may continue to serve as an appropriate measure on which to establish relative payments weights. However, as discussed above, the metric's resistance to outlier observations is balanced by its limited ability to be reflective of changes to the dataset used to model cost or changes beyond the center of the dataset. While there was significant concern in the initial years of the OPPS regarding outlier cost values and the possible introduction of potentially aberrant values in the cost modeling, hospital experience in coding under the system, the data modeling improvements we have made to obtain more accurate cost information while removing erroneous data, and other changes in our experience with the system have all lessened the potential impact of error values (rather than actual, accurate cost outliers). As noted above, over the history of the OPPS, we have made multiple refinements to the data process to better capture service costs, respond to commenter concerns regarding the degree to which OPPS relative payment weights accurately reflect service cost and APC payment volatility from year to year, and better capture the variety of resource cost associated with providing a service as provided under section 1833(t)(2)(C) of the Act. For CY 2013, we are proposing to shift the basis for the CY 2013 APC relative payment weights that underpin the OPPS from median costs to geometric means based costs.

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

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

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

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

For the reasons described above, we are proposing to establish the CY 2013 OPPS relative payment weights based on geometric mean costs. While this would involve a change to the metric used to develop the relative payment weights, the use of claims would not be affected. We are proposing to continue subsetting claims using the data processes for modeling the standard APCs and the criteria-based APCs described in section II.A.2. of this

proposed rule, where appropriate. The reasoning behind implementing modeling edits or changes in the criteria-based APCs would not be affected because the process of developing the relative payment weights based on a measure of central tendency is the last step of the modeling process, and occurs only once the set of claims used in ratesetting has been established.

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

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

We note that this proposal to establish all OPPS relative payment weights using geometric mean costs would apply to all APCs that would have previously been paid based on median costs. In addition, we are proposing that the relative payment weights for line item based payments such as brachytherapy sources, which are discussed in section II.A.2.d.(6) of this proposed rule, as well as blood and blood products, which are discussed in II.A.2.d.(2) of this proposed rule, be calculated based on their geometric mean costs for the CY 2013 OPPS.

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

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

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

We are proposing for CY 2013 that payment for nonpass-through separately payable drugs and biologicals will continue to be developed through its own separate process. Payments for drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, but the budget neutral weight scaler is not applied to their payments because they are developed through a separate methodology, outside the relative payment weight based process. We note that, for CY 2013, we are proposing to pay for nonpass-through separately payable drugs and biologicals under the OPPS at ASP+6 percent, based upon the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. Also, as is our standard methodology, for CY 2013, we are proposing to use payment rates based on the ASP data from the fourth quarter of CY 2011 for budget neutrality estimates, packaging determinations, and the impact analyses. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we are proposing to use their mean unit cost derived from the CY 2011 hospital claims data to determine their per day cost. The proposed nonpass-through separately payable drug and biological payment policy for CY 2013 is described in greater detail in section V.B. of this proposed rule.

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

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

In the Addenda to this proposed rule (which are available via Internet on the CMS Web site), we are including a comparison file that identifies differences in the proposed payments between a geometric means-based OPPS and a median-based OPPS. In section XXII. of this proposed rule, which

discusses the regulatory impact analysis, we are providing an additional column in the impact tables for the OPPS that identifies the estimated impact due to APC recalibration of a geometric means-based OPPS as well as a column that estimates the impact of recalibration based on CY 2011 claims and historical cost report data. We are including in the Addenda to this proposed rule (which is available via the Internet on the CMS Web site) data that compare the budget neutral OPPS payments based on geometric means to the budget neutral OPPS payments based on medians. As depicted in the impact tables, many provider categories would experience limited impacts under the proposal to base the OPPS relative payment weights on geometric means. We note that the impact tables only estimate the OPPS payment impact based on the most current available claims and cost report data, and that providers' actual payments may vary, depending on the mix of services provided in the actual claims year. Also, the budget neutral payment adjustments ensure that, under either a geometric mean-based system or a median cost-based system, aggregate OPPS payments would remain the same.

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

In our experience developing the OPPS, we have implemented many changes to obtain more cost information from the claims and cost report data available to us, in an effort to arrive at more accurate estimates of service cost. Many of those changes are described above and in prior OPPS final rules. Despite the challenges created by the complexity of the data and the diversity of facility accounting systems, we continue to examine possible process and data changes that may further improve precision, validity, and utility. Commenters have historically expressed concerns about the degree to which OPPS relative payment weights are reflective of the service costs associated with providing them, APC payment rate volatility from year to year, and other cost modeling related issues. We recognize that some of those issues will continue because they are related to naturally occurring changes in the economic environment, clinical practice, and the nature of payment systems, among other reasons. However, we believe that basing the OPPS relative payment weights on geometric means would better capture the range of costs associated with providing services, improve payment accuracy while limiting year-to-year volatility, and allow reconfigurations in the APC environment using a metric that provides greater computational depth. For these reasons, and those discussed above, we are proposing to base the CY 2013 OPPS/ASC relative payment weights on geometric mean costs.

3. Proposed Changes to Packaged Services

a. Background

Like other prospective payment systems, the OPPS relies on the concept of averaging, where the payment may be more or less than the estimated cost of providing a specific service or bundle of specific services for a particular patient. However, with the exception of outlier cases, overall payment is adequate to ensure access to appropriate care. The OPPS packages payment for multiple interrelated services into a single payment to create incentives for providers to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby encouraging long-term cost containment. For example, where there are a variety of supplies that could be used to furnish a service, some of which are more expensive than others, packaging encourages hospitals to use the least expensive item that meets the patient's needs, rather than to routinely use a more expensive item, which could result if separate payment is provided for the items. Packaging also encourages hospitals to negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging also may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary services and lower cost cases requiring fewer ancillary services. For these reasons, packaging payment for items and services that are typically ancillary and supportive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000.

We use the term ''dependent service'' to refer to the HCPCS codes that represent services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality. We use the term ''independent service'' to refer to the HCPCS codes that represent the primary therapeutic or diagnostic modality into which we package payment for the dependent service. In future years, as we consider the development of larger payment groups that more broadly reflect services provided in an encounter or episode of care, it is possible that we might propose to bundle payment for a service that we now refer to as ''independent.''

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

We assign status indicator ''Q1'' (STVX-Packaged Codes), ''Q2'' (T-Packaged Codes), or ''Q3'' (Codes that may be paid through a composite APC) to each conditionally packaged HCPCS code. An STVX-packaged code describes a HCPCS code whose payment is packaged with one or more separately paid primary services with the status indicator of ''S,'' ''T,'' ''V,'' or ''X'' furnished in the hospital outpatient encounter. A T-packaged code describes a code whose payment is only packaged

with one or more separately paid surgical procedures with the status indicator of ''T'' are provided during the hospital outpatient encounter. STVX-packaged codes and T-packaged codes are paid separately in those uncommon cases when they do not meet their respective criteria for packaged payment. STVX-packaged codes and T-packaged codes are conditionally packaged. We refer readers to section XII.A.1. of this proposed rule and Addendum D1, which is available via the Internet on the CMS Web site with other Addenda, for a complete listing of status indicators and the meaning of each status indicator.

Hospitals include HCPCS codes and charges for packaged services on their claims, and the estimated costs associated with those packaged services are then added to the costs of separately payable procedures on the same claims to establish prospective payment rates. We encourage hospitals to report all HCPCS codes that describe packaged services provided, unless the CPT Editorial Panel or CMS provides other guidance. The appropriateness of the OPPS payment rates depends on the quality and completeness of the claims data that hospitals submit for the services they furnish to Medicare beneficiaries.

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

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

We are proposing to clarify the regulatory language at 42 CFR 419.2(b) to make explicit that the OPPS payments for the included costs of the nonexclusive list of items and services covered under the OPPS referred to in this paragraph are packaged into the payments for the related procedures or services with which such items and services are provided. This proposed clarification is consistent with our interpretation and application of § 419.2(b) since the inception of the OPPS. We invite public comments on this proposed clarification.

c. Packaging Recommendations of the HOP Panel (''The Panel'') at Its February 2012 Meeting

During its February 2012 meeting, the Panel made five recommendations related to packaging and to the function of the subcommittee. One additional recommendation that originated from the APC Groups and Status Indicator (SI) Assignment Subcommittee about observation services is discussed in section II.A.2.e. of this proposed rule. The report of the February 2012 meeting of the Panel may be found on the CMS Web site at: *http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp*.

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

Panel Recommendation: CMS should delete HCPCS code G0259 (Injection procedure for sacroiliac joint; arthrography) and HCPCS code G0260 (Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography), and instead use CPT code 27096 (Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography, when performed) with a status indicator of ''T,'' and assign CPT code 27096 to APC 0207 (Level III Nerve Injections).

CMS Response: For CY 2012, we assigned CPT code 27096 to status indicator ''B,'' meaning that this code is not payable under the OPPS. In order to receive payment for procedures performed on the sacroiliac joint with or without arthrography or with image guidance under the OPPS, hospitals must use either HCPCS code G0259, which is assigned to status indicator ''N'' for CY 2012, or HCPCS code G0260, which is assigned to status indicator ''T'' for CY 2012, as appropriate. CMS created HCPCS codes G0259 and G0260 to separate and distinguish the image guidance procedure from the therapeutic injection procedure for the sacroiliac joint. As stated above, guidance procedures are packaged under the OPPS because we believe that they are typically ancillary and supportive to a primary diagnostic or therapeutic modality and are an integral part of the primary service they support.

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

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

- HCPCS code 21116 (Injection procedure for temporomandibular joint arthrography);
- HCPCS code 23350 (Injection procedure for shoulder arthrography or enhanced CT/MRI shoulder arthrography);
- HCPCS code 24220 (Injection procedure for elbow arthrography);
- HCPCS code 25246 (Injection procedure for wrist arthrography);
- HCPCS code 27093 (Injection procedure for hip arthrography; without anesthesia);
- HCPCS code 27095 (Injection procedure for hip arthrography; with anesthesia);
- HCPSC code 27096 (Injection procedure for sacroiliac joint, anesthetic/steroid with image guidance (fluoroscopy or CT) including arthrography when performed);
- HCPCS code 27370 (Injection procedure for knee arthrography); and
- HCPCS code 27648 (Injection procedure for ankle arthrography).

CMS Response: We are accepting the Panel's recommendation that CMS provide data to the APC Groups and SI Assignment Subcommittee on HCPCS codes 21116, 23350, 24220, 25246, 27093, 27095, 27096, 27370, and 27648 at a future Panel meeting.

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

CMS Response: We agree with the Panel that proposing a status indicator of ''Q1'' is appropriate for HCPCS code

19290. This status indicator would allow for separate payment when this procedure is performed alone or packaged payment when this procedure is performed with an associated surgical procedure. Therefore, we are accepting the Panel's recommendation and are proposing to assign HCPCS code 19290 to APC 0340 (Minor Ancillary Procedures) and status indicator ''Q1'' for the CY 2013 OPPS. APC 0340 has a proposed cost of approximately $50.19 for CY 2013.

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

CMS Response: We are accepting the Panel's recommendation that Judith Kelly, R.H.I.T., R.H.I.A., C.C.S., continue to chair the APC Groups and SI Assignment Subcommittee.

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

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

d. Proposed Packaging of Drugs, Biologicals, and Radiopharmaceuticals

(1) Existing Packaging Policies

In the OPPS, we currently package five categories of drugs, biologicals, and radiopharmaceuticals (unless temporary pass-through status applies): (1) Those with per day costs at or below the packaging threshold; (2) diagnostic radiopharmaceuticals; (3) contrast agents; (4) anesthesia drugs; and (5) drugs treated as surgical supplies. Anesthesia drugs are discussed further in section II.A.3.c.(2) of this proposed rule. For detailed discussions of the established packaging policies for diagnostic radiopharmaceuticals and contrast agents, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765 through 66768). For further details on drugs treated as surgical supplies, we refer readers to the CY 2003 OPPS final rule (67 FR 66767) and Chapter 15, Section 50.2 of the Medicare Benefit Policy Manual.

(2) Clarification of Packaging Policy for Anesthesia Drugs

It has been longstanding OPPS policy to package ''anesthesia'' and ''supplies and equipment for administering and monitoring anesthesia or sedation,'' as described in 42 CFR 419.2(b)(4) and (b)(5). As described above, items and services paid under the OPPS that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are considered dependent items and services are packaged into the payment of their accompanying independent primary service. In accordance with our current policy on packaging items and services, drugs that are used to produce anesthesia in all forms are ancillary and supportive to a primary diagnostic or therapeutic modality, and are included in our definition of ''anesthesia'' as described in § 419.2(b)(4) and (b)(5). However, we recognize that some anesthesia drugs may qualify for transitional pass-through status under section 1833(t)(6) of the Act. Therefore, in this proposed rule, we are clarifying that our general policy is to package drugs used to produce anesthesia, and that those anesthesia drugs with pass-through status will be packaged upon the expiration of pass-through status. We are inviting public comment on our clarification of the existing packaging policies for anesthesia drugs under § 419.2(b)(4) and (b)(5).

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

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

As set forth at § 419.2(b), as a prospective payment system, the OPPS establishes a national payment rate, standardized for geographical wage differences, that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis, and in general, these costs include, but are not limited to, implantable prosthetics, implantable durable medical equipment, and medical and surgical supplies. Packaging costs into a single aggregate payment for a service, encounter, or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiency and also enables hospitals to manage their resources with maximum flexibility.

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

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

Therefore, we believe it is appropriate to propose to continue to treat diagnostic radiopharmaceuticals and contrast agents differently from specified covered outpatient drugs (SCODs) for CY 2013. Therefore, we are proposing to continue packaging payment for all contrast agents and diagnostic radiopharmaceuticals, collectively referred to as ''policy-packaged'' drugs, regardless of their per

day costs, for CY 2013. We also are proposing to continue to package the payment for diagnostic radiopharmaceuticals into the payment for the associated nuclear medicine procedure and to package the payment for contrast agents into the payment for the associated echocardiography imaging procedure, regardless of whether the agent met the OPPS drug packaging threshold. We refer readers to the CY 2010 OPPS/ASC final rule with comment period for a detailed discussion of nuclear medicine and echocardiography services (74 FR 35269 through 35277).

For CY 2013, we are proposing to make an additional payment of $10 for diagnostic radiopharmaceuticals that utilize the Tc-99m radioisotope produced by non-HEU methods. We are proposing to base this payment on the best available estimations of the marginal costs associated with non-HEU radioisotope production, pursuant to our authority described in section 1833(t)(2)(E) of the Act which allows us to establish ''other adjustments as determined to be necessary to ensure equitable payments'' under the OPPS. We describe this proposed policy in further detail in section III.C.3. of this proposed rule.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68634), we began packaging the payment for all nonpass-through implantable biologicals into payment for the associated surgical procedure because we consider these products to always be ancillary and supportive to independent services, similar to implantable nonbiological devices that are always packaged. We continued to follow this policy in CY 2012 (76 FR 74306 through 74310). Specifically, we continue to package payment for nonpass-through implantable biologicals, also known as devices that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body. For CY 2013, we are proposing to continue to apply the policies finalized in CY 2012, to package payment for nonpass-through implantable biologicals (''devices'') that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body.

Although our final CY 2009 policy (which we are proposing to continue for CY 2013 as discussed below) packaged payment for all diagnostic radiopharmaceuticals and contrast agents into the payment for their associated procedures, we are proposing to continue to provide payment for these items in CY 2013 based on a proxy for average acquisition cost, as we did in CY 2009. We continue to believe that the line-item estimated cost for a diagnostic radiopharmaceutical or contrast agent in our claims data is a reasonable approximation of average acquisition and preparation and handling costs for diagnostic radiopharmaceuticals and contrast agents, respectively. As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68645), we believe that hospitals have adapted to the CY 2006 coding changes for radiopharmaceuticals and responded to our instructions to include charges for radiopharmaceutical handling in their charged for the radiopharmaceutical products. Further, because the standard OPPS packaging methodology packaged the total estimated cost of each diagnostic radiopharmaceutical and contrast agent on each claim (including the full range of costs observed on the claims) with the costs of associated procedures for ratesetting, this packaging approach is consistent with considering the average cost for diagnostic radiopharmaceuticals and contrast agents. In addition, as we noted in the CY 2009 OPPS/ASC final rule with comment period (72 FR 68646), these drugs, biologicals, or radiopharmaceuticals for which we have not established a separate APC and, therefore, for which payment would be packaged rather than separately provided under the OPPS, are considered to not be SCODs. Similarly, drugs and biologicals with per day costs of less than $80 in CY 2013, which is the proposed packaging threshold for CY 2013, that are packaged and for which a separate APC has not been established also are not SCODs. This reading is consistent with our proposed payment policy whereby we package payment for diagnostic radiopharmaceuticals and contrast agents and provide payment for these products through payment for their associated procedures.

f. Summary of Proposals

The HCPCS codes that we are proposing for unconditionally packaged (for which we are proposing to continue to assign status indicator ''N''), or conditionally packaged (for which we are proposing continue to assign status indicators ''Q1,'' ''Q2,'' or ''Q3''), are displayed in Addendum B of this proposed rule (which is available via the Internet on the CMS Web site). The supporting documents for this CY 2013 OPPS/ASC proposed rule, including, but not limited to, Addendum B, are available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. To view the proposed status indicators by HCPCS code in Addendum B, select ''CMS 1589–P'' and then select the folder labeled ''2013 OPPS Proposed Rule Addenda'' from the list of supporting files. Open the zipped file and select Addendum B, which is available as both an Excel file and a text file.

4. Proposed Calculation of OPPS Scaled Payment Weights

For CY 2013, we are proposing to calculate the relative payment weights for each APC for CY 2013 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 CY 2013, we are proposing to base the relative payment weights on which OPPS payments will be made by using geometric mean costs, as described in section II.A.2.f. of this proposed rule. However, in an effort to maintain consistency in calculating unscaled weights that represent the cost of some of the most frequently provided services, we are proposing to continue to use the cost of the mid-level clinic visit APC (APC 0606) in calculating unscaled weights. Following our general methodology for establishing relative payment weights derived from APC costs, but using the proposed CY 2013 geometric mean cost for APC 0606, for CY 2013, we are proposing to assign APC 0606 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the proposed geometric mean cost for APC 0606 to derive the proposed unscaled relative payment weight for each APC. The choice of the APC on which to base the proposed relative payment weights for all other APCs does not affect the payments made under the OPPS

because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2013 is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To comply with this requirement concerning the APC changes, we are proposing to compare the estimated aggregate weight using the CY 2012 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2013 unscaled relative payment weights. For CY 2012, we multiplied the CY 2012 scaled APC relative weight applicable to a service paid under the OPPS by the volume of that service from CY 2011 claims to calculate the total weight for each service. We then added together the total weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2013, we are proposing to perform the same process using the proposed CY 2013 unscaled weights rather than scaled weights. We then calculate the proposed weight scaler by dividing the CY 2012 estimated aggregate weight by the proposed CY 2013 estimated aggregate weight. The service-mix is the same in the current and prospective years because we use the same set of claims for service volume in calculating the aggregate weight for each year. For a detailed discussion of the weight scaler calculation, we refer readers to the OPPS claims accounting document available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. We are proposing to include estimated payments to CMHCs in our comparison of estimated unscaled weights in CY 2013 to estimated total weights in CY 2012 using CY 2011 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we adjusted the proposed unscaled relative payment weights for purposes of budget neutrality. The proposed CY 2013 unscaled relative payment weights were adjusted by multiplying them by a proposed weight scaler of 1.3504 to ensure that the proposed CY 2013 relative payment weights are budget neutral.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act states that ''Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.'' Therefore, the cost of those SCODs (as discussed in section V.B.3. of this proposed rule) was included in the proposed budget neutrality calculations for the CY 2013 OPPS.

We note that we are providing additional information, in association with this proposed rule, so that the public can provide meaningful comment on our proposal to base the CY 2013 OPPS relative payment weights on geometric mean costs. We will make available online a file that compares the calculated CY 2013 proposed OPPS payments using geometric mean costs to those that would be calculated based on median costs. The proposed scaled 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 us to update the conversion factor used to determine payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27975), consistent with current law, based on IHS Global Insight, Inc.'s first quarter 2012 forecast of the FY 2013 market basket increase, the proposed FY 2013 IPPS market basket update is 3.0 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(ii) of the Act, as added by section 3401(i) of Public Law 111–148 and as amended by section 10319(g) of that law and further amended by section 1105(e) of Public Law 111–152, provide adjustments to the OPD fee schedule increase factor for CY 2013.

Specifically, section 1833(t)(3)(F) requires that the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the adjustments described in that section. Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27975 through 27976), we discuss the calculation of the proposed MFP adjustment for FY 2013, which is 0.8 percentage point.

We are proposing that if more recent data are 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 2013 market basket update and the MFP adjustment, components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and (F) of the Act, in the CY 2013 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that for, each of 2010 through 2019, the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act be reduced by the adjustment described in section 1833(t)(3)(G) of the Act. For CY 2013, section 1833(t)(3)(G)(ii) of the Act provides a 0.1 percentage point reduction to the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act. Therefore, in accordance with sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act, we are proposing to apply a 0.1 percentage point reduction to the OPD fee schedule increase factor for CY 2013.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 for a year, and may result in payment rates under the OPPS for a year being less than such payment rates for the preceding year. As described in further detail below, we are proposing to apply an OPD fee schedule increase factor of 2.1 percent for the CY 2013 OPPS (3.0 percent, which is the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.8

percentage point MFP adjustment, less the 0.1 percentage point additional adjustment).

We note that hospitals that fail to meet the Hospital OQR Program reporting requirements would to be 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 made 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 0.1 (3.0 percent, which is the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.8 percentage point MFP adjustment, less the 0.1 percentage point additional adjustment, less 2.0 percentage point for the Hospital OQR Program reduction). For further discussion of the Hospital OQR Program, we refer readers to section XV.F. 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 (*4*) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2013, we reduce the OPD fee schedule increase factor by the multifactor productivity adjustment as determined by CMS, and to reflect the requirement in section 1833(t)(3)(G)(ii) of the Act, as required by section 1833(t)(3)(F)(ii) of the Act, that we reduce the OPD fee schedule increase factor by an additional 0.1 percentage point for CY 2013.

To set the OPPS conversion factor for CY 2013, we are proposing to increase the CY 2012 conversion factor of $70.016 by 2.1 percent. In accordance with section 1833(t)(9)(B) of the Act, we are proposing to further adjust the conversion factor for CY 2013 to ensure that any revisions we make to the updates for a revised wage index and rural adjustment are made on a budget neutral basis. We calculated an overall proposed budget neutrality factor of 1.0003 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2013 IPPS wage indices to those payments using the current (FY 2012) IPPS wage indices, as adopted on a calendar year basis for the OPPS (77 FR 27946 through 27955).

For CY 2013, 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 2013, 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 2013 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing the estimated total CY 2013 payments under section 1833(t) of the Act including the proposed CY 2013 cancer hospital payment adjustment to the estimated CY 2013 total payments using the CY 2012 final cancer hospital payment adjustment under sections 1833(t)(18)(B) and 1833(t)(2)(E) of the Act. The difference in the CY 2013 estimated payments due to applying the proposed CY 2013 cancer hospital payment adjustment relative to the CY 2012 final cancer hospital payment adjustment does not have a significant impact on the budget neutrality calculation. Therefore, we are proposing to apply a proposed budget neutrality adjustment factor of 1.0000 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 2013 would equal approximately $84 million, which represents 0.18 percent of total projected CY 2013 OPPS spending. Therefore, the proposed conversion factor would also be adjusted by the difference between the 0.22 percent estimate of pass-through spending for CY 2012 and the 0.18 percent estimate of CY 2013 pass-through spending, resulting in a proposed adjustment for CY 2013 of 0.04 percent. Finally, estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2013.

The proposed OPD fee schedule increase factor of 2.1 percent for CY 2013 (that is, the estimate of the hospital inpatient market basket percentage increase of 3.0 percent less the proposed 0.8 percentage point MFP adjustment and less the 0.1 percentage point required under section 1833(t)(3)(F) of the Act), the required proposed wage index budget neutrality adjustment of approximately 1.0003, the proposed cancer hospital payment adjustment of 1.000, and the proposed adjustment of 0.04 percent of projected OPPS spending for the difference in the pass-through spending result in a proposed conversion factor for CY 2013 of $71.537.

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 XV.F. of this proposed rule. To calculate the proposed CY 2013 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the Hospital OQR Program for the full CY 2013 payment update, we are proposing to make all other adjustments discussed above, but using a proposed reduced OPD fee schedule update factor of 0.1 percent (that is, the proposed OPD fee schedule increase factor of 2.1 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 2013 of $70.106 for those hospitals that fail to meet the Hospital OQR requirements (a difference of -$1.431 in the conversion factor relative to those hospitals that met the Hospital OQR requirements).

In summary, for CY 2013, we are proposing to use a conversion factor of $71.537 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs. For further discussion on the proposal to base the CY 2013 OPPS relative payment weights using geometric mean costs, we refer readers to section II.A.2.f. of this proposed rule. We are proposing to amend § 419.32(b)(1)(iv)(B) by adding a new paragraph (*4*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2013 in order to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(ii) of the Act. We are proposing to use a reduced conversion factor of $70.106 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 account for geographic wage differences in a portion of the OPPS payment rate, which

includes the copayment standardized amount and is attributable to labor and labor-related costs. This portion of the OPPS payment rate is called the OPPS labor-related share. This adjustment must be made in a budget neutral manner and budget neutrality is discussed in section II.B. of this 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 2013 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 FY 2013 pre-reclassified wage index that the IPPS uses to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and the copayment amount.

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

The Affordable Care Act contained provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (77 FR 74191). As discussed in that final rule with comment period, section 10324 of the Affordable Care Act requires a ''frontier State'' wage index floor of 1.00 in certain cases. For the CY 2013 OPPS, we are proposing to implement this provision in the same manner as we did for CY 2012. That is, frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, rural floor, and rural floor budget neutrality) is less than 1.00. Similar to our current policy for HOPDs that are affiliated with multicampus hospital systems, the HOPD 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 and FY 2012 IPPS/LTCH PPS final rules (75 FR 50160 through 50161 and 76 FR 51586, respectively) and the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27951) for a detailed discussion regarding this provision, including our methodology for identifying which areas meet the definition of frontier States as provided for in section 1886(d)(3)(E)(iii)(II) of the Act.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2013 IPPS wage indices continue to reflect a number of adjustments implemented over the past few years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, an adjustment for occupational mix, and an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment). We refer readers to the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27946 through 27955) for a detailed discussion of all proposed changes to the FY 2013 IPPS wage indices. In addition, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65842 through 65844) and subsequent OPPS rules for a detailed discussion of the history of these wage index adjustments as applied under the OPPS.

Section 102 of the Medicare and Medicaid Extender Act, extended through FY 2011, section 508 reclassifications as well as certain special exceptions. The most recent extension of these special wage indices was included in section 302 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112–78), as amended by section 3001 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96). These legislative provisions extended certain section 508 reclassifications and special exception wage indices for a 6-month period during FY 2012, from October 1, 2011 through March 31, 2012. We implemented this latest extension in a notice (CMS–1442–N) published in the **Federal Register** on April 20, 2012 (77 FR 23722). Therefore, the extension is no longer applicable, effective with FY 2013. As we did for CY 2010, we revised wage index values for certain special exception hospitals from January 1, 2012 through June 30, 2012, under the OPPS, in order to give these hospitals the special exception wage indices under the OPPS for the same time period as under the IPPS. In addition, because the OPPS pays on a calendar year basis, the end date under the OPPS for certain nonsection 508 and nonspecial exception providers to receive special wage indices was June 30, 2012, instead of March 31, 2012, so that these providers also received a full 6 months of payment under the revised wage index comparable to the IPPS.

For purposes of the OPPS, we are proposing to continue our policy in CY 2013 of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage adjustment. Table 4J listed in the FY 2013 IPPS/LTCH PPS proposed rule (and made 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 2013. We note that, beginning with FY 2012, under the IPPS, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, including being considered rural for the disproportionate share hospital (DSH) payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. We refer readers to the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27952) 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 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 2013 OPPS. Addendum L is available via the Internet on the CMS Web site.

In response to concerns frequently expressed by providers and other relevant parties that the current wage index system does not effectively reflect the true variation in labor costs for a large cross-section of hospitals, two studies were undertaken by the Department. First, section 3137(b) of the Affordable Care Act required the Secretary to submit to Congress a report that includes a plan to comprehensively reform the Medicare wage index applied under section 1886(d) of the Act. In developing the plan, the Secretary was directed to take into consideration the goals for reforming the wage index that were set forth by the Medicare Payment Advisory Commission (MedPAC) in its June 2007 report entitled ''Report to Congress: Promoting Greater Efficiency in Medicare'' and to ''consult with relevant affected parties.'' Second, the Secretary commissioned the Institute of Medicine (IOM) to ''evaluate hospital and physician geographic payment adjustments, the validity of the adjustment factors, measures and methodologies used in those factors, and sources of data used in those factors.'' Reports on both of these studies for geographic adjustment to hospital payments recently have been released. For summaries of the studies, their findings, and recommendations on reforming the wage index system, we refer readers to section IX.B. of the preamble of the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28116 through 28119).

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 proposing to use the final FY 2013 IPPS wage indices for calculating OPPS payments in CY 2013. 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 2013 IPPS wage indices referenced in this discussion of the wage index. We refer readers to the CMS Web site for the OPPS at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* At this link, readers will find a link to the proposed FY 2013 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 2013 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 2013, 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 2013 OPPS relative weights. Table 12 below lists the proposed CY 2013 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 weight each hospital's CCR by the volume of separately paid line-items on hospital claims that correspond 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 this CY 2013 OPPS/ASC proposed rule, approximately 62 percent of the submitted cost reports utilized in the default ratio calculations represented data for cost reporting periods ending in CY 2010, and approximately 38 percent were for cost reporting periods ending in CY 2009. For Maryland, we used an overall weighted average CCR for all hospitals in the Nation as a substitute for Maryland CCRs. Few hospitals in Maryland are eligible to receive payment under the OPPS, which limits the data available to calculate an accurate and representative CCR. The weighted CCR is used for Maryland because it takes into account each hospital's volume, rather than treating each hospital equally. We refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65822) for further discussion and the rationale for our longstanding policy of using the national average CCR for Maryland. In general, observed changes in the statewide average default CCRs between CY 2012 and CY 2013 are modest and the few significant changes are associated with areas that have a small number of hospitals.

Table 12 below lists the proposed statewide average default CCRs for OPPS services furnished on or after January 1, 2013.

TABLE 12—PROPOSED CY 2013 STATEWIDE AVERAGE CCRS

State	Urban/rural	Proposed CY 2013 default CCR	Previous default CCR (CY 2012 OPPS final rule)
ALASKA	RURAL	0.489	0.487
ALASKA	URBAN	0.303	0.305
ALABAMA	RURAL	0.208	0.210
ALABAMA	URBAN	0.193	0.194
ARKANSAS	RURAL	0.219	0.221
ARKANSAS	URBAN	0.233	0.245
ARIZONA	RURAL	0.238	0.237
ARIZONA	URBAN	0.191	0.190
CALIFORNIA	RURAL	0.192	0.193
CALIFORNIA	URBAN	0.203	0.201
COLORADO	RURAL	0.331	0.342
COLORADO	URBAN	0.227	0.226
CONNECTICUT	RURAL	0.364	0.365
CONNECTICUT	URBAN	0.287	0.288
DISTRICT OF COLUMBIA	URBAN	0.300	0.302
DELAWARE	RURAL	0.280	0.280
DELAWARE	URBAN	0.349	0.347
FLORIDA	RURAL	0.182	0.182
FLORIDA	URBAN	0.166	0.164
GEORGIA	RURAL	0.237	0.238
GEORGIA	URBAN	0.213	0.214
HAWAII	RURAL	0.323	0.321
HAWAII	URBAN	0.306	0.306
IOWA	RURAL	0.297	0.296
IOWA	URBAN	0.267	0.269
IDAHO	RURAL	0.417	0.417
IDAHO	URBAN	0.357	0.353
ILLINOIS	RURAL	0.239	0.238
ILLINOIS	URBAN	0.230	0.230
INDIANA	RURAL	0.285	0.292
INDIANA	URBAN	0.256	0.262
KANSAS	RURAL	0.276	0.279
KANSAS	URBAN	0.211	0.208
KENTUCKY	RURAL	0.215	0.217
KENTUCKY	URBAN	0.241	0.239
LOUISIANA	RURAL	0.242	0.247
LOUISIANA	URBAN	0.225	0.224
MARYLAND	RURAL	0.275	0.276
MARYLAND	URBAN	0.246	0.246
MASSACHUSETTS	RURAL	0.427	0.427
MASSACHUSETTS	URBAN	0.322	0.322
MAINE	RURAL	0.445	0.438
MAINE	URBAN	0.449	0.453
MICHIGAN	RURAL	0.303	0.305
MICHIGAN	URBAN	0.302	0.305
MINNESOTA	RURAL	0.470	0.482
MINNESOTA	URBAN	0.321	0.320
MISSOURI	RURAL	0.242	0.243
MISSOURI	URBAN	0.263	0.260
MISSISSIPPI	RURAL	0.226	0.224
MISSISSIPPI	URBAN	0.183	0.189
MONTANA	RURAL	0.431	0.434
MONTANA	URBAN	0.384	0.386
NORTH CAROLINA	RURAL	0.253	0.251
NORTH CAROLINA	URBAN	0.254	0.257
NORTH DAKOTA	RURAL	0.322	0.322
NORTH DAKOTA	URBAN	0.414	0.421
NEBRASKA	RURAL	0.318	0.318
NEBRASKA	URBAN	0.254	0.252
NEW HAMPSHIRE	RURAL	0.317	0.323
NEW HAMPSHIRE	URBAN	0.292	0.291
NEW JERSEY	URBAN	0.207	0.212
NEW MEXICO	RURAL	0.256	0.264
NEW MEXICO	URBAN	0.278	0.288
NEVADA	RURAL	0.234	0.233
NEVADA	URBAN	0.162	0.167
NEW YORK	RURAL	0.420	0.419
NEW YORK	URBAN	0.367	0.356
OHIO	RURAL	0.321	0.320
OHIO	URBAN	0.237	0.234

TABLE 12—PROPOSED CY 2013 STATEWIDE AVERAGE CCRS—Continued

State	Urban/rural	Proposed CY 2013 default CCR	Previous default CCR (CY 2012 OPPS final rule)
OKLAHOMA	RURAL	0.239	0.239
OKLAHOMA	URBAN	0.213	0.217
OREGON	RURAL	0.314	0.311
OREGON	URBAN	0.335	0.328
PENNSYLVANIA	RURAL	0.266	0.270
PENNSYLVANIA	URBAN	0.200	0.199
PUERTO RICO	URBAN	0.504	0.492
RHODE ISLAND	URBAN	0.264	0.270
SOUTH CAROLINA	RURAL	0.210	0.211
SOUTH CAROLINA	URBAN	0.215	0.214
SOUTH DAKOTA	RURAL	0.307	0.307
SOUTH DAKOTA	URBAN	0.252	0.252
TENNESSEE	RURAL	0.210	0.211
TENNESSEE	URBAN	0.195	0.199
TEXAS	RURAL	0.235	0.236
TEXAS	URBAN	0.205	0.196
UTAH	RURAL	0.373	0.379
UTAH	URBAN	0.359	0.359
VIRGINIA	RURAL	0.227	0.226
VIRGINIA	URBAN	0.237	0.239
VERMONT	RURAL	0.408	0.407
VERMONT	URBAN	0.384	0.384
WASHINGTON	RURAL	0.366	0.368
WASHINGTON	URBAN	0.301	0.298
WISCONSIN	RURAL	0.352	0.351
WISCONSIN	URBAN	0.310	0.311
WEST VIRGINIA	RURAL	0.281	0.280
WEST VIRGINIA	URBAN	0.341	0.337
WYOMING	RURAL	0.379	0.386
WYOMING	URBAN	0.301	0.302

E. Proposed OPPS Payments to Certain Rural and Other Hospitals

1. Hold Harmless Transitional Payment Changes

When the OPPS was implemented, every provider was eligible to receive an additional payment adjustment (called either transitional corridor payments or transitional outpatient payments (TOPs)) if the payments it received for covered OPD services under the OPPS were less than the payments it would have received for the same services under the prior reasonable cost-based system (referred to as the pre-BBA amount). Section 1833(t)(7) of the Act provides that the TOPs were temporary payments for most providers and intended to ease their transition from the prior reasonable cost-based payment system to the OPPS system. There are two types of hospitals excepted from the policy described above, cancer hospitals and children's hospitals. Specifically, such a hospital could receive TOPs to the extent its PPS amount was less than its pre-BBA amount in the applicable year. Section 1833(t)(7)(D)(i) of the Act originally provided for TOPs to rural hospitals with 100 or fewer beds for covered OPD services furnished before January 1, 2004. However, section 411 of Public Law 108–173 (the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) amended section 1833(t)(7)(D)(i) of the Act to extend these payments through December 31, 2005, for rural hospitals with 100 or fewer beds. Section 411 also extended the TOPs to sole community hospitals (SCHs) located in rural areas for services furnished during the period that began with the provider's first cost reporting period beginning on or after January 1, 2004, and ending on December 31, 2005. Accordingly, the authority for making TOPs under section 1833(t)(7)(D)(i) of the Act, as amended by section 411 of Public Law 108–173, for rural hospitals having 100 or fewer beds and SCHs located in rural areas expired on December 31, 2005.

Section 5105 of Public Law 109–171 (the Deficit Reduction Act of 2005) extended the TOPs for covered OPD services furnished on or after January 1, 2006, and before January 1, 2009, for rural hospitals having 100 or fewer beds that are not SCHs. Section 5105 of Public Law 109–171 also reduced the TOPs to rural hospitals from 100 percent of the difference between the provider's OPPS payments and the pre-BBA amount. This provision provided that, in cases in which the OPPS payment was less than the provider's pre-BBA amount, the amount of payment would be increased by 95 percent of the amount of the difference between the two amounts for CY 2006, by 90 percent of the amount of that difference for CY 2007, and by 85 percent of the amount of that difference for CY 2008.

For CY 2006, we implemented section 5105 of Public Law 109–171 through Transmittal 877, issued on February 24, 2006. In the Transmittal, we did not specifically address whether TOPs applied to essential access community hospitals (EACHs), which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act. Accordingly, by law, EACHs are treated as SCHs. In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010), we stated that EACHs were not eligible for TOPs under Public Law 109–171. However, we stated they were eligible for the adjustment for rural SCHs authorized under section 411 of Public Law 108–173. In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68228), we updated § 419.70(d) of our regulations to reflect the requirements of Public Law 109–171.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41461), we stated that, effective for services provided on or after January 1, 2009, rural hospitals with 100 or fewer beds that are not SCHs would no longer be eligible for TOPs, in accordance with section 5105 of Public Law 109–171. However, subsequent to issuance of the CY 2009 OPPS/ASC proposed rule, section 147 of Public Law 110–275 (the Medicare Improvements for Patients and Providers Act of 2008) amended section 1833(t)(7)(D)(i) of the Act by extending the period of TOPs to rural hospitals with 100 beds or fewer for 1 year, for services provided before January 1, 2010. Section 147 of Public Law 110–275 also extended TOPs to SCHs (including EACHs) with 100 or fewer beds for covered OPD services provided on or after January 1, 2009, and before January 1, 2010. In accordance with section 147 of Public Law 110–275, when the OPPS payment is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payment amounts for CY 2009.

For CY 2009, we revised our regulations at §§ 419.70(d)(2) and (d)(4) and added a paragraph (d)(5) to incorporate the provisions of section 147 of Public Law 110–275. In addition, we made other technical changes to § 419.70(d)(2) to more precisely capture our existing policy and to correct an inaccurate cross-reference. We also made technical corrections to the cross-references in paragraphs (e), (g), and (i) of § 419.70.

For CY 2010, we made a technical correction to the heading of § 419.70(d)(5) to correctly identify the policy as described in the subsequent regulation text. The paragraph heading now indicates that the adjustment applies to small SCHs, rather than to rural SCHs.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60425), we stated that, effective for services provided on or after January 1, 2010, rural hospitals and SCHs (including EACHs) having 100 or fewer beds would no longer be eligible for TOPs, in accordance with section 147 of Public Law 110–275. However, subsequent to issuance of the CY 2010 OPPS/ASC final rule with comment period, section 3121(a) of the Affordable Care Act (Pub. L. 111–148) amended section 1833(t)(7)(D)(i)(III) of the Act by extending the period of TOPs to rural hospitals that are not SCHs with 100 beds or fewer for 1 year, for services provided before January 1, 2011. Section 3121(a) of the Affordable Care Act amended section 1833(t)(7)(D)(i)(III) of the Act and extended the period of TOPs to SCHs (including EACHs) for 1 year, for services provided before January 1, 2011, and section 3121(b) of the Affordable Care Act removed the 100-bed limitation applicable to such SCHs for covered OPD services furnished on and after January 1, 2010, and before January 1, 2011. In accordance with section 3121 of the Affordable Care Act, when the OPPS payment is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payment amounts for CY 2010. Accordingly, in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71882), we updated § 419.70(d) of the regulations to reflect the self-implementing TOPs extensions and amendments described in section 3121 of the Affordable Care Act.

Section 108 of the Medicare and Medicaid Extenders Act of 2010 (MMEA) (Pub. L. 111–309) extended for 1 year the hold harmless provision for a rural hospital with 100 or fewer beds that is not an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act). Therefore, for such a hospital, for services furnished before January 1, 2012, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment to the hospital is increased by 85 percent of the amount of the difference between the two payments. In addition, section 108 of the MMEA also extended for 1 year the hold harmless provision for an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act (including EACHs) and removed the 100-bed limit applicable to such SCHs for covered OPD services furnished on or after January 1, 2010, and before January 1, 2012. Therefore, for such hospitals, for services furnished before January 1, 2012, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment to the hospital is increased by 85 percent of the amount of the difference between the two payments. Effective for services provided on or after January 1, 2012, a rural hospital with 100 or fewer beds that is not an SCH and an SCH (including EACHs) are no longer be eligible for TOPs, in accordance with section 108 of the MMEA. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74199), we revised our regulations at § 419.70(d) to conform the regulation text to the self-implementing provisions of section 108 of the MMEA described above.

Subsequent to issuance of the CY 2012 OPPS/ASC final rule with comment period, section 308 of the Temporary Payroll Tax Cut Continuation Act of CY 2011 (Pub. L. 112–78), as amended by section 3002 of the Middle Class Tax Relief and Jobs Creation Act (Pub. L. 112–96), extended through December 31, 2012, the hold harmless provision for a rural hospital with 100 or fewer beds that is not an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act). Therefore, for such a hospital, for services furnished before January 1, 2013, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payments.

Section 308 of Public Law 112–78 also extended through February 29, 2012 the hold harmless provision for an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act), including an EACH, without the bed size limitation. Therefore, for such hospitals, for services furnished before March 1, 2012, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payments. However, section 3002 of Public Law 112–96 extended through December 31, 2012, the hold harmless provision for an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act), including an EACH, that has no more than 100 beds. Therefore, for such hospitals, for services furnished before January 1, 2013, when the PPS amount is less than the provider's pre-BBA amount, the amount of payment is increased by 85 percent of the amount of the difference between the two payments. Accordingly, we are proposing to revise § 419.70(d) of the regulations to reflect the TOPs extensions and amendments described in section 308 of Public Law 112–78 and section 3002 of Public Law 112–96.

Effective for services provided on or after March 1, 2012, SCHs (including EACHs) with greater than 100 beds are no longer eligible for TOPs, in accordance with section 308 of Public Law 112–78. Effective for services provided on or after January 1, 2013, a rural hospital with 100 or fewer beds that is not an SCH and an SCH (including an EACH) are no longer eligible for TOPs, in accordance with section 3002 of Public Law 112–96.

2. 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 Public Law 108–173. Section 411 gave the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In CY 2007, we became aware that we did not specifically address whether the adjustment applies to EACHs, which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act. Thus, under the statute, EACHs are treated as SCHs. Therefore, in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised § 419.43(g) to clarify that EACHs are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, three hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of 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 copayment. As we stated in the CY 2006 OPPS final rule with comment period (70 FR 68560), we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2012. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For the CY 2013 OPPS, we are proposing to continue our policy of a budget neutral 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs (76 FR 46232). We intend to reassess the 7.1 percent adjustment in the future by examining differences between urban hospitals' costs and rural hospitals' costs using updated claims data, cost reports, and provider information.

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

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA), Medicare has paid cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act (cancer hospitals) under the OPPS for covered outpatient hospital services. There are 11 cancer hospitals that meet the classification criteria in section 1886(d)(1)(B)(v) of the Act. These 11 cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999, Congress created section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' to serve as a permanent payment floor by limiting cancer hospitals' potential losses under the OPPS. Through section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a ''pre-BBA'' amount. That is, cancer hospitals are permanently held harmless to their ''pre-BBA'' amount, and they receive TOPs to ensure that they do not receive a payment that is lower under the OPPS than the payment they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA'' payment amount is an amount equal to the product of the reasonable cost of the hospital for covered outpatient services for the portions of the hospital's cost reporting period (or periods) occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital. The ''pre-BBA'' amount, including the determination of the base PCR, are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital and Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, as applicable) each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

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

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

for a cost reporting period. For CY 2012, the target PCR for purposes of the cancer hospital payment adjustment is 0.91.

2. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2013

For CY 2013, 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 this proposed rule. To calculate the proposed CY 2013 target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A of this proposed rule, used to estimate costs for the CY 2013 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled. We then limited the dataset to the hospitals with CY 2011 claims data that we used to model the impact of the proposed CY 2013 APC relative weights (3,975 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2013 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2010 to 2011. We then removed the cost report data of the 48 hospitals located in Puerto Rico from our dataset because we do not believe that their cost structure reflects the costs of most hospitals paid under the OPPS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed 177 hospitals with cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,750 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS are approximately 91 percent of reasonable cost (weighted average PCR of 0.91). Based on these data, we are proposing a target PCR of 0.91 that would be used to determine the CY 2013 cancer hospital payment adjustment that would be paid at cost report settlement. Therefore, we 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 0.91 for each cancer hospital.

G. Proposed Hospital Outpatient Outlier Payments

1. Background

Currently, the OPPS provides outlier payments on a service-by-service basis. In CY 2011, the outlier threshold was determined to be met when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $2,025 fixed-dollar threshold. We introduced a fixed-dollar threshold in CY 2005, in addition to the traditional multiple threshold, in order to better target outlier payments to those high cost and complex procedures where a very costly service could present a hospital with significant financial loss. If the cost of a service meets both of these conditions, the multiple threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate. Before CY 2009, this outlier payment had historically been considered a final payment by longstanding OPPS policy. However, we implemented a reconciliation process similar to the IPPS outlier reconciliation process for cost reports with cost reporting periods beginning on or after January 1, 2009, in our CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy for the past several years to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the proposed OPPS. Our current estimate of total outlier payments as a percent of total CY 2011 OPPS payment, using available CY 2011 claims and the revised OPPS expenditure estimate for the 2012 Trustee's Report, is approximately 1.06 percent of the total aggregated OPPS payments. Therefore, for CY 2011, we estimate that we paid 0.06 percent above the CY 2011 outlier target of 1.0 percent of total aggregated OPPS payments.

As explained in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71887 through 71889), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for CY 2011. The outlier thresholds were set so that estimated CY 2011 aggregate outlier payments would equal 1.0 percent of the total estimated aggregate payments under the OPPS. Using CY 2011 claims data and CY 2012 payment rates, we currently estimate that the aggregate outlier payments for CY 2012 will be approximately 1.03 percent of the total CY 2012 OPPS payments. The difference between 1.0 percent and 1.03 percent is reflected in the regulatory impact analysis in section XXII. of this proposed rule. We note that we provide proposed estimated CY 2013 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital-Specific Impacts—Provider-Specific Data file on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

2. Proposed Outlier Calculation

For CY 2013, 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 0.12 percent of outlier payments (or 0.0012 percent of total OPPS payments) would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. As discussed in section VIII.C. of 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 for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate. For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of this proposed rule.

To ensure that the estimated CY 2013 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 $2,400 fixed-dollar threshold. This proposed threshold reflects the methodology discussed below in this section, as well as the

proposed APC recalibration for CY 2013.

We calculated the proposed fixed-dollar threshold for this proposed rule using largely the same methodology as we did in CYs 2011 and 2012 (75 FR 71887 through 71889 and 76 FR 74207 through 74209). For purposes of estimating outlier payments for this proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2012 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCR, which are maintained by the Medicare contractors and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years. For this proposed rule, we used CY 2011 claims to model the CY 2013 OPPS. In order to estimate the proposed CY 2013 hospital outlier payments for this proposed rule, we inflated the charges on the CY 2011 claims using the same inflation factor of 1.1406 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28142). We used an inflation factor of 1.0680 to estimate CY 2012 charges from the CY 2011 charges reported on CY 2011 claims. The methodology for determining this charge inflation factor is discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28142). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors are appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, for this CY 2013 OPPS/ASC proposed rule, we are proposing to apply the same CCR inflation adjustment factor that we are proposing to apply for the proposed FY 2013 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2013 OPPS outlier payments that determine the fixed-dollar threshold. Specifically, for CY 2013, we are proposing to apply an adjustment factor of 0.9790 to the CCRs that were in the April 2012 OPSF to trend them forward from CY 2012 to CY 2013. The methodology for calculating this proposed adjustment was discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28142 through 28144). We note that due to the issue described in the IPPS proposed rule correction notice published on June 11, 2012, the operating and capital CCR inflation factors were reversed (77 FR 34326). In estimating the proposed CY 2013 OPPS fixed-dollar outlier threshold, we have applied the corrected CCR inflation factor.

Therefore, to model hospital outlier payments for this CY 2013 OPPS/ASC proposed rule, we applied the overall CCRs from the April 2012 OPSF file after adjustment (using the proposed CCR inflation adjustment factor of 0.9644 to approximate CY 2013 CCRs) to charges on CY 2011 claims that were adjusted (using the proposed charge inflation factor of 1.1406 to approximate CY 2013 charges). We simulated aggregated CY 2013 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2013 OPPS payments. We estimated that a proposed fixed-dollar threshold of $2,400, combined with the 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 $2,400 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 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 our policy that we implemented in CY 2010 that the hospitals' costs would be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XV. of this proposed rule.

3. Proposed Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 CFR 68599), we adopted as final policy a process to reconcile hospital or CMHC outlier payments at cost report settlement for services furnished during cost reporting periods beginning in CY 2009. OPPS outlier reconciliation more fully ensures accurate outlier payments for those facilities that have CCRs that fluctuate significantly relative to the CCRs of other facilities, and that receive a significant amount of outlier payments (73 FR 68598). As under the IPPS, we do not adjust the fixed-dollar threshold or the amount of total OPPS payments set aside for outlier payments for reconciliation activity because such action would be contrary to the prospective nature of the system. Our outlier threshold calculation assumes that overall ancillary CCRs accurately estimate hospital costs based on the information available to us at the time we set the prospective fixed-dollar outlier threshold. For these reasons, and as we have previously discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68596), we are proposing for CY 2013, to not incorporate any assumptions about the effects of reconciliation into our calculation of the OPPS fixed-dollar outlier threshold.

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 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 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 2013 scaled weight for the APC by the proposed CY 2013 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XV. of this 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: ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''U,'' ''V,'' or ''X'' (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.

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 reporting ratio of 0.980 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements in order to receive the full CY 2013 OPPS fee schedule increase factor of 2.1 percent.

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

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

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

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

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. The wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2013 under the IPPS, reclassifications through the MGCRB, section 1886(d)(8)(B) ''Lugar'' hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in § 412.103 of the regulations, and hospitals designated as urban under section 601(g) of Public Law 98–21. We note that the reclassifications of hospitals under section 508 of Public Law 108–173, as extended by sections 3137 and 10317 of the Affordable Care Act, expired on September 30, 2010. Section 102 of the Medicare and Medicaid Extenders Act of 2010 extended section 508 and certain additional special exception hospital reclassifications from October 1, 2010 through September 30, 2011. Section 302 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112–78) as amended by section 3001 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96) extended section 508 and certain additional special exception hospital reclassifications from October 1, 2011 through March 31, 2012. Therefore, these reclassifications will not apply to the CY 2013 OPPS. (For further discussion of the proposed changes to the FY 2013 IPPS wage indices, as applied to the CY 2013 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.

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 2013 IPPS and listed as Table 4J in the FY 2013 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 payment rate for the specific service by the wage index.

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

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

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

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

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

Y = .40 * (national unadjusted payment rate)

Adjusted Medicare Payment = $Y + X_a$

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

The formula below is a mathematical representation of Step 6 and applies the 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 full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined above. For purposes of this example, we use 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 2013 full national unadjusted payment rate for APC 0019 is $337.48. The proposed reduced national unadjusted payment rate for a hospital that fails to meet the Hospital OQR Program requirements is $330.73. 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 2013 wage index for a provider located in CBSA 35644 in New York is 1.2991. The proposed labor-related portion of the full national unadjusted payment is $263.05 (.60 * $337.48 * 1.2991). The labor-related portion of the proposed reduced national unadjusted payment is $257.79 (.60 * $330.73 * 1.2991). The nonlabor-related portion of the full national unadjusted payment is $134.99 (.40 * $337.48). The nonlabor-related portion of the proposed reduced national unadjusted payment is $132.29 (.40 * $330.73). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is $398.04 ($263.05 + $134.99). The sum of the reduced national adjusted payment is $390.08 ($257.79 + $132.29).

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 to the amount of the inpatient deductible.

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

2. Proposed OPPS Copayment Policy

For CY 2013, 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, 2013, 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 XV. of this proposed rule, for CY 2013, 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. The CY 2013 proposal to base APC relative weights on geometric mean costs also affects proposed APC payment rates and, through them, the corresponding beneficiary copayments. However, as described in the CY 2004 OPPS/ASC final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459). For a more detailed discussion of the proposal to base the APC relative payment weights on geometric mean costs, we refer readers to section II.A.2.f. of this proposed rule.

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, $67.50 is 20 percent of the full national unadjusted payment rate of $337.48. For APCs with only a minimum unadjusted copayment in Addenda A and B of 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 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 percentage to the adjusted payment rate for a service calculated under section II.H. of this proposed rule, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

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

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

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

The proposed unadjusted copayments for services payable under the OPPS that would be effective January 1, 2013, 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 2013 OPD fee schedule increase factor discussed in section II.B. of this proposed rule.

Also, as noted above, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected to the amount of the inpatient deductible.

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

CPT codes are established by the American Medical Association (AMA) and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and HCPCS code changes that affect the OPPS are published both through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). CMS releases new Level II HCPCS codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS quarterly update CRs. This quarterly process offers hospitals access to codes that may more accurately describe items or services furnished and/or provides payment or more accurate payment for these items or services in a timelier manner than if CMS waited for the annual rulemaking process. We solicit public comments on these new codes and finalize our proposals related to these codes through our annual rulemaking process. In Table 13 below, we summarize our proposed process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing their treatment under the OPPS. 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 2012 OPPS quarterly update CR could not be included in Addendum B to this proposed rule. Nevertheless, we are requesting public comments on the codes included in the July 2012 OPPS quarterly update and including these codes in the preamble to this proposed rule.

TABLE 13—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April I, 2012	Level II HCPCS Codes	April 1, 2012	CY 2013 OPPS/ASC proposed rule.	CY 2013 OPPS/ASC final rule with comment period.
July 1, 2012	Level II HCPCS Codes	July 1, 2012	CY 2013 OPPS/ASC proposed rule.	CY 2013 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2012	CY 2013 OPPS/ASC proposed rule.	CY 2013 OPPS/ASC final rule with comment period.
October 1, 2012	Level II HCPCS Codes	October 1, 2012	CY 2013 OPPS/ASC final rule with comment period.	CY 2014 OPPS/ASC final rule with comment period.

TABLE 13—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES—Continued

OPPS quarterly update CR	Type of code	Effective date	Comments sought	When finalized
January 1, 2013	Level II HCPCS Codes	January 1, 2013	CY 2013 OPPS/ASC final rule with comment period.	CY 2014 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes.	January 1, 2013	CY 2013 OPPS/ASC final rule with comment period.	CY 2014 OPPS/ASC final rule with comment period.

This process is discussed in detail below. We have separated our discussion into two sections based on whether we solicited public comments in this CY 2013 OPPS/ASC proposed rule or whether we will be soliciting public comments in the CY 2013 OPPS/ASC final rule with comment period. We note that we sought public comments in the CY 2012 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2012. We also sought public comments in the CY 2012 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2011. These new codes, with an effective date of October 1, 2011, or January 1, 2012, were flagged with comment indicator ''NI'' (New code, interim APC assignment; comments will be accepted on the interim APC assignment for the new code) in Addendum B to the CY 2012 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and an APC and payment rate, if applicable, which were subject to public comment following publication of the CY 2012 OPPS/ASC final rule with comment period. We will respond to public comments and finalize our interim OPPS treatment of these codes in the CY 2013 OPPS/ASC final rule with comment period.

1. Proposed Treatment of New CY 2012 Level II HCPCS and CPT Codes Effective April 1, 2012 and July 1, 2012 for Which We Are Soliciting Public Comments in This CY 2013 Proposed Rule

Through the April 2012 OPPS quarterly update CR (Transmittal 2418, Change Request 7748, dated March 2, 2012) and the July 2012 OPPS quarterly update CR (Transmittal 2483, Change Request 7847, dated June 8, 2012), we recognized several new HCPCS codes for separate payment under the OPPS. Effective April 1 and July 1 of CY 2012, we made effective 13 new Level II HCPCS codes and 7 Category III CPT codes. Specifically, 5 new Level II HCPCS codes were effective for the April 2012 update and another 8 new Level II HCPCS codes were effective for the July 2012 update for a total of 13. Seven new Category III CPT codes were effective for the July 2012 update. Of the 13 new Level II HCPCS codes, we recognized for separate payment 11 of these codes, and of the 7 new Category III CPT codes, we recognized for separate payment all 7 new Category III CPT codes, for a total of 18 new Level II HCPCS and Category III CPT codes that are recognized for separate payment for CY 2013.

Through the April 2012 OPPS quarterly update CR, we allowed separate payment for each of the five new Level II HCPCS codes. Specifically, as displayed in Table 14 below, we provided separate payment for the following HCPCS codes:

- HCPCS code C9288 (Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial)
- HCPCS code C9289 (Injection, asparaginase Erwinia chrysanthemi, 1,000 international units (I.U.))
- HCPCS code C9290 (Injection, bupivacaine liposome, 1 mg)
- HCPCS code C9291 (Injection, aflibercept, 2 mg vial)
- HCPCS code C9733 (Non-ophthalmic fluorescent vascular angiography)

In this proposed rule, we are proposing to assign the Level II HCPCS codes listed in Table 14 to the specific proposed APCs and status indicators for CY 2013.

TABLE 14—LEVEL II HCPCS CODES WITH A CHANGE IN OPPS STATUS INDICATOR OR NEWLY IMPLEMENTED IN APRIL 2012

CY 2012 HCPCS Code	CY 2012 long descriptor	Proposed CY 2013 status indicator	Proposed CY 2013 APC
C9288	Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial	G	9288
C9289	Injection, asparaginase Erwinia chrysanthemi, 1,000 international units (I.U.)	G	9289
C9290	Injection, bupivacaine liposome, 1 mg	G	9290
C9291*	Injection, aflibercept, 2 mg vial	G	9291
C9733	Non-ophthalmic fluorescent vascular angiography	Q2	0397

*Level II HCPCS code C9291 (Injection, aflibercept, 2 mg vial) was deleted June 30, 2012, and replaced with HCPCS code Q2046 effective July 1, 2012.

Through the July 2012 OPPS quarterly update CR, which included HCPCS codes that were made effective July 1, 2012, we allowed separate payment for six of the eight new Level II HCPCS codes. Specifically, as displayed in Table 15 of this proposed rule, we provided separate payment for the following HCPCS codes:

- HCPCS code C9368 (Grafix core, per square centimeter)
- HCPCS code C9369 (Grafix prime, per square centimeter)
- HCPCS code Q2045 (Injection, human fibrinogen concentrate, 1 mg)
- HCPCS code Q2046 (Injection, aflibercept, 1 mg)
- HCPCS code Q2048 (Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg)
- HCPCS code Q2049 (Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg)

We note that three of the Level II HCPCS Q-codes that were made effective July 1, 2012, were previously

described by HCPCS J-codes or C-codes that were separately payable under the hospital OPPS. First, HCPCS code Q2045 replaced HCPCS code J1680 (Injection, human fibrinogen concentrate, 100 mg), beginning July 1, 2012. HCPCS code J1680 was assigned to status indicator ''K'' (Nonpass-through drugs and nonimplantable biologicals, including therapeutic radiopharmaceuticals; paid under OPPS; separate APC payment) on January 1, 2012. However, because HCPCS code J1680 is replaced by HCPCS code Q2045 effective July 1, 2012, we changed its status indicator to ''E'' (Not Payable by Medicare) effective July 1, 2012. Because HCPCS code Q2045 describes the same drug as HCPCS code J1680, we continued its separate payment status and assigned it to status indicator ''K'' effective July 1, 2012. However, because the dosage descriptor for HCPCS code Q2045 is not the same as HCPCS code J1680, we assigned HCPCS code Q2045 to a new APC to maintain data consistency for future rulemaking. Specifically, HCPCS code Q2045 is assigned to APC 1414 (Human fibrinogen conc inj) effective July 1, 2012.

Second, HCPCS code Q2046 replaced HCPCS code C9291 (Injection, aflibercept, 2 mg vial) effective July 1, 2012. HCPCS code C9291 was assigned pass-through status when it was made effective April 1, 2012. Because HCPCS code Q2046 describes the same product as HCPCS code C9291, we continued its pass-through status and assigned HCPCS code Q2046 to status indicator ''G'' as well as assigned it to the same APC, specifically APC 9291 (Injection, aflibercept), effective July 1, 2012. HCPCS code C9291 is deleted effective June 30, 2012.

Third, the HCPCS Workgroup replaced HCPCS code J9001 (Injection, doxorubicin hydrochloride, all lipid formulations, 10 mg) with new HCPCS code Q2048, effective July 1, 2012. Consequently, the status indicator for HCPCS code J9001 is changed to ''E'' (Not Payable by Medicare) effective July 1, 2012. Because HCPCS code Q2048 describes the same drug as HCPCS code J9001, we continued its separate payment status and assigned HCPCS code Q2048 to status indicator ''K'' effective July 1, 2012. In addition, because, HCPCS code Q2049 is similar to HCPCS code Q2048, we assigned HCPCS code Q2049 to status indicator ''K'' effective July 1, 2012.

Of the 15 HCPCS codes that were made effective July 1, 2012, we did not recognize for separate payment two HCPCS codes because they are both paid under a payment system other than OPPS. Specifically, HCPCS code Q2047 (Injection, peginesatide, 0.1 mg (for ESRD on dialysis)) is assigned to status indicator ''A'' (Not paid under OPPS; paid by fiscal intermediaries/MACs under a fee schedule or payment system other than OPPS), and HCPCS code Q2034 (Influenza virus vaccine, split virus, for intramuscular use (Agriflu)) is assigned to status indicator ''L'' (Not paid under OPPS; paid at reasonable cost).

Table 15 below includes a complete list of the Level II HCPCS codes that were made effective July 1, 2012, with their proposed status indicators, proposed APC assignments, and proposed payment rates for CY 2013.

TABLE 15—NEW LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2012

CY 2012 HCPCS code	CY 2012 long descriptor	Proposed CY 2013 status indicator	Proposed CY 2013 APC	Proposed CY 2013 payment rate
C9368	Grafix core, per square centimeter	G	9368	$7.96
C9369	Grafix prime, per square centimeter	G	9369	0.61
Q2034	Influenza virus vaccine, split virus, for intramuscular use (Agriflu)	L	N/A	N/A
Q2045*	Injection, human fibrinogen concentrate, 1 mg	K	1414	0.73
Q2046**	Injection, aflibercept, 1 mg	G	1420	980.50
Q2047	Injection, peginesatide, 0.1 mg (for ESRD on dialysis)	A	N/A	N/A
Q2048***	Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg	K	7046	537.21
Q2049†	Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg	K	1421	498.26

*HCPCS code Q2045 replaced HCPCS code J1680 effective July 1, 2012. The status indicator for HCPCS code J1680 was changed to ''E'' (Not Payable by Medicare) effective July 1, 2012. The proposed payment rate for HCPCS code Q2045 is based on ASP+6 percent.

**HCPCS code Q2046 replaced HCPCS code C9291 effective July 1, 2012.

***HCPCS code Q2048 replaced HCPCS code J9001 effective July 1, 2012. The status indicator for HCPCS code J9001 was changed to ''E'' (Not Payable by Medicare) effective July 1, 2012. The proposed payment rate for HCPCS code Q2048 is based on ASP+6 percent.

†The proposed payment rate for HCPCS code Q2049 is based on ASP+6 percent.

For CY 2013, 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 quarterly update CR, consistent with the AMA's implementation date for the codes. For the July 2012 update, there were no new Category I CPT vaccine codes. Through the July 2012 OPPS quarterly update CR (Transmittal 2483, Change Request 7847, dated June 8, 2012), we allowed separate payment for all seven new Category III CPT codes effective July 1, 2012. Specifically, as displayed in Table 16 of this proposed rule, we allowed separate payment for the following Category III CPT codes:

- CPT code 0302T (Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode))
- CPT code 0303T (Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only)
- CPT code 0304T (Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only)
- CPT code 0305T (Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report)

• CPT code 0306T (Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report)

• CPT code 0307T (Removal of intracardiac ischemia monitoring device)

• CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens)

Table 16 below lists the Category III CPT codes that were implemented in July 2012, along with their proposed status indicators, proposed APC assignments, where applicable, and proposed payment rates for CY 2013.

TABLE 16—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2012

CY 2012 CPT code	CY 2012 long descriptor	Proposed CY 2013 status indicator	Proposed CY 2013 APC	Proposed CY 2013 payment rate
0302T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode).	T	0089	$8,275.79
0303T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only.	T	0106	3,780.92
0304T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only.	T	0090	6,663.83
0305T	Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report.	S	0690	33.92
0306T	Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report.	S	0690	33.92
0307T	Removal of intracardiac ischemia monitoring device	T	0105	1,718.55
0308T	Insertion of ocular telescope prosthesis including removal of crystalline lens.	T	0234	1,669.74

We are soliciting public comments on the CY 2013 proposed status indicators and the proposed APC assignments and payment rates for the Level II HCPCS codes and the Category III CPT codes that were effective April 1, 2012, and July 1, 2012, through the respective OPPS quarterly update CRs. These codes are listed in Tables 14, 15, and 16 of this proposed rule. We are proposing to finalize their status indicators and their APC assignments and payment rates, if applicable, in the CY 2013 OPPS/ASC final rule with comment period. Because the new Category III CPT and Level II HCPCS codes that become effective for July are not available to us in time for incorporation into the Addenda to this 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 to the proposed rule but not in the Addenda to the proposed rule. These codes are listed in Tables 15 and 16, respectively. We are proposing to incorporate these codes into Addendum B to the CY 2013 OPPS/ASC final rule with comment period, which is consistent with our annual OPPS update policy. The Level II HCPCS codes implemented or modified through the April 2012 OPPS update CR and displayed in Table 14 are included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site), where their proposed CY 2013 payment rates are also shown.

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

As has been our practice in the past, we incorporate those new Category I and III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the OPPS for the following calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January OPPS quarterly update CRs. In the past, we also have released new Level II HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period updating the OPPS for the following calendar year. For CY 2013, these codes 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, 2013, will be flagged with comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period. Specifically, the status indicator and the APC assignment and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the final rule with comment period, and we respond to these comments in the OPPS/ASC final rule with comment period for the next calendar year's OPPS/ASC update. We are proposing to continue this process for CY 2013. Specifically, for CY 2013, we are proposing to include in Addendum B to the CY 2013 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2013 (including the Category III CPT codes that are released by the AMA in July 2012) that would be incorporated in the January 2013 OPPS quarterly update CR and the new Level II HCPCS codes, effective October 1, 2012, or January 1, 2013, that would be released by CMS in its October 2012 and January 2013 OPPS quarterly update CRs. The October 1, 2012 and January 1, 2013 codes would be flagged with comment indicator ''NI'' in Addendum B to the CY 2013 OPPS/ASC final rule

with comment period to indicate that we have assigned them an interim OPPS payment status for CY 2013. 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 2014 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 have also developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices.

We have packaged into payment for each procedure or service within an APC group the costs associated with those items or services that are directly related to, and supportive of, performing the main independent procedures or furnishing the services. Therefore, we do not make separate payment for these packaged items or services. For example, packaged items and services include:

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

(b) Use of a recovery room;

(c) Observation services;

(d) Anesthesia;

(e) Medical/surgical supplies;

(f) Pharmaceuticals (other than those for which separate payment may be allowed under the provisions discussed in section V. of this proposed rule);

(g) Incidental services such as venipuncture;

(h) Guidance services, image processing services, intraoperative services, imaging, supervision and interpretation services, diagnostic radiopharmaceuticals, and contrast media.

Further discussion of packaged services is included in section II.A.3. of this 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 CY 2012 OPPS policy, we provide composite APC payment for certain extended assessment and management services, low dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation, mental health services, multiple imaging services, and cardiac resynchronization therapy services. Further discussion of composite APCs is included in section II.A.2.e. of this 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 weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 0606 (Level 3 Hospital Clinic Visits). The APC weights are scaled to APC 0606 because it is the middle level hospital clinic visit APC (the Level 3 hospital clinic visit CPT code out of five levels), and because middle level hospital clinic visits are among the most frequently furnished services in the hospital outpatient setting.

Section 1833(t)(9)(A) of the Act requires the Secretary to review, on a recurring basis occurring no less than annually, and revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights recommendations for specific services for the CY 2013 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''). For CY 2013, we are proposing to use the cost of the item or service in implementing this provision, as discussed in section II.A.2.f. of this proposed 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 2013.

We have identified APCs with 2 times violations for which we are proposing

changes to their HCPCS codes' APC assignments in Addendum B (available via the Internet on the CMS Web site) to this proposed rule. In these cases, to eliminate a 2 times 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 2013 included in the proposed rule are related to changes in costs of services that were observed in the CY 2011 claims data newly available for CY 2013 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 2013. In addition, we are proposing to rename existing APCs or create new clinical APCs to complement proposed HCPCS code reassignments. Addendum B to this CY 2013 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 2012 Addendum B Update (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

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 2013, we reviewed all the APCs to determine which APCs would not satisfy the 2 times rule. Then we used the following criteria to decide whether to propose exceptions to the 2 times rule for affected APCs:

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

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

Table 17 of this proposed rule lists 21 APCs that we are proposing to exempt from the 2 times rule for CY 2013 based on the criteria cited above and based on claims data processed from January 1, 2011, through December 31, 2011. For the final rule with comment period, we plan to use claims data for dates of service between January 1, 2011, and December 31, 2011, that were processed on or before June 30, 2012, and updated CCRs, if available. Based on the CY 2011 claims data, we found 21 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 2013, and identified 21 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 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, such as device-dependent APCs, with 2 times rule violations. These proposed APC exceptions are listed in Table 17 below.

TABLE 17—PROPOSED APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2013

Proposed CY 2013 APC	Proposed CY 2013 APC title
0006	Level I Incision & Drainage.
0012	Level I Debridement & Destruction.
0045	Bone/Joint Manipulation Under Anesthesia.
0057	Bunion Procedures.
0060	Manipulation Therapy.
0105	Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices.
0128	Echocardiogram with Contrast.
0152	Level I Percutaneous Abdominal and Biliary Procedures.
0173	Level II Partial Hospitalization (4 or more services) for CMHCs.
0230	Level I Eye Tests & Treatments.
0272	Fluoroscopy.
0325	Group Psychotherapy.
0330	Dental Procedures.
0340	Minor Ancillary Procedures.
0369	Level III Pulmonary Tests.
0403	Level I Nervous System Imaging.
0409	Red Blood Cell Tests.
0604	Level 1 Hospital Clinic Visits.
0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing.
0688	Revision/Removal of Neurostimulator Pulse Generator Receiver.
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 New Technology APCs

1. Background

In the November 30, 2001 final rule (66 FR 59903), we finalized changes to the time period a service was eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This

policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

We note that the cost bands for New Technology APCs range from $0 to $50 in increments of $10, from $50 to $100 in increments of $50, from $100 to $2,000 in increments of $100, and from $2,000 to $10,000 in increments of $500. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level VII ($500–$600)) is made at $550. Currently, there are 82 New Technology APCs, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level IA ($0–$10)) through the highest cost band assigned to APC 1574 (New Technology—Level XXXVII ($9,500–$10,000). In CY 2004 (68 FR 63416), we last restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs, one set with a status indicator of ''S'' (Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

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

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

For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the techniques and their clinical utility. Quite often, parties request that Medicare make higher payment amounts under our New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies.

We note that, in a budget neutral environment, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice.

2. Proposed Movement of Procedures From New Technology APCs to Clinical APCs

As we explained in the November 30, 2001 final rule (66 FR 59902), we generally keep a procedure in the New Technology APC to which it is initially assigned until we have collected sufficient data to enable us to move the procedure to a clinically appropriate APC. However, in cases where we find that our original New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that most appropriately reflects its cost.

Consistent with our current policy, for CY 2013, we are proposing to retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to a clinically appropriate APC. The flexibility associated with this policy allows us to move a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for reassignment have not been collected.

Currently, in CY 2012, there are three procedures described by HCPCS G-codes receiving payment through a New Technology APC. Specifically, HCPCS code G0417 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 21–40 specimens) is assigned to New Technology APC 1505 (New Technology—Level V ($300–$400)); HCPCS code G0418 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41–60 specimens) is assigned to New Technology APC 1506 (New Technology—Level VI ($400–$500)); and HCPCS code G0419 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens) is assigned to New Technology APC 1508 (New Technology—Level VIII ($600–$700)). These HCPCS codes have been assigned to New Technology APCs since CY 2009.

Analysis of the hospital outpatient data for claims submitted for CY 2011 indicates that prostate saturation biopsy procedures are rarely performed on Medicare beneficiaries. For OPPS claims submitted from CY 2010 through CY 2011, our claims data show no single claim submitted for HCPCS code G0417 in CY 2010 or in CY 2011. Similarly, our claims data did not show any hospital

outpatient claims for HCPCS codes G0418 and G0419 from either CY 2010 or CY 2011. Given the continued lack of cost data for these HCPCS codes, we are proposing to reassign these procedures to an APC that is appropriate from a clinical standpoint. Specifically, we are proposing to reassign HCPCS G-codes G0417, G0418, and G0419 to clinical APC 0661 (Level V Pathology), which has a proposed APC cost of approximately $160 for CY 2013. We believe that all three procedures, as described by HCPCS codes G0417, G0418, and G0419, are comparable clinically to other pathology services currently assigned to APC 0661 and likely require similar resources.

Table 18 below lists the HCPCS G-codes and associated status indicators that we are proposing to reassign from New Technology APCs 1505, 1506, and 1508 to APC 0661 for CY 2013.

TABLE 18—PROPOSED REASSIGNMENT OF PROCEDURES ASSIGNED TO NEW TECHNOLOGY APCS FOR CY 2013

CY 2012 HCPCS Code	CY 2012 Short Descriptor	CY 2012 SI	CY 2012 APC	Proposed CY 2013 SI	Proposed CY 2013 APC
G0417	Sat biopsy prostate 21–40	S	1505	X	0661
G0418	Sat biopsy prostate 41–60	S	1506	X	0661
G0419	Sat biopsy prostate: >60	S	1508	X	0661

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

a. Background

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

The Administration has established an agenda to eliminate domestic reliance on these reactors, and is promoting the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, and conversion to such production has begun and is expected to be completed within a 5-year time period. We expect this change in the supply source for the radioisotope used for modern medical imaging will introduce new costs into the payment system that are not accounted for in the historical claims data.

Full Cost Recovery, which is routinely considered in CMS reimbursement, is the accounting practice used by producers and suppliers to describe the recovery of all contributing costs. Unlike legacy sources that often benefit from government subsidized multi-function facilities, the cost of these alternative methods will be increased over the cost of medical radioisotopes produced using HEU because hospitals' payments to producers and suppliers will have to cover capital expense (such as, for example, the cost of building new reactors, particle accelerators, or other very long term investments), as well as all other new industry-specific ancillary costs (such as, for example, the cost of long-term storage of radioactive waste). Hospitals that use medical radioisotopes that are produced from non-HEU sources can expect producers and suppliers to pass on to them the full impact of these costs.

In the short term, some hospitals will be able to depend on low cost legacy producers using aging subsidized reactors while other hospitals will be forced to absorb the full cost of non-HEU alternative sources. Over several years, we believe that these cost differentials will promote increased regional shortages and create larger cost differentials and greater cost variations between hospitals. As a result, we believe this change in supply source will create a significant payment inequity among hospitals resulting from factors that are outside of normal market forces.

b. Proposed Payment Policy

We are proposing to exercise our authority to establish ''other adjustments as determined to be necessary to ensure equitable payments'' under the OPPS in accordance with section 1833(t)(2)(E) of the Act. We do not believe that we can ensure equitable payments to hospitals over the next 4 to 5 years in the absence of an adjustment to account for the significant payment inequities created by factors that will likely arise due to the change in supply source for the radioisotope used commonly in modern medical imaging procedures. We are proposing to provide an adjustment for the marginal cost for radioisotopes produced from non-HEU sources over the costs for radioisotopes produced by HEU sources. We believe such an adjustment would ensure equitable payments in light of the Administration's HEU agenda, market influences, cost differentials, and cost variations that will create significant payment inequities among hospitals.

For CY 2013, we are proposing to make an additional payment of $10, which is an amount based on the best available estimations of the marginal costs associated with non-HEU Tc-99m production as calculated using Full Cost Recovery. We are proposing to establish a new HCPCS code, QXXXX (Tc-99m from non-HEU source, full cost recovery add-on, per dose) to describe the Tc-99m radioisotope produced by non-HEU methods and used in a diagnostic procedure. Hospitals would be able to report this code once per dose along with any diagnostic scan or scans using Tc-99m as long as the Tc-99m doses used can be certified by the hospital as coming from non-HEU sources and have been priced using a Full Cost Recovery accounting methodology. The code would pay hospitals for the additional (marginal) cost of using Tc-99m from a non-HEU source.

Hospitals would not be required to make a separate certification of the non-HEU source on the claim; the inclusion of the proposed new HCPCS QXXXX code on the claim would indicate that the hospital has met the conditions of the service definition as it does for any billed service. However, in the event of an audit, hospitals would be expected to be able to produce documentation that the individual dose delivered to the patient was completely produced from a non-HEU source. We are proposing three ways in which hospitals could accomplish this.

First, the hospital could produce documentation such as invoices or patient dose labels or tracking sheets that indicated that the patient's dose was completely produced from non-HEU sources and priced based on Full Cost Recovery. In this first case, the supplier would be expected to be able to trace a specific dose to a completely

non-HEU batch. Current pharmacy recordkeeping is generally able to trace all components of radiopharmaceuticals back to their source production batches. A hospital would not be compliant with the code definition if the documentation indicated the supplier had produced a mixed batch and labeled a fraction of the doses equal to the non-HEU fraction in the batch.

Second, a hospital could produce documentation that the entire batch of Tc-99m doses derives from non-HEU sources for a specified period of time, for example, the time that a single non-HEU based generator is in use. This approach would obviate the need for specific dose tracking from a claims audit perspective, although that information is typically required for other purposes. An attestation from the generator supplier would be sufficient evidence for the hospital, as would invoices that showed that all Tc-99m during a specified period came from inherently non-HEU alternative sources.

Third, if the industry should implement labeling of generators and/or doses with labels attesting to 100 percent non-HEU sources priced at Full Cost Recovery, documentation of labeled isotope usage using either the specific dose approach or the 100 percent hospital usage approach could provide evidence of hospital compliance. The hospital would be required to retain appropriate documentation within the hospital (including pharmacy) records but would not need to keep any specific documentation within the individual medical record. Also, we would consider a dose to be priced for Full Cost Recovery when the supplier could attest that the supply chain adheres to usual industry practices to account for Full Cost Recovery, specifically including the capital cost of sustainable production and the environmental cost of waste management.

To reduce the administrative overhead for hospitals, we are proposing not to require hospitals to separately track additional costs for the non-HEU Tc-99m, but to include the cost of the radioisotope in the cost of the diagnostic radiopharmaceutical as usual, reporting only a token $1 charge for the HCPCS QXXXX code line. We would continue to calculate the total costs of radionuclide scans using claims data, and would periodically recalculate the estimated marginal cost of non-HEU Full Cost Recovery sources using models relying on the best available industry reports and projections, and would adjust the payment for HCPCS QXXXX code accordingly, reducing the payment for the scans by the amount of cost paid through HCPCS QXXXX code payment. We believe this proposal would allow us to continuously compensate for unanticipated changes in Tc-99m cost attributable to new non-HEU supply sources.

D. Proposed OPPS APC-Specific Policies

1. Placement of Amniotic Membrane (APC 0233)

In CY 2011, the AMA CPT Editorial Panel revised the long descriptor for CPT code 65780 (Ocular surface reconstruction; amniotic membrane transplantation, multiple layers) to include the words ''multiple layers'' to further clarify the code descriptor. In addition, the AMA CPT Editorial Panel created two new CPT codes that describe the placement of amniotic membrane on the ocular surface without reconstruction: one describing the placement of a self-retaining (non-sutured/non-glued) device on the surface of the eye; and the other describing a single layer of amniotic membrane sutured to the surface of the eye. Specifically, the AMA CPT Editorial Panel established CPT codes 65778 (Placement of amniotic membrane on the ocular surface for wound healing; self-retaining) and 65779 (Placement of amniotic membrane on the ocular surface for wound healing; single layer, sutured), effective January 1, 2011.

As has been our practice since the implementation of the OPPS in 2000, we review all new procedures before assigning them to an APC. In determining the APC assignments for CPT codes 65778 and 65779, we took into consideration the clinical and resource characteristics involved with placement of amniotic membrane products on the eye for wound healing via a self-retaining device and a sutured, single-layer technique. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72402), we assigned CPT code 65778 to APC 0239 (Level II Repair and Plastic Eye Procedures), which had a payment rate of approximately $559, and CPT code 65779 to APC 0255 (Level II Anterior Segment Eye Procedures), which had a payment rate of approximately $519.

In addition, consistent with our longstanding policy for new codes, we assigned these two new CPT codes to interim APCs for CY 2011. Specifically, we assigned CPT codes 65778 and 65779 to comment indicator ''NI'' in Addendum B of the CY 2011 OPPS/ASC final rule with comment period to indicate that the codes were new with an interim APC assignment that were subject to public comment. In accordance with our longstanding policy, our interim APC assignments for each code was based on our understanding of the resources required to furnish the service as defined in the code descriptor and on input from our physicians.

At the Panel's February 28–March 1, 2011 meeting, a presenter requested the reassignment of CPT codes 65778 and 65779 to APC 0244 (Corneal and Amniotic Membrane Transplant), which is the same APC to which CPT code 65780 is assigned. The presenter indicated that prior to CY 2011, the procedures described by CPT codes 65578 and 65779 were previously reported under the original version of CPT code 65780, which did not specify ''multiple layers,'' and as such these new codes should continue to be assigned to APC 0244. Further, the presenter stated that the costs of the procedures described by CPT codes 65778 and 65779 are very similar to the procedure described by CPT code 65780.

The Panel recommended that CMS reassign the APC assignments for both CPT codes 65778 and 65779. Specifically, the Panel recommended the reassignment of CPT code 65778 from APC 0239 to APC 0233(Level III Anterior Segment Eye Procedures), and the reassignment of CPT code 65779 from APC 0255 to APC 0233. In addition, the Panel recommended that CMS furnish data when data become available for these two codes. We noted at that time that because these codes were effective January 1, 2011, the first available claims data for these codes would be for the CY 2013 OPPS rulemaking cycle.

We accepted the Panel's recommendations. However, in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74247), we indicated that, while we agreed with the Panel's recommendation to reassign CPT codes 65778 and 65779 to APC 0233, we believed that CPT code 65778 should be assigned to a conditionally packaged status indicator of ''Q2'' to indicate that the procedure would be packaged when it is reported with another procedure that is also assigned to status indicator ''T''; but in all other circumstances, the code would be paid separately. Because the procedure described by CPT code 65778 would rarely be provided as a separate, stand-alone service in the HOPD, and because the procedure would almost exclusively be provided in addition to and following another procedure or service, we proposed to reassign CPT code 65778 to a conditionally packaged status indicator of ''Q2.'' In addition, our

medical advisors indicated that the procedure described by CPT code 65778 is not significantly different than placing a bandage contact lens on the surface of the eye to cover a corneal epithelial defect. CPT code 65778 describes the simple placement of a special type of bandage (a self-retaining amniotic membrane device) on the surface of the eye, which would most commonly be used in the HOPD to cover the surface of the eye after a procedure that results in a corneal epithelial defect.

At the August 10–11, 2011 Panel Meeting, a presenter urged the Panel to recommend to CMS not to conditionally package CPT code 65778 for CY 2012, and instead, assign it to status indicator ''T.'' Based on information presented at the meeting, and after further discussion on the issue, the Panel recommended that CMS reassign the status indicator for CPT code 65778 from conditionally packaged ''Q2'' to status indicator ''T.'' Several commenters also urged CMS not to finalize its proposal to conditionally package CPT code 65778 by assigning it a status indicator ''Q2'' and instead adopt the Panel's recommendation to assign status indicator ''T.''

After consideration of the Panel's August 2011 recommendation and the public comments that we received to the CY 2012 OPPS/ASC proposed rule, we finalized our proposal and reassigned the status indicator for CPT code 65778 from ''T'' to ''Q2'' effective January 1, 2012 (76 FR 74246). Given the clinical characteristics of this procedure, we believed that conditionally packaging CPT code 65778 was appropriate under the OPPS.

For the CY 2013 OPPS update, we are proposing to continue to assign CPT code 65778 to its conditionally packaged status of ''Q2.'' Similarly, we believe that we should assign CPT code 65779 to a conditionally packaged status of ''Q2.'' Therefore, for CY 2013, we are proposing to revise the status indicator for CPT code 65779 from status indicator ''T'' to ''Q2'' to indicate that the procedure would be packaged when it is reported with another procedure that is also assigned to status indicator ''T,'' but in all other circumstances, the code would be paid separately. This reassignment would enable hospitals to perform either procedures (CPT code 65778 or 65779) when appropriate, and would not differentiate one procedure from the other because of the status indicator assignment under the OPPS.

As indicated at the February 28–March 1, 2011 Panel meeting, because CPT codes 65778 and 65779 were effective January 1, 2011, the first available claims data for these codes would be in CY 2012 for the CY 2013 OPPS rulemaking. We now have claims data for CPT codes 65778 and 65779, and our data show that both procedures are performed in the HOPD setting. Analysis of the CY 2011 claims data available for this proposed rule, which is based on claims processed from January 1 through December 31, 2011, reveals that the estimated cost for CPT code 65778 is approximately $1,025 based on 33 single claims (out of 130 total claims), and the estimated cost for CPT code 65779 is approximately $2,303 based on 35 single claims (out of 260 total claims). Based on the clinical similarity to other procedures currently assigned to APC 0233, and because there is no violation with the 2 times rule, we believe that we should continue to assign both CPT codes 65778 and 65779 to APC 0233, which has a proposed cost of approximately $1,150. Review of the procedures assigned to APC 0233 shows that the range of the CPT cost for the procedures with significant claims data is between approximately $859 (for CPT code 65400 (Removal of eye lesion)) and approximately $1,397 (for CPT code 66840 (Removal of lens material)).

In summary, for CY 2013, we are proposing to continue to assign CPT code 65778 to its conditionally packaged status of ''Q2'' and to reassign the status indicator for CPT code 65779 from ''T'' to ''Q2,'' similar to CPT code 65778. In addition, we are proposing to continue to assign both CPT codes 65778 and 65779 to APC 0233, which has a proposed cost of approximately $1,150. Both procedures and their CY 2013 proposed APC assignments are displayed in Table 19 below.

TABLE 19—PROPOSED APC ASSIGNMENTS FOR CPT CODES 65778 AND 65779 FOR CY 2013

CY 2012 HCPCS code	CY 2012 short descriptor	CY 2012 SI	CY 2012 APC	Proposed CY 2013 SI	Proposed CY 2013 APC
65778	Cover eye w/membrane	Q2	0233	Q2	0233
65779	Cover eye w/membrane suture	T	0233	Q2	0233

2. Proton Beam Therapy (APCs 0664 and 0667)

APC 0664 (Level I Proton Beam Radiation Therapy) includes two procedures, CPT code 77520 (Proton treatment delivery; simple, without compensation) with an estimated cost of approximately $331 (based on 185 single claims of 185 total claims submitted for CY 2011); and CPT code 77522 (Proton treatment delivery; simple, with compensation) with an estimated cost of approximately $1,191 (based on 14,279 single claims of 15,405 total claims submitted for CY 2011). APC 0667 (Level II Proton Beam Radiation Therapy) also includes two procedures, CPT code 77523 (Proton treatment delivery, intermediate) with an estimated cost of approximately $920 (based on 3,009 single claims of 3,202 total claims submitted for CY 2011), and CPT code 77525 (Proton treatment delivery, complex) with an estimated cost of approximately $483 (based on 1,400 single claims of 1,591 total claims submitted for CY 2011). Based on these CY 2011 claims data, the estimated cost of APC 0664 is approximately $1,171, and the estimated cost of APC 0667 is approximately $750.

Because only three providers bill Medicare for these services, their payment rates, which are set annually based on claims data according to the standard OPPS ratesetting methodology, may fluctuate significantly from year to year. For CY 2013, the estimated cost of APC 0664 is approximately the same as its CY 2012 payment rate of $1,184. However, the estimated cost of APC 0667 has decreased substantially, which is largely attributable to cost changes for CPT code 77523. For CY 2013, we are proposing to improve the resource homogeneity within the proton beam APCs by including the services requiring fewer resources in APC 0664 (Level I) and the services requiring greater resources in APC 0667 (Level II). Specifically, we are proposing to reassign CPT code 77522 to APC 0667 and to reassign CPT code 77525 to APC 0664. Under the proposed reassignment, the estimated cost of APC 0664 is $462 and the estimated cost of APC 0667 is $1,138. We are inviting public comments on this proposal.

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

a. Background

The AMA CPT Editorial Panel created three new Category I CPT codes for intraoperative radiation therapy (IORT), effective January 1, 2012: CPT codes 77424 (Intraoperative radiation treatment delivery, x-ray, single treatment session); 77425 (Intraoperative radiation treatment delivery, electrons, single treatment session); and 77469 (Intraoperative radiation treatment management). As with all new CPT codes for CY 2012, these three codes were included in Addendum B to the CY 2012 OPPS/ASC final rule with comment period (available via the CMS Web site), effective on January 1, 2012. In accordance with our standard practice each year, our clinicians review the many CPT code changes that will be effective in the forthcoming year and make decisions regarding status indicators and/or APC assignments based on their understanding of the nature of the services. We are unable to include proposed status indicators and/or APC assignments in the proposed rule for codes that are not announced by the AMA CPT Editorial Panel prior to the issuance of the proposed rule. Therefore, in accordance with our longstanding policy, we include, in the final rule with comment period, interim status indicators and/or APC assignments for all new CPT codes that are announced by the AMA CPT Editorial Panel subsequent to the issuance of the OPPS/ASC proposed rule to enable payment for new services as soon as the codes are effective.

We identified the new codes for IORT for CY 2012 in Addendum B to the CY 2012 OPPS/ASC final rule with comment period as being open to public comment by showing a comment indicator of ''NI'' and made interim status indicator assignments for each of these new IORT codes, based on our understanding of the clinical nature of the services they describe. Specifically, for CY 2012, we packaged these IORT service codes with the surgical procedures with which they are billed, assigning them interim status indicators of ''N'' (Items and Services Packaged into APC Rates). We did so based on a policy that was adopted in the CY 2008 OPPS final rule with comment period (72 FR 66610 through 66659) to package services that are typically ancillary and supportive of a principal diagnostic or therapeutic procedure, which would generally include intraoperative services. Because IORT are intraoperative services furnished as a single dose during the time of the related surgical session, we packaged them into the payment for the principal surgical procedures with which they are performed based on claims data used for the CY 2012 OPPS/ASC final rule with comment period.

Subsequent to issuance of the CY 2012 OPPS/ASC final rule with comment period, stakeholders provided comments on the interim status of these IORT service codes for CY 2012, asserting that these services are not ancillary to the surgical procedures, urging us to unpackage these codes, and requesting that we assign them to an APC reflective of the resources used to provide the IORT services. The stakeholders argued that IORT services described by CPT codes 77424 and 77425 are separate, distinct, and independent radiation treatment services from the surgical services to remove a malignant growth. According to the commenters, IORT is performed separately by a radiation oncologist and a medical physicist when there is concern for residual unresected cancer because of narrow margins related to the surgical resection.

b. CY 2013 Proposals for CPT Codes 77424, 77425, and 77469

Based on the comments and information received on the proposed IORT policies contained in the CY 2012 OPPS/ASC final rule with comment period, and after further review and consideration of those comments and the clinical nature of the IORT procedures, we agree that IORT services are not the typical intraoperative services that we package, as they are not integral to or dependent upon the surgical procedure to remove a malignancy that precedes IORT. Therefore, for CY 2013, we are proposing to unpackage CPT codes 77424 and 77425, and assign them to APC 0412, currently entitled ''IMRT Treatment Delivery.'' IORT treatment services are clinically similar to other radiation treatment forms, such as IMRT treatment, which are assigned to APC 0412. Furthermore, we are proposing to change the title of APC 0412 to ''Level III Radiation Therapy'' to encompass a greater number of clinically similar radiation treatment modalities. The proposed rule cost of APC 0412 based on CY 2011 claims data is approximately $496. As is our normal procedure for new CPT codes, we will monitor hospitals' costs for furnishing the services described by CPT codes 77424 and 77425.

We believe that CPT code 77469 should receive equal treatment to other radiation management codes, such as CPT code 77431 (Radiation therapy management with complete course of therapy consisting of 1 or 2 fractions only) and CPT code 77432 (Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of 1 session)), which are assigned status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) and are not paid under the OPPS. Therefore, we are proposing that the appropriate status indicator code assignment for CPT code 77469 be ''B'' for nonpayable status under the OPPS for CY 2013, a change from its current CY 2012 status indicator assignment of ''N'' for packaged payment status.

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 four device categories eligible for pass-through payment. These device categories are described by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device

(implantable)), which we made effective for pass-through payment October 1, 2010; HCPCS codes C1830 (Powered bone marrow biopsy needle) and C1840 (Lens, intraocular (telescopic)), which we made effective for pass-through payment October 1, 2011; and HCPCS code C1886 (Catheter, extravascular tissue ablation, any modality (insertable)), which we made effective for pass-through payment January 1, 2012. In the CY 2012 OPPS/ASC final rule with comment period, we finalized the expiration of pass-through payment for C1749, which will expire after December 31, 2012 (76 FR 74278). Therefore, after December 31, 2012, we will package the C1749 device costs into the costs of the procedures with which the devices are reported in the hospital claims data used in OPPS ratesetting.

b. Proposed CY 2013 Policy

As stated above, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2, but not more than 3 years. Device pass-through categories C1830 and C1840 were established for pass-through payments on October 1, 2011, and will have been eligible for pass-through payments for more than 2 years but less than 3 years as of the end of CY 2013. Also, device pass-through category C1886 was established for pass-through payments on January 1, 2012, and will have been eligible for pass-through payments for at least 2 years but less than 3 years as of the end of CY 2013. Therefore, we are proposing a pass-through payment expiration date for device categories C1830, C1840, and C1886 of December 31, 2013. Under our proposal, beginning January 1, 2014, device categories C1830, C1840, and C1886 will no longer be eligible for pass-through payments, and their respective device costs would be packaged into the costs of the procedures with which the devices are reported in the claims data.

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

We currently have published a list of all procedural APCs with the CY 2012 portions (both percentages and dollar amounts) of the APC payment amounts that we determine are associated with the cost of devices, on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The dollar amounts are used as the device APC offset amounts. In addition, in accordance with our established practice, the device APC offset amounts in a related APC are used in order to evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices, as specified in our regulations at § 419.66(d).

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

b. Proposed CY 2013 Policy

For CY 2013, we are proposing to continue our 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. We are proposing to continue our policy, for CY 2013, that the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only. The rationale for this policy is provided in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60471 through 60477). We also 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 2013, 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 a new device pass-through category that includes a newly eligible implantable biological beginning in CY 2013 using the same methodology we have historically used to calculate and set device APC offset amounts for device categories eligible for pass-through payment, and to include the costs of implantable biologicals in the calculation of the device APC offset amounts.

In addition, we are proposing to update, on the CMS Web site at

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html, the list of all procedural APCs with the final CY 2013 portions (once available at the time of final rulemaking) of the APC payment amounts that we determine are associated with the cost of devices so that this information is available for use by the public in developing potential CY 2013 device pass-through payment applications and by CMS in reviewing those applications.

3. Proposed Clarification of Existing Device Category Criterion

a. Background

Section 1833(t)(6)(B)(ii)(IV) of the Act directs the Secretary to establish a new device category for pass-through payment for which none of the pass-through categories in effect (or that were previously in effect) is appropriate. Commenters who responded to our various proposed rules, as well as applicants for new device categories, had expressed concern that some of our existing and previously in effect device category descriptors were overly broad, and that the device category descriptors as they are currently written may preclude some new technologies from qualifying for establishment of a new device category for pass-through payment (70 FR 68630 through 68631). As a result of these comments, we finalized a policy, effective January 1, 2006, to create an additional category for devices that meet all of the criteria required to establish a new category for pass-through payment in instances where we believe that an existing or previously in effect category descriptor does not appropriately describe the new device. Accordingly, effective January 1, 2006, we revised § 419.66(c)(1) of the regulations to reflect this policy change. In order to determine if a new device is appropriately described by any existing or previously in effect category of devices, we apply two tests based upon our evaluation of information provided to us in the device category application. First, an applicant for a new device category must show that its device is not similar to devices (including related predicate devices) whose costs are reflected in the currently available OPPS claims data in the most recent OPPS update. Second, an applicant must demonstrate that utilization of its device provides a substantial clinical improvement for Medicare beneficiaries compared with currently available treatments, including procedures utilizing devices in any existing or previously in effect device categories. We consider a new device that meets both of these tests not to be appropriately described by any existing or previously in effect pass-through device categories (70 FR 68630 through 68631).

b. Proposed Clarification of CY 2013 Policy

For CY 2013, we are proposing to clarify the test that requires an applicant for a new device category to show that its device is not similar to devices (including related predicate devices) whose costs are reflected in the currently available OPPS claims data in the most recent OPPS update. We are clarifying that this test includes showing that a new device is not similar to predicate devices that once belonged in any existing or previously in effect pass-through device categories. Under this test, a candidate device may not be considered to be appropriately described by any existing or previously in effect pass-through device categories if the applicant adequately demonstrates that the candidate device is not similar to devices (including related predicate devices) that belong or once belonged to an existing or any previously in effect device category, and that the candidate device is not similar to devices whose costs are reflected in the OPPS claims data in the most recent OPPS update. The substantial clinical improvement criterion, which also must be satisfied in every case, as indicated in § 419.66(c)(2) of our regulations, is separate from the criterion that a candidate device not be similar to devices in any existing or previously in effect pass-through categories. We are inviting public comments regarding this proposed clarification.

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 APCs and Devices Subject to the Adjustment Policy

For CY 2013, we are proposing to continue the existing policy of reducing OPPS payment for specified APCs by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. (We refer readers to section II.A.2.d.(1) of this proposed rule for a description of our standard ratesetting methodology for device-dependent APCs.)

For CY 2013, we also are proposing to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which this policy applies (71 FR 68072 through 68077). Specifically: (1) All procedures assigned to the selected APCs must involve implantable devices that would be reported if device insertion procedures were performed; (2) the required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and (3) the device offset amount must be significant, which, for purposes of this policy, is defined as exceeding 40 percent of the APC cost. We also 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 free devices and device credits are likely to be associated with particular cases only when the device must be reported on the claim and is of a type that is implanted and remains in the body when the beneficiary leaves the hospital. We believe that the reduction in payment is appropriate only when the cost of the device is a significant part of the total cost of the APC into which the device cost is packaged, and that the 40-percent threshold is a reasonable definition of a significant cost.

We examined the offset amounts calculated from the CY 2013 proposed rule data and the clinical characteristics of APCs to determine whether the APCs to which the no cost/full credit and partial credit device adjustment policy applied in CY 2012 continue to meet the criteria for CY 2013, and to determine whether other APCs to which the policy did not apply in CY 2012 would meet the criteria for CY 2013. Based on the CY 2011 claims data available for this proposed rule, we are not proposing any changes to the APCs and devices to which this policy applies.

Table 20 below lists the proposed APCs to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2013 and displays the proposed payment adjustment percentages for both no cost/full credit and partial credit circumstances. We are proposing that the no cost/full credit adjustment for each APC to which this policy would continue to apply would be the device offset percentage for the APC (the estimated percentage of the APC cost that is attributable to the device costs that are already packaged into the APC). We also are proposing that the partial credit device adjustment for each APC would continue to be 50 percent of the no cost/full credit adjustment for the APC.

Table 21 below lists the proposed devices to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2013. We will update the lists of APCs and devices to which the no cost/full credit and partial credit device adjustment policy would apply for CY 2013, consistent with the three criteria discussed earlier in this section, based on the final CY 2011 claims data available for the CY 2013 OPPS/ASC final rule with comment period.

We are proposing, for CY 2013, that OPPS payments for implantation procedures to which the ''FB'' modifier is appended are reduced by 100 percent of the device offset for no cost/full credit cases when both a device code listed in Table 21 below is present on the claim, and the procedure code maps to an APC listed in Table 20 below. We also are proposing that OPPS payments for implantation procedures to which the ''FC'' modifier is appended are reduced by 50 percent of the device offset when both a device code listed in Table 21 is present on the claim and the procedure code maps to an APC listed in Table 20. Beneficiary copayment is based on the reduced amount when either the ''FB'' modifier or the ''FC'' modifier is billed and the procedure and device codes appear on the lists of procedures and devices to which this policy applies.

TABLE 20—PROPOSED APCS TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY IN CY 2013

Proposed CY 2013 APC	Proposed CY 2013 APC Title	Proposed CY 2013 device offset percentage for no cost/ full credit case	Proposed CY 2013 device offset percentage for partial credit case
0039	Level I Implantation of Neurostimulator Generator	86	43
0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55	28
0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes	66	33
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	70	35
0090	Insertion/Replacement of Pacemaker Pulse Generator	71	35
0106	Insertion/Replacement of Pacemaker Leads and/or Electrodes	48	24
0107	Insertion of Cardioverter-Defibrillator	83	42
0108	Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes	84	42
0227	Implantation of Drug Infusion Device	82	41
0259	Level VII ENT Procedures	84	42
0315	Level II Implantation of Neurostimulator Generator	88	44
0318	Implantation of Cranial Neurostimulator Pulse Generator and Electrode	87	44
0385	Level I Prosthetic Urological Procedures	63	31
0386	Level II Prosthetic Urological Procedures	70	35
0425	Level II Arthroplasty or Implantation with Prosthesis	58	29
0648	Level IV Breast Surgery	50	25
0654	Insertion/Replacement of a permanent dual chamber pacemaker	74	37
0655	Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode.	73	37
0680	Insertion of Patient Activated Event Recorders	74	37

TABLE 21—PROPOSED DEVICES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY IN CY 2013

Proposed CY 2013 device HCPCS Code	Proposed CY 2013 short descriptor
C1721	AICD, dual chamber.
C1722	AICD, single chamber.
C1728	Cath, brachytx seed adm.
C1764	Event recorder, cardiac.
C1767	Generator, neurostim, imp.
C1771	Rep dev, urinary, w/sling.
C1772	Infusion pump, programmable.
C1776	Joint device (implantable).
C1777	Lead, AICD, endo single coil.
C1778	Lead, neurostimulator.
C1779	Lead, pmkr, transvenous VDD.
C1785	Pmkr, dual, rate-resp.
C1786	Pmkr, single, rate-resp.
C1789	Prosthesis, breast, imp.
C1813	Prosthesis, penile, inflatab.
C1815	Pros, urinary sph, imp.
C1820	Generator, neuro rechg bat sys.
C1881	Dialysis access system.
C1882	AICD, other than sing/dual.
C1891	Infusion pump, non-prog, perm.
C1895	Lead, AICD, endo dual coil.
C1896	Lead, AICD, non sing/dual.
C1897	Lead, neurostim, test kit.
C1898	Lead, pmkr, other than trans.
C1899	Lead, pmkr/AICD combination.
C1900	Lead coronary venous.
C2619	Pmkr, dual, non rate-resp.
C2620	Pmkr, single, non rate-resp.
C2621	Pmkr, other than sing/dual.
C2622	Prosthesis, penile, non-inf.
C2626	Infusion pump, non-prog, temp.
C2631	Rep dev, urinary, w/o sling.
L8600	Implant breast silicone/eq.
L8614	Cochlear device/system.
L8680	Implt neurostim elctr each.
L8685	Implt nrostm pls gen sng rec.
L8686	Implt nrostm pls gen sng non.
L8687	Implt nrostm pls gen dua rec.
L8688	Implt nrostm pls gen dua non.
L8690	Aud osseo dev, int/ext comp.

V. 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 (BBRA) of 1999 (Pub. L. 106–113), this provision requires the Secretary to make additional payments to hospitals for: current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act (Pub. L. 107–186); current drugs and biologicals and brachytherapy sources used for the treatment of cancer; and current radiopharmaceutical drugs and biologicals. For those drugs and biologicals referred to as ''current,'' the transitional pass-through payment began on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996, and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' Under the statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the product's first payment as a hospital outpatient service under Medicare Part B. Proposed CY 2013 pass-through drugs and biologicals and their designated APCs 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 is not proposed to be reinstated for CY 2013.

This methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological. Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this 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*.

For CYs 2005, 2006, and 2007, we estimated the OPPS pass-through payment amount for drugs and biologicals to be zero based on our interpretation that the ''otherwise applicable Medicare OPD fee schedule'' amount was equivalent to the amount to be paid for pass-through drugs and biologicals under section 1842(o) of the Act (or section 1847B of the Act). We concluded for those years that the resulting difference between these two rates would be zero. For CYs 2008 and 2009, we estimated the OPPS pass-through payment amount for drugs and biologicals to be $6.6 million and $23.3 million, respectively. For CY 2010, we estimated the OPPS pass-through payment estimate for drugs and biologicals to be $35.5 million. For CY 2011, we estimated the OPPS pass-through payment for drugs and biologicals to be $15.5 million. For CY 2012, we estimated the OPPS pass-through payment for drugs and biologicals to be $19 million. Our proposed OPPS pass-through payment estimate for drugs and biologicals in CY 2013 is $32 million, which is discussed in section VI.B. of this proposed rule.

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 2012

We are proposing that the pass-through status of 23 drugs and biologicals would expire on December 31, 2012, as listed in Table 22 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, 2012.

These drugs and biologicals were approved for pass-through status on or before January 1, 2011. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through status, specifically diagnostic radiopharmaceuticals and contrast agents, our standard methodology for providing payment for drugs and biologicals with expiring pass-through status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed at $80), as discussed further in section V.B.2. of this proposed rule. If the drug's or biological's estimated per day cost is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we would provide separate payment at the applicable relative ASP-based payment amount (which is proposed at ASP+6 percent for CY 2013, as discussed further in section V.B.3. of this proposed rule). Section II.A.3.d. of this proposed rule discusses the packaging of all nonpass-through contrast agents and diagnostic radiopharmaceuticals.

TABLE 22—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS WILL EXPIRE DECEMBER 31, 2012

Proposed CY 2013 HCPCS Code	Proposed CY 2013 long descriptor	Proposed CY 2013 SI	Proposed CY 2013 APC
C9275	Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose	N	N/A
C9279	Injection, ibuprofen, 100 mg	N	N/A
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	K	9367
J0221	Injection, alglucosidase alfa, (lumizyme), 10 mg	K	1413
J0588	Injection, incobotulinumtoxin A, 1 unit	K	9278
J0597	Injection, C-1 esterase inhibitor (human), Berinert, 10 units	K	9269
J0775	Injection, collagenase clostridium histolyticum, 0.01 mg	K	1340
J0840	Injection, crotalidae polyvalent immune fab (ovine), up to 1 gram	K	9274
J0897	Injection, denosumab, 1 mg	K	9272
J1290	Injection, ecallantide, 1 mg	K	9263
J1557	Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg	K	9270
J3095	Injection, telavancin, 10 mg	K	9258
J3262	Injection, tocilizumab, 1 mg	K	9264
J3357	Injection, ustekinumab, 1 mg	K	9261
J3385	Injection, velaglucerase alfa, 100 units	K	9271
J7183	Injection, von Willebrand factor complex (human), Wilate, per 100 IU VWF: RCO	N	N/A
J7335	Capsaicin 8% patch, per 10 square centimeters	K	9268
J8562	Fludarabine phosphate, oral, 10 mg	K	
J9043	Injection, cabazitaxel, 1 mg	K	1339
J9302	Injection, ofatumumab, 10 mg	K	9260
J9307	Injection, pralatrexate, 1 mg	K	9259
J9315	Injection, romidepsin, 1 mg	K	9265
Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion.	K	9273

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

We are proposing to continue pass-through status in CY 2013 for 21 drugs and biologicals. None of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2012. These drugs and biologicals, which were approved for pass-through status between April 1, 2011 and July 1, 2012, are listed in Table 23 below. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through April 1, 2012 are assigned status indicator ''G'' in Addenda A and B of this proposed rule and 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 2013, the amount that drugs and biologicals receive under section 1842(o) of the Act.

Thus, for CY 2013, 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 2013. We are proposing that a $0.00 pass-through payment amount would be paid for most pass-through drugs and biologicals under the CY 2013 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, proposed at ASP+6 percent, is $0.

In the case of pass-through contrast agents and diagnostic radiopharmaceuticals, their pass-through payment amount would be equal to ASP+6 percent because, if not on pass-through status, payment for these products would be packaged into the associated procedure. Therefore, we are proposing that the difference between ASP+6 percent and the ''policy-packaged'' drug APC offset amount for the associated clinical APC in which the drug or biological is utilized would be the CY 2013 pass-through payment amount for these policy-packaged products.

In addition, we are proposing to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2013 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 42722 and 42723).

In CY 2013, as is consistent with our CY 2012 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 2013, 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.d. of this proposed rule, over the last 5 years, we implemented a policy whereby payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, is packaged into payment for the associated procedure. We are proposing to continue the packaging of these items, regardless of their per day cost, in CY 2013. As stated earlier, pass-through payment is the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. Because payment for a drug that is either a diagnostic radiopharmaceutical or a contrast agent (identified as a ''policy-packaged'' drug, first described in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68639)) would otherwise be packaged if the product did not have pass-through status, we believe the otherwise applicable OPPS payment amount would be equal to the ''policy-packaged'' drug APC offset amount for the associated clinical APC in which the drug or biological is utilized. The calculation of the ''policy-packaged'' drug APC offset amounts is described in more detail in section IV.A.2. of this 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 2012, we are proposing to continue to set the associated copayment amount for pass-through diagnostic radiopharmaceuticals and contrast agents that would otherwise be packaged if the item did not have pass-through status to zero for CY 2013. Similarly, we are proposing that the associated copayment amount for pass-through anesthesia drugs that would otherwise be packaged if the item did not have pass-through status would be zero for CY 2013. As discussed in further detail in section II.3.c.2. of this proposed rule, we are clarifying that our general policy is to package drugs used for anesthesia, and that those anesthesia drugs with pass-through status will be packaged upon the expiration of pass-through status.

The separate OPPS payment to a hospital for the pass-through diagnostic radiopharmaceutical, contrast agent, or anesthesia drug is not subject to a copayment according to the statute. Therefore, we 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).

The 21 drugs and biologicals that we are proposing to continue on pass-through status for CY 2013 or that have been granted pass-through status as of July 2012 are displayed in Table 23.

TABLE 23—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN CY 2013

Proposed CY 2013 HCPCS code	CY 2013 Long descriptor	Proposed CY 2013 SI	Proposed CY 2013 APC
A9584	Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries	G	9406
C9285	Lidocaine 70 mg/tetracaine 70 mg, per patch	G	9285
C9286	Injection, belatacept, 1 mg	G	9286
C9287	Injection, brentuximab vedotin, 1 mg	G	9287
C9288	Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial	G	9288
C9289	Injection, asparaginase Erwinia chrysanthemi, 1,000 international units (I.U.)	G	9289
C9290	Injection, bupivicaine liposome, 1 mg	G	9290
C9366	EpiFix, per square centimeter	G	9366
C9368**	Grafix core, per square centimeter	G	9368
C9369**	Grafix prime, per square centimeter	G	9369
J0131	Injection, acetaminophen, 10 mg	G	9283
J0490	Injection, belimumab, 10 mg	G	1353
J0638	Injection, canakinumab, 1mg	G	1311
J0712	Injection, ceftaroline fosamil, 10 mg	G	9282
J1572	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg.	G	0947
J2507	Injection, pegloticase, 1 mg	G	9281
J7180	Injection, factor xiii (antihemophilic factor, human), 1 i.u	G	1416
J9179	Injection, eribulin mesylate, 0.1 mg	G	1426
J9228	Injection, ipilimumab, 10 mg	G	9284
Q2046*	Injection, aflibercept, 1 mg	G	1420

TABLE 23—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN CY 2013—Continued

Proposed CY 2013 HCPCS code	CY 2013 Long descriptor	Proposed CY 2013 SI	Proposed CY 2013 APC
Q4124	Oasis Ultra Tri-Layer matrix, per square centimeter	G	9365

*HCPCS code Q2046 replaced HCPCS code C9291 effective July 1, 2012. Because the payment rate associated with this code effective July 1, 2012 is 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 2012 OPPS quarterly update CR could not be included in Addendum B to this proposed rule.

**Because the payment rates associated with these codes effective July 1, 2012 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 2012 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 and Contrast Agents to Offset Costs Packaged into APC Groups

a. Background

Prior to CY 2008, diagnostic radiopharmaceuticals and contrast agents were paid separately under the OPPS if their mean per day costs were greater than the applicable year's drug packaging threshold. In CY 2008 (72 FR 66768), we began a policy of packaging payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents as ancillary and supportive items and services into their associated nuclear medicine procedures. Therefore, beginning in CY 2008, nonpass-through diagnostic radiopharmaceuticals and contrast agents were not subject to the annual OPPS drug packaging threshold to determine their packaged or separately payable payment status, and instead all nonpass-through diagnostic radiopharmaceuticals and contrast agents were packaged as a matter of policy. For CY 2013, we are proposing to continue to package payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, as discussed in section II.A.3.d. 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 it continue receiving pass-through status in CY 2013. We currently apply the established radiopharmaceutical payment offset policy to pass-through payment for this product. As described earlier in section V.A.3. of this proposed rule, we are proposing that new pass-through diagnostic radiopharmaceuticals would be paid at ASP+6 percent, while those without ASP information would be paid at WAC+6 percent or, if WAC is not available, payment would be based on 95 percent of the product's most recently published AWP.

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

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60480 through 60484), we finalized a policy to redefine ''policy-packaged'' drugs as only nonpass-through diagnostic radiopharmaceuticals and contrast agents, as a result of the policy discussed in sections V.A.4. and V.B.2.d. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60471 through 60477 and 60495 through 60499, respectively) that treats nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) with newly approved pass-through status beginning in CY 2010 or later as devices, rather than drugs. To determine the actual APC offset amount for pass-through diagnostic radiopharmaceuticals that takes into consideration the otherwise applicable OPPS payment amount, we multiply the ''policy-packaged'' drug offset fraction by the APC payment amount for the nuclear medicine procedure with which the pass-through diagnostic radiopharmaceutical is used and, accordingly, reduce the separate OPPS payment for the pass-through diagnostic radiopharmaceutical by this amount.

Beginning in CY 2011 and as discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71934 through 71936), we finalized a policy to require hospitals to append modifier ''FB'' to specified nuclear medicine procedures when the diagnostic radiopharmaceutical is received at no cost/full credit. These instructions are contained within the I/OCE CMS specifications on the CMS Web site at *http://www.cms.gov/Medicare/Coding/OutpatientCodeEdit/index.html*.

For CY 2013 and future years, we are proposing to continue to require hospitals to append modifier ''FB'' to specified nuclear medicine procedures when the diagnostic radiopharmaceutical is received at no cost/full credit. In addition, we are proposing to continue to require that when a hospital bills with an ''FB'' modifier with the nuclear medicine scan, the payment amount for procedures in the APCs listed in Table 24 of this proposed rule would be reduced by the full ''policy-packaged'' offset amount appropriate for diagnostic radiopharmaceuticals. Finally, we also are proposing to continue to require

hospitals to report a token charge of less than $1.01 in cases in which the diagnostic radiopharmaceutical is furnished without cost or with full credit.

For CY 2012, we finalized a policy to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals, as described above. For CY 2013, we are proposing to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals.

Table 24 below displays the proposed APCs to which nuclear medicine procedures would be assigned in CY 2013 and for which we expect that an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

TABLE 24—PROPOSED APCS TO WHICH NUCLEAR MEDICINE PROCEDURES WOULD BE ASSIGNED FOR CY 2013

Proposed CY 2013 APC	Proposed CY 2013 APC title
0308	Positron Emission Tomography (PET) Imaging.
0377	Level II Cardiac Imaging.
0378	Level II Pulmonary Imaging.
0389	Level I Non-imaging Nuclear Medicine.
0390	Level I Endocrine Imaging.
0391	Level II Endocrine Imaging.
0392	Level II Non-imaging Nuclear Medicine.
0393	Hematologic Processing & Studies.
0394	Hepatobiliary Imaging.
0395	GI Tract Imaging.
0396	Bone Imaging.
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, new pass-through contrast agents would be paid at ASP+6 percent, while those without ASP information would be paid at WAC+6 percent or, if WAC is not available, payment would be based on 95 percent of the product's most recently published AWP.

Although there are no contrast agents with pass-through status, we believe that a payment offset is necessary in the event that a new contrast agent is approved for pass-through status during CY 2013, in order to provide an appropriate transitional pass-through payment for them because all of these items are packaged when they do not have pass-through status. In accordance with our standard offset methodology, we are proposing for CY 2013 to deduct from the payment for new pass-through contrast agents that are approved for pass-through status as a drug or biological during CY 2013, an amount that reflects the portion of the APC payment associated with predecessor contrast agents, in order to ensure no duplicate contrast agent payment is made.

In CY 2010, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor contrast agents when considering new contrast agents for pass-through payment (74 FR 60482 through 60484). For CY 2013, as we did in CY 2012, we 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 clinical APCs calculated as 1 minus (the cost from single procedure claims in the APC after removing the cost for ''policy-packaged'' drugs divided by the cost from single procedure claims in the APC). In CY 2010, we finalized a policy to redefine ''policy-packaged'' drugs as only nonpass-through diagnostic radiopharmaceuticals and contrast agents (74 FR 60495 through 60499). To determine the actual APC offset amount for pass-through contrast agents that takes into consideration the otherwise applicable OPPS payment amount, we 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 2013 to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 25 of this proposed rule, a specific offset based on the procedural APC would be applied to payments for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

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, including contrast agents, and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, ''policy-packaged'' drugs, and ''threshold-packaged'' drugs and biologicals for every OPPS clinical APC.

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 24 above and these APCs are displayed in Table 25 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 (70 FR 60483 through 60484). For CY 2013, 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 25, a specific offset based on the procedural APC would be applied to payment for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

TABLE 25—PROPOSED APCS TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2013

Proposed CY 2013 APC	Proposed CY 2013 APC title
0080	Diagnostic Cardiac Catheterization.
0082	Coronary or Non-Coronary Atherectomy.

TABLE 25—PROPOSED APCS TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2013—Continued

Proposed CY 2013 APC	Proposed CY 2013 APC title
0083	Coronary Angioplasty, Valvuloplasty, and Level I Endovascular Revascularization
0093	Vascular Reconstruction/Fistula Repair without Device.
0104	Transcathether Placement of Intracoronary Stents.
0128	Echocardiogram with Contrast.
0152	Level I Percutaneous Abdominal and Biliary Procedures.
0229	Level II Endovascular Revascularization of the Lower Extremity.
0278	Diagnostic Urography.
0279	Level II Angiography and Venography.
0280	Level III Angiography and Venography.
0283	Computed Tomography with Contrast.
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast.
0333	Computed Tomography without Contrast followed by Contrast.
0334	Combined Abdomen and Pelvis CT with Contrast.
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast.
0375	Ancillary Outpatient Services When Patient Expires.
0383	Cardiac Computed Tomographic Imaging.
0388	Discography.
0442	Dosimetric Drug Administration.
0653	Vascular Reconstruction/Fistula Repair with Device.
0656	Transcatheter Placement of Intracoronary Drug-Eluting Stents.
0662	CT Angiography.
0668	Level I Angiography and Venography.
8006	CT and CTA with Contrast Composite.
8008	MRI and MRA with Contrast Composite.

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

1. Background

Under the CY 2012 OPPS, we currently pay for drugs, biologicals, and radiopharmaceuticals that do not have pass-through status in one of two ways: As a packaged payment included in the payment for the associated service, or as a separate payment (individual APCs). We explained in the April 7, 2000 OPPS final rule with comment period (65 FR 18450) that we generally package the cost of drugs and radiopharmaceuticals into the APC payment rate for the procedure or treatment with which the products are usually furnished. Hospitals do not receive separate payment for packaged items and supplies, and hospitals may not bill beneficiaries separately for any packaged items and supplies whose costs are recognized and paid within the national OPPS payment rate for the associated procedure or service. (Transmittal A–01–133, issued on November 20, 2001, explains in greater detail the rules regarding separate payment for packaged services.)

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

2. 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; and for CY 2012, we set the packaging threshold at $75.

Following the CY 2007 methodology, for this CY 2013 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 2013 and rounded the resulting dollar amount ($81.59) to the nearest $5 increment, which yielded a figure of $80. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics (BLS) series code WPUSI07003) from CMS' Office of the Actuary (OACT). (We note that we are not proposing a change to the PPI that is used to calculate the threshold for CY 2013; rather, this change in terminology reflects a change to the BLS naming convention for this series.) We refer below to this series generally as the PPI for Prescription Drugs.

We chose this PPI as it reflects price changes associated with the average mix of all pharmaceuticals in the overall economy. In addition, we chose this price series because it is publicly available and regularly published, improving public access and transparency. Forecasts of the PPI for Prescription Drugs are developed by IHS Global Insight, Inc., a nationally recognized economic and financial forecasting firm. As actual inflation for past quarters replaced forecasted amounts, the PPI estimates for prior quarters have been revised (compared with those used in the CY 2007 OPPS/

ASC final rule with comment period) and have been incorporated into our calculation. Based on the calculations described above, we are proposing a packaging threshold for CY 2013 of $80. (For a more detailed discussion of the OPPS drug packaging threshold and the use of the PPI for Prescription Drugs, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086).)

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

To determine the proposed CY 2013 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, nonimplantable biologicals, and therapeutic radiopharmaceuticals (collectively called ''threshold-packaged'' drugs) that had a HCPCS code in CY 2011 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2011 claims processed before January 1, 2012 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages as described in section V.B.2.c. of this proposed rule or for diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals that we are proposing to continue to package in CY 2013, as discussed in section V.B.2.d. of this proposed rule.

In order to calculate the per day costs for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2013, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 70 FR 68638). For each drug and nonimplantable biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we are proposing for separately payable drugs and nonimplantable biologicals for CY 2013, as discussed in more detail in section V.B.3.b. of this proposed rule) to calculate the CY 2013 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2011 (data that were used for payment purposes in the physician's office setting, effective April 1, 2012) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2013 we are proposing to use payment rates based on the ASP data from the fourth quarter of CY 2011 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to 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 were also the bases for drug payments in the physician's office setting, effective April 1, 2012. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2011 hospital claims data to determine their per day cost.

We are proposing to package items with a per day cost less than or equal to $80, and identify items with a per day cost greater than $80 as separately payable. Consistent with our past practice, we crosswalked historical OPPS claims data from the CY 2011 HCPCS codes that were reported to the CY 2012 HCPCS codes that we display in Addendum B of this proposed rule (which is available via the Internet on the CMS Web site) for payment in CY 2013.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period will be subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and nonimplantable biologicals in the CY 2013 OPPS/ASC final rule with comment period, we are proposing to use ASP data from the first quarter of CY 2012, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective July 1, 2012, along with updated hospital claims data from CY 2011. We note that we also are proposing to use these data for budget neutrality estimates and impact analyses for the CY 2013 OPPS/ASC final rule with comment period.

Payment rates for HCPCS codes for separately payable drugs and nonimplantable biologicals included in Addenda A and B to the final rule with comment period will be based on ASP data from the second quarter of CY 2012. 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, 2012. These physician's office payment rates would then be updated in the January 2013 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2013. For items that do not currently have an ASP-based payment rate, we are proposing to recalculate their mean unit cost from all of the CY 2011 claims data and updated cost report information available for the CY 2013 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals in this CY 2013 OPPS/ASC proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the 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 2013 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2012. Specifically, for CY 2013, consistent with our historical practice, we are proposing to apply the following policies to these HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals whose relationship to the proposed $80 drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and nonimplantable biologicals that were paid separately in CY 2012 and that are proposed for separate payment in CY 2013, and that then have per day costs equal to or less than $80, based on the updated ASPs and hospital claims data used for this CY 2013 proposed rule, would continue to receive separate payment in CY 2013.
- HCPCS codes for drugs and nonimplantable biologicals that were packaged in CY 2012 and that are proposed for separate payment in CY 2013, and that then have per day costs equal to or less than $80, based on the updated ASPs and hospital claims data

used for this CY 2013 proposed rule, would remain packaged in CY 2013.

• HCPCS codes for drugs and nonimplantable biologicals for which we are proposing packaged payment in CY 2013 but then have per day costs greater than $80, based on the updated ASPs and hospital claims data used for this CY 2013 proposed rule, would receive separate payment in CY 2013.

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 2013, we continue to believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to payment incentives for hospitals to report certain HCPCS codes for drugs instead of others. Making packaging determinations on a drug-specific basis eliminates these incentives and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, 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 2013.

For CY 2013, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2011 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. HCPCS codes J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units), Q0171 (Chlorpromazine hydrochloride, 10 mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen), Q0172 (Chlorpromazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen), Q0175 (Perphenazine, 4 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen), Q0176 (Perphenazine, 8 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen), Q0177 (Hydroxyzine pamoate, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen), and Q0178 (Hydroxyzine pamoate, 50 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen) did not have pricing information available for the ASP methodology and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the fourth quarter CY 2011 claims data to make the packaging determinations for these drugs. For all other drugs and biologicals that have HCPCS codes describing different dosages, we then multiplied the weighted average ASP+6 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to $80 (whereupon all HCPCS codes for the same drug or biological would be packaged) or greater than $80 (whereupon all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply is displayed in Table 26 below.

TABLE 26—PROPOSED HCPCS CODES TO WHICH THE CY 2013 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY

Proposed CY 2013 HCPCS code	Proposed CY 2013 long descriptor	Proposed CY 2013 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1070	Injection, testosterone cypionate, up to 100 mg	N
J1080	Injection, testosterone cypionate, 1 cc, 200 mg	N
J1440	Injection, filgrastim (g-csf), 300 mcg	K
J1441	Injection, filgrastim (g-csf), 480 mcg	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	N
J1560	Injection, gamma globulin, intramuscular over 10 cc	N
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J2270	Injection, morphine sulfate, up to 10 mg	N
J2271	Injection, morphine sulfate, 100mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	K
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	K
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3120	Injection, testosterone enanthate, up to 100 mg	N
J3130	Injection, testosterone enanthate, up to 200 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7050	Infusion, normal saline solution , 250 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7030	Infusion, normal saline solution , 1000 cc	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	K
J8521	Capecitabine, oral, 500 mg	K
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N
Q0164	Prochlorperazine maleate, 5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
Q0165	Prochlorperazine maleate, 10 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.	N
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'' is a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

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

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

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

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

It has been our longstanding policy to treat all separately payable drugs and biologicals, which includes SCODs, and drugs and biological that are not SCODs, the same. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii)(I) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy choice rather than a statutory requirement. Later in the discussion of our proposed policy for CY 2013, we are proposing to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals. Although we do not distinguish SCODs in that discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we are choosing to apply it to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

In the CY 2006 OPPS proposed rule (70 FR 42728 through 42731), we discussed the June 2005 report by MedPAC regarding pharmacy overhead costs in HOPDs and summarized the findings of that study. In response to the MedPAC findings, in the CY 2006 OPPS proposed rule (70 FR 42729), we discussed our belief that, because of the varied handling resources required to prepare different forms of drugs, it would be impossible to exclusively and appropriately assign a drug to a certain overhead category that would apply to all hospital outpatient uses of the drug. Therefore, our CY 2006 OPPS proposal included a proposal to establish three distinct Level II HCPCS C-codes and three corresponding APCs for drug handling categories to differentiate overhead costs for drugs and biologicals (70 FR 42730). We also proposed: (1) To combine several overhead categories recommended by MedPAC; (2) to establish three drug handling categories, as we believed that larger groups would minimize the number of drugs that may fit into more than one category and would lessen any undesirable payment policy incentives to utilize particular forms of drugs or specific preparation methods; (3) to collect hospital charges for these HCPCS C-codes for 2 years; and (4) to ultimately base payment for the corresponding drug handling APCs on CY 2006 claims data available for the CY 2008 OPPS.

In the CY 2006 OPPS final rule with comment period (70 FR 68659 through 68665), we discussed the public comments we received on our proposal regarding pharmacy overhead. The overwhelming majority of commenters did not support our proposal regarding pharmacy overhead and urged us not to finalize this policy, as it would be administratively burdensome for hospitals to establish charges for HCPCS codes for pharmacy overhead and to report them. Therefore, we did not finalize this proposal for CY 2006. Instead, we established payment for separately payable drugs and biologicals at ASP+6 percent, which we calculated by comparing the estimated aggregate cost of separately payable drugs and biologicals in our claims data to the estimated aggregate ASP dollars for separately payable drugs and biologicals, using the ASP as a proxy for average acquisition cost (70 FR 68642). Hereinafter, we refer to this methodology as our standard drug payment methodology. We concluded that payment for drugs and biologicals and pharmacy overhead at a combined ASP+6 percent rate would serve as an acceptable proxy for the combined acquisition and overhead costs of each of these products.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68091), we finalized our proposed policy to provide a single payment of ASP+6 percent for the hospital's acquisition cost for the drug or biological and all associated pharmacy overhead and handling costs. The ASP+6 percent rate that we finalized was higher than the equivalent average ASP-based amount calculated from claims of ASP+4 percent according to our standard drug payment methodology, but we adopted payment at ASP+6 percent for stability while we continued to examine the issue of the costs of pharmacy overhead in the HOPD and awaited the accumulation of CY 2006 data as discussed in the prior year's rule.

In the CY 2008 OPPS/ASC proposed rule (72 FR 42735), in response to ongoing discussions with interested parties, we proposed to continue our methodology of providing a combined payment rate for drug and biological acquisition and pharmacy overhead costs while continuing our efforts to improve the available data. We also proposed to instruct hospitals to remove the pharmacy overhead charge for both packaged and separately payable drugs

and biologicals from the charge for the drug or biological and report the pharmacy overhead charge on an uncoded revenue code line on the claim. We believed that this would provide us with an avenue for collecting pharmacy handling cost data specific to drugs in order to package the overhead costs of these items into the associated procedures, most likely drug administration services. Similar to the public response to our CY 2006 pharmacy overhead proposal, the overwhelming majority of commenters did not support our CY 2008 proposal and urged us to not finalize this policy (72 FR 66761). At its September 2007 meeting, the APC Panel recommended that hospitals not be required to separately report charges for pharmacy overhead and handling and that payment for overhead be included as part of drug payment. The APC Panel also recommended that CMS continue to evaluate alternative methods to standardize the capture of pharmacy overhead costs in a manner that is simple to implement at the organizational level (72 FR 66761). Because of concerns expressed by the APC Panel and public commenters, we did not finalize the proposal to instruct hospitals to separately report pharmacy overhead charges for CY 2008. Instead, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66763), we finalized a policy of providing payment for separately payable drugs and biologicals and their pharmacy overhead at ASP+5 percent as a transition from their CY 2007 payment of ASP+6 percent to payment based on the equivalent average ASP-based payment rate calculated from hospital claims according to our standard drug payment methodology, which was ASP+3 percent for the CY 2008 OPPS/ASC final rule with comment period. Hospitals continued to include charges for pharmacy overhead costs in the line-item charges for the associated drugs reported on claims.

For CY 2009, we proposed to pay separately payable drugs and biologicals at ASP+4 percent, including both SCODs and other drugs without CY 2009 OPPS pass-through status, based on our standard drug payment methodology. We also continued to explore mechanisms to improve the available data. We proposed to split the ''Drugs Charged to Patients'' cost center into two cost centers: One for drugs with high pharmacy overhead costs and one for drugs with low pharmacy overhead costs (73 FR 41492). We noted that we expected that CCRs from the proposed new cost centers would be available in 2 to 3 years to refine OPPS drug cost estimates by accounting for differential hospital markup practices for drugs with high and low overhead costs. After consideration of the public comments received and the APC Panel recommendations, we finalized a CY 2009 policy (73 FR 68659) to provide payment for separately payable nonpass-through drugs and biologicals based on costs calculated from hospital claims at a 1-year transitional rate of ASP+4 percent, in the context of an equivalent average ASP-based payment rate of ASP+2 percent calculated according to our standard drug payment methodology from the final rule claims data and cost report data. We did not finalize our proposal to split the single standard ''Drugs Charged to Patients'' cost center into two cost centers largely due to concerns raised by hospitals about the associated administrative burden. Instead, we indicated in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68659) that we would continue to explore other potential approaches to improve our drug cost estimation methodology, thereby increasing payment accuracy for separately payable drugs and biologicals.

In response to the CMS proposals for the CY 2008 and CY 2009 OPPS, a group of pharmacy stakeholders (hereinafter referred to as the pharmacy stakeholders), including some cancer hospitals, some pharmaceutical manufacturers, and some hospital and professional associations, commented that CMS should pay an acquisition cost of ASP+6 percent for separately payable drugs, should substitute ASP+6 percent for the packaged cost of all packaged drugs and biologicals on procedure claims, and should redistribute the difference between the aggregate estimated packaged drug cost in claims and payment for all drugs, including packaged drugs at ASP+6 percent, as separate pharmacy overhead payments for separately payable drugs. They indicated that this approach would preserve the aggregate drug cost observed in the claims data, while significantly increasing payment accuracy for individual drugs and procedures by redistributing drug cost from packaged drugs. Their suggested approach would provide a separate overhead payment for each separately payable drug or biological at one of three different levels, depending on the pharmacy stakeholders' assessment of the complexity of pharmacy handling associated with each specific drug or biological (73 FR 68651 through 68652). Each separately payable drug or biological HCPCS code would be assigned to one of the three overhead categories, and the separate pharmacy overhead payment applicable to the category would be made when each of the separately payable drugs or biologicals was paid.

In the CY 2010 OPPS/ASC proposed rule (74 FR 35332), we acknowledged the limitations of our data and our availability to find a method to improve that data in a way that did not impose unacceptable administrative burdens on providers. Accepting that charge compression was a reasonable but unverifiable supposition, we proposed to redistribute between one-third and one-half of the estimated overhead cost associated with coded packaged drugs and biologicals with an ASP, which resulted in our proposal to pay for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that did not have pass-through payment status at ASP+4 percent. We calculated estimated overhead cost for coded packaged drugs and biologicals by determining the difference between the aggregate claims cost for coded packaged drugs and biologicals with an ASP and the ASP dollars (ASP multiplied by the drug's or biological's units in the claims data) for those same coded drugs and biologicals; this difference was our estimated overhead cost for coded packaged drugs and biologicals. In our rationale described in the CY 2010 OPPS/ASC proposed rule (74 FR 35326 through 35333), we stated that we believed that approximately $150 million of the estimated $395 million total in pharmacy overhead cost, specifically between one-third and one-half of that cost, included in our claims data for coded packaged drugs and biologicals with reported ASP data should be attributed to separately payable drugs and biologicals and that the $150 million serves as the adjustment for the pharmacy overhead costs of separately payable drugs and biologicals. As a result, we also proposed to reduce the costs of coded drugs and biologicals that are packaged into payment for procedural APCs to offset the $150 million adjustment to payment for separately payable drugs and biologicals. In addition, we proposed that any redistribution of pharmacy overhead cost that may arise from the CY 2010 final rule data would occur only from some drugs and biologicals to other drugs and biologicals, thereby maintaining the estimated total cost of drugs and biologicals that we calculate based on the charges and costs reported by hospitals on claims and cost reports.

As a result of this approach, no redistribution of cost would occur from other services to drugs and biologicals or vice versa.

While we had no way of assessing whether this current distribution of overhead cost to coded packaged drugs and biologicals with an ASP was appropriate, we acknowledged that the established method of converting billed charges to costs had the potential to ''compress'' the calculated costs to some degree. Further, we recognized that the attribution of pharmacy overhead costs to packaged or separately payable drugs and biologicals through our standard drug payment methodology of a combined payment for acquisition and pharmacy overhead costs depends, in part, on the treatment of all drugs and biologicals each year under our annual drug packaging threshold. Changes to the packaging threshold may result in changes to payment for the overhead cost of drugs and biologicals that do not reflect actual changes in hospital pharmacy overhead cost for those products. For these reasons, we stated that we believed some portion, but not all, of the total overhead cost that is associated with coded packaged drugs and biologicals (the difference between aggregate cost for those drugs and biologicals on the claims and ASP dollars for the same drugs and biologicals), based on our standard drug payment methodology, should, at least for CY 2010, be attributed to separately payable drugs and biologicals.

We acknowledged that the observed combined payment for acquisition and pharmacy overhead costs of ASP–2 percent for separately payable drugs and biologicals may be too low and ASP+247 percent for coded packaged drugs and biologicals with reported ASP data in the CY 2010 claims data may be too high (74 FR 35327 and 35328). Therefore, we stated that a middle ground would represent the most accurate redistribution of pharmacy overhead cost. Our assumption was that approximately one-third to one-half of the total pharmacy overhead cost currently associated with coded packaged drugs and biologicals in the CY 2008 claims data offered a more appropriate allocation of drug and biological cost to separately payable drugs and biologicals (74 FR 35328). One third of the $395 million of pharmacy overhead cost associated with packaged drugs and biologicals was $132 million, whereas one-half was $198 million.

Within the one-third to one-half parameters, we proposed reallocating $150 million in drug and biological cost observed in the claims data from coded packaged drugs and biologicals with an ASP to separately payable drugs and biologicals for CY 2010 for their pharmacy overhead costs. Based on this redistribution, we proposed a CY 2010 payment rate for separately payable drugs and biologicals of ASP+4 percent.

In the CY 2010 OPPS final rule with comment period, we adopted a transitional payment rate of ASP+4 percent based on a pharmacy overhead adjustment methodology for CY 2010 that redistributed $200 million from packaged drug and biological cost to separately payable drug cost (74 FR 60499 through 60518). This $200 million included the proposed $150 million redistribution from the pharmacy overhead cost of coded packaged drugs and biologicals for which an ASP is reported and an additional $50 million dollars from the total uncoded drug and biological cost to separately payable drugs and biologicals as a conservative estimate of the pharmacy overhead cost of uncoded packaged drugs and biologicals that should be appropriately associated with the cost of separately payable drugs and biologicals (74 FR 60517). We stated that this was an intentionally conservative estimate as we could not identify definitive evidence that uncoded packaged drug and biological cost included a pharmacy overhead amount comparable to that of coded packaged drugs and biologicals with an ASP. We stated that we could not know the amount of overhead associated with these drugs without making significant assumptions about the amount of pharmacy overhead cost associated with the drugs and biologicals captured by these uncoded packaged drug costs (74 FR 60511 through 60513). In addition, as in prior years, we reiterated our commitment to continue in our efforts to refine our analyses.

For CY 2011, we continued the CY 2010 pharmacy overhead adjustment methodology (74 FR 60500 through 60512). Consistent with our supposition that the combined payment for average acquisition and pharmacy overhead costs under our standard methodology may understate the cost of separately payable drugs and biologicals and related pharmacy overhead for those drugs and biologicals, we redistributed $150 million from the pharmacy overhead cost of coded packaged drugs and biologicals with an ASP and redistributed $50 million from the cost of uncoded packaged drugs and biologicals, for a total redistribution of $200 million from costs for coded and uncoded packaged drugs to separately payable drugs and biologicals, with the result that we pay separately paid drugs and biologicals at ASP+5 percent for CY 2011. The redistribution amount of $150 million in overhead cost from coded packaged drugs and biologicals with an ASP and $50 million in costs from uncoded packaged drugs and biologicals without an ASP were within the parameters established in the CY 2010 OPPS/ASC final rule. In addition, as in prior years, we described some of our work to improve our analyses during the preceding year, including an analysis of uncoded packaged drug and biological cost and our evaluation of the services with which uncoded packaged drug cost appears in the claims data. We conducted this analysis in an effort to assess how much uncoded drugs resemble coded packaged drugs (75 FR 71966). We stated that, in light of this information, we were not confident that the drugs captured by uncoded drug cost are the same drugs captured by coded packaged drug cost, and therefore, we did not believe we could assume that they are the same drugs, with comparable overhead and handling costs. Without being able to calculate the ASP for these uncoded packaged drugs and biologicals and without being able to gauge the magnitude of overhead complexity associated with these drugs and biologicals, we did not believe that we should have assumed that the same amount of proportional overhead should be redistributed between coded and uncoded packaged drugs, and therefore, we redistributed $50 million from uncoded packaged drugs and $150 million from coded packaged drugs (75 FR 71966). We reiterated our commitment to continue to refine our drug pricing methodology and noted that we would continue to pursue the most appropriate methodology for establishing payment for drugs and biologicals under the OPPS and continue to evaluate the appropriateness of this methodology when we establish each year's payment for drugs and biologicals under the OPPS (75 FR 71967).

For CY 2012, we continued our overhead adjustment methodology of redistributing ⅓ to ½ of allocated overhead for coded packaged drugs or $150 million plus an additional $50 million in allocated overhead for uncoded packaged drugs. Additionally, we finalized a policy to update these amounts by the PPI for pharmaceuticals and redistributed $161 million in allocated overhead from coded packaged drugs and $54 million from uncoded packaged drugs. We further finalized a policy to hold the redistributed proportion of packaged drugs constant between the proposed

and the final rule, which increased the final redistribution amount in the CY 2012 final rule to $240.3 million ($169 million from coded packaged drugs and $71.3 million from uncoded packaged drugs). This approach resulted in a final payment rate of ASP+4 percent for separately payable drugs.

b. Proposed CY 2013 Payment Policy

In reexamining our current drug payment methodology for this CY 2013 OPPS/ASC proposed rule, we reviewed our past efforts to determine an appropriate payment methodology for drugs and biologicals, as described above. Since the inception of the OPPS, we have remained committed to establishing a drug payment methodology that is predictable, accurate, and appropriate. Pharmacy stakeholders and the hospital community have also, throughout the years, continually emphasized the importance of both predictable and accurate payment rates for drugs, noting that a payment methodology that emphasizes predictability and accuracy leads to appropriate payment rates that reflect the cost of drugs and biologicals (including overhead) in HOPDs. Pertinent stakeholders also have noted that predictable and accurate payment rates minimize the effect of anomalies in the claims data that may incorrectly influence the future payment for services. We understand that, with predictable payment rates, hospitals are better able to plan for the future.

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

In CY 2010, taking into consideration comments made by the pharmacy stakeholders and acknowledging the limitations of the reported data due to charge compression and hospitals' reporting practices, we added an ''overhead adjustment'' (an internal adjustment of the data) by redistributing cost from coded and uncoded packaged drugs and biologicals to separately payable drugs in order to provide more appropriate payments for drugs and biologicals in the HOPD. We continued this overhead adjustment methodology through CY 2012, and further refined our overhead adjustment methodology by finalizing a policy to update the redistribution amount for inflation and keep the redistribution ratio constant between the proposed rule and the final rule.

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

Section 1833(t)(14)(A)(iii)(II) of the Act requires an alternative methodology for determining payment rates for SCODs wherein, if hospital acquisition cost data are not available, payment shall be equal (subject to any adjustment for overhead costs) to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary. Considering stakeholder and provider feedback, continued limitations of the hospital claims and cost data on drugs and biologicals, and Panel recommendations, we are proposing for CY 2013 to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act, hereinafter referred to as the statutory default.

As noted above, section 1833(t)(14)(A)(iii)(II) of the Act authorizes the Secretary to calculate and adjust, as necessary, the average price for a drug in the year established under section 1842(o), 1847A, or 1847B of the Act, as the case may be, in determining payment for SCODs. Pursuant to sections 1842(o) and 1847A of the Act, physician Part B drugs are paid at ASP+6 percent. We believe that proposing the statutory default of ASP+6 percent is appropriate at this time as it yields increased predictability in payment for separately payable drugs and biologicals under the OPPS. We believe that ASP+6 percent is an appropriate payment amount because it is consistent with payment amounts yielded by our drug payment methodologies over the past 7 years. We 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 for CY 2013.

Our goals continue to be to develop a method that accurately and predictably estimates acquisition and overhead costs for separately payable drugs and biologicals in order to pay for them appropriately. If a better payment methodology is developed in the future, then the proposed policy to pay ASP+6 according to the statutory default would be an interim step in the development of this payment policy. We recognize the challenges in doing so given current data sources and the objective of maintaining the smallest administrative burden possible.

We 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.

At the February 2012 Panel meeting, the Panel made four recommendations on drugs and biologicals paid under the OPPS. First, the Panel recommended that CMS require hospitals to bill all drugs that are described by Healthcare Common Procedure Coding System (HCPCS) codes under revenue code 0636. While we agree that drugs and biologicals may be reported under revenue code 0636, we believe that drugs and biologicals may also be appropriately reported in revenue code categories other than revenue code

0636, including but not limited to, revenue codes 025x and 062x. As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71966), we recognize that hospitals may carry the costs of drugs and biologicals in multiple cost centers and that it may not be appropriate to report the cost of all drugs and biologicals in one specified revenue code. Additionally, we generally require hospitals to follow National Uniform Billing Committee (NUBC) guidance for the choice of an appropriate revenue code that is also appropriate for the hospital's internal accounting processes. Therefore, we are not accepting the Panel's recommendation to require hospitals to bill all drugs that are described by HCPCS codes under revenue code 0636. However, we continue to believe that OPPS ratesetting is most accurate when hospitals report charges for all items and services that have HCPCS codes using those HCPCS codes, regardless of whether payment for the items and services is packaged. It is our standard ratesetting methodology to rely on hospital cost report and charge information as it is reported to us through the claims data. We continue to believe that more complete data from hospitals identifying the specific drugs that were provided during an episode of care may improve payment accuracy for drugs in the future. Therefore, we continue to encourage hospitals to change their reporting practices if they are not already reporting HCPCS codes for all drugs and biologicals furnished, whether specific HCPCS codes are available for those drugs and biologicals.

Second, the Panel recommended that CMS exclude data from hospitals that participate in the 340B program from its ratesetting calculations for drugs. Under the proposed statutory default payment rate of ASP+6 percent, hospitals' 340B status does not affect the drug payment rate.

Third, the Panel recommended that CMS freeze the packaging threshold at $75 until the drug payment issue is more equitably addressed. The OPPS is based on the concept of payment for groups of services that share clinical and resource characteristics. We believe that the packaging threshold is reasonable based on the initial establishment in law of a $50 threshold for the CY 2005 OPPS, that updating the $50 threshold is consistent with industry and government practices, and that the PPI for Prescription Drugs is an appropriate mechanism to gauge Part B drug inflation. Therefore, we are not accepting the Panel's recommendation to freeze the packaging threshold at $75 until the drug payment issue is more equitably addressed. Instead, as discussed in section V.B.2. of this proposed rule, we are proposing an OPPS drug packaging threshold for CY 2013 of $80. However, we do believe that we have addressed the drug payment issue by proposing to pay for separately paid drugs and biologicals at ASP+6 percent for CY 2013 based upon the statutory default.

Finally, the Panel recommended that CMS pay hospitals for separately payable drugs at a rate of average sales price (ASP) + 6 percent. This Panel recommendation is consistent with our CY 2013 proposed payment rate based upon the statutory default under section 1833(t)(14)(A)(iii)(II) of the Act, which authorizes us to pay for drugs and biologicals under the OPPS at ASP+6 percent, when hospital acquisition cost data are not available.

4. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

Beginning in CY 2010 and continuing for CY 2012, we established a policy to pay for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. We allow manufacturers to submit the ASP data in a patient-specific dose or patient-ready form in order to properly calculate the ASP amount for a given HCPCS code. If ASP information is unavailable for a therapeutic radiopharmaceutical, then we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through separately payable therapeutic radiopharmaceuticals in CY 2013. Therefore, we are proposing for CY 2013 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. We are proposing to continue to set payment rates for therapeutic radiopharmaceuticals based on ASP information, if available, for a ''patient ready'' dose and updated on a quarterly basis for products for which manufacturers report ASP data. For a full discussion of how a ''patient ready'' dose is defined, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also are proposing to rely on CY 2011 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals, according to our usual process for updating the payment rates for separately payable drugs and biologicals, on a quarterly basis if updated ASP information is available. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524).

The proposed CY 2013 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 2012, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee. That is, for CY 2012, we provided payment for blood clotting factors under the OPPS at ASP+4 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2012 updated furnishing fee is $0.181 per unit.

For CY 2013, 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 after for drugs, biologicals, and radiopharmaceuticals that have assigned HCPCS codes, but that do not have a reference AWP or approval for payment as pass-through drugs or biologicals. Because there is no statutory provision that dictated payment for such drugs, biologicals, and radiopharmaceuticals in CY 2005, and because we had no hospital claims data to use in establishing a payment rate for them, we investigated several payment options for CY 2005 and discussed them in detail in the CY 2005 OPPS final rule with comment period (69 FR 65797 through 65799).

For CYs 2005 to 2007, we implemented a policy to provide separate payment for new drugs, biologicals, and radiopharmaceuticals with HCPCS codes (specifically those new drug, biological, and radiopharmaceutical HCPCS codes in each of those calendar years that did not crosswalk to predecessor HCPCS codes) but which did not have pass-through status, at a rate that was equivalent to the payment they received in the physician's office setting, established in accordance with the ASP methodology for drugs and biologicals, and based on charges adjusted to cost for radiopharmaceuticals. For CYs 2008 and 2009, we finalized a policy to provide payment for new drugs (excluding contrast agents and diagnostic radiopharmaceuticals) and biologicals (excluding implantable biologicals for CY 2009) with HCPCS codes, but which did not have pass-through status and were without OPPS hospital claims data, at ASP+5 percent and ASP+4 percent, respectively, consistent with the final OPPS payment methodology for other separately payable drugs and biologicals. New therapeutic radiopharmaceuticals were paid at charges adjusted to cost based on the statutory requirement for CY 2008 and CY 2009 and payment for new diagnostic radiopharmaceuticals was packaged in both years.

For CY 2010, we continued to provide payment for new drugs (excluding contrast agents) and nonimplantable biologicals with HCPCS codes that do not have pass-through status and are without OPPS hospital claims data at ASP+4 percent, consistent with the CY 2010 payment methodology for other separately payable nonpass-through drugs and nonimplantable biologicals. We also finalized a policy to extend the CY 2009 payment methodology to new therapeutic radiopharmaceutical HCPCS codes, consistent with our final policy in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60581 through 60526), providing separate payment for therapeutic radiopharmaceuticals that do not crosswalk to CY 2009 HCPCS codes, do not have pass-through status, and are without OPPS hospital claims data at ASP+4 percent. This policy was continued in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71970 through 71973), paying for new drugs, nonimplantable biologicals, and radiopharmaceuticals that do not crosswalk to CY 2010 HCPCS codes, do not have pass-through status, and are without OPPS hospital claims data at ASP+5 percent and the CY 2012 OPPS/ASC final rule with comment period at ASP+4 percent (76 FR 74330 through 74332).

For CY 2013, we are proposing to provide payment for new CY 2013 drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals, at ASP+6 percent, consistent with the proposed CY 2013 payment methodology for other separately payable nonpass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals to pay at ASP+6 percent based on the statutory default. We believe this proposed policy would ensure that new nonpass-through drugs, nonimplantable biologicals and therapeutic radiopharmaceuticals would be treated like other drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals under the OPPS.

We also are proposing to continue to package payment for all new nonpass-through diagnostic radiopharmaceuticals and contrast agents with HCPCS codes but without claims data (those new CY 2013 diagnostic radiopharmaceuticals, contrast agents, and implantable biological HCPCS codes that do not crosswalk to predecessor HCPCS codes). This is consistent with the proposed policy packaging all existing nonpass-through diagnostic radiopharmaceuticals and contrast agents, as discussed in more detail in section II.A.3.d. of this proposed rule.

In accordance with the OPPS ASP methodology, in the absence of ASP data, for CY 2013, 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 nonimplantable biologicals, including therapeutic radiopharmaceuticals) to HCPCS codes for new drugs and nonimplantable biologicals without OPPS claims data and for which we have not granted pass-through status. With respect to new, nonpass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals for which we do not have ASP data, we 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 2013 at ASP+6 percent) for items that have not been granted pass-through status. This proposed policy, which utilizes the ASP methodology that requires us to use WAC data when ASP data are unavailable and 95 percent of AWP when WAC and ASP data are unavailable, for new nonpass-through drugs and biologicals with an ASP, is consistent with prior years' policies for these items, and would ensure that new nonpass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals would be treated like other drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals under the OPPS,

unless they are granted pass-through status.

Similarly, we 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 2013 we are proposing to announce any changes to the payment amounts for new drugs and biologicals in the CY 2013 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2013 if later quarter ASP submissions (or more recent WACs or AWPs) indicate that changes to the payment rates for these drugs and biologicals are necessary. The payment rates for new therapeutic radiopharmaceuticals would also be changed accordingly based on later quarter ASP submissions. We note that the new CY 2013 HCPCS codes for drugs, biologicals and therapeutic radiopharmaceuticals are not available at the time of development of this proposed rule. However, these agents will be included in Addendum B to the CY 2013 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 2013 OPPS/ASC final rule with comment period.

There are several nonpass-through drugs and biologicals that were payable in CY 2011 and/or CY 2012 for which we did not have CY 2011 hospital claims data available for 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 2013, we calculated an estimate of the per day cost of each of these items by multiplying the payment rate of each product based on ASP+6 percent, similar to other nonpass-through drugs and biologicals paid separately under the OPPS, by an estimated average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting. This rationale was first adopted in the CY 2006 OPPS/ASC final rule with comment period (70 FR 68666 and 68667).

We are proposing to package items for which we estimated the per day administration cost to be less than or equal to $80, which is the general packaging threshold that we are proposing for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals in CY 2013. We are proposing to pay separately for items with an estimated per day cost greater than $80 (with the exception of diagnostic radiopharmaceuticals and contrast agents, which we are proposing to continue to package regardless of cost as discussed in more detail in section II.A.3.d. of this proposed rule) in CY 2013. We are proposing that the CY 2013 payment for separately payable items without CY 2011 claims data would be ASP+6 percent, similar to payment for other separately payable nonpass-through drugs and biologicals under the OPPS. In accordance with the ASP methodology paid in the physician's office setting, in the absence of ASP data, we 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 27 below.

TABLE 27—DRUGS AND BIOLOGICALS WITHOUT CY 2011 CLAIMS DATA

CY 2013 HCPCS code	CY 2013 long descriptor	Estimated average number of units per day	Proposed CY 2013 SI	Proposed CY 2013 APC
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	55	K	9367
J0630	Injection, calcitonin salmon, up to 400 units	1.5	K	1433
J2793	Injection, Rilonacept	320	K	1291
J7196	Injection, antithrombin recombinant, 50 IU	268	K	1332
J8562	Fludarabine phosphate, oral, 10 mg	1	K	1339
J9065	Injection, cladribine, per 1 mg	10	K	0858
J9151	Injection, daunorubicin citrate, liposomal formulation, 10 mg	5	K	0821
J0205	Injection, alglucerase, per 10 units	420	K	0900
J2724	Injection, protein c concentrate, intravenous, human, 10 iu	1540	K	1139
Q0515	Injection, sermorelin acetate, 1 microgram	70	K	3050
J2513	Injection, pentastarch, 10% solution, 100 ml	4	N	N/A
J3355	Injection, urofollitropin, 75 IU	2	K	1741
90581	Anthrax vaccine, for subcutaneous or intramuscular use	1	K	1422
J2265	Injection, minocycline hydrochloride, 1 mg	300	K	1423
J8650	Nabilone, oral, 1 mg	4	K	1424

Finally, there were 19 drugs and biologicals, shown in Table 28 below, that were payable in CY 2011, but for which we lacked CY 2011 claims data and any other pricing information for the ASP methodology for this CY 2013 OPPS/ASC proposed rule. In CY 2009, for similar items without CY 2007 claims data and without pricing information for the ASP methodology, we stated that we were unable to determine their per day cost and we packaged these items for the year, assigning these items status indicator ''N.''

For CY 2010, we finalized a policy to change the status indicator for drugs and biologicals previously assigned a

payable status indicator to status indicator ''E'' (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) whenever we lacked claims data and pricing information and were unable to determine the per day cost. In addition, we noted that we would provide separate payment for these drugs and biologicals if pricing information reflecting recent sales became available mid-year in CY 2010 for the ASP methodology. If pricing information became available, we would assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2010. We continued this policy for CY 2011 and CY 2012 (75 FR 71973 and 76 FR 74334).

For CY 2013, we are proposing to continue to assign status indicator ''E'' to drugs and biologicals that lack CY 2011 claims data and pricing information for the ASP methodology. All drugs and biologicals without CY 2011 hospital claims data and data based on the ASP methodology that are assigned status indicator ''E'' on this basis at the time of this proposed rule for CY 2013 are displayed in Table 28 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 2013.

TABLE 28—DRUGS AND BIOLOGICALS WITHOUT CY 2011 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

CY 2013 HCPCS code	CY 2013 long descriptor	Proposed CY 2013 SI
90296	Diphtheria antitoxin, equine, any route	E
90393	Vaccina immune globulin, human, for intramuscular use	E
J3305	Injection, trimetrexate glucuronate, per 25 mg	E
90706	Rubella virus vaccine, live, for subcutaneous use	E
90725	Cholera vaccine for injectable use	E
90727	Plague vaccine, for intramuscular use	E
J0190	Injection, biperiden lactate, per 5 mg	E
J1452	Injection, fomivirsen sodium, intraocular, 1.65 mg	E
J1835	Injection, itraconazole, 50 mg	E
J2670	Injection, tolazonline hcl, up to 25 mg	E
J2940	Injection, somatrem, 1 mg	E
J3305	Injection, trimetrexate glucuronate, per 25 mg	E
J3320	Injection, spectinomycin dihydrochloride, up to 2 gm	E
J9165	Injection, diethylstilbestrol diphosphate, 250 mg	E
J9212	Injection, interferon alfacon-1, recombinant, 1 microgram	E
Q4117	Hyalomatrix, per square centimeter	E
Q4120	Matristem Burn matrix, per square centimeter	E
Q4126	Memoderm, per square centimeter	E
Q4127	Talymed, per square centimeter	E

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 hospital 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 make an estimate of pass-through spending to determine not only whether payments exceed the applicable percentage, but also to determine the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year in order to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing an estimate of pass-through spending in CY 2013 entails estimating spending for two groups of items. The first group of items consists of device categories that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2013. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group contains items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2012 or beginning in CY 2013. The sum of the CY 2013 pass-through estimates for these two groups of device categories would equal the total CY 2013 pass-through spending estimate for device categories with pass-through status. We base the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2012 OPPS/ASC final rule with comment period (76 FR 74335 through 74336). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice), is the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), we include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices.

For drugs and nonimplantable biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the

Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. We note that the Part B drug CAP program has been postponed since CY 2009, and such a program is not proposed to be reinstated for CY 2013. Because we are proposing to pay for most nonpass-through separately payable drugs and nonimplantable biologicals under the CY 2013 OPPS at ASP+6 percent, which represents the otherwise applicable fee schedule amount associated with most pass-through drugs and nonimplantable biologicals, and because we are proposing to pay for CY 2013 pass-through drugs and nonimplantable biologicals at ASP+6 percent, our estimate of drug and nonimplantable biological pass-through payment for CY 2013 for this group of items would be zero, as discussed below. Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents, without pass-through status, will always be packaged into payment for the associated procedures because these products will never be separately paid. However, all pass-through diagnostic radiopharmaceuticals and contrast agents with pass-through status approved prior to CY 2013 would be paid at ASP+6 percent like other pass-through drugs and nonimplantable biologicals. Therefore, our estimate of pass-through payment for all diagnostic radiopharmaceuticals and contrast agents with pass-through status approved prior to CY 2013 is not zero. In section V.A.4. of this proposed rule, we discuss our proposed policy to determine if the cost of certain ''policy-packaged'' drugs, including diagnostic radiopharmaceuticals and contrast agents, are already packaged into the existing APC structure. If we determine that a ''policy-packaged'' drug approved for pass-through payment resembles predecessor diagnostic radiopharmaceuticals or contrast agents already included in the costs of the APCs that would be associated with the drug receiving pass-through payment, we are proposing to offset the amount of pass-through payment for diagnostic radiopharmaceuticals or contrast agents. For these drugs, the APC offset amount would be the portion of the APC payment for the specific procedure performed with the pass-through radiopharmaceuticals or contrast agents, which we refer to as the ''policy-packaged'' drug APC offset amount. If we determine that an offset is appropriate for a specific diagnostic radiopharmaceutical or contrast agent receiving pass-through payment, we are proposing to reduce our estimate of pass-through payment for these drugs by this amount.

Similar to pass-through estimates for devices, the first group of drugs and nonimplantable biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment for CY 2012 and that will continue to be eligible for pass-through payment in CY 2013. The second group contains drugs and nonimplantable biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2012 or beginning in CY 2013. The sum of the CY 2013 pass-through estimates for these two groups of drugs and nonimplantable biologicals would equal the total CY 2013 pass-through spending estimate for drugs and nonimplantable 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 2013, consistent with section 1833(t)(6)(E)(ii)(II) of the Act, and our OPPS policy from CY 2004 through CY 2012 (76 FR 74336).

For the first group of devices for pass-through payment estimation purposes, there currently are three device categories eligible for pass-through payment for CY 2013: C1830 (Powered bone marrow biopsy needle); C1840 (Lens, intraocular (telescopic)); and C1886 (Catheter, extravascular tissue ablation, any modality (insertable)). We estimate that CY 2013 pass-through expenditures related to these three eligible device categories will be approximately $42 million. In estimating our proposed CY 2013 pass-through spending for device categories in the second group we include: Device categories that we know at the time of the development of this proposed rule would be newly eligible for pass-through payment in CY 2013 (of which there are none); additional device categories that we estimate could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2013; and contingent projections for new device categories established in the second through fourth quarters of CY 2013. We 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 2013 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 2013 (spending for the first group of device categories ($42 million) plus spending for the second group of device categories ($10 million)) be $52 million.

To estimate proposed CY 2013 pass-through spending for drugs and nonimplantable biologicals in the first group, specifically those drugs (including radiopharmaceuticals and contrast agents) and nonimplantable biologicals recently made eligible for pass-through payment and continuing on pass-through status for CY 2013, we 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 nonimplantable biologicals, to project the CY 2013 OPPS utilization of the products.

For the known drugs and nonimplantable biologicals (excluding diagnostic radiopharmaceuticals and contrast agents) that would be continuing on pass-through status in CY 2013, we estimate the proposed pass-through payment amount as the difference between ASP+6 percent and the proposed payment rate for nonpass-through drugs and nonimplantable biologicals that would be separately paid at ASP+6 percent, which is zero for this group of drugs. Because payment for a diagnostic radiopharmaceutical or contrast agent would be packaged if the product were not paid separately due to its pass-through status, we are proposing to include in the proposed CY 2013 pass-through estimate the difference between payment for the drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the ''policy-packaged'' drug APC offset amount, if we have determined that the diagnostic

radiopharmaceutical or contrast agent approved for pass-through payment resembles predecessor diagnostic radiopharmaceuticals or contrast agents already included in the costs of the APCs that would be associated with the drug receiving pass-through payment. For this CY 2013 proposed rule, we are proposing to continue to use the above described methodology to calculate a proposed spending estimate for this first group of drugs and nonimplantable biologicals to be approximately $13 million.

To estimate proposed CY 2013 pass-through spending for drugs and nonimplantable biologicals in the second group (that is, drugs and nonimplantable biologicals that we know at the time of development of this proposed rule would be newly eligible for pass-through payment in CY 2013, additional drugs and nonimplantable biologicals that we estimate could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2013, and projections for new drugs and nonimplantable biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2013), we 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 proposed CY 2013 pass-through payment estimate. We also are considering the most recent OPPS experience in approving new pass-through drugs and nonimplantable biologicals. Using our proposed methodology for estimating CY 2013 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and nonimplantable biologicals to be approximately $19 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 2013 pass-through spending estimate for drugs and nonimplantable biologicals. Our proposed CY 2013 estimate for total pass-through spending for drugs and nonimplantable biologicals (spending for the first group of drugs and nonimplantable biologicals ($13 million) plus spending for the second group of drugs and nonimplantable biologicals ($19 million)) equals $32 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 nonimplantable biologicals that are continuing to receive pass-through payment in CY 2013 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2013 would be approximately $84 million (approximately $52 million for device categories and approximately $32 million for drugs and nonimplantable biologicals), which represents 0.18 percent of total projected OPPS payments for CY 2013. We estimate that pass-through spending in CY 2013 would not amount to 2.0 percent of total projected OPPS CY 2013 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 visits, and critical care services, including trauma team activation. For CY 2013, we are proposing to continue to recognize these CPT and HCPCS codes describing clinic visits, Type A and Type B emergency department visits, and critical care services, which are listed below in Table 29, for CY 2013. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74338 through 74346) for a full discussion of our longstanding policy on OPPS payment for hospital outpatient visits.

TABLE 29—PROPOSED 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).

TABLE 29—PROPOSED HCPCS CODES USED TO REPORT CLINIC AND EMERGENCY DEPARTMENT VISITS AND CRITICAL CARE SERVICES—Continued

CY 2013 HCPCS code	CY 2013 descriptor
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 Policies for Hospital Outpatient Visits

For CY 2013, we are proposing to continue our longstanding policies related to hospital outpatient visits, which includes clinic visits, emergency department visits, and critical care services. Specifically, we are proposing to continue to recognize the definitions of a new patient and an established patient, which are based on whether the patient has been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit. We also are proposing to continue to apply our policy of calculating costs for clinic visits under the OPPS using historical hospital claims data through five levels of clinic visit APCs (APCs 0604 through 0608). In addition, we are proposing to continue to recognize Type A emergency departments and Type B emergency departments for payment purposes under the OPPS, and to pay for Type A emergency department visits based on their costs through the five levels of Type A emergency department APCs (APCs 0609 and 0613 through 0616) and to pay for Type B emergency department visits based on their costs through the five levels of Type B emergency department APCs (APCs 0626 through 0630). We refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for the proposed APC assignments and payment rates for these hospital outpatient visits. Finally, we are continuing to instruct hospitals to report facility resources for clinic and emergency department hospital outpatient visits using the CPT E/M codes and to develop internal hospital guidelines for reporting the appropriate visit level. We note that our continued expectation is that hospitals' internal guidelines will comport with the principles listed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66805). We encourage hospitals with specific questions related to the creation of internal guidelines to contact their servicing fiscal intermediary or MAC. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74338 through 74346) for a full historical discussion of these longstanding policies.

We also 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 reflect the CPT billing guidance that was in effect prior to CY 2011, in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74343 through 74344), we continued the methodology established in the CY 2011 OPPS/ASC final rule with comment period of calculating a payment rate for critical care services based on our historical claims data, into which the cost of the ancillary services is intrinsically packaged for CY 2012. We also continued to implement claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment.

As discussed in section II.A.2.f. of this proposed rule, we are proposing to establish the CY 2013 relative payment weights upon which OPPS payment is based using geometric mean costs. The CY 2011 hospital claims data on which the proposed CY 2013 payment rates are based reflect the first year of claims billed under the revised CPT guidance to allow the reporting of all the ancillary services and their associated charges separately when they are provided in conjunction with critical care. Because our proposal to establish relative payment weights based on geometric mean cost data for CY 2013 represents a change from our historical practice to base payment rates on median costs and because we now have hospital claims data for the first time reflecting the revised coding guidance for critical care, we reviewed the CY 2011 hospital claims data available for this proposed rule and determined that the data show increases in both the mean and median line item costs as well as the mean and median line item charges for CPT code 99291, when compared to CY 2010 hospital claims data. Specifically, the mean and median line item costs increased 13 percent and 16 percent, respectively, and the mean and median line item charges increased 11 percent and 14 percent, respectively. Additionally, when compared to CY 2010 hospital claims data, CY 2011 hospital claims data show no substantial change in the ancillary services that are present on the same claims as critical care services, and also show continued low volumes of many ancillary services. 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. The lack of a substantial change in the services reported on critical care claims, along with the increases in the line item costs and charges for critical care services, strongly suggests that many hospitals did not change their billing practices for CPT code 99291 following the revision to the CPT coding guidance effective January 1, 2011.

In light of not having claims data to support a significant change in hospital billing practices, we continue to believe that it is inappropriate to pay separately in CY 2013 for the ancillary services that hospitals may now report in addition to critical care services. Therefore, for CY 2013, we are proposing to continue our CY 2011 and CY 2012 policy to recognize the existing CPT codes for critical care services and establish a payment rate based on historical claims data. We also 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.

C. Transitional Care Management

In the CY 2013 MPFS proposed rule, we discuss a multiple year strategy exploring the best means to encourage the provision of primary care and care coordination services to Medicare beneficiaries. As part of the strategy discussed in that proposed rule, we are proposing to address the non-face-to-face work involved in hospital or SNF discharge care coordination by creating a HCPCS G-code for care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital stay (inpatient, outpatient observation services, or outpatient partial hospitalization), SNF stay, or CMHC partial hospitalization program to care furnished by the beneficiary's physician or qualified nonphysician practitioner in the community. As discussed in the CY 2013 MPFS proposed rule, care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital or a SNF stay to the beneficiary's primary physician or qualified nonphysician practitioner in the community could avoid adverse events such as readmissions or subsequent illnesses, improve beneficiary outcomes, and avoid a financial burden on the health care system. Successful efforts to improve hospital discharge care coordination and care transitions could improve the quality of care while simultaneously decreasing costs.

The proposed HCPCS G-code included in the CY 2013 MPFS proposed rule, GXXX1, specifically describes post-discharge transitional care management services, which include all non-face-to-face services related to the transitional care management, furnished by the community physician or nonphysician practitioner within 30 calendar days following the date of discharge from an inpatient acute care hospital, psychiatric hospital, LTCH, SNF, and IRF; discharge from hospital outpatient observation or partial hospitalization services; or discharge from a PHP at a CMHC, to the community-based care. The post-discharge transitional care management services include non-face-to-face care management services provided by clinical staff member(s) or office-based case manager(s) under the supervision of the community physician or qualified nonphysician practitioner.

Transitional care management services include:

1. Assuming responsibility for the beneficiary's care without a gap.

2. Establishing or adjusting a plan of care to reflect required and indicated elements, particularly in light of the services furnished during the stay at the specified facility and to reflect the result of communication with beneficiary.

3. Communication (direct contact, telephone, electronic) with the beneficiary and/or caregiver, including education of the patient and/or caregiver within 2 business days of discharge based on a review of the discharge summary and other available information such as diagnostic test results.

While we do not pay for physician or nonpractitioner professional services under the OPPS (42 CFR 419.22), we recognize that certain elements of the transitional care coordination services described by proposed HCPCS code GXXX1 could be provided to a hospital outpatient as an ancillary or supportive service in conjunction with a primary diagnostic or therapeutic service that would be payable under the OPPS, such as a clinic visit. As described in section II.A.3. of this proposed rule, we package payment for services that are typically ancillary and supportive to a primary service. While we do not make separate payment for such services, their costs are included in the costs of other services furnished by the hospital to the beneficiary on the same day. Because

we believe that transitional care management services may be ancillary and supportive to a primary service provided to a hospital outpatient, for purposes of OPPS payment, we are proposing to assign HCPCS code (GXXX1), a status indicator of ''N'' (Items and Services Packaged into APC Rates) signifying that its payment is packaged. We refer readers to the CY 2013 MPFS proposed rule for a full discussion of post-discharge transitional care management services in particular and, more broadly, the multiple year strategy exploring the best means to encourage primary care and care coordination services.

VIII. 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 plan sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan.'' Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a partial hospitalization program (PHP) is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC) (as defined in subparagraph (B)), and ''which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care other than in an individual's home or in an inpatient or residential setting.'' Section 1861(ff)(3)(B) of the Act defines community mental health center.

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

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

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

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

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

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

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

In CY 2011, in accordance with section 1301(b) of the Health Care and Education Reconciliation Act of 2010 (HCERA 2010), we amended the description of a PHP in our regulations to specify that a PHP must be a distinct and organized intensive ambulatory treatment program offering less than 24-hour daily care ''other than in an individual's home or in an inpatient or residential setting.'' In addition, in accordance with section 1301(a) of

HCERA 2010, we revised the definition of a CMHC in the regulations to conform to the revised definition now set forth at section 1861(ff)(3)(B) of the Act. We discussed our finalized policies for these two provisions of HCERA 2010 under section X.C. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71990).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we also established four separate PHP APC per diem payment rates, two for CMHCs (for Level I and Level II services) and two for hospital-based PHPs (for Level I and Level II services). In the CY 2011 OPPS/ASC proposed rule, we proposed that CMHC APC medians would be based only on CMHC data and hospital-based PHP APC medians would be based only on hospital-based PHP data (75 FR 46300). As stated in the CY 2011 OPPS/ASC proposed rule (75 FR 46300) and the final rule with comment period (75 FR 71991), for CY 2011, using CY 2009 claims data, CMHC costs had significantly decreased again. We attributed the decrease to the lower cost structure of CMHCs compared to hospital-based PHP providers, and not the impact of CY 2009 policies. CMHCs have a lower cost structure than hospital-based PHP providers, in part because the data showed that CMHCs provide fewer PHP services in a day and use less costly staff than hospital-based PHPs. Therefore, it was inappropriate to continue to treat CMHCs and hospital-based providers in the same manner regarding payment, particularly in light of such disparate differences in costs. We also were concerned that paying hospital-based PHP programs at a lower rate than their cost structure reflects could lead to hospital-based PHP program closures and possible access problems for Medicare beneficiaries, given that hospital-based programs offer the widest access to PHP services because they are located across the country. Creating the four payment rates (two for CMHCs and two for hospital-based PHPs) based on each provider's data supported continued access to the PHP benefit, while also providing appropriate payment based on the unique cost structures of CMHCs and hospital-based PHPs. In addition, separation of data by provider type was supported by several hospital-based PHP commenters who responded to the CY 2011 OPPS/ASC proposed rule (75 FR 71992).

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

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

For CY 2012, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74348 through 74352), we determined the relative payment weights for PHP services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for hospital-based PHP services based exclusively on hospital data. The statute is reasonably interpreted to allow the relative payment weights for the OPPS payment rates for PHP services provided by CMHCs to be based solely on CMHC data and relative payment weights for hospital-based PHP services to be based exclusively on hospital data. Section 1833(t)(2)(C) of the Act requires the Secretary to ''establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on * * * hospital costs.'' In pertinent part, subparagraph (B) provides that ''the Secretary may establish groups of covered OPD services * * * so that services classified within each group are comparable clinically and with respect to the use of resources.'' In accordance with subparagraph (B), we developed the APCs, as set forth in § 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. Similarly, we established new APCs for PHP services based exclusively on hospital data. For CY 2009, we adopted a two-tiered APC methodology (in lieu of the original APC 0033) under which CMS paid one rate for days with 3 services (APC 0172) and a different payment rate for days with 4 or more services (APC 0173). These two new APCs were established using only hospital data. For CY 2011, we added two new APCs (APCs 0175 and 0176) for PHP services provided by hospitals and based the relative payment weights for these APCs solely on hospital data. APCs 0172 and 0173 were designated for PHP services provided by CMHCs and were based on a mixture of hospital and CMHC data. As the Secretary

argued in the Paladin case, the courts have consistently held that the phrase ''based on'' does not mean ''based exclusively on.'' Thus, the relative payment weights for the two APCs for PHP services provided by CMHCs in CY 2011 were ''based on'' hospital data, no less than the relative payment weights for the two APCs for hospital-based PHP services.

Although we used hospital data to establish the relative payment weights for APCs 0033, 0172, 0173, 0175, and 0176 for PHP services, we believe that we have the authority to discontinue the use of hospital data in determining the OPPS relative payment weights for PHP services provided by CMHCs. Other parts of section 1833(t)(2)(C) of the Act make plain that the data source for the relative payment weights is subject to change from one period to another. Section 1833(t)(2)(C) of the Act provides that, in establishing the relative payment weights, ''the Secretary shall [ ] us[e] data on claims from 1996 and us[e] data from the most recent available cost reports.'' However, we used 1996 data (plus 1997 data) in determining only the original relative payment weights for 2000; in the ensuing calendar year updates, we continually used more recent cost report data.

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

B. Proposed PHP APC Update for CY 2013

As discussed in section II.A.2.g. of this proposed rule, for CY 2013, we are proposing to develop the relative payment weights that underpin the OPPS using geometric means rather than the current median-based methodology. This proposal to base the relative payment weights on geometric means would also apply to the per diem costs used to determine the relative payment weights for the four PHP APCs. For PHP APCs, as with all other OPPS APCs, the proposal to base the relative payment weights on geometric means rather than medians would not affect the general process to establish appropriate claims for modeling. As with the current median-based methodology, the PHP APC payment rates would continue to be calculated by computing a separate per diem cost for each day of PHP. When there are multiple days of PHP services entered on a claim, a unique cost would continue to be computed for each day of care. However, a geometric mean would be used to calculate the per diem costs rather than a median. The process would still be repeated separately for CMHCs and hospital-based PHPs using that provider's claims data for the two categories of days with 3 services and days with 4 or more services. The four PHP APC per diem costs would continue to be included in the scaling of all APCs in OPPS to the mid-level office visit (APC 0606). Again, for a detailed discussion of the proposed CY 2013 OPPS weight scaler, we refer readers to section II.A.4. of this proposed rule.

For CY 2013, using CY 2011 claims data, we computed proposed CMHC PHP APC geometric mean per diem costs for Level I (3 services per day) and Level II (4 or more services per day) services using only CY 2011 CMHC claims data, and proposed hospital-based PHP APC geometric mean per diem costs for Level I and Level II services using only CY 2011 hospital-based PHP claims data. These proposed geometric mean per diem costs are shown in Table 30 below.

TABLE 30—PROPOSED CY 2013 GEOMETRIC MEAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHP SERVICES, BASED ON CY 2011 CLAIMS DATA

APC	Group title	Proposed geometric mean per diem costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$87.76
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	111.89
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	182.66
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	232.74

Under the CY 2013 proposal to base the OPPS relative payment weights on geometric mean costs, the proposed geometric mean per diem costs for CMHCs would continue to be substantially lower than the proposed geometric mean per diem costs for hospital-based PHPs for the same units of service. For CY 2013, the proposed geometric mean per diem costs for days with 3 services (Level I) is approximately $88 for CMHCs and approximately $183 for hospital-based PHPs. The proposed geometric mean per diem costs for days with 4 or more services (Level II) is approximately $112 for CMHCs and approximately $233 for hospital-based PHPs. This analysis indicates that there continues to be fundamental differences between the cost structures of CMHCs and hospital-based PHPs.

The CY 2013 proposed geometric mean per diems costs for CMHCs calculated under the proposed CY 2013 methodology using CY 2011 claims data also have decreased compared to the CY 2012 final median per diem costs for CMHCs established in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352), with per diem costs for Level I services decreasing from approximately $98 to approximately $88, and costs for Level II services decreasing from approximately $114 to approximately $112. In contrast, the CY 2013 proposed geometric mean per diem costs for hospital-based PHPs calculated under the proposed CY 2013 methodology using CY 2011 claims data have increased compared to the CY 2012 final median per diem costs for hospital-based PHPs, with per diem costs for Level I services increasing from approximately $161 to approximately $183, and per diem costs for Level II services increasing from approximately $191 to approximately $233.

To provide a comparison, we also calculated PHP median per diem costs for CY 2013 using CY 2011 claims data. We computed median per diem costs for each provider type using that provider's

claims data for Level I services and for Level II services. These comparative median per diem costs are shown in Table 31 below.

TABLE 31—COMPARATIVE PHP MEDIAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHP SERVICES, BASED ON CY 2011 CLAIMS DATA

APC	Group title	Comparative median per diem costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$87.52
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	121.27
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	163.86
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	224.57

The proposed geometric mean per diem costs for hospital-based PHPs for Level I and Level II services calculated under the proposed CY 2013 methodology using CY 2011 claims data would be higher than the median per diem costs calculated under the current median-based methodology, using CY 2011 claims data. For hospital-based PHPs, the per diem costs would increase from approximately $164 under the current median-based methodology to approximately $183 under the proposed geometric mean-based methodology for Level I services, and from approximately $225 to approximately $233 for Level II services.

The proposed geometric mean per diem costs for CMHCs for Level I services calculated under the proposed CY 2013 methodology using CY 2011 claims data would be approximately the same as the median per diem costs calculated under the current median-based methodology, using CY 2011 claims data. The proposed geometric mean per diem costs for CMHCs for Level II services calculated under the proposed CY 2013 methodology using CY 2011 claims data would be slightly lower than the median per diem costs calculated under the current median-based methodology, using CY 2011 claims data. For CMHCs, the per diem costs would be approximately $88 under both the current median-based methodology and the proposed geometric mean-based methodology for CMHC Level I services, and would decrease from approximately $121 under the current median-based methodology to approximately $112 under the proposed geometric mean-based methodology for CMHC Level II services.

The data analysis also shows that the median per diem costs for CMHCs continue to be substantially lower than the median per diem costs for hospital-based PHPs for the same units of service provided. The median per diem costs for Level I services is approximately $88 for CMHCs and approximately $164 for hospital-based PHPs. The median per diem costs for Level II services is approximately $121 for CMHCs and approximately $225 for hospital-based PHPs. The significant difference in per diem costs between CMHCs and hospital-based PHPs emphasizes the distinct cost structures between the two provider types.

Finally, the data analysis indicates that CMHC median per diem costs for Level I services would have decreased from CY 2012 final median per diem costs (using CY 2010 claims data) (established in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352)) to CY 2013 (using CY 2011 claims data) from approximately $98 to approximately $88, using only CMHC claims data. The CMHC median per diem costs for Level II services would have slightly increased from CY 2012 final median per diem costs (using CY 2010 claims data) to CY 2013 (using CY 2011 claims data) from approximately $114 to approximately $121, using only CMHC claims data. Hospital-based PHP median per diem costs for Level I and Level II services would have increased from the CY 2012 final median per diem costs (using CY 2010 claims data) to CY 2013 (using CY 2011 claims data) from approximately $161 to approximately $164 for Level I services and from approximately $191 to approximately $225 for Level II services, using only hospital claims data.

In summary, while we have historically based the OPPS payments on median costs for services in the APC groups, for CY 2013, we are proposing to calculate the relative payment weights for the OPPS APCs using geometric means, including the four PHP APCs, as discussed in section II.A.2.g. of this proposed rule. The proposed CY 2013 geometric mean per diem costs for the PHP APCs are shown in Tables 32 and 33 below. We invite public comments on these proposals. We will continue our efforts to explore payment reforms that will support quality and result in greater payment accuracy and reduction of fraud and abuse within the partial hospitalization program.

TABLE 32—PROPOSED CY 2013 GEOMETRIC MEAN PER DIEM COSTS FOR CMHC PHP SERVICES

APC	Group title	Proposed mean per diem costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$87.76
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	111.89

TABLE 33—PROPOSED CY 2013 GEOMETRIC MEAN PER DIEM COSTS FOR HOSPITAL-BASED PHP SERVICES

APC	Group title	Proposed mean per diem costs
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	$182.66

TABLE 33—PROPOSED CY 2013 GEOMETRIC MEAN PER DIEM COSTS FOR HOSPITAL-BASED PHP SERVICES—Continued

APC	Group title	Proposed mean per diem costs
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	$232.74

C. Proposed Separate Threshold for Outlier Payments to CMHCs

In the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), we indicated that, given the difference in charges for PHP services provided between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Prior to that time, there was a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP services. Therefore, we designated a portion of the estimated OPPS outlier target amount specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments. In addition, further analysis indicated that using the same OPPS outlier threshold for both hospitals and CMHCs did not limit outlier payments to high-cost cases and resulted in excessive outlier payments to CMHCs. Therefore, beginning in CY 2004, we established a separate outlier threshold for CMHCs. The separate outlier threshold for CMHCs has resulted in more commensurate outlier payments.

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

We are proposing to continue our policy of identifying 1.0 percent of the aggregate total payments under the OPPS for outlier payments for CY 2013. We are proposing that a portion of that 1.0 percent, an amount equal to 0.12 percent of outlier payments (or 0.0012 percent of total OPPS payments) would be allocated to CMHCs for PHP outlier payments. In section II.G. of this proposed rule, for hospital outpatient outlier payments 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. We are proposing to set the outlier threshold for CMHCs for CY 2013 at 3.40 times the APC payment amount and the CY 2013 outlier payment percentage applicable to costs in excess of the threshold at 50 percent. Specifically, we 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 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 invite 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 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 2013 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 are being performed a significant amount of the time on an outpatient basis, and appropriately may be removed from the list. The established criteria upon which we make such a determination are as follows:

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

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

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

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

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

Using this methodology, we identified two procedures that potentially could be removed from the inpatient list for CY 2013: CPT code 22856 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical); and CPT code 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)). We then reviewed the clinical characteristics and related evidence for these two potential procedures for possible removal from the inpatient list and found them to be appropriate candidates for removal from the inpatient list. For CY 2013, we are proposing to remove the procedures described by CPT codes 22856 and 27447 from the inpatient list because we believe that the procedures may be appropriately provided as hospital outpatient procedures for some Medicare beneficiaries, based upon the evaluation criteria mentioned above and should thus be paid under the OPPS.

The two procedures we are proposing to remove from the inpatient only list for CY 2013 and their CPT codes, long descriptors, proposed APC assignments, and proposed status indictors are displayed in Table 34 below.

TABLE 34—PROCEDURES PROPOSED TO BE REMOVED FROM THE INPATIENT ONLY LIST AND THEIR PROPOSED APC ASSIGNMENTS FOR CY 2013

HCPCS Code	Long descriptor	Proposed CY 2013 APC assignment	Proposed CY 2013 status indicator
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical.	0208	T
27447	Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty).	0425	T

The complete list of codes that we are proposing to be paid by Medicare in CY 2013 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 Policies for the Supervision of Outpatient Services in Hospitals and CAHs

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

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74360 through 74371), we clarified that hospital outpatient therapeutic services and supplies, including those described by benefit categories other than the hospital outpatient ''incident to'' category under section 1861(s)(2)(B) of the Act, are subject to the conditions of payment in 42 CFR 410.27 when they are paid under the OPPS or paid to CAHs under section 1834(g) of the Act. We issued this clarification in response to inquiries regarding the application of these conditions of payment to radiation therapy services that are described under section 1861(s)(4) of the Act when these services are furnished to hospital outpatients.

In the CY 2012 OPPS/ASC final rule with comment period, in our response to public comments (76 FR 74369), we indicated that the supervision and other requirements of § 410.27 do not apply to professional services or to services that are paid under other fee schedules such as the Clinical Laboratory Fee Schedule (CLFS). After the publication of the final rule with comment period, we continued to receive questions about the applicability of the regulations to physical therapy (PT), speech-language pathology (SLP), and occupational therapy (OT) services furnished in CAHs. Several stakeholders expressed concern that the rules could be applied differently in CAHs than in OPPS hospitals. The stakeholders were concerned that OPPS hospitals, which are paid for outpatient therapy services at the applicable amount based on the Medicare Physician Fee Schedule (MPFS), would not be subject to the regulations, but that CAHs, which are paid for outpatient therapy services on a reasonable cost basis, would be subject to them.

In this proposed rule, we are clarifying that it was not our intent in the CY 2012 OPPS/ASC final rule with comment period to establish different requirements for CAHs and for OPPS hospitals for the same services. The supervision and other requirements of § 410.27 apply to facility services that are paid to hospitals under the OPPS and to these same services when they are furnished in CAHs and paid on a reasonable cost basis. In OPPS hospitals, these requirements do not apply to professional services that are separately billed under the MPFS or to PT, SLP, and OT services that are billed by the hospital as therapy services and are paid at the applicable amount based on the MPFS. The payment rules under § 410.27 also do not apply to these same services when they are furnished in CAHs.

In OPPS hospitals, a small subset of ''sometimes therapy'' PT, SLP, or OT services are paid under the OPPS when they are not furnished as therapy, meaning not under a certified therapy plan of care. Because the supervision and other conditions of payment under § 410.27 apply to this subset of ''sometimes therapy'' services when they are furnished in OPPS hospitals as nontherapy services (because they are paid under the OPPS and not based on the MPFS), those conditions of payment also apply to this subset of ''sometimes therapy'' services when they are furnished as nontherapy in CAHs. When OPPS hospitals and CAHs furnish these services as therapy services (under a therapy plan of care by a qualified therapist), the conditions of payment under § 410.27 do not apply because OPPS hospitals are paid for these services based on the MPFS and not under the OPPS. We are providing a list of the ''sometimes therapy'' services that may be paid under the OPPS in Table 35 below.

TABLE 35—''SOMETIMES THERAPY'' SERVICES THAT ARE PAID UNDER THE OPPS WHEN NOT FURNISHED AS THERAPY SERVICES

HCPCS Code	Descriptor
97597	Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less.
97598	Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof (list separately in addition to code for primary procedure).
97602	Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (e.g., wet-to-moist dressings, enzymatic, abrasion), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session.

TABLE 35—"SOMETIMES THERAPY" SERVICES THAT ARE PAID UNDER THE OPPS WHEN NOT FURNISHED AS THERAPY SERVICES—Continued

HCPCS Code	Descriptor
97605	Negative pressure wound therapy (e.g., vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.
97606	Negative pressure wound therapy (e.g., vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.
0183T	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day.

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

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74371), we extended through CY 2012 the notice of nonenforcement of the requirement for direct supervision of outpatient therapeutic services furnished in CAHs and small rural hospitals having 100 or fewer beds (available on the CMS Web Site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html?redirect=/HospitalOutpatientPPS/01_overview.asp*). We extended this enforcement instruction to our contractors for another year, through CY 2012, to allow time for the initiation of supervision reviews by the Advisory Panel on Hospital Outpatient Payment (the Panel), which began in early 2012 and are continuing in accordance with the provisions of the CY 2012 OPPS/ASC final rule with comment period. The Panel will meet again this summer to consider requests that are referred by CMS for a change in the minimum required supervision level for individual hospital outpatient therapeutic services for the CY 2013 payment year. In this proposed rule, we are requesting that CAHs and small rural hospitals submit to CMS for potential evaluation by the Panel at the summer meeting any services for which they anticipate difficulty complying with the direct supervision standard in CY 2013. In developing evaluation requests, hospitals should refer to the evaluation criteria that we finalized in the CY 2012 OPPS/ASC final rule with comment period. We recognize that hospitals have had little experience in submitting evaluation requests to CMS for consideration by the Panel. In order to give hospitals additional opportunity this year to become familiar with the submission and review process at the summer Panel meeting, and to allow hospitals time to meet the required supervision levels for services that may be considered for CY 2013, we anticipate extending the nonenforcement instruction one additional year through CY 2013. We expect that this will be the final year for the instruction, regardless of the services reviewed by the Panel during its summer meeting.

XI. Outpatient Status: Solicitation of Public Comments

Under section 402(a)(1)(A) of the Social Security Amendments of 1967 (Pub. L. 90–248), the Secretary is permitted to engage in demonstration projects to determine whether changes in methods of payment for health care and services under the Medicare program would increase the efficiency and economy of those services through the creation of incentives to those ends without adversely affecting the quality of such services. Under this statutory authority, CMS has implemented the Medicare Part A to Part B Rebilling (AB Rebilling) Demonstration, which allows participating hospitals to receive 90 percent of the allowable Part B payment for Part A short-stay claims that are denied on the basis that the inpatient admission was not reasonable and necessary. Participating hospitals can rebill these denied Part A claims under Part B and be paid for additional Part B services than would usually be payable when an inpatient admission is deemed not reasonable and necessary. This demonstration is slated to last for 3 years, from CY 2012 through CY 2014. In this proposed rule, we are providing an update of the status of the demonstration. In addition, we are soliciting public comments on a related issue: Potential policy changes we could make to improve clarity and consensus among providers, Medicare, and other stakeholders regarding the relationship between admission decisions and appropriate Medicare payment, such as when a Medicare beneficiary is appropriately admitted to the hospital as an inpatient and the cost to hospitals associated with making this decision.

When a Medicare beneficiary presents to a hospital in need of medical or surgical care, the physician or other qualified practitioner must decide whether to admit the beneficiary for inpatient care or treat him or her as an outpatient. In some cases, when the physician admits the beneficiary and the hospital provides inpatient care, a Medicare claims review contractor, such as the Medicare Administrative Contractor (MAC), the Recovery Audit Contractor (RAC), or the Comprehensive Error Rate Testing (CERT) Contractor, determines that inpatient care was not reasonable and necessary under section 1862(a)(1)(A) of the Act and denies the hospital inpatient claim for payment. In these cases, under Medicare's longstanding policy, hospitals may rebill a separate inpatient claim for only a limited set of Part B services, referred to as ''Inpatient Part B'' or ''Part B Only'' services (Section 10, Chapter 6 of the Medicare Benefit Policy Manual (Pub. 100–02)). The hospital also may bill Medicare Part B for any outpatient services that were provided in the 3-day payment window prior to the admission (Section 10.12, Chapter 4 of the Medicare Claims Processing Manual (Pub. 100–04)). These claims are subject to the timely filing restrictions.

Once a Medicare beneficiary is discharged from the hospital, the hospital cannot change the beneficiary's patient status to outpatient and submit an outpatient claim because of the potentially significant impact on beneficiary liability. As we discuss below, hospital inpatients have significantly different Medicare benefits and liabilities than hospital outpatients, notably coverage of self-administered drugs and, for patients who are admitted to the hospital for 3 or more consecutive calendar days, coverage of postacute SNF care (to the extent all other SNF coverage requirements are met). To enable beneficiaries to make informed financial and other decisions, Medicare allows the hospital to change a beneficiary's inpatient status to outpatient (using condition code 44 on an outpatient claim) and bill all medically necessary services that it provided to Part B as outpatient

services, but only if the change in patient status is made prior to discharge, the hospital has not submitted a Medicare claim for the admission, and both the practitioner responsible for the care of the patient and the utilization review committee concur in the decision (Section 50.3, Chapter 1 of the Medicare Claims Processing Manual (Pub. 100–04); MLN Matters article SE0622, ''Clarification of Medicare Payment Policy When Inpatient Admission Is Determined Not To Be Medically Necessary, Including the Use of Condition Code 44: 'Inpatient Admission Changed to Outpatient,' '' September 2004). Medicare beneficiaries are provided with similar protections that are outlined in the Hospital Conditions of Participation. For example, in accordance with 42 CFR 482.13(b), Medicare beneficiaries have the right to participate in the development and implementation of their plan of care and treatment, to make informed decisions, and to accept or refuse treatment. Informed discharge planning between the patient and physician is important for patient autonomy and for achieving efficient outcomes.

While the limited scope of allowed rebilling for ''Part B Only'' services protects Medicare beneficiaries and provides disincentives for hospitals to admit patients inappropriately, hospitals have expressed concern that this policy provides inadequate payment for resources that they have expended to take care of the beneficiary in need of medically necessary hospital care, although not necessarily at the level of inpatient care. A significant proportion of the Medicare CERT error rate consists of short (1- or 2-day) stays where the beneficiary received medically necessary services that the CERT contractor determined should have been provided as outpatient services and not as inpatient services. Hospitals have indicated that often they do not have the necessary staff (for example, utilization review staff or case managers) on hand after normal business hours to confirm the physician's decision to admit the beneficiary. Thus, for a short stay, the hospital may be unable to review and change a beneficiary's patient status from inpatient to outpatient prior to discharge in accordance with the condition code 44 requirements.

We have heard from various stakeholders that hospitals appear to be responding to the financial risk of admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review, by electing to treat beneficiaries as outpatients receiving observation services, often for longer periods of time, rather than admit them. In recent years, the number of cases of Medicare beneficiaries receiving observation services for more than 48 hours, while still small, has increased from approximately 3 percent in 2006 to approximately 7.5 percent in 2010. This trend is concerning because of its effect on Medicare beneficiaries. There could be significant financial implications for Medicare beneficiaries of being treated as outpatients rather than being admitted as inpatients, of which CMS has informed beneficiaries.[1] For instance, if a beneficiary is admitted as an inpatient, the beneficiary pays a one-time deductible for all hospital services provided during the first 60 days in the hospital. As a hospital inpatient, the beneficiary would not pay for self-administered drugs or have any copayments for the first 60 days; whereas if the beneficiary is treated as an outpatient, the beneficiary has a copayment for each individual outpatient hospital service. While the Medicare copayment for a single outpatient hospital service cannot be more than the inpatient hospital deductible, the beneficiary's total copayment for all outpatient services may be more than the inpatient hospital deductible. In addition, usually self-administered drugs provided in an outpatient setting are not covered by Medicare Part B and hospitals may charge the beneficiary for them. Also, the time spent in the hospital as an outpatient is not counted towards the 3-day qualifying inpatient stay that the law requires for Medicare Part A coverage of postacute care in a SNF (section 1861(i) of the Act).

As a result of these concerns related to the impact of extended time as an outpatient on Medicare beneficiaries, the CERT error rate, and the impact on hospitals of a later inpatient denial, CMS initiated the 3-year AB Rebilling Demonstration for voluntary hospital participants. This demonstration allows the participants to rebill outside of the usual timely filing requirements for services relating to all inpatient short-stay claims that are denied for lack of medical necessity because, despite the provision of reasonable and necessary hospital care, the inpatient admission itself was denied as not medically necessary. Under the demonstration, hospitals may receive 90 percent of the allowable payment for all Part B services that would have been medically necessary had the beneficiaries originally been treated as outpatients and not admitted as inpatients. (We note that hospitals cannot rebill for observation services, which, by definition, must be ordered prospectively to determine whether an inpatient admission is necessary). Hospitals that participate in the AB Rebilling Demonstration will waive any appeal rights associated with the denied inpatient claims eligible for rebilling. Under the demonstration, Medicare beneficiaries are protected from any adverse impacts of expanded rebilling. For example, hospitals cannot bill them for self-administered drugs or additional cost-sharing. The demonstration will provide information on the impact that expanded rebilling may have on the Medicare Trust Funds, beneficiaries, hospitals, and the CERT error rate should CMS change its policy regarding the services that can be rebilled to Medicare Part B. The demonstration is designed to evaluate potential impacts of expanded rebilling on admission and utilization patterns, including whether expanded rebilling would reduce hospitals' incentive to make appropriate initial admission decisions.

Hospitals expressed significant interest in the AB Rebilling Demonstration which began on January 1, 2012. The demonstration was approved to accept up to 380 participants. In order to participate in the demonstration, a facility must not be receiving periodic interim payments from CMS, and must be a Medicare-participating hospital as defined by section 1886(d) of the Act, a category that includes all hospitals paid under the Medicare IPPS, but excludes hospitals paid under the Inpatient Psychiatric Facilities (IPF) PPS, the IRF PPS, and the LTCH PPS, cancer hospitals, CAHs, and children's hospitals.

The hospitals that volunteered to participate and were accepted in the demonstration began rebilling in the early spring of 2012. We are currently accepting applications to participate in the ongoing AB Rebilling Demonstration, and more information about the demonstration is available on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/Part_A_to_Part_B_Rebilling_Demonstration.html*. We plan to conduct an evaluation of the demonstration during and after its completion. While we are monitoring progress and evaluating the demonstration, we also are soliciting public comments on other actions we

[1] CMS Pamphlets: ''Are You a Hospital Inpatient or Outpatient? If You Have Medicare—Ask!'', CMS Product No. 11435, Revised, February 2011; ''How Medicare Covers Self-Administered Drugs Given in Hospital Outpatient Settings,'' CMS Product No. 11333, Revised, February 2011.

could potentially undertake to address concerns about this issue. For example, we have heard from some stakeholders who have suggested a need for us to clarify our current instruction regarding the circumstances under which Medicare will pay for an admission in order to improve hospitals' ability to make appropriate admission decisions. We have issued instructions that the need for admission is a complex medical judgment that depends upon multiple factors, including an expectation that the beneficiary will require an overnight stay in the hospital (Section 10, Chapter 1 of the Medicare Benefit Policy Manual (Pub. 100–02)). We are interested in receiving public comments and suggestions regarding whether and how we might improve our current instructions and clarify the application of Medicare payment policies for both hospitals and physicians, keeping in mind the challenges of implementing national standards that are broad enough to contemplate the range of clinical scenarios but prescriptive enough to provide greater clarity.

Some stakeholders also have suggested that CMS has authority to define whether a patient is an inpatient or an outpatient. They believe that it may be permissible and appropriate for us to redefine ''inpatient'' using parameters in addition to medical necessity and a physician order that we currently use, such as length of stay or other variables. For example, currently a beneficiary's anticipated length of stay at the hospital may be a factor in determining whether a beneficiary should be admitted to the hospital, but is not the only factor. We have issued instructions that state that, typically, the decision to admit should be made within 24 to 48 hours, and that expectation of an overnight stay may be a factor in the admission decision (Section 20.6, Chapter 6 and Section 10, Chapter 1 of the Medicare Benefit Policy Manual (Pub. 100–02)). However, we are interested in hearing from stakeholders regarding whether it may be appropriate and useful to establish a point in time after which the encounter becomes an inpatient stay if the beneficiary is still receiving medically necessary care to treat or evaluate his or her condition. Such a policy could potentially limit the amount of time that a beneficiary is treated as an outpatient receiving observation services before the hospital encounter becomes inpatient, provided the additional time in the hospital is medically necessary. Currently, we do not specify a limit on the time a beneficiary may be an outpatient receiving observation services, although, in the past, we have limited payment of observation services to a specific timeframe, such as 24 or 48 hours. Some in the hospital community have indicated that it may be helpful for the agency to establish more specific criteria for patient status in terms of how many hours the beneficiary is in the hospital, or to provide a limit on how long a beneficiary receives observation services as an outpatient. We are inviting public comments regarding whether there would be more clarity regarding patient status under such alternative approaches to defining inpatient status. We also note that it is important for CMS to maintain its ability to audit and otherwise carry out its statutory obligation to ensure that the Medicare program pays only for reasonable and necessary care. We are asking that commenters consider opportunities for inappropriately taking advantage of the Medicare system that time-based and other changes in criteria for patient status may create.

Another option stakeholders have suggested is the establishment of more specific clinical criteria for admission and payment, such as adopting specific clinical measures or requiring prior authorization for payment of an admission. We are inviting public comments on this approach. In addition, we are asking commenters to consider how aligning payment rates more closely with the resources expended by a hospital when providing outpatient care versus inpatient care of short duration might reduce payment disparities and influence financial incentives and disincentives to admit. Finally, we are asking commenters to consider the responsibility of hospitals to utilize all of the tools necessary to make appropriate initial admission decisions. We believe this is important because some hospitals have indicated that simply having case management and utilization review staff available to assist in decisionmaking outside of regular business hours may improve the accuracy of admission decisions.

In summary, there may be several ways of approaching the multifaceted issues that have been raised in recent months around a beneficiary's patient status and Medicare hospital payment. Given the complexity of this topic, we are providing an update on the rebilling demonstration and are seeking public perspectives on potential options the agency might adopt to provide more clarity and consensus regarding patient status for purposes of Medicare payment. We are inviting commenters to draw on their knowledge of these issues to offer any suggestions that they believe would be most helpful to them in addressing the current challenges, while keeping in mind the various impacts in terms of recently observed increases in the length of time for which patients receive observation services, beneficiary liability, Medicare spending, and the feasibility of implementation of any suggested changes for both the Medicare program and hospitals.

XII. Proposed CY 2013 OPPS Payment Status and Comment Indicators

A. Proposed CY 2013 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs play an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code. The proposed CY 2013 status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. We note that, in the past, a majority of the Addenda referred to throughout the preamble of our OPPS/ASC proposed and final rules appeared in the printed version of the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 proposed rule, the Addenda will no longer appear in the printed version of the OPPS/ASC rules that are found in the **Federal Register**. Instead, these Addenda will be published and available only via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

For CY 2013, we are not proposing to make any changes to the definitions of status indicators that were listed in Addendum D1 of the CY 2012 OPPS/ASC final rule with comment period. We continue to believe that these definitions of the OPPS status indicators continue to be appropriate for our CY 2013 proposal.

The complete list of the proposed CY 2013 status indicators and their definitions is displayed in Addendum D1 on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

B. Proposed CY 2013 Comment Indicator Definitions

For the CY 2013 OPPS, we are proposing to use the same two comment indicators that are in effect for the CY 2012 OPPS.

- ''CH''—Active HCPCS codes in current and next calendar year; status indicator and/or APC assignment have changed or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

We are proposing to use the ''CH'' comment indicator in this CY 2013 OPPS/ASC proposed rule to indicate HCPCS codes for which the status indicator or APC assignment, or both, are proposed for change in CY 2013 compared to their assignment as of June 30, 2012. We believe that using the ''CH'' indicator in this CY 2013 OPPS/ASC proposed rule will facilitate the public's review of the changes that we are proposing for CY 2013. The use of the comment indicator ''CH'' in association with a composite APC indicates that the configuration of the composite APC is proposed to be changed in this CY 2013 OPPS/ASC proposed rule.

We are proposing to use the ''CH'' comment indicator in the CY 2013 OPPS/ASC final rule with comment period to indicate HCPCS codes for which the status indicator or APC assignment, or both, would change in CY 2013 compared to their assignment as of December 31, 2012.

In addition, any existing HCPCS code numbers with substantial revisions to the code descriptors for CY 2013 compared to the CY 2012 descriptors are labeled with comment indicator ''NI'' in Addendum B to this CY 2013 OPPS/ASC proposed rule. However, in order to receive the comment indicator ''NI,'' the CY 2013 revision to the code descriptor (compared to the CY 2012 descriptor) must be significant such that the new code descriptor describes a new service or procedure for which the OPPS treatment may change. We use comment indicator ''NI'' to indicate that these HCPCS codes are open to comment as part of this CY 2013 OPPS/ASC proposed rule. Like all codes labeled with comment indicator ''NI,'' we will respond to public comments and finalize their OPPS treatment in the CY 2014 OPPS/ASC final rule with comment period.

In accordance with our usual practice, CPT and Level II HCPCS code numbers that are new for CY 2013 are also labeled with comment indicator ''NI'' in Addendum B to this CY 2013 OPPS/ASC proposed rule.

Only HCPCS codes with comment indicator ''NI'' in this CY 2013 OPPS/ASC proposed rule are subject to comment. HCPCS codes that do not appear with comment indicator ''NI'' in this CY 2013 OPPS/ASC proposed rule are not open to public comment, unless we specifically request additional comments elsewhere in this proposed rule. The CY 2013 treatment of HCPCS codes that appear in this CY 2013 OPPS/ASC proposed rule to which comment indicator ''NI'' is not appended will be open for public comment during the comment period for the proposed rule, and we will respond to those comments in the CY 2013 OPPS/ASC final rule with comment period. We believe that the CY 2012 definitions of the OPPS status indicators continue to be appropriate for CY 2013, and therefore, we are proposing to continue to use those definitions without modification for CY 2013. Their 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*.

XIII. OPPS Policy and Payment Recommendations

A. MedPAC Recommendations

MedPAC was established under section 1805 of the Act to advise the Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to Congress no later than March and June of each year that contain its Medicare payment policy recommendations. In this section of our proposed rule, we note several recommendations regarding the Hospital outpatient prospective payment system in the March 2012 report (''Report to the Congress: Medicare Payment Policy,'' available on MedPAC's Web site at: *http://www.medpac.gov/documents/Mar12_EntireReport.pdf*).

MedPAC recommended that Congress increase payment rates for the outpatient prospective payment system in 2013 by 1.0 percent. We discuss our proposal to follow the statutory requirements for the CY 2013 OPD fee schedule increase factor in section II.B of this proposed rule.

In addition, MedPAC recommended that Congress enact legislation to reduce payment rates for evaluation and management office visits provided in hospital outpatient departments to the rates paid for these services in physician offices. MedPAC recommended that the change be phased in over 3 years. During the phase-in, MedPAC stated that the associated payment reductions to hospitals with a disproportionate share patient percentage at or above the median should be limited to 2 percent of overall Medicare payments. MedPAC also recommended that the Secretary of Health and Human Services conduct a study by January 2015 to examine whether this policy change would reduce access by low-income patients to ambulatory physician and other services. Congress has yet to accept this recommendation and enact such legislation.

B. GAO Recommendations

Congress established the U.S. Government Accountability Office (GAO) under the Budget and Accounting Act of 1921 (Pub. L. 67–13) as an independent agency that advises Congress and the heads of Executive agencies regarding Federal program expenditures. The GAO conducts audits and other analyses to ensure that Federal funds are being spent efficiently and effectively. Since the issuance of the CY 2012 OPPS/ASC final rule with comment period, the GAO has not released any reports regarding the Hospital OPPS.

C. OIG Recommendations

The mission of the Office of the Inspector General (OIG) as mandated by Public Law 95–452 (as amended) is to protect the integrity of the Department of Health and Human Services programs and the health and welfare of program beneficiaries. The OIG conducts independent audits, inspections, and investigations to improve the efficiency of these programs and to identify and prevent fraud, waste and abuse. Since the issuance of the CY 2012 OPPS/ASC final rule with comment period, the OIG has not made any recommendations regarding the Hospital OPPS.

XIV. 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).

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

Under § 416.2 and § 416.166 of the regulations, subject to certain exclusions, covered surgical procedures are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and that would not be expected to require active medical monitoring and care at midnight following the procedure (''overnight stay''). We adopted this standard for defining which surgical procedures are covered under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs. We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate for Medicare beneficiaries in ASCs. We define surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999, as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to ASC covered surgical procedures (72 FR 42478).

In the August 2, 2007 final rule, we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) Brachytherapy sources; (2) certain implantable items that have pass-through status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. These covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment (72 FR 42495). Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (§ 416.173; 72 FR 42535). In addition, as discussed in detail in section XIV.B. of this 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, the updates are to implement newly created Level II HCPCS and Category III CPT codes for ASC payment and to update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New Category I CPT codes, except vaccine codes, are released only once a year and, therefore, are implemented only through the January quarterly update. New Category I CPT vaccine codes are released twice a year and, therefore, are implemented through the January and July quarterly updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for the process used to update the HCPCS and CPT codes (76 FR 42291).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures (including all procedures newly proposed for removal from the OPPS inpatient list), new procedures, and procedures for which there is revised coding, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

B. Proposed Treatment of New Codes

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

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims: (1) Category I CPT codes, which describe surgical procedures; (2) Category III CPT codes, which describe new and emerging technologies, services, and procedures; and (3) Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule to evaluate each year all new Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether 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 2013 OPPS/ASC proposed rule (and respond to those comments in the CY 2013 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2013 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2014 OPPS/ASC final rule with comment period).

We note that we sought public comment in the CY 2012 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2012. We also sought public comments in the CY 2012 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2011. These new codes, with an effective date of October 1, 2011, or January 1, 2012, were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2012 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable,

which were subject to public comment following publication of the CY 2012 OPPS/ASC final rule with comment period. We will respond to public comments and finalize the ASC treatment of these codes in the CY 2013 OPPS/ASC final rule with comment period.

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

In the April and July CRs, we made effective for April 1, 2012 or July 1, 2012, respectively, a total of 12 new Level II HCPCS codes and 5 new Category III CPT codes that were not addressed in the CY 2012 OPPS/ASC final rule with comment period. The 12 new Level II HCPCS codes describe covered ancillary services.

In the April 2012 ASC quarterly update (Transmittal 2425, CR 7754, dated March 16, 2012), we added one new radiology Level II HCPCS code and four new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 36 below, we added the following codes to the list of covered ancillary services:

- HCPCS code C9288 (Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial);
- HCPCS code C9289 (Injection, asparaginase Erwinia chrysanthemi, 1,000 international units (I.U.));
- HCPCS code C9290 (Injection, bupivacaine liposome, 1 mg);
- HCPCS code C9291 (Injection, aflibercept, 2 mg vial); and
- HCPCS code C9733 (Non-ophthalmic fluorescent vascular angiography).

In the July 2012 quarterly update (Transmittal 2479, Change Request 7854, dated May 25, 2012), we added seven new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 37 below, we added the following codes to the list of covered ancillary services:

- HCPCS code C9368 (Grafix core, per square centimeter);
- HCPCS code C9369 (Grafix prime, per square centimeter);
- HCPCS code Q2034 (Influenza virus vaccine, split virus, for intramuscular use (Agriflu));
- HCPCS code Q2045 (Injection, human fibrinogen concentrate, 1 mg);
- HCPCS code Q2046 (Injection, aflibercept, 1 mg);
- HCPCS code Q2048 (Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg); and
- HCPCS code Q2049 (Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg).

We note that HCPCS code Q2045 replaced code J1680, HCPCS code Q2046 replaced code C9291, and HCPCS code Q2048 replaced code J9001 beginning July 1, 2012.

We assigned payment indicator ''K2'' (Drugs and biologicals paid separately when provided integral to a surgical procedure on the ASC list; payment based on OPPS rate) to the 10 new Level II HCPCS codes that are separately paid when provided in ASCs. We assigned payment indicator ''L1'' (Influenza vaccine; pneumococcal vaccine; packaged item/service; no separate payment made) or payment indicator ''N1'' (Packaged service/item; no separate payment made) to the two new Level II HCPCS codes that are packaged when provided in ASCs. We are soliciting public comment on the proposed CY 2012 ASC payment indicators and payment rates for the covered ancillary services listed in Tables 36 and 37 below. Those HCPCS codes became payable in ASCs, beginning in April or July 2012, and are paid at the ASC rates posted for the appropriate calendar quarter on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html.*

The HCPCS codes listed in Table 36 are included in Addendum 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 for July 2012 (listed in Table 37) 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 2013 OPPS/ASC final rule with comment period. Thus, the codes implemented by the July 2012 ASC quarterly update CR and their proposed CY 2013 payment rates (based on July 2012 ASP data) that are displayed in Table 37 are not included in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site). The final list of covered ancillary services and the associated payment weights and payment indicators will be included in Addendum BB to the CY 2013 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 ancillary services in April and July 2012 through the quarterly update CRs, as listed in Tables 36 and 37 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2013 OPPS/ASC final rule with comment period.

TABLE 36—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2012

CY 2012 HCPCS code	CY 2012 long descriptor	Proposed CY 2013 payment indicator
C9288	Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial	K2
C9289	Injection, asparaginase Erwinia chrysanthemi, 1,000 international units (I.U.)	K2
C9290	Injection, bupivacaine liposome, 1 mg	K2
C9291	Injection, aflibercept, 2 mg vial	K2
C9733	Non-ophthalmic fluorescent vascular angiography	N1

TABLE 37—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2012

CY 2012 HCPCS code	CY 2012 long descriptor	Proposed CY 2013 payment indicator	Proposed CY 2013 payment rate
C9368	Grafix core, per square centimeter	K2	$7.96
C9369	Grafix prime, per square centimeter	K2	0.61
Q2034	Influenza virus vaccine, split virus, for intramuscular use (Agriflu)	L1	N/A
Q2045	Injection, human fibrinogen concentrate, 1 mg*	K2	0.73
Q2046	Injection, aflibercept, 1 mg*	K2	980.50
Q2048	Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg*	K2	537.21
Q2049	Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg	K2	498.26

*HCPCS code Q2045 replaced code J1680, HCPCS code Q2046 replaced code C9291, and HCPCS code Q2048 replaced code J9001 beginning July 1, 2012.

Through the July 2012 quarterly update CR, we also implemented ASC payment for five new Category III CPT codes as ASC covered surgical procedures, effective July 1, 2012. These codes are listed in Table 38 below, along with their proposed payment indicators and proposed payment rates for CY 2013. Because the payment rates associated with the new Category III CPT codes that became effective for July 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 38 and their final payment indicators and rates will be included in Addendum AA to the CY 2013 OPPS/ASC final rule with comment period.

We are proposing to assign payment indicator ''G2'' (Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) to three of the five new Category III CPT codes implemented in July 2012 and to assign payment indicator ''J8'' (Device-intensive procedure added to ASC list in CY 2008 or later; paid at adjusted rate) to the remaining two new Category III CPT codes implemented in July 2012. We believe that these procedures would not be expected to pose a significant safety risk to Medicare beneficiaries or would not be expected to require an overnight stay if performed in ASCs. We 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 surgical procedures in July 2012 through the quarterly update CR, as listed in Table 38 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2013 OPPS/ASC final rule with comment period.

TABLE 38—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2012 AS ASC COVERED SURGICAL PROCEDURES

CY 2012 CPT code	CY 2012 long descriptor	Proposed CY 2013 payment indicator	Proposed CY 2013 payment rate
0302T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode).	J8	$7,181.95
0303T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only.	G2	2,129.99
0304T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only.	J8	5,816.80
0307T	Removal of intracardiac ischemia monitoring device	G2	968.15
0308T	Insertion of ocular telescope prosthesis including removal of crystalline lens*	G2	940.65

*CPT code 0308T replaced HCPCS code C9732 beginning July 1, 2012.

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 2013 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Category I and Category III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January ASC quarterly update CRs. In the past, we also have released new Level II HCPCS codes that are effective October 1 through the October ASC quarterly update CRs and incorporated these new codes in the final rule with comment period updating the ASC payment system for the following calendar year. All of these codes are flagged with comment indicator ''NI'' in Addenda AA and BB to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. The payment indicator and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the OPPS/ASC final rule with comment period, and we respond to these comments in the final rule with comment period for the next calendar year's OPPS/ASC update.

We are proposing to continue this process for CY 2013. Specifically, for CY

2013, we are proposing to include in Addenda AA and BB to the CY 2013 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2013, that would be incorporated in the January 2013 ASC quarterly update CR and the new Level II HCPCS codes, effective October 1, 2012 or January 1, 2013, that would be released by CMS in its October 2012 and January 2013 ASC quarterly update CRs. These codes would be 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 have assigned them an interim payment status. Their payment indicators and payment rates, if applicable, would be open to public comment in the CY 2013 OPPS/ASC final rule with comment period and would be finalized in the CY 2014 OPPS/ASC final rule with comment period.

C. Proposed Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Proposed Additions to the List of ASC Covered Surgical Procedures

We conducted a review of all HCPCS codes that currently are paid under the OPPS, but not included on the ASC list of covered surgical procedures, to determine if changes in technology and/or medical practice changed the clinical appropriateness of these procedures for the ASC setting. We are proposing to update the list of ASC covered surgical procedures by adding 16 procedures to the list. We determined that these 16 procedures would not be expected to pose a significant safety risk to Medicare beneficiaries and would not be expected to require an overnight stay if performed in ASCs.

The 16 procedures that we are proposing to add to the ASC list of covered surgical procedures, including their HCPCS code long descriptors and proposed CY 2013 payment indicators, are displayed in Table 39 below. We invite public comment on this proposal.

TABLE 39—PROPOSED NEW ASC COVERED SURGICAL PROCEDURES FOR CY 2013

CY 2012 HCPCS code	CY 2012 long descriptor	Proposed CY 2013 ASC payment indicator**
37205	Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; initial vessel.	G2
37206	Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; each additional vessel (list separately in addition to code for primary procedure).	G2
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty.	G2
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed.	G2
37226	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed.	G2
37227	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed.	J8
37228	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty.	G2
37229	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed.	G2
37230	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed.	G2
37231	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed.	J8
37232	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (list separately in addition to code for primary procedure).	G2
37233	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with atherectomy, includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure).	G2
37234	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure).	G2
37235	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure).	G2
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound.	R2*
0300T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care.	R2*

*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. At the time this proposed rule is being developed for publication, current law authorizes a negative update to the MPFS payment rates for CY 2013. For a discussion of those rates, we refer readers to the CY 2013 MPFS proposed rule.

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 2013 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 2011 volume and utilization data and the clinical characteristics for all surgical procedures that are assigned payment indicator ''G2'' in CY 2012, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2*,'' ''P3*,'' or ''R2*'' in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74400 through 74408).

Our review of the CY 2011 volume and utilization data resulted in our identification of six covered surgical procedures that we believe meet the criteria for designation as office-based. The data indicate that the procedures are performed more than 50 percent of the time in physicians' offices, and that our medical advisors believe the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The six CPT codes we are proposing to permanently designate as office-based are listed in Table 40 below. We invite public comment on this proposal.

TABLE 40—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR PERMANENT OFFICE-BASED DESIGNATION FOR CY 2013

CY 2012 CPT code	CY 2012 long descriptor	CY 2012 ASC payment indicator	Proposed CY 2013 ASC payment indicator *
31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa.	G2	P2
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)	G2	P2
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)	G2	P2
53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence.	G2	P2
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming.	G2	P3
G0365	Vessel mapping of vessels for hemodialysis access (services for preoperative vessel mapping prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous outflow).	G2	P2

* Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. At the time this proposed rule is being developed for publication, current law authorizes a negative update to the MPFS payment rates for CY 2013. For a discussion of those rates, we refer readers to the CY 2013 MPFS proposed rule.

We also reviewed CY 2011 volume and utilization data and other information for the eight procedures finalized for temporary office-based status in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74404 through 74408). Among these eight procedures, there were very few claims data for six procedures: CPT code 0099T (Implantation of intrastromal corneal ring segments); CPT code 0124T (Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication)); CPT code 0226T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed); CPT code 0227T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)); CPT code C9800 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies); and CPT code 67229 (Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy). Consequently, we are proposing to maintain their temporary office-based designations for CY 2013.

The volume and utilization data for the remaining two procedures that have temporary office-based designations for CY 2012 are sufficient to indicate that these procedures are not performed predominantly in physicians' offices and, therefore, should not be assigned an office-based payment indicator in CY 2013. Consequently, we are proposing to assign payment indicator ''G2'' to the following two covered surgical procedure codes in CY 2013:

- CPT code 37761 (Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg); and
- CPT code 0232T (Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed).

The proposed CY 2013 payment indicator designations for the eight procedures that were temporarily designated as office-based in CY 2012 are displayed in Table 41 below. The procedures for which the proposed office-based designations for CY 2013 are temporary also are indicated by asterisks in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site). We invite public comment on this proposal.

TABLE 41—PROPOSED CY 2013 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2012 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2012 CPT code	CY 2012 long descriptor	CY 2012 ASC payment indicator	Proposed CY 2013 ASC payment indicator **
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg.	R2 *	G2
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy.	R2 *	R2 *
0099T	Implantation of intrastromal corneal ring segments	R2 *	R2 *
0124T	Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication).	R2 *	R2 *
0226T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed.	R2 *	R2 *
0227T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies).	R2 *	R2 *
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed.	R2 *	G2
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies.	R2 *	R2 *

* If designation is temporary.

** Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. At the time this proposed rule is being developed for publication, current law authorizes a negative update to the MPFS payment rates for CY 2013. For a discussion of those rates, we refer readers to the CY 2013 MPFS proposed rule.

c. ASC Covered Surgical Procedures Designated as Device-Intensive

(1) Background

As discussed in the August 2, 2007 final rule (72 FR 42503 through 42508), we adopted a modified payment methodology for calculating the ASC payment rates for covered surgical procedures that are assigned to the subset of OPPS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS, in order to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures.

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

For CY 2013, we are proposing to update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with the proposed OPPS device-dependent APC update, reflecting the proposed APC assignments of procedures, designation of APCs as device-dependent, and APC device offset percentages based on the CY 2011 OPPS claims and cost report data available for the proposed rule. The OPPS device-dependent APCs are discussed further in section II.A.2.d.(1) of this 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 2013 are listed in Table 42 below. The CPT code, the CPT code short descriptor, the proposed CY 2013 ASC payment indicator (PI), the proposed CY 2013 OPPS APC assignment, the proposed CY 2013 OPPS APC device offset percentage, and an indication if the full credit/partial credit (FB/FC) device adjustment policy would apply are also listed in Table 42 below. A review of the FB/FC device adjustment policy is also found 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

We generally discuss the no cost/full credit and partial credit devices under the heading entitled ''Proposed ASC Payment for Covered Surgical Procedure.'' However, because the no cost/full credit and partial credit device policy applies to a subset of device-intensive procedures, we believe it would be clearer to discuss the device-intensive procedure policy and the no cost/full credit and partial credit device policy consecutively and to consolidate the tables that we usually publish separately. Our ASC policy with regard to payment for costly devices implanted in ASCs at no cost/full credit or partial credit as set forth in § 416.179 is consistent with the OPPS policy. The proposed CY 2013 OPPS APCs and devices subject to the adjustment policy are discussed in section IV.B.2. of this

proposed rule. 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 68745).

Consistent with the OPPS, we are proposing to update the list of ASC covered device-intensive procedures and devices that would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2013. Table 42 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 2013. Specifically, when a procedure that is listed in Table 42 is subject to the no cost/full credit or partial credit device adjustment policy and is performed to implant a device that is listed in Table 43 below, where that device is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS ''FB'' modifier on the line with the procedure to implant the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost to the ASC or with full credit. We would provide the same amount of payment reduction based on the device offset amount in ASCs that would apply under the OPPS under the same circumstances. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure being furnished by the ASC.

For partial credit, we are proposing to reduce the payment for implantation procedures listed in Table 42 that are subject to the no cost/full credit or partial credit device adjustment policy by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more of the cost of the new device. The ASC would append the HCPCS ''FC'' modifier to the HCPCS code for a surgical procedure listed in Table 42 that is subject to the no cost/full credit or partial credit device adjustment policy, when the facility receives a partial credit of 50 percent or more of the cost of a device listed in Table 43 below. In order to report that they received a partial credit of 50 percent or more of the cost of a new device, ASCs would have the option of either: (1) Submitting the claim for the device replacement procedure to their Medicare contractor after the procedure's performance but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment once the credit determination is made; or (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more of the cost of the replacement device. Beneficiary coinsurance would continue to be based on the reduced payment amount.

We invite public comments on these proposals.

TABLE 42—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE-INTENSIVE DESIGNATION FOR CY 2013, 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 2013 ASC PI	Proposed CY 2013 OPPS APC	Proposed CY 2013 device-dependent APC offset percent	Proposing that the FB/FC policy would apply
0282T	Periph field stimul trial	J8	0040	55	Yes.
0283T	Periph field stimul perm	J8	0318	87	Yes.
0302T	Icar ischm mntrng sys compl	J8	0089	70	Yes.
0304T	Icar isch mntrng sys device	J8	0090	71	Yes.
19296	Place po breast cath for rad	J8	0648	50	Yes.
19297	Place breast cath for rad	J8	0648	50	Yes.
19298	Place breast rad tube/caths	J8	0648	50	Yes.
19325	Enlarge breast with implant	J8	0648	50	Yes.
19342	Delayed breast prosthesis	J8	0648	50	Yes.
19357	Breast reconstruction	J8	0648	50	Yes.
24361	Reconstruct elbow joint	J8	0425	58	Yes.
24363	Replace elbow joint	J8	0425	58	Yes.
24366	Reconstruct head of radius	J8	0425	58	Yes.
25441	Reconstruct wrist joint	J8	0425	58	Yes.
25442	Reconstruct wrist joint	J8	0425	58	Yes.
25446	Wrist replacement	J8	0425	58	Yes.
27446	Revision of knee joint	J8	0425	58	Yes.
33206	Insertion of heart pacemaker	J8	0089	70	Yes.
33207	Insertion of heart pacemaker	J8	0089	70	Yes.
33208	Insertion of heart pacemaker	J8	0655	73	Yes.
33212	Insertion of pulse generator	J8	0090	71	Yes.
33213	Insertion of pulse generator	J8	0654	74	Yes.
33214	Upgrade of pacemaker system	J8	0655	73	Yes.
33221	Insert pulse gen mult leads	J8	0654	74	Yes.
33224	Insert pacing lead & connect	J8	0655	73	Yes.
33225	Lventric pacing lead add-on	J8	0655	73	Yes.
33227	Remove&replace pm gen singl	J8	0090	71	Yes.
33228	Remv&replc pm gen dual lead	J8	0654	74	Yes.
33229	Remv&replc pm gen mult leads	J8	0654	74	Yes.

TABLE 42—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE-INTENSIVE DESIGNATION FOR CY 2013, 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 2013 ASC PI	Proposed CY 2013 OPPS APC	Proposed CY 2013 device-dependent APC offset percent	Proposing that the FB/FC policy would apply
33230	Insrt pulse gen w/dual leads	J8	0107	83	Yes.
33231	Insrt pulse gen w/dual leads	J8	0107	83	Yes.
33240	Insert pulse generator	J8	0107	83	Yes.
33249	Eltrd/insert pace-defib	J8	0108	84	Yes.
33262	Remv&replc cvd gen sing lead	J8	0107	83	Yes.
33263	Remv&replc cvd gen dual lead	J8	0107	83	Yes.
33264	Remv&replc cvd gen mult lead	J8	0107	83	Yes.
33282	Implant pat-active ht record	J8	0680	74	Yes.
37227	Fem/popl revasc stnt & ather	J8	0319	53	No.
37231	Tib/per revasc stent & ather	J8	0319	53	No.
53440	Male sling procedure	J8	0385	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	54	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	82	Yes.
62362	Implant spine infusion pump	J8	0227	82	Yes.
63650	Implant neuroelectrodes	J8	0040	55	Yes.
63655	Implant neuro-electrodes	J8	0061	66	Yes.
63663	Revise spine eltrd perq aray	J8	0040	55	Yes.
63664	Revise spine eltrd plate	J8	0040	55	Yes.
63685	Insrt/redo spine n generator	J8	0039	86	Yes.
64553	Implant neuro-electrodes	J8	0040	55	Yes.
64555	Implant neuro-electrodes	J8	0040	55	Yes.
64561	Implant neuro-electrodes	J8	0040	55	Yes.
64565	Implant neuro-electrodes	J8	0040	55	Yes.
64568	Implant neuro-electrodes	J8	0318	87	Yes.
64575	Implant neuro-electrodes	J8	0061	66	Yes.
64580	Implant neuro-electrodes	J8	0061	66	Yes.
64581	Implant neuro-electrodes	J8	0061	66	Yes.
64590	Insrt/redo pn/gastr stimul	J8	0039	86	Yes.
65770	Revise cornea with implant	J8	0293	65	No.
69714	Implant temple bone w/stimul	J8	0425	60	Yes.
69715	Temple bne implnt w/stimulat	J8	0425	60	Yes.
69717	Temple bone implant revision	J8	0425	60	Yes.
69718	Revise temple bone implant	J8	0425	60	Yes.
69930	Implant cochlear device	J8	0259	84	Yes.
G0448	Place perm pacing cardiovert	J8	0108	84	Yes.

TABLE 43—PROPOSED DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2013 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT

CY 2012 device HCPCS Code	CY 2012 short descriptor
C1721	AICD, dual chamber.
C1722	AICD, single chamber.
C1728	Cath, brachytx seed adm.
C1762	Conn tiss, human (inc fascia).
C1763	Conn tiss, non-human.

TABLE 43—PROPOSED DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2013 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT—Continued

CY 2012 device HCPCS Code	CY 2012 short descriptor
C1764	Event recorder, cardiac.
C1767	Generator, neurostim, imp.
C1771	Rep dev, urinary, w/sling.
C1772	Infusion pump, programmable.

TABLE 43—PROPOSED DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2013 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT—Continued

CY 2012 device HCPCS Code	CY 2012 short descriptor
C1776	Joint device (implantable).
C1777	Stent, non-coat/cov w/o del.
C1778	Lead, neurostimulator.
C1779	Lead, pmkr, transvenous VDD.

TABLE 43—PROPOSED DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2013 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT—Continued

CY 2012 device HCPCS Code	CY 2012 short descriptor
C1781	Mesh (implantable).
C1785	Pmkr, dual, rate-resp.
C1786	Pmkr, single, rate-resp.
C1789	Prosthesis, breast, imp.
C1813	Prosthesis, penile, inflatab.
C1815	Pros, urinary sph, imp.
C1820	Generator, neuro rechg bat sys.
C1881	Dialysis access system.
C1882	AICD, other than sing/dual.
C1891	Infusion pump, non-prog, perm.
C1895	Lead, AICD, endo dual coil.
C1897	Lead, neurostim, test kit.
C1898	Lead, pmkr, other than trans.
C1900	Lead coronary venous.
C2618	Probe, cryoablation.
C2619	Pmkr, dual, non rate-resp.
C2620	Pmkr, single, non rate-resp.

TABLE 43—PROPOSED DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2013 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT—Continued

CY 2012 device HCPCS Code	CY 2012 short descriptor
C2621	Pmkr, other than sing/dual.
C2622	Prosthesis, penile, non-inf.
C2626	Infusion pump, non-prog, temp.
C2631	Rep dev, urinary, w/o sling.
L8600	Implant breast silicone/eq.
L8614	Cochlear device/system.
L8680	Implt neurostim elctr each.
L8685	Implt nrostm pls gen sng rec.
L8686	Implt nrostm pls gen sng non.
L8687	Implt nrostm pls gen dua rec.
L8688	Implt nrostm pls gen dua non.
L8690	Aud osseo dev, int/ext comp.

e. ASC Treatment of Surgical Procedures Proposed for Removal From the OPPS Inpatient List for CY 2013

As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68724), we adopted a policy to include in our annual evaluation of the ASC list of covered surgical procedures, a review of the procedures that are being proposed for removal from the OPPS inpatient list for possible inclusion on the ASC list of covered surgical procedures. We evaluated each of the two procedures we are proposing to remove from the OPPS inpatient list for CY 2013 according to the criteria for exclusion from the list of covered ASC surgical procedures. We believe that these two procedures should continue to be excluded from the ASC list of covered surgical procedures for CY 2013 because they would be expected to pose a significant risk to beneficiary safety or to require an overnight stay in ASCs. The CPT codes for these two procedures and their long descriptors are listed in Table 44 below.

TABLE 44—PROCEDURES PROPOSED FOR EXCLUSION FROM THE ASC LIST OF COVERED PROCEDURES FOR CY 2013 THAT ARE PROPOSED FOR REMOVAL FROM THE CY 2013 OPPS INPATIENT LIST

CPT code	Long descriptor
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical.
27447	Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty).

We invite public comments on this proposal.

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 2013 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary items and services because of changes that are being proposed under the OPPS for CY 2013. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2012 may be proposed for packaged status under the CY 2013 OPPS and, therefore, also under the ASC payment system for CY 2013. Comment indicator "CH," discussed in section XII.B. of this proposed rule, is used in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site) to indicate covered ancillary services for which we are proposing a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2013.

Except for the Level II HCPCS codes listed in Table 37 of this proposed rule, all ASC covered ancillary services and their proposed payment indicators for CY 2013 are included in Addendum BB to this proposed rule.

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

1. Proposed Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are fully described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy for the revised ASC payment system, the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year is used to calculate the national unadjusted payment rates for procedures with payment indicators "G2" and "A2." Payment indicator "A2" was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and were, therefore, subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator "A2" is no longer required to identify surgical procedures subject to transitional payment, we retained payment indicator "A2" because it is used to identify procedures that are exempted from application of the office-based designation.

The rate calculation established for device-intensive procedures (payment indicator "J8") is structured so that the packaged device payment amount is the same as under the OPPS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2012 OPPS/ASC final rule with comment period (76

FR 74377 through 74451), we updated the CY 2011 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2,'' ''G2,'' and ''J8'' using CY 2010 data, consistent with the CY 2012 OPPS update. Payment rates for device-intensive procedures also were updated to incorporate the CY 2012 OPPS device offset percentages.

Payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') are the lower of the MPFS nonfacility PE RVU-based amount (we refer readers to the CY 2013 MPFS proposed rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2012 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') using the most recent available MPFS and OPPS data. We compared the estimated CY 2012 rate for each of the office-based procedures, calculated according to the ASC standard ratesetting methodology, to the MPFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2012 payment rate for the procedure according to the final policy of the revised ASC payment system (§ 416.171(d)).

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

We are proposing to update ASC payment rates for CY 2013 using the established rate calculation methodologies under § 416.171. We note that, as discussed in section II.A.2.f. of this proposed rule, because we are proposing to base the OPPS relative payment weights on geometric mean costs for CY 2013, the ASC system would shift to the use of geometric means to determine relative payment weights under the ASC standard ratesetting methodology. We 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 based on the CY 2013 OPPS proposal that reflects updated proposed OPPS device offset percentages, and to make payment for office-based procedures at the lesser of the proposed CY 2013 MPFS nonfacility PE RVU-based amount or the proposed CY 2013 ASC payment amount calculated according to the standard ratesetting methodology.

We 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 identified 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 list of services. We identify these services with a double asterisk in Addenda AA and BB to this proposed rule.

d. Payment for the Cardiac Resynchronization Therapy Composite

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. CRT utilizes a pacing electrode implanted in combination with either a pacemaker or an implantable cardioverter defibrillator (ICD). CRT performed by the implantation of an ICD along with a pacing electrode is referred to as ''CRT–D.'' In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to establish the CY 2012 ASC payment rate for CRT–D services based on the OPPS payment rate applicable to APC 0108 when procedures described by CPT codes 33225 and 33249 are performed on the same date of service in an ASC. ASCs use the corresponding HCPCS Level II G-code (G0448) for proper reporting when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service. For a complete discussion of our policy regarding payment for CRT–D services in ASCs, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74427 through 74428). We are not proposing any changes to our current policy regarding ASC payment for CRT–D services for CY 2013.

e. Proposed 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 our without cystoscopy) and CPT code 77778 (Interstitial radiation source application; complex). Generally, the component services represented by both codes are provided in the same operative session on the same date of services to the Medicare beneficiary being treated with LDR brachytherapy for prostate cancer.

As detailed in section II.A.2.e.(2) of this proposed rule, beginning in CY 2008 under the OPPS, we began providing a single payment for LDR prostate brachytherapy when the composite service, reported as CPT codes 55875 and 77778, is furnished in a single hospital encounter. We based the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the cost derived from claims for the same date of service that contain both CPT codes 55875 and 77778 and that do not contain other separately paid codes that are not on the bypass list. We implemented this policy in the OPPS because reliance on single procedure claims to set payment rates for these services resulted in the use of mainly incorrectly coded claims for LDR prostate brachytherapy because a correctly coded claim should include, for the same date of service, CPT codes for both needle/catheter placement and application of radiation sources, as well as separately coded imaging and

radiation therapy planning services (72 FR 66652 through 66655).

Currently under the ASC payment system, ASCs receive separate payment for the component services that comprise the LDR Prostate Brachytherapy Composite when the two services are provided on the same date of service. Specifically, ASCs that report CPT codes 55875 and 77778 on the same date of service receive a payment for CPT code 55875 where the payment rate is based on the OPPS relative payment weight for single procedure claims, and a separate payment for CPT code 77778 where payment is the lower of the rate based on the OPPS relative payment weight for single procedure claims or the MPFS non-facility PE–RVU based amount.

A commenter to the CY 2012 OPPS/ASC proposed rule (76 FR 74429 through 74430) requested that CMS pay for LDR prostate brachytherapy services under the ASC payment system based on the composite OPPS payment rate rather than making two separate payments for the service reported by CPT codes 55875 and 77778. The commenter asserted that basing ASC payments for the services on the composite APC methodology in which one payment is made for the combination of the two services would result in a more accurate payment than is currently being made to ASCs because ASC payment is based on costs from single-service claims that CMS has acknowledged are mostly incorrectly coded claims. We responded that we would take the commenter's request into consideration in future rulemaking, recognizing the lead time that is necessary for the creation of the associated G-code that would be used to identify when the procedures in the LDR prostate brachytherapy composite are performed on the same date of service in an ASC.

Because we agree that data from OPPS claims reporting both services required for LDR prostate brachytherapy provide the most accurate relative payment weight upon which to base ASC payment for the component services, we are proposing to establish an ASC payment rate that is based on the OPPS relative payment weight applicable to APC 8001 when CPT codes 55875 and 77778 are performed on the same date of service in an ASC. We also are proposing to create a HCPCS Level II G-code so that ASCs can properly report when the procedures described by CPT codes 55875 and 77778 are performed on the same date of service to receive the appropriate LDR Prostate Brachytherapy Composite payment. The payment rate associated with the LDR Prostate Brachytherapy Composite will be temporarily identified by G-code ''GXXX1'' in Addendum AA of this proposed rule. The permanent G-code that will identify the LDR Prostate Brahytherapy Composite for ASCs will appear in the CY 2013 OPPS/ASC final rule with comment period. When not performed on the same day as the service described by CPT code 55875, the service described by CPT code 77778 will continue to be assigned to APC 0651. When not performed on the same day as the service described by CPT code 77778, the service described by CPT code 55875 will continue to be assigned to APC 0163. We invite public comment on this proposal.

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. We want to further clarify 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, we established a final policy to align ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates, while we generally pay for separately payable radiology services at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount, regardless of which is lower. This modification to the ASC payment methodology for ancillary services was finalized in response to a comment on the CY 2011 OPPS/ASC proposed rule that suggested it is inappropriate to use the MPFS-based payment methodology for nuclear medicine procedures because the associated diagnostic radiopharmaceutical, although packaged under the ASC payment system, is separately paid under the MPFS. We set the payment indicator to ''Z2'' for these nuclear medicine procedures in the ASC setting so that payment for these procedures would be based on the OPPS relative payment weight rather than the MPFS nonfacility PE RVU-based amount to ensure that the ASC will be compensated for the cost associated with the diagnostic radiopharmaceuticals.

In addition, because the same issue exists for radiology procedures that use contrast agents (the contrast agent is packaged under the ASC payment system but is separately paid under the MPFS), we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430) to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight and will, therefore, include the cost for the contrast agent.

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical

procedures at prospective rates adopted under the OPPS.

Other separately paid covered ancillary services in ASCs, specifically corneal tissue acquisition and device categories with OPPS pass-through status, do not have prospectively established ASC payment rates according to the final policies of the revised ASC payment system (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the revised ASC payment system, corneal tissue acquisition is paid based on the invoiced costs for acquiring the corneal tissue for transplantation. Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system. Currently, the four devices that are eligible for pass-through payment in the OPPS are described by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (Implantable)), HCPCS code C1830 (Powered bone marrow biopsy needle), HCPCS code C1840 (Lens, intraocular (telescopic)), and HCPCS code C1886 (Catheter, extravascular tissue ablation, any modality (insertable)). Payment amounts for HCPCS codes C1749, C1830, C1840, and C1886 under the ASC payment system are contractor priced. In the CY 2012 OPPS/ASC final rule with comment period, we finalized the expiration of pass-through payment for HCPCS code C1749, which will expire after December 31, 2012 (76 FR 74278). Therefore, after December 31, 2012, the HCPCS code C1749 device costs will be packaged into the costs of the procedures with which the devices are reported in the hospital claims data used in the development of the OPPS relative payment weights that will be used to establish ASC payment rates for CY 2013.

b. Proposed Payment for Covered Ancillary Services for CY 2013

For CY 2013, 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 2013 OPPS and ASC payment rates. The proposed CY 2013 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 2013 ASC payment rates for those services equal to the proposed CY 2013 OPPS rates.

Consistent with established ASC payment policy (72 FR 42497), the proposed CY 2013 payment for separately payable covered radiology services is based on a comparison of the CY 2013 proposed MPFS nonfacility PE RVU-based amounts (we refer readers to the CY 2013 MPFS proposed rule) and the proposed CY 2013 ASC payment rates calculated according to the ASC standard ratesetting methodology and then set at the lower of the two amounts (except as discussed below for nuclear medicine procedures and radiology services that use contrast agents). Alternatively, payment for a radiology service may be packaged into the payment for the ASC covered surgical procedure if the radiology service is packaged or conditionally packaged under the OPPS. The payment indicators in Addendum BB to 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 is made based on the OPPS relative payment weights rather than the MPFS nonfacility PE RVU-based amount, regardless of which is lower. We are proposing to continue this modification to the payment methodology and, therefore, set the payment indicator to ''Z2'' for these nuclear medicine procedures in CY 2013. As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430), we are proposing that payment indicators for radiology services that use contrast agents will be set to ''Z2'' in CY 2013 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.

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 Cycle and Evaluation Criteria

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68176), we finalized our current process for reviewing applications to establish new classes of new technology intraocular lenses (NTIOLs) and for recognizing new candidate intraocular lenses (IOLs) inserted during or subsequent to cataract extraction as belonging to an NTIOL class that is qualified for a payment adjustment. Specifically, we established the following process:

- We announce annually in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of 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; and
  - Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68227), we finalized our proposal to base our determinations on consideration of the following major criteria set out at 42 CFR 416.195:

- 42 CFR 416.195(a)(1): The IOL is approved by the FDA;
- 42 CFR 416.195(a)(2): Claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs are approved by the FDA for use in labeling and advertising;
- 42 CFR 416.195(a)(3): The IOL is not described by an active or expired

NTIOL class; that is, it does not share the predominant, class-defining characteristic associated with the improved clinical outcome with designated members of an active or expired NTIOL class; and

- 42 CFR 416.195(a)(4): Evidence demonstrates that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. The statute requires us to consider the following improved outcomes:
  - Reduced risk of intraoperative or postoperative complication or trauma;
  - Accelerated postoperative recovery;
  - Reduced induced astigmatism;
  - Improved postoperative visual acuity;
  - More stable postoperative vision; or
  - Other comparable clinical advantages.

Since implementation of the process for adjustment of payment amounts for NTIOLs that was established in the June 16, 1999 **Federal Register**, we have approved three classes of NTIOLs, as shown in the table with the associated qualifying IOL models, at the link entitled ''NTOL Application Determination Reference document Updated 01/06/2012,'' posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*.

2. NTIOL Application Process for Payment Adjustment

For a request to be considered complete, we require submission of the information that is found in the guidance document entitled ''Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lens (NTIOL)'' posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*. For each completed request for a new class that is received by the established deadline, a determination is announced annually in the final rule updating the ASC and OPPS payment rates for the next calendar year.

We also summarize briefly in the final rule the evidence that we reviewed, the public comments we received timely, and the basis for our determinations in consideration of applications for establishment of a new NTIOL class. When a new NTIOL class is created, we identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome. The date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class would be set prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

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

We received no requests for review to establish a new NTIOL class for CY 2013 by the March 2, 2012 due date (76 FR 74443).

4. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we are not proposing to revise the payment adjustment amount for CY 2013.

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

The last significant revisions to the regulations containing the substantive NTIOL evaluation criteria under 42 CFR 416.195 occurred in 2007. We are proposing significant revisions to § 416.195(a)(2) and § 416.195(a)(4). We believe that revising § 416.195 is necessary in order to improve the quality of the NTIOL applications. In recent years, we have received low quality NTIOL applications that may have been due in part to overly-broad evaluation criteria.

We are proposing to revise § 416.195(a)(2) to require that the IOL's FDA-approved labeling contains a claim of a specific clinical benefit imparted by a new lens characteristic. The IOL shall have a new lens characteristic in comparison to currently available IOLs. We also are proposing to revise § 416.195(a)(4) to require that any specific clinical benefit referred to in § 416.195(a)(2) must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved outcome. Improved outcomes include: (i) Reduced risk of intraoperative or postoperative complication or trauma; (ii) accelerated postoperative recovery; (iii) reduced induced astigmatism; (iv) improved postoperative visual acuity; (v) more stable postoperative vision; and (vi) other comparable clinical advantages.

The proposed revision to § 416.195(a)(2) is necessary because recent NTIOL applications have not included FDA labeling claims of clinical benefit. Instead, the candidate IOLs have, in most cases, had some characteristic for which the applicant has tried to prove clinical relevance through various kinds of evidence that have not been evaluated by the FDA because the evidence is not associated with a labeling claim. The result has been the submission of low quality evidence that has been insufficient for NTIOL status. We believe that the quality of the evidence would improve if applicants were required to obtain a labeling claim for the NTIOL benefit and therefore have the evidence for such benefit evaluated by FDA. We believe that this proposed approach would better serve CMS, FDA, and the applicants because any ultimate grant of NTIOL status would be supported by a labeling claim. The manufacturer could then advertise the NTIOL benefit without running afoul of FDA advertising limitations. We would have the benefit of an FDA review of the relevant evidence, which would be particularly valuable because the FDA has a dedicated team of scientists, physicians, and engineers who are experts in evaluating IOLs.

The proposed revision to § 416.195(a)(4) is necessary to insure that the claim is clinically relevant and represents an improved outcome for Medicare beneficiaries. We request public comments on these proposed revisions to the NTIOL regulations.

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

Section 416.195(a)(4)), discussed above, lists the following improved outcomes: (i) Reduced risk of intraoperative or postoperative complication or trauma; (ii) accelerated postoperative recovery; (iii) reduced induced astigmatism; (iv) improved postoperative visual acuity; (v) more stable postoperative vision; and (vi) other comparable clinical advantages.

This list is from the original 1994 NTIOL statutory provision. Because this provision is almost 20 years old, outcomes (i) through (v) have only limited relevance to modern cataract surgery. For example, regarding outcome (i), it is unclear what, if any, type of IOL could reduce the risk of complication or trauma associated with cataract surgery, or what, if any, contemporary cataract surgery complication could be affected by a new type of IOL. As for outcome (ii), postoperative recovery is already rapid in uncomplicated cataract surgery; therefore, it is difficult to see how it

could be significantly accelerated. Also, regarding outcome (iii), clinically significant induced astigmatism would be reflective of poor surgical technique and would not depend upon IOL design. Regarding outcome (iv), currently available IOLs provide such high quality postoperative visual acuity that it would be difficult to measure clinically significant improved postoperative visual acuity due to a new type of IOL. Finally, for outcome (v), postoperative vision is typically stable after uncomplicated cataract surgery, so again it would be difficult to improve upon this outcome.

The last of the listed improved outcomes is the nonspecific category described as ''other comparable clinical advantages.'' Given that present-day cataract surgery is such a successful procedure that results in significantly improved vision for almost all patients who undergo the procedure and who are appropriate candidates for cataract surgery, we are soliciting comments on what potential benefits associated with a new IOL could be considered to be a ''comparable clinical advantage'' as compared to the list of the five improved outcomes from the statute and regulation described above.

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 2013 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 2012 OPPS/ASC final rule with comment period. These addenda can be found in a file labeled ''January 2012 ASC Approved HCPCS Code and Payment Rates'' in the ASC Addenda Update section of the CMS Web site.

The ''CH'' comment indicator is used in Addenda AA and BB to this CY 2013 OPPS/ASC 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; 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 2013. 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 2013 update.

G. ASC Policy and Payment Recommendations

MedPAC was established under section 1805 of the Act to advise Congress on issues affecting the Medicare program. Subparagraphs (C) and (D) of section 1805(b)(1) of the Act require MedPAC to submit reports to Congress not later than March 15 and June 15 of each year that present its Medicare payment policy reviews and recommendations and its examination of issues affecting the Medicare program, respectively. The March 2012 MedPAC ''Report to the Congress: Medicare Payment Policy'' included the following recommendations relating specifically to the ASC payment system for CY 2013:

Recommendation 5–1: ''The Congress should update the payment rates for ambulatory surgical centers by 0.5 percent for calendar year 2013. The Congress should also require ambulatory surgical centers to submit cost data.''

Regarding the ASC payment update for CY 2013, MedPAC further stated that: ''On the basis of our payment adequacy indicators, the lack of ASC cost data, and our concerns about the potential effect of ASC growth on overall program spending, we believe a moderate update of 0.5 percent is warranted for CY 2013.'' With regard to the collection of cost data, MedPAC indicated that cost data are needed to fully assess ASC payment adequacy under the revised ASC payment system and to examine whether an alternative input price index would be an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed to annually update ASC payment rates.

CMS Response: We note that MedPAC's recommendation is for the Congress to increase ASC payment rates by 0.5 percent in CY 2013 and require ASCs to submit cost data. Congress has not acted on these recommendations. We are proposing to continue our current policy to update the ASC conversion factor using the CPI–U, and we are not proposing to require ASC to submit cost data in this proposed rule. However, as discussed in section XIV.H.2.b. of this proposed rule, the CPI–U may not be the best measure of inflation for the goods and services provided by ASCs and, therefore, we are seeking public comment on the type of cost information that would be feasible to collect from ASCs that would assist us in determining possible alternatives to using the CPI–U to update ASC payment rates for inflation.

H. 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 XIV.D.2.b. of this proposed rule) the established policy is to set the payment rate at the lower of the MPFS unadjusted non-facility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage indices to the labor-related share, which is 50 percent of the ASC payment amount. Beginning in CY 2008, CMS accounted for geographic wage variation in labor cost when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003. The reclassification provision provided at section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available raw pre-floor and pre-reclassified hospital wage indices results in the most appropriate adjustment to the labor portion of ASC costs. In addition, use of the unadjusted hospital wage data avoids further reductions in certain rural statewide wage index values that result from reclassification. We continue to believe that the unadjusted hospital wage indices, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs.

We note that in certain instances there might be urban or rural areas for which there is no IPPS hospital whose wage index data would be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indices for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a border). We have applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 Hinesville-Fort Stewart, GA, and CBSA 22 Rural Massachusetts.

In CY 2011, we identified another area, specifically, CBSA 11340 Anderson, SC for which there is no IPPS hospital whose wage index data would be used to set the wage index for that area. Generally, we would use the methodology described above; however, in this situation, all of the areas contiguous to CBSA 11340 Anderson, SC are rural. Therefore, in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72058 through 72059), we finalized our proposal to set the ASC wage index by calculating the average of all wage indices for urban areas in the State when all contiguous areas to a CBSA are rural and there is no IPPS hospital whose wage index data could be used to set the wage index for that area. In other situations, where there are no IPPS hospitals located in a relevant labor market area, we will continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indices for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.

2. Proposed Calculation of the ASC Payment Rates

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

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). We note that, as discussed in section II.A.2.f. of this proposed rule, because we are proposing to base the OPPS relative payment weights on geometric mean costs for CY 2013, the ASC system would shift to the use of geometric means to determine relative payment weights under the ASC standard ratesetting methodology. Consistent with our established policy, we are proposing to scale the CY 2013 relative payment weights for ASCs according to the following method. Holding ASC utilization and the mix of services constant from CY 2011, we are proposing to compare the total payment using the CY 2012 ASC relative payment weights with the total payment

using the CY 2013 relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2012 and CY 2013. We would use the ratio of CY 2012 to CY 2013 total payment (the weight scaler) to scale the ASC relative payment weights for CY 2013. The proposed CY 2013 ASC scaler is 0.9331 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 2011 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 2011 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2011 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for the proposed rule, is posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.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 2013 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 2013, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2011 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2013 pre-floor and pre-reclassified hospital wage indices. Specifically, holding CY 2011 ASC utilization and service-mix and the proposed CY 2013 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2012 pre-floor and pre-reclassified hospital wage indices and the total adjusted payment using the proposed CY 2013 pre-floor and pre-reclassified hospital wage indices. We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2012 pre-floor and pre-reclassified hospital wage indices to the total adjusted payment calculated with the proposed CY 2013 pre-floor and pre-reclassified hospital wage indices and applied the resulting ratio of 1.0002 (the proposed CY 2013 ASC wage index budget neutrality adjustment) to the CY 2012 ASC conversion factor to calculate the proposed CY 2013 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, ''if the Secretary has not updated amounts established'' under the revised ASC payment system in a calendar year, the payment amounts ''shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.'' The statute, therefore, does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at 42 CFR 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years. Therefore, the annual update to the ASC payment system is the CPI–U (referred to as the CPI–U update factor).

ASC stakeholders, as well as MedPAC, have commented throughout the years that the CPI–U may not adequately measure inflation for the goods and services provided by ASCs (see, for example, 76 FR 74444, 74448 through 74450; 73 FR 68757; and 72 FR 66859). While we believe the CPI–U is appropriate to apply to update the ASC payment system, the CPI–U is highly weighted for housing and transportation and may not best reflect inflation in the cost of providing ASC services. In developing this proposed rule, we considered possible alternatives to using the CPI–U to update ASC payment rates for inflation.

ASC stakeholders have urged us to adopt the hospital market basket to update ASC payment rates for inflation when commenting on each proposed rule since the beginning of the revised ASC payment system (72 FR 66859; 73 FR 68757; 74 FR 60628 through 60629; 75 FR 72063; 76 FR 74449). We considered the hospital market basket as an alternative to the CPI–U and, while the items included in the hospital market basket seem reflective of the kinds of costs incurred by ASCs, as stated in the CY 2012 OPPS/ASC final rule with comment period, we believe that the hospital market basket does not align with the cost structures of ASCs. A much wider range of services, such as room and board and emergency services, are provided by hospitals but are not costs associated with providing services in ASCs (76 FR 74450). As other possible alternatives to the CPI–U update, we considered using the physician's practice expense (PE) component of the Medicare Economic Index (MEI) update, as well as using an average of the hospital market basket update and the PE component of the MEI update. However, until we have more information regarding the cost inputs of ASCs, we are not confident that any of these alternatives are a better proxy for ASC costs than the CPI–U. Therefore, we are proposing a continuation of the established policy of basing the ASC update on the CPI–U. In addition, we are seeking public comment on the type of cost information that would be feasible to collect from ASCs in the future in order to determine if one of these alternative updates or an ASC-specific market basket would be a better proxy for ASC cost inflation than the CPI–U.

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new clause (v) which requires that ''any annual update under [the ASC payment] system for the year,

after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II)'' of the Act effective with the calendar year beginning January 1, 2011. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). Clause (iv) authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized a policy that ASCs begin submitting data on quality measures for services beginning on October 1, 2012 for the CY 2014 payment determination under the ASCQR Program. Section XVI.D. of this proposed rule provides a discussion of the proposed payment reduction to the annual update for ASCs that fail to meet the ASCQR Program requirements. In summary, we are proposing to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements. The reduced rates would apply beginning in CY 2014. We are proposing that application of the 2.0 percentage point reduction to the annual update factor, which currently is the CPI–U, may result in the update to the ASC payment system being less than zero for a year for ASCs that fail to meet the ASCQR Program requirements. We are proposing changes to §§ 416.160(a)(1) and 416.171 to reflect this proposal.

In accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determines the ''percentage increase'' in the CPI–U, which we interpret cannot be a negative number. Thus, in the instance where the percentage change in the CPI–U for a year is negative, we would hold the CPI–U update factor for the ASC payment system to zero. For the CY 2014 payment determination and subsequent payment determination years, under section 1833(i)(2)(D)(iv) of the Act, we would reduce the annual update by 2.0 percentage points for an ASC that fails to submit quality information under the rules established by the Secretary in accordance with section 1833(i)(7) of the Act. Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that the Secretary reduce the annual update factor, after application of any quality reporting reduction by the MFP adjustment, and states that application of the MFP adjustment may reduce this percentage change below zero. If the application of the MFP adjustment to the annual update factor after application of any quality reporting reduction would result in an MFP-adjusted update factor that is less than zero, the resulting update to the ASC payment rates would be negative and payments would decrease relative to the prior year. Illustrative examples of how the MFP adjustment would be applied to the ASC payment system update are found in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064).

For this proposed rule, for the 12-month period ending with the midpoint of CY 2013, the CPI–U update is projected to be 2.2 percent. Because the ASCQR Program does not affect payment rates until CY 2014, there would be no quality reporting reduction to the CPI–U for CY 2013. The MFP adjustment for the period ending with the midpoint of CY 2013 is projected to be 0.9 percent based on the methodology for calculating the MFP adjustment finalized in the CY 2011 MPFS final rule with comment period (75 FR 73394 through 73396) as revised in the CY 2012 MPFS final rule with comment period (76 FR 73300 through 73301). We are proposing to reduce the CPI–U update of 2.2 percent by the MFP adjustment of 0.9 percent, resulting in an MFP-adjusted CPI–U update factor of 1.3 percent. Therefore, we are proposing to apply a 1.3 percent MFP-adjusted CPI–U update factor to the CY 2012 ASC conversion factor.

For CY 2013, we also are proposing to adjust the CY 2012 ASC conversion factor ($42.627) by the wage adjustment for budget neutrality of 1.0002 in addition to the MFP-adjusted update factor of 1.3 percent discussed above, which results in a proposed CY 2013 ASC conversion factor of $43.190.

We invite public comment on these proposals.

3. Display of Proposed CY 2013 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 2013 for covered surgical procedures and covered ancillary services, respectively. These addenda contain several types of information related to the proposed CY 2013 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''Subject to Multiple Procedure Discounting'' indicates that the surgical procedure will be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session. Display of the comment indicator ''CH'' in the column titled ''Comment Indicator'' indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2012. 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 on the final rule with comment period.

The values displayed in the column titled ''CY 2013 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2013. The payment weights for all covered surgical procedures and covered ancillary services whose ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Thus, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs.

To derive the proposed CY 2013 payment rate displayed in the ''CY 2013 Payment'' column, each ASC payment weight in the ''CY 2013 Payment Weight'' column was multiplied by the proposed CY 2013 conversion factor of $43.190. 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 XV.H.2.b. of this proposed rule).

In Addendum BB, there are no relative payment weights displayed in the ''CY 2013 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''CY 2013 Payment'' column displays the proposed CY 2013 national unadjusted ASC payment rates for all items and services. The proposed CY 2013 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in April 2012.

XV. Hospital Outpatient Quality Reporting Program Updates

A. Background

1. Overview

CMS has implemented quality measure reporting programs for multiple settings of care. These programs promote higher quality, more efficient health care for Medicare beneficiaries. The quality data reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (Hospital OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), has been generally modeled after the quality data reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (Hospital IQR) Program (formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program). Both of these quality reporting programs for hospital services have financial incentives for the reporting of quality data to CMS.

CMS also has implemented quality reporting programs for long term care hospitals, inpatient rehabilitation hospitals, the hospice program, ambulatory surgical centers (the Ambulatory Surgical Center Quality Reporting (ASCQR) Program), as well as a program for physicians and other eligible professionals, known as the Physician Quality Reporting System (PQRS) (formerly known as the Physician Quality Reporting Initiative (PQRI)). CMS has recently proposed to implement quality reporting programs for inpatient psychiatric facilities and PPS-exempt cancer hospitals.

Finally, CMS has implemented a Hospital Value-Based Purchasing Program and an end-stage renal disease (ESRD) Quality Incentive Program (76 FR 628 through 646) that link payment to performance.

In implementing the Hospital OQR Program and other quality reporting programs, we have focused on measures that have high impact and support national priorities for improved quality and efficiency of care for Medicare beneficiaries as reflected in the National Quality Strategy, as well as conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. Our ultimate goal is to align the clinical quality measure requirements of the Hospital OQR Program and various other programs, such as the Hospital IQR Program, the ASCQR Program, and those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, so that the burden for reporting will be reduced. As appropriate, we will consider the adoption of measures with electronic specifications, to enable the collection of this information as part of care delivery. Establishing such an alignment will require interoperability between electronic health records (EHRs), and CMS data collection systems, with data being calculated and submitted via certified EHR technology; additional infrastructural development on the part of hospitals and CMS; and the adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. Once these activities are accomplished, the adoption of many measures that rely on data obtained directly from EHRs will enable us to expand the Hospital OQR Program measure set with less cost and burden to hospitals.

In implementing this and other quality reporting programs, we generally applied the same principles for the development and the use of measures, with some differences:

- Our overarching goal is to support the National Quality Strategy's three-part aim of better health care for individuals, better health for populations, and lower costs for health care. The Hospital OQR Program will help achieve the three-part aim 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.hhs.gov/secretary/about/priorities/priorities.html* and *http://www.ahrq.gov/workingforquality/*. HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act.
- Pay-for-reporting and public reporting should rely on a mix of standards, processes, outcomes, efficiency, and patient experience of care measures, including measures of care transitions and changes in patient functional status.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare and Medicaid public reporting and incentive payment systems to promote coordinated efforts to improve quality. The measure sets should evolve so that they include a focused set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider category.
- We weigh the relevance and the utility of measures compared to the burden on hospitals in submitting data under the Hospital OQR Program. The collection of information burden on providers should be minimized to the extent possible. To this end, we are working toward the eventual adoption of electronically-specified measures so that data can be calculated and submitted via certified EHR technology with minimal burden. We also seek to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all-payer claims databases. In recent years we have adopted measures that do not require chart abstraction, including structural measures and claims-based measures that we can calculate using other data sources.
- To the extent practicable and feasible, and recognizing differences in statutory authorities, measures used by CMS should be endorsed by a national, multi-stakeholder organization. We take into account the views of the Measure Application Partnership (MAP). The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay for reporting programs. The MAP views

patient safety as a high priority area and it strongly supports the use of NQF-endorsed safety measures. Accordingly, we consider the MAP's recommendations in selecting quality and efficiency measures *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 HAIs in clinical settings and the Partnership for Patients exemplify these programs.

• CMS Strategic Plan. We strive to ensure that measures for different Medicare and Medicaid programs are aligned with priority quality goals, that measure specifications are aligned across settings, that outcome measures are used whenever possible, and that quality measures are collected from EHRs as appropriate.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74451 through 74452), we responded to public comment on many of these principles. In this proposed rulemaking, we generally applied the same principals for our considerations for future measures, with some differences.

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*. We maintain the technical specifications for the measures by updating this Hospital OQR Specifications Manual and including detailed instructions and calculation algorithms. In some cases where the specifications are available elsewhere, we may include links to Web sites hosting technical specifications. These resources are for hospitals to use when collecting and submitting data on required measures.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established an additional subregulatory process for making updates to the measures we have adopted for the Hospital OQR Program. This process is necessary so that the Hospital OQR measures are calculated based on the most up-to-date scientific and consensus standards. Under this process, when a national consensus building entity updates the specifications for a measure that we have adopted for the Hospital OQR Program, we update our specifications for that measure accordingly. For measures that are not endorsed by a national consensus building entity, the subregulatory process is based on scientific advances as determined necessary by CMS, in part, through our measure maintenance process involving Technical Expert Panels (73 FR 68767). We provide notice of the updates via the QualityNet Web site, *http://www.QualityNet.org*, and in the Hospital OQR Specifications Manual.

We generally release the Hospital OQR Specifications Manual every 6 months and release addenda as necessary. This release schedule provides at least 3 months of advance notice for non-substantive 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.

b. Publication of Hospital OQR Program Data

Section 1833(t)(17)(E) of the Act requires that the Secretary establish procedures to make data collected under the Hospital OQR Program available to the public. It also states that such procedures must ensure that a hospital has the opportunity to review the data that are to be made public, with respect to the hospital prior to such data being made public. To meet these requirements, data that a hospital has submitted for the Hospital OQR Program are typically provided to hospitals for a preview period via QualityNet, and then displayed on CMS Web sites such as the *Hospital Compare* Web site, *http://www.hospitalcompare.hhs.gov* following the preview period. The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care. 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 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. Consistent with our current policy, we make Hospital IQR and Hospital OQR data publicly available whether or not the data have been validated for payment purposes. The *Hospital Compare* Web site currently displays information covering process of care, structural, ED throughput timing, health IT, and imaging efficiency measure data under the Hospital OQR Program.

In general, we strive to display hospital quality measures on the *Hospital Compare* Web site as soon as possible, after they have been adopted and have been reported to CMS. However, if there are unresolved display issues or pending design considerations, we may make the data available on other, non-interactive, CMS Web sites such as *http://www.cms.hhs.gov/HospitalQualityInits/*. Publicly reporting the information in this manner, though not on the interactive *Hospital Compare* Web site, allows us to meet the requirement under section 1833(t)(17)(E) of the Act for establishing procedures to make quality data submitted available to the public following a preview period. When we display hospital quality information on

non-interactive CMS Web sites, affected parties will be notified via CMS listservs, CMS email blasts, memorandums, Hospital Open Door Forums, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than *Hospital Compare.*

We also require hospitals to complete and submit a registration form (''participation form'') in order to participate in the Hospital OQR Program. With submission of this participation form, participating hospitals agree that they will allow CMS to publicly report the quality measure data submitted under the Hospital OQR Program, including measures that we calculate using Medicare claims.

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

In past rulemakings, we have proposed to retain previously adopted measures for each payment determination on a year-by-year basis and invited public comments on the proposal to retain such measures for all future payment determinations unless otherwise specified. For the purpose of streamlining the rulemaking process, beginning with this rulemaking, we are proposing that when we adopt measures for the Hospital OQR Program beginning with a payment determination and subsequent years, these measures are automatically adopted for all subsequent year payment determinations unless we propose to remove, suspend, or replace the measures. We invite public comment on this proposal.

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). At this time, we have not proposed to retire any measures from the Hospital OQR Program.

In previous Hospital IQR Program rulemakings, we have referred to the removal of measures from the Hospital IQR Program as ''retirement.'' We have used this term to indicate that Hospital IQR Program measures are no longer included in the Hospital IQR Program measure set for one or more indicated reasons. However, we note that this term may imply that other payers/purchasers/programs should cease using these measures that are no longer required for the Hospital IQR Program. In order to clarify that this is not our intent, we stated in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28034) that we will use the term ''remove'' rather than ''retire'' to refer to the action of no longer including a measure in the Hospital IQR Program. We are proposing to adopt the same terminology of ''removal'' in the Hospital OQR Program to indicate future action of discontinuing a measure in the Hospital OQR Program.

In the future, we are proposing to apply the same Hospital IQR Program measure removal criteria that we finalized, based on comments suggested during rulemaking, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185), 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) availability of alternative measures with a stronger relationship to patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (5) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and (7) collection or public reporting of a measure leads to negative unintended consequences such as patient harm. These criteria were suggested by commenters during Hospital IQR Program rulemaking, and we agreed that these criteria are also applicable in evaluating Hospital OQR Program quality measures for removal. We are proposing to adopt these measure retirement criteria for the Hospital OQR Program as well, and we invite public comments on these proposals.

In addition, in the evaluation of measure removal, we take into account the views of the Measure Application Partnership (MAP). The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for certain quality reporting programs and pay for performance programs. The MAP views patient safety as a high priority area and it strongly supports the use of NQF-endorsed measures. Furthermore, for efficiency and streamlining purposes, we strive to eliminate redundancy of similar measures.

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

In the 2012 IPPS/LTCH PPS final rule (76 FR 51611), we adopted a policy to immediately suspend collection of a measure when there is a reason to believe that continued collection of the measure raises patient safety concerns.

For CY 2014 and subsequent year payment determination, we are confirming that we have suspended the collection of OP–19: Transition Record with Specified Elements Received by Discharged Patients measure. We adopted measure OP–19 for the Hospital OQR Program for the CY 2013 payment determination with data collection beginning with January 1, 2012 encounters. Since data collection for this measure began, concerns have been raised about the current measure specifications, including potential privacy concerns which may lead to potential patient harm in the form of family violence.

After consideration of these issues and internal review of the measure specifications, we decided to suspend data collection for OP–19 effective with January 1, 2012 encounters until further notice. On April 2, 2012 we released a Memorandum ''Temporary Suspension of Hospital Outpatient Quality Reporting Measure OP–19: Transition Record with Specified Elements Received by Discharged Patients.'' This memo notified the Hospital OQR Program stakeholder community that we had suspended data collection for the OP–19 measure effective with January 1, 2012 encounters and until further notice.

On April 12, 2012, we released a Memorandum, ''Revised: Temporary Suspension of Hospital Outpatient Quality Reporting Measure OP–19: Transition Record with Specified Elements Received by Discharged Patients'' to make clear our intent not to use any data submitted on this measure for payment determinations, public reporting, or in validation.

The updated memorandum is available for review at the QualityNet Web site (*http://www.qualitynet.org*)

under the option ''Email Notifications'' within the ''Hospitals—Outpatient'' drop down menu found at the top of the page.

When NQF completes its maintenance review on this measure, and we have incorporated the necessary changes to the measure specifications in our measure manual, we anticipate being able to resume data collection, and will notify hospitals of changes in the suspension status of the measure for Hospital OQR via email blast.

Because CMS system constraints prevent immediate cessation of data collection, hospitals must continue to submit information for this measure during this temporary suspension. The data collection system currently requires a populated value for OP–19. During the period of time that the measure is suspended, hospitals may choose to populate their OP–19 submission field with a value that is not meaningful. Hospitals should not submit a null value because the lack of data for OP–19 will cause the submitted case to be rejected entirely from the data warehouse. In other words, failure to populate the OP–19 field could compromise reporting data for other measures for that same case because more than one measure can be reported within a single case.

Some vendors may have the capability to provide a default value for this measure to reduce data abstraction. Hospitals are encouraged to work with their vendors to determine options to reduce abstraction burden.

If a case is rejected from the data warehouse on the basis of a system error due to the current system's inability to accept a case without OP–19 data populated, in the event that the rejected case would have also fulfilled reporting requirements for one or more other measures, this rejection would create an unwanted consequence for a hospital participating in the Hospital OQR Program. Data rejection due to a system constraint could impact a hospital's ability to meet Hospital OQR Program requirements for receiving a full outpatient hospital annual payment update.

Therefore, we recommend continuing to submit a value for OP–19, although we will not use data submitted on OP–19 for payment determinations, will not publicly report these data, and will not validate these data until all concerns are resolved and measure specifications refined as necessary.

Because the developer is working to revise the measure specifications to address the concerns raised by affected parties, and the measure is undergoing NQF maintenance review this year, we are not proposing to remove the measure from the program at this time. After completion of the NQF maintenance process, we anticipate that normal program operations for this measure could resume once we have updated the Hospital OQR Specifications Manual and made any necessary changes to our data collection infrastructure. However, should we determine that these concerns cannot be addressed, we would propose to remove this measure in a future OPPS/ASC rule. We invite public comment on the suspension of OP–19 until further notice. We also invite public comment on whether the measure should be removed from the program at this time.

3. Deferred Data Collection of OP–24: Cardiac Rehabilitation Measure: Patient Referral From an Outpatient Setting for the CY 2014 Payment Determination

In the CY 2012 OPPS/ASC final rule with comment period, we finalized OP–24: Cardiac Rehabilitation Measure: Patient Referral from an Outpatient Setting for CY 2014 payment determination and indicated that the applicable quarters for data collection for this measure would be 1st quarter CY 2013 and 2nd quarter CY 2013 (76 FR 74464, 74481). In order for us to adhere to this data collection schedule, we would need to publish the measure specifications in the July 2012 release of the Hospital OQR Specifications Manual. While there are NQF-endorsed specifications for this measure, in order to implement standardized data collection on a national scale, we must include detailed abstraction instructions for chart-based measures in our Specifications Manual. These instructions will not be completed and tested in time to include in the July 2012 release of the Specifications Manual, which includes collection instructions for measures beginning January 1, 2013. This is an unanticipated delay in implementation that we do not expect to be a regularly occurring issue for the Hospital OQR program.

Therefore, we are proposing to defer the data collection for this measure to January 1, 2014 encounters. We are also proposing that the measure would no longer be used for the CY 2014 payment determination, and that its first application would be for the CY 2015 payment determination. The data collection deferral for this measure is detailed in the ''Form, Manner, and Timing'' section of this proposed rule. We invite public comments on these proposals.

D. Quality Measures for CY 2015 Payment Determination

We previously finalized 26 measures for the CY 2015 Hospital OQR Program measure set in the 2012 OPPS/ASC rulemaking (76 FR 74472 through 74474).

Taking into consideration the time and effort for CMS to develop, align, and implement the infrastructure necessary to collect data on the Hospital OQR Program measures and make payment determinations, as well as the time and effort on the part of hospital outpatient departments to plan and prepare for reporting additional measures, we are not proposing any additional quality measures for CY 2015 and subsequent years payment determination in this rulemaking. As discussed above, we have suspended measure OP–19 and deferred data collection for OP–24 until the measure specifications can be further refined. We also are clarifying that the public reporting of the claims-based imaging efficiency measure OP–15 has been deferred until July 2013 at the earliest, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74456).

In summary, we are proposing no additional measures for the CY 2015 payment determination, and we are proposing to retain the 25 measures previously adopted for the CY 2014 payment determination for CY 2015 and subsequent year payment determinations. We are confirming the suspension of data collection for the OP–19 measure, and consequently its use in the Hospital OQR Program, until further notice. We also are proposing to defer data collection on OP–24, and to first apply this measure toward the CY 2015 payment determination rather than to the CY 2014 payment determination as originally finalized. Set out below are the previously adopted measures which we are proposing to retain for the CY 2014, CY 2015, and subsequent years payment determinations under the Hospital OQR Program.

HOSPITAL OQR PROGRAM MEASURES ADOPTED FOR THE CY 2014, CY 2015 AND SUBSEQUENT YEAR PAYMENT DETERMINATIONS

OP–1: Median Time to Fibrinolysis.
OP–2: Fibrinolytic Therapy Received Within 30 Minutes.
OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
OP–4: Aspirin at Arrival.
OP–5: Median Time to ECG.
OP–6: Timing of Antibiotic Prophylaxis.
OP–7: Prophylactic Antibiotic Selection for Surgical Patients.
OP–8: MRI Lumbar Spine for Low Back Pain.
OP–9: Mammography Follow-up Rates.
OP–10: Abdomen CT—Use of Contrast Material.
OP–11: Thorax CT—Use of Contrast Material.
OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data.
OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery.
OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.*
OP–16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of Arrival.
OP–17: Tracking Clinical Results between Visits.
OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
OP–19: Transition Record with Specified Elements Received by Discharged ED Patients.**
OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
OP–21: ED- Median Time to Pain Management for Long Bone Fracture.
OP–22: ED Patient Left Without Being Seen.
OP–23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival.
OP–24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting.***
OP–25: Safe Surgery Checklist Use.
OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures.

Procedure category	Corresponding HCPCS Codes
Gastrointestinal	40000 through 49999, G0104, G0105, G0121, C9716, C9724, C9725, 0170T.
Eye	65000 through 68999, 0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, 0099T.
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0062T.
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, 0201T.
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, C9727.
Genitourinary	50000 through 58999, 0193T, 58805.
Cardiovascular	33000 through 37999.
Respiratory	30000 through 32999.

* Information for OP–15 will not be reported in Hospital Compare in 2012. Public Reporting for this measure would occur in July 2013 at the earliest.
** Data collection for OP–19 was suspended effective with January 1, 2012 encounters until further notice.
*** Data collection for OP–24 would be postponed from January 1, 2013 to January 1 2014, and its first application toward a payment determination would be for CY 2015 rather than CY 2014.

We invite public comments on these proposals.

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

The current measure set for the Hospital OQR Program includes measures that assess process of care, imaging efficiency patterns, care transitions, ED Throughput efficiency, the use of HIT care coordination, patient safety, and volume. We anticipate that as EHR technology evolves, and more infrastructure are put in place, we will have the capacity to accept electronic reporting of many clinical chart-abstracted measures that are currently part of the Hospital OQR Program using certified EHR technology. We work diligently toward this goal. We believe that this future progress at a future date, such as FY 2015, would significantly reduce the administrative burden on hospitals under the Hospital OQR Program to report chart-abstracted measures. We recognize that considerable work needs to be done by measure owners and developers to make this possible with respect to the clinical quality measures targeted for e-specifications. This includes completing electronic specifications for measures, pilot testing, reliability and validity testing, and implementing such specifications into certified EHR technology to capture and calculate the results, and implementing the systems.

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the hospital outpatient setting. Therefore, through future rulemaking, we intend to propose new measures that help us further our goal of achieving better health care and improved health for Medicare beneficiaries who receive health care in hospital outpatient settings. In addition, we are considering initiating a call for input to assess the following measure domains: clinical quality of care; care coordination; patient safety; patient and caregiver experience of care; population/community health; and efficiency. We believe this approach will promote better care while bringing the Hospital OQR Program in line with other established quality reporting and pay for performance programs such as the Hospital IQR and ASCQR Programs.

We invite public comment on this approach and suggestions and rationale for possible quality measures for future inclusion in the Hospital OQR Program.

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

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on the measures selected by the Secretary, in the form and manner, and at a time, required by the Secretary will incur a 2.0 percentage point reduction to their OPD fee schedule increase factor, that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent payment year.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772), we discussed how the payment reduction for failure to meet the administrative, data collection, and data submission requirements of the Hospital OQR Program affected the CY 2009 payment update applicable to OPPS payments for HOPD services furnished by the hospitals defined under section 1886(d)(1)(B) of the Act to which the program applies. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. All other hospitals paid under the OPPS that meet the reporting requirement receive the full OPPS payment update without the reduction.

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site): ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' ''U,'' or ''X.'' In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770), we adopted a policy that payment for all services assigned these status indicators would be subject to the reduction of the national unadjusted payment rates for applicable hospitals, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or ''T,'' and brachytherapy sources with assigned status indicator ''U,'' which were paid at charges adjusted to cost in CY 2009. We excluded services assigned to New Technology APCs from the list of services subject to the reduced national unadjusted payment rates because the OPD fee schedule increase factor is not used to update the payment rates for these APCs.

In addition, section 1833(t)(16)(C) of the Act, as amended by section 142 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), specifically required that brachytherapy sources be paid during CY 2009 on the basis of charges adjusted to cost, rather than under the standard OPPS methodology. Therefore, the reduced conversion factor also was not applicable to CY 2009 payment for brachytherapy sources because payment would not be based on the OPPS conversion factor and, consequently, the payment rates for these services were not updated by the OPD fee schedule increase factor. However, in accordance with section 1833(t)(16)(C) of the Act, as amended by section 142 of the MIPPA, payment for brachytherapy sources at charges adjusted to cost expired on January 1, 2010. Therefore, in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60641), we finalized our CY 2010 proposal, without modification, to apply the reduction to payment for brachytherapy sources to hospitals that fail to meet the quality data reporting requirements of the Hospital OQR Program for brachytherapy services furnished on and after January 1, 2010.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To implement the requirement to reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors: A full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative weights by the reduced conversion factor. To determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiply the final full national unadjusted payment rate in Addendum B to 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, outlier payments will continue to be made when the criteria are met. For hospitals that fail to meet the quality

data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. This policy conforms to current practice under the IPPS. We continued this policy in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642), in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72099), and in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74478). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this proposed rule.

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

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 2013 annual payment update factor. For the CY 2013 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of $70.106 by the proposed full conversion factor of $71.537. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2013 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,'' ''U,'' and ''X'' (other than new technology APCs to which we have assigned status indicators ''S'' and ''T''). 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 comments on these proposals.

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

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

In order to participate in the Hospital OQR Program, hospitals must meet administrative, data collection and submission, and data validation requirements (if applicable). Hospitals that do not meet Hospital OQR Program requirements, as well as hospitals not participating in the program and hospitals that withdraw from the program, will not receive the full OPPS payment rate update. Instead, in accordance with section 1833(t)(17)(A) of the Act, those hospitals will receive a reduction of 2.0 percentage points to their OPD fee schedule increase factor for the applicable payment year.

We established administrative requirements for the payment determination requirements for the CY 2013 and subsequent years' payment updates in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74479 through 74487).

With respect to the payment determinations for CY 2014 and subsequent years, we are proposing one modification to these requirements. Under current requirements, CMS deadlines for hospitals to submit notice of participation forms are based on the date identified as a hospital's Medicare acceptance date on the CMS Certification and Survey Provider Enhanced Reporting (CASPER) system. Deadlines are based on whether a hospital's Medicare acceptance date falls before January 1 of the year prior to the annual payment update, or on or after January 1 of the year prior to the annual payment update (for example, 2013 would be the year prior to the affected CY 2014 annual payment update). Currently, for a hospital whose Medicare acceptance date is before January 1 of the year prior to the affected payment update affected, the notice of participation form is due by March 31 of the year prior to the affected annual payment update (76 FR 74479 through 74480). We are proposing to extend this deadline for hospitals, as described below.

Hospitals with Medicare acceptance dates before January 1 of the year prior to the affected annual payment update: For the CY 2014 and subsequent years payment update, we are proposing that any hospital that has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update (for example, 2013 would be the year prior to the affected CY 2014 annual payment update) that is not currently participating in Hospital OQR and wishes to participate in the Hospital OQR Program must submit a participation form by July 31, rather than March 31, of the year prior to the affected annual payment update. We are proposing a deadline of July 31 to give hospitals the maximum amount of time to decide whether they wish to participate in the Hospital OQR Program, as well as put into place the necessary staff and resources to timely report chart-abstracted data for first quarter of the year's services which are due August 1.

We invite public comment on this proposed modification to Hospital OQR Program administrative requirements for the CY 2014 and subsequent years' payment determinations.

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

a. Background

We are not proposing any additional measures for the CY 2014 payment determination year. We refer readers to the following OPPS/ASC final rules with comment periods for a history of measures adopted for the Hospital OQR Program, including lists of: 11 measures finalized for the CY 2011 payment determination (74 FR 60637); 15 measures finalized for the CY 2012 payment determination (75 FR 72083 through 72084); 23 measures finalized for the CY 2013 payment determination (75 FR 72090); and 26 measures finalized for the CY 2014 and CY 2015 payment determinations (76 FR 74469 and 74473).

We refer readers to section XV.D. of this proposed rule for a discussion of the OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache measure. Because of the clarification that public reporting is not planned until July 2013 at the earliest, we confirm this measure will not be used in the CY 2014 payment determination. We will confirm our intent to include or exclude this measure in the CY 2015 payment determination in future rulemaking.

We refer readers to section XV.C.2. of this proposed rule for a discussion of the OP–19: Transition Record with Specified Elements Received by Discharged ED Patients measure. Because the data collection for this measure is currently suspended, this measure will not be used in the CY 2014 payment determination. We will

indicate whether data collection for this measure will resume in time for the CY 2015 payment determination in future rulemaking.

We refer readers to section XV.C.3. of this proposed rule for a discussion of the OP–24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting measure. We are proposing not to use this measure in the CY 2014 payment determination and to use this measure in the CY 2015 payment determination.

b. General Requirements

We are proposing to continue the policy that, to be eligible to receive the full OPD fee schedule increase factor for any payment determination, hospitals must comply with our submission requirements for chart-abstracted data, population and sampling data, claims-based measure data, and structural quality measure data, including all-patient volume data. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74480 through 74482) for a discussion of these requirements.

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

The table in section XV.D. of this proposed rule includes measures that are collected by abstracting the information from the patient chart. The full list of these chart abstracted measures is set out below:

- 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–16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest pain) Received Within 30 minutes of Arrival
- OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
- OP–19: Transition Record with Specified Elements Received by Discharged Patients
- OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional
- OP–21: ED—Median Time to Pain Management for Long Bone Fracture
- OP–22: ED Patient Left Without Being Seen
- OP–23: ED—Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 Minutes of Arrival
- OP–24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting

We have suspended OP–19 from the CY 2014 payment determination and are proposing to defer data collection for OP–24 for the CY 2014 payment year. We invite public comment on our proposal to collect data for only those measures that are finalized to be included in the CY 2014 payment determination.

Of those measures for which we are proposing to collect data for in CY 2014, the form and manner for submission of one of these measures, OP–22: ED Patient Left Without Being Seen, is unique, and the form and manner for this measure is detailed in section XV.G.2.f. of this proposed rule.

For the remaining chart-abstracted measures for which we are proposing to collect data for the CY 2014 payment determination, we are proposing that the applicable quarters for data collection would be as follows: 3rd quarter CY 2012, 4th quarter CY 2012, 1st quarter CY 2013, and 2nd quarter CY 2013 for hospitals that are continuing participants; newly participating hospitals would follow reporting requirements as outlined in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74480) and in section XV.G.1. of this proposed rule.

Submission deadlines would be, in general, approximately 4 months after the last day of each calendar quarter. Thus, for example, the proposed submission deadline for data for services furnished during the first quarter of CY 2013 (January—March, 2013) would be on or around August 1, 2013. The actual submission deadlines would be posted on the *http://www.QualityNet.org* Web site.

Hospitals that did not participate in the CY 2013 Hospital OQR Program, but would like to participate in the CY 2014 Hospital OQR Program, and that have a Medicare acceptance date on the CASPER system before January 1, 2013, would begin data submission with respect to 1st quarter CY 2013 encounters using this CY 2013 measure set that was finalized in the CY 2012 OPPS/ASC final rule with comment period. For those hospitals with Medicare acceptance dates on or after January 1, 2013, data submission must begin with the first full quarter following the submission of a completed online participation form.

For the CY 2015 payment determination, we are proposing that the applicable quarters for previously finalized chart-abstracted measures would be as follows: 3rd quarter CY 2013, 4th quarter CY 2013, 1st quarter CY 2014, and 2nd quarter CY 2014.

Hospitals that did not participate in the CY 2014 Hospital OQR Program, but would like to participate in the CY 2015 Hospital OQR Program, and that have a Medicare acceptance date on the CASPER system before January 1, 2014, would begin data submission with respect to 1st quarter CY 2014 encounters using the CY 2015 measure set that we finalized in the CY 2012 OPPS/ASC final rule with comment period. For those hospitals with Medicare acceptance dates on or after January 1, 2014, data submission must begin with the first full quarter following the submission of a completed online participation form. We invite public comments on these proposals.

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

The table in section XV.D. of this proposed rule includes measures that the Hospital OQR Program collects by accessing electronic claims data submitted by hospitals for reimbursement. The full list of these claims-based measures is set out below:

- OP–8: MRI Lumbar Spine for Low Back Pain
- OP–9: Mammography Follow-up Rates
- OP–10: Abdomen CT—Use of Contrast Material
- OP–11: Thorax CT—Use of Contrast Material
- OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery
- OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)
- OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache

OP–15 has not been implemented for public reporting through rulemaking, and it is not required for the CY 2014 payment determination.

Therefore, for the CY 2014 payment determination, the 6 remaining claims-based measures (OP–8 to OP–11, OP–13 and OP–14) from the list above will be used (76 FR 74469).

We will continue our policy of calculating the measures using the hospital's Medicare claims data as specified in the Hospital OQR Specifications Manual; no additional

data submission is required for hospitals. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74483), we stated that for the CY 2013 and CY 2014 payment updates, we will use paid Medicare FFS claims for services furnished from January 1, 2010 to December 31, 2010 and January 1, 2011 to December 31, 2011, respectively.

For the CY 2015 Hospital OQR payment determination, we are proposing to use Medicare FFS claims for services from a 12-month period from July 1, 2012 through June 30, 2013 for the calculation of the claims-based measures. While this would be a departure from the traditional 12 month calendar year period we have used for these measures, we are proposing this period in order to align the data period for inpatient and outpatient claims based measures reported on the Hospital Compare Web site, and also to be able to post more recent data for the outpatient imaging efficiency on the Web site. We invite public comment on this proposal.

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

A summary of the previously finalized structural measures that we require for the CY 2014 and subsequent years payment determinations is set out below:

- OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data
- OP–17: Tracking Clinical Results Between Visits
- OP 25—Safe Surgical Check List Use
- OP 26—Hospital Outpatient Volume for Selected Outpatient Surgical Procedures

We previously finalized that for the CY 2014 payment determination, hospitals will be required to submit data on all structural measures between July 1, 2013 and August 15, 2013 with respect to the time period from January 1, 2012 to December 31, 2012. We are proposing to extend this submission deadline. Under this proposed change, for the CY 2014 payment determination, hospitals would be required to submit data on all structural measures between July 1, 2013 and November 1, 2013 with respect to the time period from January 1, 2012 to December 31, 2012. In section XV.G.2.f. of this proposed rule, we describe how this proposal would likewise extend the deadline to submit data for OP–22: ED Patient Left without Being Seen. We are proposing to continue this schedule so that, for the FY 2015 payment determination, hospitals would be required to submit data on all structural measures between July 1, 2014 and November 1, 2014 with respect to the time period from January 1, 2013 to December 31, 2013. We invite public comments on these proposals.

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

OP–22: ED–Patient Left Without Being Seen is a chart-abstracted measure for which aggregate data is collected via a Web-based tool, as previously finalized. In other words, for purposes of data collection, this measure is treated like a structural measure. For this reason, it is collected on the same schedule as the structural measures described above, and we are proposing to extend the submission window for all structural measures, including OP–22. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), with respect to OP–22, we stated that hospitals would be required to submit data once for the CY 2014 payment determinations via a Web-based tool located on the QualityNet Web site. For the CY 2014 payment determination, we are proposing that hospitals would be required to submit data, including numerator and denominator counts, between July 1, 2013 and November 1, 2013 (comparable to the submission window that we are proposing for the structural measures data collection in the section above) with respect to the time period of January 1, 2012 to December 31, 2012.

For the CY 2015 payment determination, we are proposing to continue this policy. Hospitals would be required to submit data between July 1, 2014 and November 1, 2014 with respect to the time period of January 1, 2013 to December 31, 2013. We invite public comment on these proposals.

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

For the CY 2014 payment determination and subsequent years, we are proposing to continue our policy that hospitals may submit voluntarily on a quarterly basis, aggregate population and sample size counts for Medicare and non-Medicare encounters for the measure populations for which chart-abstracted data must be submitted, but they will not be required to do so. Where hospitals do choose to submit this data, the deadlines for submission are the same as those for reporting data for chart-abstracted measures, and hospitals may also choose to submit data prior to these deadlines. The deadline schedule is available on the QualityNet Web site. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72101 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of these policies. We invite public comments on these proposals.

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

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

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74484 through 74485), similar to our approach for the CY 2012 payment determination (75 FR 72103 through 72106), we adopted a policy to validate chart-abstracted patient-level data submitted directly to CMS from randomly selected hospitals for the CY 2013 payment determination.

For the CY 2013 payment determination, we reduced the number of randomly selected hospitals from 800 to 450.

We are proposing to continue this policy for the CY 2014 payment determination and for subsequent years. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (FR 76 74484) for a discussion of sample size, eligibility for validation selection, and encounter minimums for chart abstracted data submitted directly to CMS from randomly selected hospitals. We invite public comment on this proposal.

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

In the CY 2011 OPPS/ASC proposed rule (75 FR 46380) we discussed applying, to CY 2013 and subsequent year's data submission, criteria to determine whether a hospital would be included in our validation selection based on abnormal data patterns or a specific situation. At that time we provided, for public comment, specific examples of what we thought could be appropriate criteria.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72106) we stated our belief that the targeting

criteria we shared for comment were reasonable. We considered one commenter's concern that we should use targeting criteria to ensure we do not over-select a hospital for validation. We reiterated our intent to propose the specific targeting criteria in the upcoming CY 2012 OPPS/ASC proposed rule (76 FR 42332), in order to finalize and apply it to 2012 encounter data collected for the CY 2013 validation process year. We did so, and finalized our proposal without modification in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485).

In summary, we finalized our intent to select a random sample of hospitals for validation purposes, and to select an additional 50 hospitals selected based on specific criteria designed to measure whether the data these hospitals have reported raises a concern regarding data accuracy.

For the CY 2014 payment determination and subsequent years, we are proposing to continue these policies and to continue to use the targeting criteria finalized previously. Specifically, a hospital will be preliminarily selected for validation based on targeting criteria if it:

- Fails the validation requirement that applies to the CY 2012 payment determination; or
- Has an outlier value for a measure based on the data it submits.

In the CY 2012 OPPS/ASC proposed rule (76 FR 42333) and CY 2012 OPPS/ASC final rule with comment period (76 FR 74486) we describe additional data validation conditions under consideration for the CY 2014 payment determination and subsequent years. We thank those who commented on the CY 2012 proposed additional data validation targeting conditions and will take their views under consideration as we develop any future proposals on these issues. At this time, we are not proposing any additional targeting criteria to use in selecting the additional 50 hospitals we include in the validation process for CY 2014 payment determination or in subsequent years. We invite public comment on this proposal.

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

For each selected hospital (random or targeted), we are proposing to continue the approach we adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485 through 74486) for the CY 2014 payment determination and subsequent years. For the CY 2014 payment determination, for each selected hospital (random or targeted), we would continue to validate up to 48 randomly selected patient encounters (12 per quarter; 48 per year) from the total number of encounters that the hospital successfully submitted to the OPPS Clinical Warehouse. If a selected hospital has submitted less than 12 encounters in one or more quarters, only those encounters available would be validated. For each selected encounter, a designated CMS contractor would request that the hospital submit the complete supporting medical record documentation that corresponds to the encounter. We refer readers to 42 CFR 482.24(c) for a definition of what is expected in a medical record submitted for validation. The validation process requires full supporting medical documentation, including ECG tapes and/or other pieces of a medical record that may not be stored in a single location. The hospital must ensure a full medical record goes to the contractor for accurate validation.

We continue to believe that validating a larger number of encounters per hospital for fewer hospitals at the measure level has several benefits. We believe that this approach is suitable for the Hospital OQR Program because it will: (1) produce a more reliable estimate of whether a hospital's submitted data have been abstracted accurately; (2) provide more statistically reliable estimates of the quality of care delivered in each measured hospital as well as at a national level; and (3) reduce overall burden, for example, in submitting validation documentation, because hospitals most likely will not be selected to undergo validation each year, and a smaller number of hospitals per year will be selected.

For all selected hospitals, we would not be selecting cases stratified by measure or topic; our interest is whether the data submitted by hospitals accurately reflects the care delivered and documented in the medical record, not what the accuracy is by measure or whether there are differences by measure or topic. We would be validating data from April 1 to March 31 of the year preceding the payment determination year. This provides validation results data in time to use to make the payment determination. For example, encounter data from April 1, 2012 to March 31, 2013 provides a full year of the most recent data possible to validate in time to make the CY 2014 payment determination. We invite public comment on our proposal to continue to use our established methodology for encounter selection and our proposed annual schedule for encounters to be validated and used in payment determinations.

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

We are proposing to retain the medical record return policy that we finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72104) for the CY 2014 payment determination and subsequent years. For the CY 2014 payment determination, we are proposing to continue the validation score policies we adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74486), for the CY 2013 payment determination. We are proposing to use the validation calculation approach finalized for the CY 2012 and CY 2013 payment determinations with validation being done for each selected hospital. Specifically, we are proposing to conduct a measures level validation by calculating each measure within a submitted record using the independently abstracted data and then comparing this to the measure reported by the hospital; a percent agreement would then be calculated. We would also compare the measure category for quality measures with continuous units of measurement, such as time, so that for these measures, both the category and the measure would need to match.

For the CY 2014 payment determination and subsequent years, we are proposing to use the medical record validation procedure we finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72105). A designated CMS contractor would, for each quarter that applies to the validation, ask each of the selected hospitals to submit medical documentation for up to 12 randomly selected cases submitted to and accepted by the OPPS Clinical Warehouse. The CMS contractor would request paper copies of medical documentation corresponding to selected cases from each hospital via certified mail or another trackable method that requires a hospital representative to sign for the request letter. A trackable method would be used so that we would be assured that the hospital received the request. The hospital would have 45 calendar days from the date of the request as documented in the request letter to submit the requested documentation and have the documentation received by the CMS contractor. If the hospital does not comply within 30 calendar days of receipt of the initial medical documentation request, the CMS contractor would send a second letter by

certified mail or other trackable method to the hospital, reminding the hospital that paper copies of the requested documentation must be submitted and received within 45 calendar days following the date of the initial CMS contractor request. If the hospital does not submit the requested documentation and the documentation is not received by the CMS contractor within the 45 calendar days, then the CMS contractor would assign a ''zero'' score to each data element for each selected case and the case would fail for all measures in the same topic (for example, OP–6 and OP–7 measures for a Surgical Care case).

We are proposing that the letter from the designated CMS contractor would be addressed to the hospital's medical record staff identified by the hospital for the submission of records under the Hospital IQR Program (that is, the hospital's medical records staff identified by the hospital to its State QIO). If CMS has evidence that the hospital received both letters requesting medical records, the hospital would be deemed responsible for not returning the requested medical record documentation and the hospital would not be allowed to submit such medical documentation as part of its reconsideration request so that information not utilized in making a payment determination is not included in any reconsideration request.

Once the CMS contractor receives the requested medical documentation, the contractor would independently reabstract the same quality measure data elements that the hospital previously abstracted and submitted, and the CMS contractor would then compare the two sets of data to determine whether the two sets of data match. Specifically, the CMS contractor would conduct a measures level validation by calculating each measure within a submitted case using the independently reabstracted data and then comparing this to the measure reported by the hospital; a percent agreement would then be calculated. The validation score for a hospital would equal the total number of measure matches divided by the total number of measures multiplied by 100 percent.

We invite public comment on our proposals regarding the medical record request policy for CY 2014 payment determination and subsequent payment determination years.

To receive the full OPPS OPD fee schedule increase factor for CY 2014, we are proposing that hospitals must attain at least a 75 percent reliability score, based upon the proposed validation process. We are proposing to use the upper bound of a two-tailed 95 percent confidence interval to estimate the validation score. If the calculated upper limit is above the required 75 percent reliability threshold, we would consider a hospital's data to be ''validated'' for payment purposes. Because we are more interested in whether the measure has been accurately reported, we would continue to focus on whether the measure data reported by the hospital matches the data documented in the medical record as determined by our reabstraction.

We are proposing to calculate the validation score using the same methodology we finalized for the CY 2012 and CY 2013 payment determinations (75 FR 72105 and 76 FR 74486). We also are proposing to use the same medical record documentation submission procedures that we also finalized for the CY 2012 and CY 2013 payment determinations (75 FR 72104 and 76 FR 74486). We invite public comments on these proposals.

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

When the Hospital IQR Program was initially implemented, it did not include a reconsideration process for hospitals. Subsequently, we received many requests for reconsideration of those payment decisions and, as a result, established a process by which participating hospitals would submit requests for reconsideration. We anticipated similar concerns with the Hospital OQR Program and, therefore, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66875), we stated our intent to implement for the Hospital OQR Program a reconsideration process modeled after the reconsideration process we implemented for the Hospital IQR Program. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68779), we adopted a reconsideration process that applied to the CY 2010 payment decisions. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60654 through 60655), we continued this process for the CY 2011 payment update. This process required that a hospital's CEO sign any request for a reconsideration.

In the CY 2011 and CY 2012 OPPS/ASC final rules with comment periods (75 FR 72106 through 72108 and 76 FR 74486 through 75587), we continued this process for the CY 2012 and CY 2013 payment updates with some modification. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72107), we finalized that the CEO was not required to sign the reconsideration request form.

We are proposing to continue this process, with additional modifications, for the CY 2014 payment determination and subsequent years payment determinations. We have now realized that, in eliminating the requirement that a CEO sign a request form, we did not include any requirement for a signature on the reconsideration request form. To increase accountability, we are proposing for the CY 2014 payment determination and subsequent years payment determinations, that the hospital designate a contact on its reconsideration request form, who may or may not be the CEO. We would communicate with this designee. We also are proposing the hospital's designee must sign its reconsideration request form. This process is consistent with our recent proposals for reconsideration requests under the ASCQR Program (77 FR 28105).

Under this process, a hospital seeking reconsideration must—

- Submit to CMS, via QualityNet, a Reconsideration Request form that will be made available on the QualityNet Web site; this form must be submitted by February 3 of the affected payment year (for example, for the CY 2014 payment determination, the request must be submitted by February 3, 2014) and must contain the following information:
  - Hospital CCN.
  - Hospital Name.
  - CMS-identified reason for not meeting the requirements of the affected payment year's Hospital OQR Program as provided in any CMS notification to the hospital.
  - Hospital basis for requesting reconsideration. This must identify the hospital's specific reason(s) for believing it met the affected year's Hospital OQR Program requirements and should receive the full OPD fee schedule increase factor.
  - Designated hospital personnel contact information, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box). We are proposing that the designee, who may or may not be the hospital's CEO, must sign the form submitted to request reconsideration.
  - A copy of all materials that the hospital submitted to comply with the requirements of the affected year's Hospital OQR Program. Such material might include, but does not need to be limited to, the applicable Notice of Participation form or completed online registration form, and measure data that the hospital submitted via QualityNet.

• Paper copies of all the medical record documentation that it submitted for the initial validation (if applicable). Hospitals submit this documentation to a designated CMS contractor which has authority to review patient level information. We post the address where hospitals are to send this documentation on the QualityNet Web site.

• To the extent that the hospital is requesting reconsideration on the basis that CMS has determined it did not meet an affected year's validation requirement, the hospital must provide a written justification for each appealed data element classified during the validation process as a mismatch. Only data elements that affect a hospital's validation score would be eligible to be reconsidered. We review the data elements that were labeled as mismatched as well as the written justifications provided by the hospital, and make a decision on the reconsideration request.

We are proposing these requirements for the CY 2014 payment determination year program and for subsequent years. We invite public comment on these proposed changes.

Following receipt of 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 that we finalized for the CY 2012 and CY 2013 payment determinations regarding the scope of our review when a hospital requests reconsideration because it failed our validation requirement.

These policies are as follows:

• If a hospital requests reconsideration on the basis that it disagrees with a determination that one or more data elements were classified as mismatches, we only consider the hospital's request if the hospital timely submitted all requested medical record documentation to the CMS contractor each quarter under the validation process.

• If a hospital requests reconsideration on the basis that it disagrees with a determination that one or more of the complete medical records it submitted during the quarterly validation process was classified as an invalid record selection (that is, the CMS contractor determined that one or more of the complete medical records submitted by the hospital did not match what was requested, thus resulting in a zero validation score for the encounter(s), our review is initially limited to determining whether the medical documentation submitted in response to the designated CMS contractor's request was the correct and complete documentation. If we determine that the hospital did submit the correct and complete medical documentation, we abstract the data elements and compute a new validation score for the encounter. If we conclude that the hospital did not submit the correct and complete medical record documentation, we do not further consider the hospital's request.

• If a hospital requests reconsideration on the basis that it disagrees with a determination that it did not submit the requested medical record documentation to the CMS contractor within the proposed 45 calendar day timeframe, our review is initially limited to determining whether the CMS contractor received the requested medical record documentation within 45 calendar days, and whether the hospital received the initial medical record request and reminder notice. If we determine that the CMS contractor timely received paper copies of the requested medical record documentation, we abstract data elements from the medical record documentation submitted by the hospital and compute a validation score for the hospital. If we determine that the hospital received two letters requesting medical documentation but did not submit the requested documentation within the 45 calendar day period, we do not further consider the hospital's request.

If a hospital is dissatisfied with the result of a Hospital OQR reconsideration decision, the hospital is able to file an appeal under 42 CFR Part 405, Subpart R (PRRB appeal).

We invite public comment on the modifications we have proposed to the Hospital OQR Program reconsideration and appeals procedures.

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

In our experience, there have been times when hospitals have been unable to submit required quality data due to extraordinary circumstances that are not within their control. It is our goal to not penalize hospitals for such circumstances and we do not want to unduly increase their burden during these times. Therefore, in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60046 through 60047), we adopted a process for hospitals to request and for CMS to grant extensions or waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the hospital. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72103), we retained these procedures with a modification to eliminate redundancy in the information a hospital must provide in the request. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74478 through 74479), for CY 2012 and subsequent years, we retained these procedures with one modification. The CY 2012 modification allowed that the original procedures for requesting an extension or waiver of quality data submission would thereafter also extend to include medical record documentation submission for purposes of complying with our validation requirement for the Hospital OQR Program. We are proposing to retain these procedures with a modification for CY 2013 and subsequent years.

We are proposing to modify one element of the information required on the CMS request form. Under the procedures set out in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74479), hospitals were required to submit ''CEO *and* any other designated personnel contact information'' (emphasis added), the CEO was required to sign the form, and CMS was required to respond to the CEO and additional designated hospital personnel. The information required in CY 2013 and subsequent years would include ''CEO *or* other hospital-designated personnel contact information'' (emphasis added). This proposed change would allow the hospital to designate an appropriate, non-CEO, contact at its discretion. This individual would be responsible for the submission, and would be the one signing the form. Therefore, the hospital's designated-contact may or may not hold the title of CEO. We invite public comment on this proposed modification to the process for granting extraordinary circumstances extensions or waivers for the Hospital OQR Program.

Thus, we are proposing that, in the event of extraordinary circumstances, such as a natural disaster, not within the control of the hospital, for the hospital to receive consideration for an extension or waiver of the requirement to submit quality data or medical record documentation for one or more quarters, a hospital would submit to CMS a

request form that would be made available on the QualityNet Web site. The following information should be noted on the form:

- Hospital CCN;
- Hospital Name;
- CEO or other hospital-designated personnel contact information, including name, 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 would again be able to submit Hospital OQR data and/or medical record documentation, and a justification for the proposed date.

The request form would be signed by the hospital's designated contact, whether or not that individual is the CEO. A request form would be required to be submitted within 45 days of the date that the extraordinary circumstance occurred.

Following receipt of such a request, CMS would—

(1) Provide a written acknowledgement using the contact information provided in the request notifying the designated contact that the hospital's request has been received;

(2) Provide a formal response to the hospital's designated contact using the contact information provided in the request notifying them of our decision; and

(3) Complete our review of any CY 2013 request and communicate our response within 90 days following our receipt of such a request.

We note that we might also decide to grant waivers or extensions to hospitals that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, hurricane) affects an entire region or locale. If we make the determination to grant a waiver or extension to hospitals in a region or locale, we would communicate this decision to hospitals and vendors through routine communication channels, including but not limited to emails and notices on the QualityNet Web site. We invite public comments on these proposals.

J. Electronic Health Records (EHRs)

Starting with the FY 2006 IPPS final rule, we have encouraged hospitals to take steps toward the adoption of EHRs (also referred to in previous rulemaking documents as electronic medical records) that will allow for reporting of clinical quality data from EHRs to a CMS data repository (70 FR 47420 through 47421). We sought to prepare for future EHR submission of quality measures by sponsoring the creation of electronic specifications for quality measures under consideration for the Hospital IQR Program. Through the Medicare and Medicaid EHR Incentive Programs, we expect that the submission of quality data through EHRs will provide a foundation for establishing the capacity of hospitals to send, and for CMS, in the future, to receive, quality measures via hospital EHRs for Hospital IQR Program and Hospital OQR Program measures. We expect the Hospital IQR and Hospital OQR Programs to transition to the use of certified EHR technology, for measures that otherwise require information from the clinical record. This would allow us to collect data for measures without the need for manual chart abstraction.

In the FY 2012 IPPS/LTCH PPS proposed rule (75 FR 25894), we identified FY 2015 as a potential transition date to move to EHR-based submission and phase out manual chart abstraction for the Hospital IQR Program. We also anticipate such a transition for hospital outpatient measures, although likely somewhat after the transition for hospital inpatient measures. This is because we hope to first align the clinical quality measures in the Medicare EHR Incentive Program with the Hospital IQR Program measures. Our goals are to align the hospital quality reporting programs, to seek to avoid redundant and duplicative reporting of quality measures for hospitals, and to rely largely on EHR submission for many measures based on clinical record data.

As noted below, the Stage 2 Medicare EHR Incentive Program proposed rule would require electronic reporting of clinical quality measures beginning in 2014 for eligible hospitals and CAHs that are beyond the first year of Stage 1 of meaningful use. Under our timeline for EHR-based submission under the Hospital OQR Program, some eligible hospitals would be in their second year of Stage 2 reporting and these eligible hospitals could be using two methods to report similar information for the Medicare and Medicaid EHR Incentive Programs and the Hospital OQR Program. We considered allowing, but not requiring, EHR-based submission at the earliest possible date, so as to reduce the burden of hospitals. We are not proposing this approach because we believe that it would not be consistent with our goal that measure results that must be publicly reported should be based on consistent, comparable results among reporting hospitals and because our first priority is to align EHR-based submissions under the Hospital IQR Program. We invite public comment on this issue.

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

In the 2012 OPPS/ASC final rule with comment period we finalized the voluntary 2012 Electronic Reporting Pilot for eligible hospitals and CAHs participating in the Medicare EHR Incentive Program for the 2012 payment year and also revised our regulations at § 495.8(b)(2) accordingly. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74489 through 74492) for detailed discussion of the Electronic Reporting Pilot.

We are proposing to continue the Electronic Reporting Pilot for the 2013 payment year as finalized for the 2012 payment year. We are proposing to revise our regulations at § 495.8(b)(2)(vi) to reflect the continuation of the Electronic Reporting Pilot for 2013, and also to remove the reference to § 495.6(f)(9) in order to conform with the proposed changes to § 495.6(f) that were included in the EHR Incentive Program—Stage 2 proposed rule (77 FR 13817). We invite public comments on these proposals.

We note that we finalized reporting clinical quality measures for the Medicare EHR Incentive Program by attestation of clinical quality measure results in the CY 2012 OPPS/ASC final rule with comment period for 2012 and subsequent years, such as 2013 (76 FR 74489). Thus, eligible hospitals and CAHs may continue to report clinical quality measure results as calculated by certified EHR technology by attestation for 2013, as they did for 2011 and 2012. We also note the intent of CMS to move to electronic reporting. In the Stage 2 Medicare EHR Incentive Program proposed rule, we proposed that the Medicare EHR Incentive Program would require electronic reporting of clinical quality measures beginning in 2014 for eligible hospitals and CAHs that are beyond the first year of Stage 1 of meaningful use (77 FR 13764).

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

A. Background

1. Overview

We refer readers to section XV.A.1. of this 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. History of the ASCQR Program

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66875), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68780), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60656), and the CY 2011 OPPS/ASC final rule with comment period (75 FR 72109), we did not implement a quality data reporting program for ASCs. We determined that it would be more appropriate to allow ASCs to acquire some experience with the revised ASC payment system, which was implemented for CY 2008, before implementing new quality reporting requirements. However, in these rules, we indicated that we intended to implement a quality reporting program for ASCs in the future.

In preparation for proposing a quality reporting program for ASCs, in the CY 2011 OPPS/ASC proposed rule (75 FR 46383), we solicited public comments on 10 measures. In addition to preparing to propose implementation of a quality reporting program for ASCs, HHS developed a plan to implement a value-based purchasing (VBP) program for payments under title XVIII of the Act for ASCs as required by section 3006(f) of the Affordable Care Act, as added by section 10301(a) of the Affordable Care Act. We also submitted a report to Congress, as required by section 3006(f)(4) of the Affordable Care Act, entitled ''Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan'' that details this plan. This report is found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/Downloads/C_ASC_RTC-2011.pdf*. Currently, we do not have express statutory authority to implement an ASC VBP program. If and when legislation is enacted that authorizes CMS to implement an ASC VBP program, we will develop the program and propose it through rulemaking.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized our proposal to implement the ASCQR Program beginning with the CY 2014 payment determination. We adopted quality measures for the CY 2014, CY 2015, and CY 2016 payment determination years and finalized some data collection and reporting timeframes for these measures. We also adopted policies with respect to the maintenance of technical specifications and updating of measures, publication of ASCQR Program data, and, for the CY 2014 payment determination, data collection and submission requirements for the claims-based measures. For a discussion of these final policies, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517).

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74515), we indicated our intent to issue proposals for administrative requirements, data validation and completeness requirements, and reconsideration and appeals processes in the FY 2013 IPPS/LTCH PPS proposed rule, rather than in the CY 2013 OPPS/ASC proposed rule, because the FY 2013 IPPS/LTCH PPS proposed rule is scheduled to be finalized earlier and prior to data collection for the CY 2014 payment determination, which is to begin with services furnished on October 1, 2012. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28101 through 28105), we issued proposals for administrative requirements, data completeness requirements, extraordinary circumstances waiver or extension requests, and a reconsideration process. For a complete discussion of these proposals, we refer readers to the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28101 through 28105).

Because we have included proposals in the FY 2013 IPPS/LTCH PPS proposed rule for the ASCQR Program, we are limiting the number of proposals in this proposed rule. In addition, in an effort to prevent confusion regarding what we are proposing in this proposed rule and what we have proposed in the FY 2013 IPPS/LTCH PPS proposed rule, in this proposed rule, we are limiting our discussion of the proposals contained in the FY 2013 IPPS/LTCH PPS proposed rule primarily to background related to the proposals being made in this proposed rule.

B. ASCQR Program Quality Measures

1. Proposed Considerations in the Selection of ASCQR Program Quality Measures

Section 1833(i)(7)(B) of the Act states that section 1833(t)(17)(C) of the Act shall apply with respect to ASC services in a similar manner in which they apply to hospitals for the Hospital OQR Program, ''except as the Secretary may otherwise provide.'' The requirements under section 1833(t)(17)(C)(i) of the Act state that measures developed shall ''be appropriate for the measurement of quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.''

In addition to following the statutory requirements, in selecting measures for the ASCQR Program and other quality reporting programs, we have focused on measures that have a high impact on and support HHS and CMS priorities for improved health care outcomes, quality, safety, efficiency, and satisfaction for patients. Our goal for the future is to expand any measure set adopted for the ASCQR Program to address these priorities more fully and to align ASC quality measure requirements with those of other reporting programs as appropriate, including the Hospital OQR Program, so that the burden for reporting will be reduced.

In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to consensus development. However, as discussed above, the Hospital OQR Program statute only requires that we adopt measures that are appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings, reflect consensus among affected parties, and, to the extent feasible and practicable, include measures set forth by one or more national consensus building entities. Therefore, measures are not required to be endorsed by the NQF or any other national consensus building entity and, as we have noted in a previous rulemaking for the Hospital OQR Program (75 FR 72065), the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment. Further, the Secretary has broader authority under the ASCQR Program statute, as discussed above, to adopt nonendorsed measures or measures that do not reflect consensus for the ASCQR Program because, under the ASCQR Program statute, these Hospital OQR Program provisions apply ''except as the Secretary may otherwise provide.''

In developing the ASCQR Program, we applied the principles set forth in the CY 2011 OPPS/ASC proposed rule

and final rule with comment period (76 FR 42337 through 42338 and 74494 through 74495, respectively). Although we are not proposing any new measures for the ASCQR Program in this proposed rule as discussed below, we plan to apply the following principles in future measure selection and development for the ASCQR Program. These principles were applied in developing other quality reporting programs and many are the same principles applied in developing the ASCQR Program last year.

- Our overarching goal is to support the National Quality Strategy's three-part aim of better health care for individuals, better health for populations, and lower costs for health care. The ASCQR Program will help achieve this three-part aim by creating transparency around the quality of care at ASCs to support patient decisionmaking and quality improvement. More information regarding the National Quality Strategy can be found at: *http://www.hhs.gov/secretary/about/priorities/priorities.html* and *http://www.ahrq.gov/workingforquality/*. HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act.
- Pay-for-reporting and public reporting programs should rely on a mix of standards, process, outcomes, and patient experience of care measures. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider/supplier characteristics.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across public reporting and payment systems under Medicare and Medicaid. The measure sets should evolve so that they include a focused core set of measures appropriate to the specific provider/supplier category that reflects the level of care and the most important areas of service and measures for that provider/supplier.
- We weigh the relevance and the utility of measures compared to the burden on ASCs in submitting data under the ASCQR Program. The collection of information burden on providers and suppliers should be minimized to the extent possible. To this end, we continuously seek to adopt electronic-specified measures so that data can be calculated and submitted via certified EHR technology with minimal burden. We also seek to use measures based on alternative sources of data that do not require chart abstraction or that use data already being reported by ASCs.
- We take into account the views of the Measure Application Partnership (MAP). The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay-for-reporting programs. The MAP views patient safety as a high priority area and it strongly supports the use of NQF-endorsed safety measures. Accordingly, we consider the MAP's recommendations in selecting quality and efficiency measures (we refer readers to the Web sites at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*, and *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885*).
- Measures should be developed with the input of providers/suppliers, purchasers/payers and other stakeholders. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature.
- HHS Strategic Plan and Initiatives. HHS is the U.S. Government's principal agency for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. Every 4 years HHS updates its Strategic Plan and measures its progress in addressing specific national problems, needs, or mission-related challenges. The current goals of the HHS Strategic Plan can be located at *http://www.hhs.gov/about/FY2012budget/strategicplandetail.pdf*.
- CMS Strategic Plan. We strive to ensure that measures for different Medicare and Medicaid programs are aligned with priority quality goals, that measure specifications are aligned across settings, that outcome measures are used whenever possible, and that quality measures are collected from EHRs as appropriate.

We believe that ASCs are similar to HOPDs, insofar as the delivery of surgical and related nonsurgical services. Similar standards and guidelines can be applied between HOPDs and ASCs with respect to surgical care improvement, because many of the same surgical procedures are provided in both settings. Measure harmonization assures that comparable care in these settings can be evaluated in similar ways, which further assures that quality measurement can focus more on the needs of a patient with a particular condition rather than on the specific program or policy attributes of the setting in which the care is provided.

We invite public comment on this approach in future measure selection and development for the ASCQR Program.

2. ASCQR Program Quality Measures

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized our proposal to implement the ASCQR Program beginning with the CY 2014 payment determination and adopted measures for the CY 2014, CY 2015, and CY 2016 payment determinations. We also finalized our policy to retain measures from one calendar year payment determination to the next so that measures adopted for a previous payment determination year would be retained for subsequent payment determination years (76 FR 74504, 74509, and 74510).

We adopted the following five claims-based measures for the CY 2014 payment determination for services furnished between October 1, 2012 and December 31, 2012: (1) Patient Burns (NQF #0263); (2) Patient Fall (NQF #0266); (3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267); (4) Hospital Transfer/Admission (NQF #0265); and (5) Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264).

For the CY 2015 payment determination, we retained the five claims-based measures we adopted for the CY 2014 payment determination and adopted the following two structural measures: (1) Safe Surgery Checklist Use; and (2) ASC Facility Volume Data on Selected ASC Surgical Procedures. We specified that reporting for the structural measures would be between July 1, 2013 and August 15, 2013, for services furnished between January 1, 2012 and December 31, 2012, using an online measure submission Web page available at: *https://www.QualityNet.org*. We did not specify the data collection period for the five claims-based measures for the CY 2015 payment determination.

For the CY 2016 payment determination, we finalized the retention of the seven measures from the CY 2015 payment determination (five claims-based measures and two structural measures) and adopted Influenza Vaccination Coverage Among

Healthcare Personnel (NQF #0431), a process of care, healthcare-associated infection measure. We specified that data collection for the influenza vaccination measure would be via the National Healthcare Safety Network from October 1, 2014 through March 31, 2015. We did not specify the data collection period for the claims-based or structural measures.

We stated that, to the extent we finalize some or all of the measures for future payment determination years, we would not be precluded from adopting additional measures or changing the list of measures for future payment determination years through annual rulemaking cycles so that we may address changes in program needs arising from new legislation or from changes in HHS and CMS priorities.

Considering the time and effort required for us to develop, align, and implement the infrastructure necessary to collect data on the ASCQR Program measures and make payment determinations, and likewise the time and effort required on the part of ASCs to plan and prepare for quality reporting, at this time we are not proposing to delete or add any quality measures for the ASCQR Program for the CY 2014, CY 2015, and CY 2016 payment determination years or to adopt quality measures for subsequent payment determination years. For readers' reference, the following table lists the ASCQR Program quality measures we previously finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74504 through 74511).

ASC PROGRAM MEASUREMENT SET ADOPTED IN PREVIOUS RULEMAKING

ASC–1: Patient Burn.*
ASC–2: Patient Fall.*
ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.*
ASC–4: Hospital Transfer/Admission.*
ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing.*
ASC–6: Safe Surgery Checklist Use.**
ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures.**

Procedure category	Corresponding HCPCS Codes.
Gastrointestinal.	40000 through 49999, G0104, G0105, G0121, C9716, C9724, C9725, and 0170T.
Eye	65000 through 68999, G0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, and 0099T.
Nervous System.	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, and 0062T.
Musculoskeletal.	20000 through 29999, 0101T, 0102T, 0062T, 0200T, and 0201T.
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, and C9727.
Genitourinary	50000 through 58999, 0193T, and 58805.
ASC–8: Influenza Vaccination Coverage among Healthcare Personnel.***	

*New measure for the CY 2014 payment determination.
**New measure for the CY 2015 payment determination.
***New measure for the CY 2016 payment determination.

3. ASC Measure Topics for Future Consideration

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the ASC setting. Therefore, through future rulemaking, we intend to propose new measures consistent with the principles discussed in section XVI.B.1. of this proposed rule, in order to select measures that address clinical quality of care, patient safety, and patient and caregiver experience of care. We invite public comment specifically on the inclusion of procedure-specific measures for cataract surgery, colonoscopy, endoscopy, and for anesthesia-related complications in the ASCQR Program measure set.

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

In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures (76 FR 74513 through 74514). This process includes the same subregulatory process for the ASCQR Program as used for the Hospital OQR Program for updating measures, including issuing regular manual releases at 6-month intervals, providing addenda as necessary, and providing at least 3 months of advance notice for nonsubstantive changes such as changes to ICD–9–CM, CPT, NUBC, and HCPCS codes, and at least 6 months' notice for substantive changes to data elements that would require significant systems changes. We provided a citation to the CY 2009 OPPS/ASC final rule with comment period where the final Hospital OQR Program policies are discussed (73 FR 68766 through 68767).

In examining last year's finalized policy for the ASCQR Program, we recognize that we may need to provide additional clarification of the ASCQR Program policy in the context of the previously finalized Hospital OQR Program policy in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767). Therefore, in this proposed rule, we seek to more clearly articulate the policy that we adopted for the ASCQR Program, which is the same policy that has been adopted for the Hospital OQR Program.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established a subregulatory process for making updates to the measures we have adopted for the Hospital OQR Program. This process is necessary so that the Hospital OQR measures are calculated based on the most up-to-date scientific evidence and consensus standards. Under this process, when a national consensus building entity updates the specifications for a measure that we have adopted for the Hospital OQR Program, we update our specifications for that measure accordingly and provide notice as described above and in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514). An example of such an entity is the NQF. For measures that are not endorsed by a national consensus building entity, the subregulatory process is based on scientific advances as determined necessary by CMS, in part, through our measure maintenance process involving Technical Expert Panels (73 FR 68767). We invite public comment on this clarification of the finalized ASCQR Program policy of using a subregulatory process to update measures.

C. Proposed Requirements for Reporting of ASC Quality Data

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

a. Background

In the CY 2012 OPPS/ASC final rule with comment period, we adopted claims-based measures for the CY 2014, CY 2015, and CY 2016 payment determination years (76 FR 74504 through 74511). We also finalized that, to be eligible for the full CY 2014 ASC annual payment update, an ASC must submit complete data on individual quality measures through a claims-based

reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims (76 FR 74515 through 74516). As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), ASCs will add the appropriate QDCs on their Medicare Part B claims forms, the Form CMS–1500s submitted for payment, to submit the applicable quality data. A listing of the QDCs with long and short descriptors is available in Transmittal 2425, Change Request 7754 released March 16, 2012 (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Transmittals-Items/ASC-CR7754-R2425CP.html*). Details on how to use these codes for submitting numerators and denominator information are available in the ASCQR Program Specifications Manual located on the QualityNet Web site (*https://www.QualityNet.org*). We also finalized the data collection period for the CY 2014 payment determination, as the Medicare fee-for-service ASC claims submitted for services furnished between October 1, 2012 and December 31, 2012. We did not finalize a date by which claims would be processed to be considered for the CY 2014 payment determination.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28104), we proposed 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 would allow 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. We did not finalize a data collection and processing period for the CY 2015 payment determination, but stated our intention to do so in this proposed rule (77 FR 28104).

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

We are proposing that, for the CY 2015 payment determination and subsequent payment determination years, an ASC must submit complete data on individual quality claims-based measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims. We are proposing that the data collection period for such claims-based measures will be for the calendar year 2 years prior to a payment determination. We also are proposing that the claims for services furnished in each calendar year would 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. Thus, for example, for the CY 2015 payment determination, we are proposing the data collection period to be claims for services furnished in CY 2013 (January 1, 2013 through December 31, 2013) which are paid by the administrative contractor by April 30, 2014. We believe that this claim paid date would allow 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. We invite public comment on these proposals.

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

a. Background

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized our proposal that data completeness for claims-based measures for the CY 2014 payment determination be determined by comparing the number of claims meeting measure specifications that contain the appropriate QDCs with the number of claims that would meet measure specifications but did not have the appropriate QDCs on the submitted claims. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28104), we proposed, 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 50 percent is a reasonable minimum threshold based upon the considerations discussed above for the initial implementation years of the ASCQR Program. We stated in the proposed rule that we intend to propose to increase this percentage for subsequent payment determination years as ASCs become more familiar with reporting requirements for this quality data reporting program.

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

After publication of the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28101 through 28105), we realized that we did not propose a methodology for determining data completeness for the CY 2015 payment determination and subsequent payment determination years. Therefore, we are proposing that data completeness for claims-based measures for the CY 2015 payment determination and subsequent payment determination years be determined by comparing the number of Medicare claims (where Medicare is the primary or secondary payer) meeting measure specifications that contain the appropriate QDCs with the number of Medicare claims (where Medicare is the primary or secondary payer) that would meet measure specifications, but did not have the appropriate QDCs on the submitted claims for the CY 2015 payment determination and subsequent payment determination years. This is the same method for determining data completeness for claims-based measures that was finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516) for the CY 2014 payment determination. We note that the claims we use include claims where Medicare is either the primary or secondary payor. We invite public comment on this proposal.

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

The national unadjusted payment rates for many services paid under the ASC payment system equal the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. Currently, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the MFP-adjusted CPI–U update factor, which is the adjustment set forth in section 1833(i)(2)(D)(v) of the Act. The MFP-adjusted CPI–U update factor is the Consumer Price Index for all urban consumers (CPI–U), which currently is the annual update for the ASC payment system, minus the MFP adjustment. As discussed in the CY 2011 MPFS final rule with comment period (75 FR 73397), if the CPI–U is a negative number, the CPI–U would be held to zero. Under the ASCQR Program, any annual update would be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction would apply beginning with the CY 2014 payment rates. For a complete discussion of the calculation of the ASC conversion factor, we refer readers to section XIV.H. of this proposed rule.

To implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we are proposing that we would calculate two conversion factors: A full update conversion factor and an ASCQR Program reduced update conversion factor. We are proposing 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 are proposing 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 are proposing 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 are proposing that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update.

Office-based surgical procedures (performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XIV.D.2.b. of this proposed rule) are paid at the lesser of the MPFS non-facility PE RVU-based amounts and the standard ASC ratesetting methodology. We are proposing 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 are proposing 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 are proposing 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 invite public comment on these proposals.

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

A. Overview

In accordance with section 1886(j)(7) of the Act, as added by section 3004 of the Affordable Care Act, the Secretary established a quality reporting program (QRP) for Inpatient Rehabilitation Facilities (IRFs). The IRF Quality Reporting Program (IRF QRP) was implemented in the FY 2012 IRF PPS final rule (76 FR 47836). We refer readers to the FY 2012 IRF PPS final rule (76 FR 47873 through 47883) for a detailed discussion on the background and statutory authority for the IRF QRP.

In this proposed rule, we are proposing to: (1) Adopt updates on a previously adopted measure for the IRF QRP that will affect annual prospective

payment amounts in FY 2014; (2) adopt a policy that would provide that any measure that has been adopted for use in the IRF QRP will remain in effect until the measure is actively removed, suspended, or replaced; and (3) adopt policies regarding when notice-and-comment rulemaking will be used to update existing IRF QRP measures.

While we generally would expect to publish IRF QRP proposals in the annual IRF Prospective Payment System (PPS) rule, there are no proposals for substantive changes to the IRF PPS this year, so we are only publishing an update notice. Because full notice-and-comment rulemaking is required for what we are proposing for the IRF QRP, we needed to identify an appropriate rulemaking process in which we could insert our IRF QRP proposals. As this proposed rule was already scheduled to include additional pay-for-reporting proposals for the Hospital OQR Program and quality reporting requirements for the ASCQR Program, it offered an opportunity to allow the public to review all three quality programs' proposals in concert with one another in a timeframe that would be appropriate for implementing these IRF QRP proposals in time for the FY 2014 IRF PPS payment cycle. Therefore, we elected to include the IRF QRP proposals in this CY 2013 OPPS/ASC proposed rule.

B. Updates to IRF QRP Measures Which Are Made as a Result of Review by the NQF Process

Section 1886(j)(7) of the Act generally requires the Secretary to adopt measures that have been endorsed by the entity with a contract under section 1890(a) of the Act. This contract is currently held by the NQF. The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process.[2]

The NQF undertakes to: (1) Review new quality measures and national consensus standards for measuring and publicly reporting on performance; (2) provide for annual measure maintenance updates to be submitted by the measure steward for endorsed quality measures; (3) provide for measure maintenance endorsement on a 3-year cycle;(4) conduct a required follow-up review of measures with time limited endorsement for consideration of full endorsement; and (5) conduct ad hoc review of endorsed quality measures, practices, consensus standards, or events when there is adequate justification for a review.[3] In the normal course of measure maintenance, the NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle. In this measure maintenance process, the measure steward is responsible for updating and maintaining the currency and relevance of the measure and for confirming existing specifications to the NQF on an annual basis.[4] As part of the ad hoc review process, the ad hoc review requester and the measure steward are responsible for submitting evidence for review by a NQF Technical Expert panel which, in turn, provides input to the Consensus Standards Approval Committee which then makes a decision on endorsement status and/or specification changes for the measure, practice, or event.

Through the NQF's measure maintenance process, the NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what can be considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

We are proposing that, if the NQF updates an endorsed measure that we have adopted for the IRF QRP in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the information that is posted on the CMS IRF QRP Web site at: *http://www.cms.gov/IRF-Quality-Reporting/* so that it clearly identifies the updates and provides links to where additional information on the updates can be found. In addition, we would refer IRFs to the NQF Web site for the most up-to-date information about the quality measures (*http://www.qualityforum.org/*). We would provide sufficient lead time for IRFs to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. We believe that our proposal adequately balances our need to incorporate NQF updates to NQF-endorsed IRF QRP measures in the most expeditious manner possible, while preserving the public's ability to comment on updates to measures that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We note that, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27870), we proposed a similar policy for the Hospital IQR Program, the PPS Cancer Exempt Hospital (PCH) Quality Reporting Program; the Long-Term Care Hospital Quality Reporting (LTCHQR) Program, and the Inpatient Psychiatric Facility (IPF) Quality Reporting Program.

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

We expect that the measures that we adopt for purposes of the IRF QRP will remain current and useful for a number of years after their initial adoption. While we could elect to adopt measures for each fiscal year's payment determinations, we believe that it would be easier for all concerned if we adopt the measures in perpetuity with an expectation that we will propose to remove, suspend or replace them through future rulemaking if necessary. Therefore, for the purpose of streamlining the rulemaking process, we are proposing that when we initially adopt a measure for the IRF QRP for a payment determination, this measure will be automatically adopted for all subsequent fiscal year payment determinations or until such time as we might propose and finalize its removal, suspension, or replacement.

Quality measures may be considered for removal by CMS if: (1) Measure performance among IRFs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made; (2) performance or improvement on a measure does not

[2] For more information about the NQF Consensus Development Process, we refer readers to the Web site at: *http://www.qualityforum.org/Measuring_Performance/Maintenance_of_NQF-Endorsed%C2%AE_Performance_Measures.aspx*).

[3] For more information about the NFQ Ad Hoc Review process, we refer readers to the Web site at: *http://www.qualityforum.org/Projects/ab/Ad_Hoc_Reviews/CMS/Ad_Hoc_Reviews-CMS.aspx*).

[4] For more information about the NQF Measure Maintenance process, we refer readers to the NQF Web site at: *http://www.qualityforum.org/Measuring_Performance/Improving_NQF_Process/Process_Assessment_Measure_Maintenance.aspx.*

result in better patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) a more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic is available; (6) if a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; or (7) collection or public reporting of a measure leads to negative unintended consequences.

For any such removal, the public will generally be given an opportunity to comment through the annual rulemaking process. However, if there is reason to believe continued data collection of a measure raises potential safety concerns, we will take immediate action to remove the measure from IRF QRP and not wait for the annual rulemaking cycle. Such measures will be promptly removed with IRFs and the public being immediately notified of such a decision through the usual IRF QRP communication channels, including listening session, memos, email notification, and Web postings. In such instances, the removal of a measure will also be formally announced in the next annual rulemaking cycle. We are inviting public comment on our proposal that once a quality measure is adopted, it is retained for use in the subsequent fiscal year payment determinations unless otherwise stated.

We are proposing to apply this principle to the two measures that were selected for use in the IRF QRP beginning on October 1, 2012. These adopted measures are: (1) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138),[5] and (2) Percent of Residents with Pressure Ulcers that Are New or Worsened (NQF #0678).

We invite public comment on our proposal to apply the principle of retention of the two above-stated quality measures that were adopted for use in the IRF QRP in the FY 2012 IRF PPS final rule (76 FR 47874 through 47878). Likewise, we invite public comment on our proposed use of the process, as stated above, for retention of future IRF QRP quality measures after adoption into the IRF QRP.

D. Adopted Measures for the FY 2014 Payment Determination

We have previously identified the measurement of pressure ulcers and the prevalence of urinary tract infections (UTI) as two critical areas for quality measurement under the IRF QRP. While section 1886(j)(7) of the Act generally requires the adoption of endorsed measures, there were no NQF-endorsed measures for the two desired areas in the IRF context at the time CMS was conducting its rulemaking. As section 1886(j)(7)(D)(ii) of the Act authorizes the use of measures that are not endorsed when there are no feasible and practicable endorsed options, in the FY 2012 IRF PPS final rule (76 FR 47874 through 47876), we adopted applications of an NQF-endorsed pressure ulcer measure that had been endorsed for use in skilled nursing facilities (NQF #678) and a CDC measure, the CDC's Urinary Catheter Associated Urinary Tract Infection [CAUTI] rate per 1, 000 urinary catheter days, for Intensive Care Unit [ICU] Patients (NQF #0138), that had NQF endorsement for use in intensive care settings of hospitals.

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

In the FY 2012 IRF PPS final rule (76 FR 47874 through 47876), we used the endorsement exception authority under section 1886(j)(7)(D)(ii) of the Act. This authority permitted us to adopt the Urinary Catheter-Associated Urinary Tract Infection [CAUTI] rate per 1, 000 urinary catheter days, for Intensive Care Unit [ICU] Patients measure (NQF #0138). We chose to adopt this measure because there was no NQF-endorsed CAUTI measure available to assess the prevalence of urinary catheter-associated urinary tract infection [CAUTI] rates in the IRF setting.

As stated in section XVII.C. of this proposed rule, the CAUTI measure steward, the CDC, submitted the CAUTI Measure to NQF for a scheduled measure maintenance review in late 2011. At that time the CDC also filed a request to expand the CAUTI measure to non-ICU settings, including IRFs. The NQF granted the CDC's request for an expansion of the scope of endorsement of the CAUTI measure to additional non-ICU care settings, including ''rehabilitation hospitals.'' The NQF defined the term ''rehabilitation hospitals'' as including both freestanding IRFs as well as IRF units that are located within an acute care facility. Despite the expansion in the scope of endorsement of the CAUTI measure, the original NQF endorsement number was retained. However, the measure was re-titled ''National Health Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.'' [6]

As amended, the expanded CAUTI measure also uses a different data calculation method, which is referred to as the standardized infection ratio (SIR).[7] [8] [9] [10] The change in the data calculation method does not, however, change the way in which IRFs will submit CAUTI data to the CDC. IRFs will still be required to submit their CAUTI data to the CDC via the National Healthcare Safety Network (NHSN) online system.

Under the originally endorsed version of the CAUTI measure the CDC calculated an infection rate per 1,000 urinary catheter days. Under the new method, CDC will use a SIR calculation method, which is comprised of the actual rate of infection over the expected rate of infection.[11] We believe that the SIR calculation method is a more accurate way to calculate the CAUTI measure results for comparative

[5] The CAUTI measure that was adopted in the FY 2012 IRF PPS final rule dated August 5, 2011 was titled ''Urinary Catheter-Associated Urinary Tract Infection [CAUTI] Rate Per 1,000 Urinary Catheter Days for ICU patients.'' However, this measure was submitted by the CDC (measure steward) to the NQF for a measure maintenance review. As part of their NQF submission, the CDC asked for changes to the measure, including expansion of the scope of the measure to non-ICU settings, including IRFs. The NQF approved the CDC's request on January 12, 2012. Due to the changes that were made to the measure, the CDC believed that it was appropriate that the measure title be changed. This measure is now titled ''National Health Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.''

[6] *http://www.qualityforum.org/MeasureDetails.aspx?actid=0&SubmissionId=1121#k=0138&e=0&st=&sd=&s=n&so=a&p=1&mt=&cs=&ss=.*

[7] Centers for Disease Control and Prevention (2012, January), Central Line-Associated Bloodstream Infection (CLABSI) Event. Retrieved from *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf.*

[8] National Quality Forum (2012), National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure. Retrieved from *http://www.qualityforum.org/QPS/0139.*

[9] Centers for Disease Control and Prevention (2012, January), Catheter Associated Urinary Tract Infection Event. Retrieved from: *http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf.*

[10] National Quality Forum (2012), National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure. Retrieved from *http://www.qualityforum.org/QPS/0138.*

[11] The SIR calculation requires the establishment of ''expected'' rates of infection. We understand that CDC will need to collect the CAUTI data that will be submitted under the IRF QRP for a period of time (at least 12 months) in order to establish an ''expected'' rate for each IRF location type prior to being able to calculate a SIR. As required by Section 3004 of the Affordable Care Act, we will, at a later date, establish public reporting policies in a separate rulemaking. However, we do not intend to publicly report IRF QRP CAUTI measure data until sometime after CDC has established the expected rate and is capable of generating SIR values.

purposes because it takes into account an IRF's case mix. In addition, use of the SIR calculation does not require any change to the type of data required to be submitted by IRFs or method of data submission that IRFs must use in order to comply with the CAUTI measure reporting requirements.

We are making the following proposals in regards to the CAUTI measure: (1) We are proposing to adopt changes made to the NQF #0138 CAUTI measure which will apply to the FY 2014 annual payment update determination; (2) we are proposing to adopt the CAUTI measure, as revised by the NQF on January 12, 2012, for the FY 2015 payment determination and all subsequent fiscal year payment determinations; and (3) we are proposing to incorporate, for use in the IRF QRP, any future changes to the CAUTI measure to the extent these changes are consistent with our proposal in section XVII.B. of this proposed rule to update measures. We welcome comments on these proposals.

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

In the FY 2012 IRF PPS final rule (76 FR 47876 through 47878), we again used the endorsement exception authority under section 1886(j)(7)(D)(ii) of the Act to adopt an application of the ''Percent of Residents with Pressure Ulcers that Are New or Worsened'' measure (NQF #0678). We selected this measure because there was no other NQF-endorsed measure available to assess the percentage of patients with pressure ulcers that are new or worsened in the IRF setting at that time. We recognized that the NQF endorsement of this measure was, at that time, limited to short-stay nursing home patients, but we noted our belief that this measure was highly relevant to patients in any setting who are at risk of pressure ulcer development and a high priority quality issue in the care of IRF patients. Therefore, in the FY 2012 IRF PPS final rule, we finalized the adoption of an application of the NQF-endorsed #0678 pressure ulcer measure. We also said that we would request that the NQF extend its endorsement of this short-stay nursing home pressure ulcer measure to the IRF setting (76 FR 47876 through 47878).

In April 2012, CMS filed an ad hoc request for review of the NQF #0678 short-stay pressure ulcer measure with the NQF. In addition, we also requested an expansion of this measure to other care settings. As noted in the FY 2012 IRF PPS final rule discussion of our adoption of an application of this measure in the IRF context, we believe this measure is highly applicable to all post acute care settings, including IRFs (76 FR 47876). If the pressure ulcer measure is revised by the NQF, we anticipate that it will be re-titled ''Percent of Patients or Residents with Pressure Ulcers That Are New Or Worsened'' (NQF #0678) so as to reflect the expansion in the scope of the applicable patient population.

As of the publication of this proposed rule, the NQF review process for the NQF #0678 pressure ulcer measure expansion request is still in progress. If the NQF expands the scope of endorsement for this measure to the IRF setting, without any substantive changes, we are proposing to adopt and use the revised pressure ulcer measure in the IRF QRP, in accordance with the policy set forth above in XVII.B. of this proposed rule. We believe that, in this anticipated scenario, the pressure ulcer measure, as revised, will be substantively the same measure, although broader in scope, as the current NQF-endorsed #0678 pressure ulcer measure. We invite public comments on our proposed use of this policy.

In the meantime, we are proposing to proceed with our plan, as finalized in the FY 2012 IRF PPS final rule, to use an application of the Percent of Residents With Pressure Ulcers that Are New or Worsened (NQF #0678) measure for the FY 2014 payment determination and all subsequent fiscal year payment determinations.

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

A. Summary of Proposed Changes

The Utilization and Quality Control Peer Review Program was originally established by sections 142 and 143 of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982 (Pub. L. 97–248). The name of the individual organizations covered under the program was previously changed from ''Peer Review Organizations'' to ''Quality Improvement Organizations'' through rulemaking (67 FR 36539). We have identified several changes that we are proposing because they are essential to remedying longstanding problematic aspects of the QIOs' review activities. These proposed changes would enable us to improve the QIO program by ensuring that QIOs are better able to meet the needs of Medicare beneficiaries.

Several of the proposed changes are specific to the QIOs' processing of quality of care reviews, which includes beneficiary complaint reviews. Although references are made to QIO sanction activities, the proposed changes do not impact QIO sanction activities or the regulations located in 42 CFR Part 1004.

In addition, as part of our review of our regulations in light of the President's Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011), we have identified several technical corrections that would improve the readability and use of the QIO regulations.

Below, in this proposed rule, we are setting forth our proposals for revising our regulations under 42 CFR Parts 476, 478, and 480 relating to the QIO Program.

B. Quality of Care Reviews

Section 9353(c) of Public Law 99–509 amended section 1154(a) of the Act (adding a new paragraph (14)) to require QIOs (then PROs), effective August 1, 1987, to conduct an appropriate review of all written complaints from beneficiaries or their representatives about the quality of services (for which payment may otherwise be made under Medicare) not meeting professionally recognized standards of health care. This authority was in addition to the QIOs' already existing authority under section 1154(a)(1)(B) of the Act to perform quality of care reviews. In order to provide more clarity regarding the QIOs' roles, in this proposed rule, we are proposing to add a definition of ''quality of care review'' under § 476.1 to make clear that this review type refers to both beneficiary complaint reviews (written or oral) and general quality of care reviews. We also are proposing to add under § 476.1 definitions for ''beneficiary complaint'' to mean a complaint by a beneficiary or a beneficiary's representative alleging that the quality of services received by the beneficiary did not meet professionally recognized standards of care and may consist of one or more quality of care concerns; ''beneficiary complaint review'' to mean a review conducted by a QIO in response to the receipt of a written beneficiary complaint to determine whether the quality of Medicare covered services provided to beneficiaries was consistent with professionally recognized standards of health care; and ''general quality of care review'' to mean a review conducted by a QIO to determine whether the quality of services provided to a beneficiary(s) was consistent with professionally recognized standards of health care. We are proposing that a general quality of care review may be carried out as a

result of a referral to the QIO or a QIO's identification of a potential concern during the course of another review activity or through the analysis of data. In addition, we are proposing to revise the language under § 476.71(a)(2) to make clear that the scope of a QIO's review includes the right to conduct quality of care reviews, including beneficiary complaint reviews and general quality of care reviews, as well as a new review process that QIOs can offer Medicare beneficiaries called ''immediate advocacy,'' which is described more fully in section XVIII.B.1. of this proposed rule.

We are proposing additional changes to the QIO regulations related to the following issues:

1. Beneficiary Complaint Reviews

At the time QIOs assumed the authority under section 9353(c) of Public Law 99–509 to conduct reviews of written beneficiary complaints, we made a decision to rely upon the existing regulations for certain requirements (for example, the timeframes for requesting medical records and the practitioner's right to consent to the release of specific findings to beneficiaries), and to subsequently establish other remaining procedural requirements through manual instructions. While this approach has provided QIOs with a basic framework for completing the reviews, we have become aware of other issues that need to be addressed through the promulgation of new regulations as well as revisions to existing regulations. In 2003, the United States Court of Appeals for the District of Columbia Circuit issued a decision in the case of *Public Citizen, Inc.* v. *U.S. Department of Health and Human Services* (332 F.3d 654, June 20, 2003) (referred to below as Public Citizen) in which the court determined that QIOs must, at a minimum, notify a complainant of the results of its review. We recently completed a comprehensive revision to the manual instructions governing both beneficiary complaints and quality of care reviews, which, in part, was designed to ensure compliance with this court decision (Transmittal 17, April 6, 2012, CMS Manual System, Pub. 100–10 Medicare Quality Improvement Organizations, Chapter 5, Quality of Care Review) (available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R17QIO.pdf*). These new instructions were effective May 7, 2012. While these manual revisions were necessary, we believe that additional regulatory changes are needed in order to improve QIO operations. In order to subject these additional changes to the processing of beneficiary complaint reviews and general quality of care reviews to notice-and-comment rulemaking, in this proposed rule, we are proposing to add new §§ 476.110, 476.120, 476.130, 476.140, 476.150, 476.160, and 476.170 as described below in this section. We also are proposing to add new definitions of ''authorized representative'', ''appointed representative; ''beneficiary representative'' and ''quality improvement initiative,'' and revise the definition of ''preadmission certification'' in § 476.1. In addition, to ensure consistency with the proposed revisions to or additional sections under Part 476, we are proposing to revise §§ 480.107, 480.132, and 480.133, as discussed more fully below.

The proposed revisions to the regulations under Part 476 include several changes that would improve the beneficiary's experience when contacting a QIO about the quality of health care he or she has received and also shorten key timeframes so that beneficiaries can achieve resolution of their health care concerns in less time. We are proposing regulations under new proposed § 476.110 regarding a new alternative dispute resolution process called ''immediate advocacy.'' We are proposing to add a definition of ''immediate advocacy'' under § 476.1, and to make clear that this process is specific to oral complaints. We are proposing to define ''immediate advocacy'' as an informal alternative dispute resolution process used to quickly resolve an oral complaint that a beneficiary or his or her representative has regarding the quality of health care received, and that this process involves a QIO representative's direct contact with the provider and/or practitioner. Historically, the only option available to beneficiaries, regardless of the severity or type of issue, is the right to file a written complaint. Once a written complaint is received, the QIO is then obligated to conduct a formal peer review of the complaint, which includes a review of the beneficiary's medical information. Although this peer review process is effective, it can be quite lengthy and burdensome on providers and practitioners, given the various steps that must be completed by the QIO prior to the QIO rendering its final decision, with providers and practitioners cooperating with the QIO throughout this process. These steps include the time needed by the QIO to follow up with beneficiaries to ensure receipt of the complaint in writing, request and receive the medical information from the provider and/or practitioner, discuss the QIO's interim decision with the practitioner and/or provider, respond to a practitioner's and/or provider's request that a QIO conduct a re-review of the initial peer reviewer's decision, and obtain the practitioner's consent to the release of specific findings in the final letter to the beneficiary. By regulation, QIOs must disclose to patients or their representatives information they have requested within 30 calendar days (42 CFR 480.132); it is possible that obtaining a practitioner's consent alone could take 30 calendar days. Even if there are no delays at any point in the current peer review process, it can take over 150 calendar days for a QIO to complete its review of a beneficiary's written complaint.

At times, the length of the current peer review process can render the beneficiary's original concern moot, particularly where the beneficiary's concern relates to a communication issue between his or her providers and/or practitioners, the prescribing of medications, or the failure to receive a necessary medical item, such as a wheelchair. For these types of concerns, we believe that requiring a beneficiary to submit the complaint in writing and waiting more than 150 calendar days so that the QIO can complete its review does not provide prompt and customer friendly service to Medicare beneficiaries. Moreover, at times, certain issues raised by a Medicare beneficiary in a complaint may not even be documented in the beneficiary's medical information. This is particularly true for complaints related to communication or coordination issues surrounding the beneficiary's care. Thus, a QIO may actually know at the outset of a review that the peer review process will not divulge any information related to the beneficiary's complaint.

We believe that, by proposing to establish an informal process such as ''immediate advocacy,'' the QIO would be able to offer an alternative to a Medicare beneficiary in those situations where a resolution is needed more quickly than the current traditional peer review process. We believe that this proposed new informal process would also be beneficial in those instances where information relevant to a complaint would most likely not be contained in the medical information or where the Medicare beneficiary may simply be put off by the formality of the traditional peer review process. In proposing this new informal process, we are specifying in proposed § 476.110(a) that the process is available for oral

complaints so that there is a clear distinction from the process requiring a written complaint under section 1154(a)(14) of the Act. Again, the proposed definition of ''immediate advocacy'' under § 476.1 also would make this clear.

We also are proposing that the use of ''immediate advocacy'' would not be available if the QIO makes a preliminary determination that the complaint includes concerns that could be deemed significant, substantial, or gross and flagrant violations of the standard of care to which a beneficiary is entitled (proposed § 476.110(a)(2)(ii)). In addition, we are proposing to add definitions of ''quality of care concern'' and ''significant quality of care concern'' under § 476.1, and to incorporate the definitions of ''gross and flagrant violation'' and ''substantial violation in a substantial number of cases'' as these two terms are used in 42 CFR 1004.1. We are proposing to define ''quality of care concern'' to mean a concern that care provided did not meet a professionally recognized standard of health care, and that a general quality of care review or a beneficiary complaint review may cover a single concern or multiple concerns. ''Significant quality of care concern'' would mean a determination by the QIO that the quality of care provided to a beneficiary(s) did not meet the standard of care and while not a gross and flagrant or substantial violation of the standard, represents a noticeable departure from the standard that could reasonably be expected to have a negative impact on the health of a beneficiary. ''Gross and flagrant violation'' would mean that a violation of an obligation specified in section 1156(a) of the Act has occurred in one or more instances which presents an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations (as specified in 42 CFR 1004.1). ''Substantial violation in a substantial number of cases'' would mean a pattern of providing care that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the QIO (as specified in 42 CFR 1004.1). We believe that the proposed definitions would give improved clarity to the distinctions made among concerns that do not meet the standard of care and demonstrate that QIOs are responsible for identifying all instances where care could have been improved and not just the most significant or flagrant failures to meet a standard of care. With regard to ''immediate advocacy,'' we believe that this informal process is not appropriate for those situations where a QIO preliminarily determines that a complaint could involve a ''gross and flagrant'' or ''substantial'' concern. In these circumstances, the QIO would not offer the immediate advocacy process, but instead would inform the beneficiary of the right to file a written complaint. Moreover, while we are proposing to exclude the use of the immediate advocacy process for those instances where ''significant quality of care concerns'' might be present, we are requesting public comments regarding whether the immediate advocacy process should be made available for these concerns as well. In addition, while we are proposing to restrict the use of the immediate advocacy process to a period of 6 months after a beneficiary has received the care at issue (proposed § 476.110(a)(1)), we also are requesting public comments on whether this time period should be extended beyond 6 months, whether based on the proposed structure or in order to accommodate the potential broadening of its use for ''significant quality of care concerns.''

In proposed § 476.110(a)(2), we are specifying that the immediate advocacy process can be used for issues that are not directly related to the clinical quality of health care itself or that accompany or are incidental to the medical care received. This includes, but is not limited to, issues such as delays in obtaining much needed medical items (for example, wheelchairs). In addition, in § 476.110(a)(3), we are proposing that the Medicare beneficiary must agree to the disclosure of his or her name in order for the immediate advocacy process to be used. We believe that it is important for the Medicare beneficiary to disclose his or her name because the immediate advocacy process is based on the need for open discussions to quickly resolve a beneficiary's concerns. Moreover, we also are proposing that all parties orally consent to the use of immediate advocacy (proposed § 476.110(a)(4)). Because our goal is to work with the providers and practitioners to resolve a beneficiary's concerns, we believe that consent is necessary. The use of oral consent, and not written consent, is in keeping with the cost-saving attributes of alternative dispute resolution processes.

Although we believe that the immediate advocacy process will be of great value to Medicare beneficiaries, providers, practitioners, and the QIOs, we recognize that, for some, the process may not provide the desired resolution. In addition, there could be situations where a QIO determines, after the immediate advocacy process has begun, that more serious concerns are evident. Therefore, we are proposing under § 476.110(b) that the QIO and either party can discontinue participation in immediate advocacy at any time and the steps a QIO will take when this occurs. This includes informing the beneficiary of his or her right to submit a written complaint.

In proposed § 476.110(c), we are conveying the need to maintain the confidentiality of the immediate advocacy proceedings by specifically referencing the redisclosure restrictions under § 480.107. We are proposing to make a corresponding change to § 480.107 by adding new paragraph (l), which will specify that the redisclosure of confidential information related to immediate advocacy proceedings can occur when there is consent of all parties. In proposed § 476.110(d), we are proposing to include procedures that QIOs would follow in those instances where a party fails to participate or otherwise comply with the immediate advocacy procedures. This includes making a beneficiary aware of his or her right to submit a written complaint.

We believe that the use of the immediate advocacy process will greatly reduce the burden on practitioners and providers by avoiding the formality of the traditional peer review process in appropriate situations and quickly identifying resolutions and improvements in the provision of health care. In fact, the immediate advocacy process has already been introduced through the recently completed manual instructions, and preliminary feedback indicates that it is being received positively by providers, practitioners, and Medicare beneficiaries. Medicare beneficiaries have indicated their appreciation of the quicker and more appropriate resolution of their concerns. Many times, Medicare beneficiaries would wait months for the resolution of a formal written complaint, only to be disappointed in what the QIO actually found or frustrated that the concern initially raised was rendered obsolete by more recent events. Under the immediate advocacy process, the QIO has a mechanism to resolve beneficiaries' concerns, sometimes the same day the beneficiary calls. Moreover, providers and practitioners have responded positively to being given the opportunity to immediately address beneficiary's concerns and improve care, particularly where communication is one of the

beneficiary's primary concerns. In addition, the provider's or practitioner's ability to avoid receiving and processing a formal complaint letter from the QIO and the related time and costs related to forwarding of medical records and engaging in the lengthy review process also have been positively received. The decreased burden on Medicare beneficiaries, providers, and practitioners and the time and cost savings are cornerstones of alternative dispute resolution processes. We are confident the positive responses to this new option will continue.

While we believe that the immediate advocacy process represents a significant step forward in ensuring the timely, appropriate, and cost-efficient resolution of Medicare beneficiaries' concerns, we recognize that additional changes are needed to improve the QIOs' review process in general. Therefore, we are proposing regulations governing written beneficiary complaint reviews as well as general quality of care reviews. We are proposing to add a new § 476.120 that would govern a Medicare beneficiary's submission of a written complaint, and are proposing under proposed § 476.120(a), language limiting the time period for submitting a written complaint to 3 years from the date on which the care giving rise to the complaint occurred. We believe this is necessary because the ability of a QIO to thoroughly review a complaint becomes more problematic the longer the period of time is between the circumstances giving rise to a complaint and the actual filing of the complaint. An individual's memory can fade, and we are aware of some instances where Medicare beneficiaries have submitted complaints about issues that have occurred decades ago. In these situations, the QIOs' ability to obtain the necessary information, let alone render a valid decision, has been severely compromised. As such, we believe that a 3-year look back period should be sufficient to ensure that a QIO can effectively complete its review.

We are specifying in proposed § 476.120(a)(1) that a complaint submitted electronically to the QIO meets the requirement for the submission of a written complaint. We are specifying in proposed § 476.120(a)(2) that if a beneficiary contacts a QIO about a potential complaint, but decides not to submit it in writing (and the QIO did not offer immediate advocacy), the QIO may use its authority under section 1154(a)(1)(B) of the Act to complete a general quality of care review in accordance with new proposed procedures at proposed § 476.160. We note that, in these situations, the beneficiary would not receive any results of the QIO's review. We also are proposing to limit the QIO's authority to conduct a general quality of care review in response to an oral complaint to those situations where the QIO makes a preliminary determination that the complaint contains a potential gross and flagrant, substantial, or significant quality of care concern.

In proposed § 476.120(b), we are proposing instructions for QIOs when a beneficiary submits additional concerns after the initial submission of a written complaint. We believe that the focus on an episode of care, which we are proposing in § 476.130(a)(1), gives the QIO adequate flexibility to consider all related concerns surrounding a complaint, but for those rare instances where a beneficiary does convey a new concern, the QIO would now have specific instructions regarding the right to consider the additional concerns either during the same complaint review or as a separate complaint.

In proposed § 476.130(a), we are proposing to convey the QIO's obligation to consider any information submitted by the beneficiary or his/her representative and by the provider and/or practitioner, along with the QIO's obligation to maintain the information received as confidential information, if that information falls within the definition of ''confidential information'' under existing § 480.101. Moreover, proposed § 476.130(a)(1) also would convey that the focus of the QIO's review will be on the episode of care from which the complaint arose and that in completing its review, the QIO will respond to the specific concerns raised by the beneficiary along with any additional concerns the QIO identifies while processing the complaint. We believe that the focus on the episode of care will significantly reduce the burden on providers and practitioners and reduce timeframes for completing reviews. Historically, QIOs would closely track the complaint as originally conveyed by a Medicare beneficiary. Often, however, Medicare beneficiaries would become dissatisfied with the focus and/or results of the QIO's review, and the QIO would be forced to reexamine the complaint in light of these new issues. On occasion, this could even require the submission of an entirely new complaint for issues that were related to, but not reviewed in, the original complaint. These situations also added to the burden on providers and practitioners because they would be required to participate in the review of the additional concerns and even provide additional medical documentation that may not have originally been requested.

In addition, proposed § 476.130(a)(1) would specify the details of the QIO's authority to separate a beneficiary's concerns into separate complaints if the QIO determines that the concerns relate to different episodes of care. We believe that focusing on the episode of care will put QIOs in a better position to identify all potential concerns at the onset and help alleviate any potential back and forth based on the specter of new or different concerns arising after the review has begun.

Proposed § 476.130(a)(2) would set forth the QIO's use of evidence-based standards of care to the maximum extent practicable, and specify the method that the QIO must use to establish standards if no standard exists. Moreover, this paragraph (a)(2) also conveys the finality of a QIO's determination regarding the standard to be used for a particular concern, in that the QIO's determination regarding the standard used is not subject to appeal. We believe that the focus on evidence-based standards of care is vital to the improvement of health care nationally.

In proposed § 476.130(b), we are proposing to specify the timeframes that practitioners and providers must follow when a QIO requests medical information in response to a written beneficiary complaint. We are proposing a 10 calendar day timeframe for responding to these requests. While this timeframe is significantly shorter than the 21 and 30 calendar day timeframes specified in existing § 476.78, we believe that it is warranted in light of the need to give Medicare beneficiaries a more timely resolution to their complaints. We believe providers and practitioners would also benefit from the faster resolution of complaints and would shift the focus from being available during the lengthy review process to moving forward with improvements to the health care given to Medicare beneficiaries. In addition, where, for other review activities, a QIO may be requesting multiple medical records, most often a single medical record will be requested in response to a written beneficiary complaint. Thus, the ability to respond within the shorter 10 calendar day timeframe should be much easier and less burdensome. Moreover, we also considered that an increasing number of providers and practitioners are using vendors to respond to requests for medical information, and this timeframe is comparable to models typically used by these vendors in responding to requests. In fact, even shorter timeframes can exist for larger providers and/or

practitioner groups. In addition, QIOs have historically employed a different, shorter timeframe for reviews where a Medicare beneficiary is still receiving care (concurrent review), compared to those situations where a Medicare beneficiary has already been discharged (retrospective review). For concurrent reviews, QIOs request that medical information be received within 1 calendar day, and typically this timeframe has been adhered to by providers and practitioners. Although we are not proposing the continued use of the concurrent and retrospective review framework for responding to written complaints, we recognize that there could be circumstances in which an even shorter timeframe for receiving medical information is warranted, and we are proposing to include language detailing a QIO's right to earlier receipt of medical information. We are proposing that this right to earlier receipt of medical information be related to potential gross and flagrant or substantial quality of care concerns. However, we are requesting public comments on whether there are other circumstances, involving less serious kinds of concerns, for which this authority to employ a shorter timeframe should be used. In addition, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28119 through 28120), we included proposed changes to § 476.78 to add references to ''practitioners'' in parts of this section, which currently refer only to ''providers,'' in order to equalize the 30-day and 21-day timeframes for submitting records. We also proposed changes to § 476.90 to equalize the ramifications for not submitting records on time because we see no reason to differentiate between a provider's and a practitioner's records. While these proposed changes in the FY 2013 IPPS/LTCH PPS proposed rule have not been finalized, in this proposed rule, we are requesting public comment on whether changes similar to those we are proposing for beneficiary complaints, including shortening of the 30-day and 21-day timeframes, should be incorporated into § 476.78(b) for requests for medical information in general, for any kind of QIO reviews, including nonquality related reviews. We are proposing to apply a shorter timeframe for all of a QIO's requests for records, without limiting this application to quality reviews in just one instance: Where secure transmissions of electronic versions of medical information are available. Our proposal regarding secure transmissions of electronic versions of medical information is discussed more fully later in this section.

In proposed § 476.130(c), we are proposing to include a requirement for beneficiary complaints that the QIO issue its interim initial determination within 7 calendar days after receiving all medical information. We believe that this timeframe is sufficient to evaluate a complaint and identify the key aspects of the care provided. Proposed § 476.130(c)(1) would specify the provider's and/or practitioner's right to discuss the QIO's determination before it is finalized, and would specify that the QIO's initial notification will be made by telephone. We are proposing a 7-calendar day timeframe for completion of the discussion. In addition, we are proposing that the QIO's interim initial determination would become the QIO's final determination if the discussion is not completed timely because the provider and/or practitioner has failed to respond (proposed § 476.130(c)(2)). Again, our focus is on obtaining resolutions to complaints within reasonable timeframes, and the completion of the discussion is an area where improved instructions may benefit the timeliness of complaint processing because we have experienced significant delays in completing this particular step. The term ''final initial determination'' should not be confused with the term used in 42 CFR Part 405, because Part 405 relates to whether a beneficiary is entitled to services or the amount of those services, while this regulation covers only the quality of services as specified in the QIO statute. At the same time, we are proposing under proposed § 476.130(c)(3) the provider's or practitioner's right to submit a written statement in lieu of a discussion, with the requirement that the written statement be received within the same 7-calendar day timeframe from the date of the initial offer. We believe that allowing the submission of a written statement would benefit practitioners or providers that may have trouble being available at a specific time within the 7-calendar day timeframe. Moreover, in proposed § 476.130(c)(4), we have included the QIO's right to extend the timeframe for holding the discussion or submission of a written statement in lieu of a discussion in those rare instances where a practitioner or provider is unavailable, whether because of military tours of duty, travel or other unforeseen circumstances.

In addition, we are considering restricting a provider's or practitioner's right to submit new or additional medical evidence in the form of test results, x-rays, and other evidence, as part of this discussion. We believe that doing so would emphasize the need for providers and practitioners to supply all relevant evidence when first requested by the QIO and also would maintain the focus on the discussion a physician or provider is due in accordance with section 1154(a)(14) of the Act. Allowing the submission of additional or new evidence could also substantially raise the possibility that the discussion will become, in effect, an entirely new review by the QIO. Moreover, providers and practitioners will still be able to submit information as part of a request for a reconsideration review. We are requesting public comments on whether providers and/or practitioners should be prohibited from submitting new or additional medical evidence in response to the offer of a discussion.

In proposed § 476.130(d), we are specifying the QIO's obligation to issue a written final initial determination, regardless of whether care did or did not meet standards for all concerns, and that this determination must be issued within 72 hours after completion of the QIO's review or, in cases where the standard was not met, the QIO's discussion or receipt of the provider's and/or practitioner's written statement. In addition, proposed § 476.130(d)(1) would specify that the notice of the final initial determination will be forwarded to all parties, and paragraph (d)(2) lists the actual content of the notice. We are specifying that the QIO would not forward the notice if either party requests a reconsideration of the final initial determination.

These proposed changes represent significant departures from the process QIOs have historically used when resolving beneficiary complaints and are necessary to improve the fairness of the review process and increase the transparency of the QIO review process. When the process was originally established, CMS determined that physicians, providers, or Medicare beneficiaries would not be afforded the right to request a reconsideration of these determinations under section 1155 of the Act. However, providers and practitioners were afforded an administratively created option, referred to as a ''re-review,'' if the provider or practitioner disagreed with the QIO's initial decision. Medicare beneficiaries were not provided this re-review opportunity and, in fact, were not given any response until after completion of the re-review. Moreover, the actual information a beneficiary received in response to the submission of a complaint was further limited by certain other provisions in the existing regulations. Section 480.132 covers the

general requirements that a QIO must meet in disclosing information to a beneficiary when that beneficiary has requested information about him or herself. Section 480.132(a)(1)(iii) states that this information cannot include any practitioner-specific information. We have read this provision in conjunction with § 480.133(a)(2)(iii), which authorizes a QIO to disclose practitioner-specific information when the practitioner has consented to the disclosure. In the past, we have interpreted these provisions as applying in the context of beneficiary complaints. This limitation greatly reduced a beneficiary's access to information related to the QIO's specific findings. In fact, § 480.132 also gave attending practitioners the authority to direct that a QIO not provide results directly to a Medicare beneficiary should that practitioner determine that the released information could ''harm the patient.'' This same provision gave QIOs a full 30 calendar days before they had to respond to a beneficiary's request for information, which would apply even in the context of a complaint. Thus, the QIO was required to obtain a practitioner's consent to disclose information within this 30-calendar day timeframe before the QIO could disclose the specific results of its complaint review to the beneficiary.

As a result of the current provisions in the regulation, the QIO was often delayed in its ability to respond to the beneficiary, and was sometimes forced to identify a representative and then give the results to the representative even if the Medicare beneficiary believed he or she was able to represent himself or herself and legally had not been deemed otherwise. Clearly, this scenario has frustrated Medicare beneficiaries over time and placed QIOs in difficult situations. Furthermore, if a practitioner did not consent to any disclosures or to limited disclosures of information that would identify the practitioner, a QIO's decision typically contained a conclusory statement about the results of the QIO's review but no information about the standards of care the QIO used, the evidence the QIO considered, or the rationale for how the QIO arrived at its conclusion. The limitations on what information Medicare beneficiaries received and broad authority given to attending practitioners have been particularly troubling in those instances in which the beneficiary's complaint relates to care that an attending physician provided. In fact, the lack of information given to Medicare beneficiaries in response to a complaint was the precise issue addressed in the Public Citizen decision.

We believe that the proposed changes to § 476.130(d), including paragraphs (d)(1) and (d)(2), are necessary to ensure beneficiaries are given the same information and rights as practitioners and providers. The proposed changes make clear that the timeframe given to QIOs for issuing the final initial determination in response to a complaint is separate and distinct from the timeframe given to QIOs when responding to a beneficiary's request for information. Any requests for information, including requests for information pertaining to beneficiary complaint reviews that are unrelated to a QIO's issuance of its final initial determination, would continue to be governed by § 480.132. Moreover, while the proposed 72-hour timeframe in § 476.130 appears short in comparison to the 30-calendar day timeframe in § 480.132 that has historically been used, we believe that the 72-hour timeframe represents a more appropriate and reasonable period of time in which to issue these decisions. In most cases, the QIO's final initial determination may not change significantly from the interim initial determination. Thus, QIOs would be able to rely heavily upon the interim initial determination in most instances, with only minor adjustments being made in light of information received in response to the opportunity for discussion. In addition, paragraph (d)(2) proposes the content of the written decision to be given to the beneficiary, provider, and/or practitioner. We are proposing that the content include a statement for each concern that the care did or did not meet the standard of care, the standard identified by the QIO for each of the concerns, and a summary of the specific facts that the QIO determines are pertinent to its findings. This list makes clear that § 480.132 will no longer govern what information a QIO may provide to a beneficiary in resolving a complaint. We believe this approach more fully supports the Court's decision in the Public Citizen case.

In addition, we believe that the language under section 1155 of the Act supports the decision to give all parties the right to request that the QIO reconsider its initial decision, and we are proposing to offer providers, practitioners, and beneficiaries the right to request a reconsideration in proposed § 476.140(a) for complaints filed after July 31, 2014. This includes proposed specific requirements regarding the manner in which these requests are to be submitted and the obligations of beneficiaries, providers, and practitioners to participate in the reconsideration process in proposed § 476.140(a)(1) through (a)(3). We are delaying implementation of this new proposed right to ensure all processing requirements are fully developed for QIOs to follow in reviewing these reconsideration requests.

In addition to proposing the specific content of the notice at proposed § 476.130(d)(2) when a final initial determination is issued and under proposed § 476.140(b) when a reconsideration final decision is issued, we are proposing to make corresponding changes to existing §§ 480.132(a) and (b) and 480.133(a) (proposed new paragraph (a)(2)(iv)). In order to make clear that § 480.132 relates solely to a beneficiary's request for information, but not to a beneficiary's receipt of information from a QIO in resolution of a complaint review, we are proposing the inclusion of a cross-reference to §§ 476.130(d) and 476.140(b) in paragraph (a). Similarly, we are proposing to include language in § 480.132 (a)(1)(iii) to denote that the removal of all other patient and practitioner identifiers does not apply to disclosures described in § 480.132 (b). We also are proposing clarifications to § 480.132(b) to improve the link between paragraph (b) and the provisions of § 478.24, which are cross-referenced in paragraph (b). We note that § 478.24 does not require seeking the advice or consent of the practitioner that treated the patient, nor does it prohibit the QIO from disclosing practitioner identifiers. We have made this clear by proposing the deletion of paragraph (b)(1)(i) and added language to the end of current paragraph (b)(1)(ii) to indicate that the information provided under § 478.24 includes relevant practitioner identifiers. With the deletion of paragraph (b)(1)(i), there is no longer a need for multiple paragraphs in (b)(1). Therefore, we are proposing to eliminate the current designation for paragraph (b)(1)(ii), with the provision being included as part of paragraph (b)(1). We also are proposing a corresponding change to § 480.133(a)(2)(iv) that makes clear a practitioner's or provider's consent is not required prior to releasing information to a beneficiary in connection with an initial denial determination or in providing a beneficiary with the results of the QIO's findings related to a beneficiary complaint review as described in §§ 476.130(d) and 476.140(b).

We also are proposing to remove from existing § 480.132(a)(2) and (c)(1) the right of an attending practitioner to direct a QIO to withhold information

based on a ''harm'' determination. This includes the proposed removal of the requirement from existing § 480.132(c)(2) that a QIO release results to a beneficiary's representative if a ''harm'' determination has been made by the attending practitioner. This also includes our proposed decrease in the timeframe that QIOs must follow in responding to a beneficiary's request for information (in any situation, as well as in the context of a beneficiary complaint) in § 480.132(a)(2) from 30 calendar days to 14 calendar days. This timeframe is strictly related to those situations where a beneficiary is making a request for information and will no longer be associated with obtaining responses to beneficiary complaints, which are detailed in proposed §§ 476.130(d) and 476.140(b). We believe the decrease from 30 calendar days to 14 calendar days is warranted in light of the improved ability to maintain data, including in electronic formats, so that less time is needed when responding to requests. The proposed changes would ensure that Medicare beneficiaries have more control over the designation of their representatives and also give a QIO more appropriate steps to follow in identifying a representative when one is actually needed. As an example, the existing regulations at § 480.132(c)(3) direct a QIO to ''first'' look to the medical record to identify a representative but then direct the QIO to ''rely on the attending practitioner'' if no information is contained in the medical record. The changes we are proposing to § 480.132(c) place more emphasis on the obligation of the QIO to follow the requirements under State law regarding the designation of health care representatives or agents, rather than focusing on ''where'' the information might be contained.

Lastly, at proposed § 476.140(b), we are specifying that the QIO must notify the beneficiary and the practitioner and/or provider of its final, reconsidered, decision within 72 hours after receipt of the request for a reconsideration or, if later, 72 hours after receipt of any medical or other records needed for such a reconsideration. The QIO may do so orally, by telephone, in order to meet this timeframe. Proposed § 476.140(b)(1) also would specify that a written notice must be mailed by noon of the next calendar day and specifies the content of the notice. In addition, proposed § 476.140(b)(2) describes the QIO's authority to provide information in its final decision to beneficiaries, providers and/or practitioners regarding improvement opportunities. The information QIOs provide regarding potential improvements could include specific opportunities related to the practitioner's or the provider's delivery of care and/or even broader improvements focusing on the community served by the practitioners and/or the providers. Some QIOs have, in fact, been providing this information to beneficiaries since it can offer the beneficiaries assurance that their complaints and any underlying problems are being addressed.

We are proposing to include under proposed new § 476.150 specific requirements for QIOs to follow in response to abandoned complaints. We believe that these instructions are necessary in light of a QIO's experience when handling complaints where a Medicare beneficiary initially submits a complaint but then all attempts by the QIO to contact the beneficiary are unsuccessful. Historically, QIOs have been responsible for continual follow-up with beneficiaries, even if months later the beneficiary still had not responded. We believe that giving QIOs the discretion to close these cases will eliminate this unnecessary follow-up and reduce costs. Moreover, it will alleviate provider's and/or practitioner's concern in those situations where the QIO may have already reached out to them about a potential complaint. We also are proposing to add under proposed § 476.150(b) instructions for QIOs to follow in those situations, which we believe will be rare, where a QIO must reopen a beneficiary complaint review. We would have QIOs apply the same procedures that appear in the already existing regulations at § 476.96 for the reopening of cases involving initial denial determinations and changes as a result of DRG validation, simply using those same procedures for a different purpose. We are proposing to do this by placing a reference in § 476.150(b) to the procedures in § 476.96.

2. Completion of General Quality of Care Reviews

Although the QIO's responsibility for completing quality of care reviews is already set forth in the QIO program regulations at existing § 476.71(a)(2), the procedures that QIOs use in completing these reviews are not. Again, the precise steps that QIOs use in completing these reviews were established through manual instructions. However, we believe that the proposed changes discussed below are necessary to the processing of these reviews in light of the knowledge we have gained since the program began. We believe that these proposed changes can bring about necessary improvements as quickly as possible and also support our efforts to thoroughly evaluate how the program should be structured moving forward.

First, in proposed new § 476.160(a)(1), we are proposing to specify those circumstances in which a QIO may conduct a general quality of care review. These circumstances would include those situations where a potential quality of care issue is referred to the QIO by another source, such as by another CMS contractor, an individual submitting a request anonymously, or another Federal or State entity. In addition, we recognize that more frequently the QIOs are working to use the substantial data available to them to identify potential areas where improvements in the quality of health care could be attained, and we believe these instances should be accounted for as we move forward. We also are aware that QIOs frequently identify potential quality of care issues when conducting other case review activities, including medical necessity reviews, expedited discharge appeals, among others; therefore, we have included this as an instance where a general quality of care review can be initiated.

In proposed new § 476.160(a)(2), we are specifying that the QIO's review will focus on all concerns raised by the source of a referral or report and/or identified by the QIO. While the episode of care should still be considered, it may be less significant for these reviews than those in response to a complaint submitted by a beneficiary, because the main goal of complaint reviews is to address a beneficiary's particular experiences with receiving certain services at a particular time. However, we again are proposing under proposed § 476.160(a)(3) that the QIO will use evidence-based standards of care to the maximum extent practicable in completing these reviews, and that the QIO's determination regarding the standard used in completing the review is not subject to appeal.

In proposed new § 476.160(b), we are proposing to specify the responsibility of providers and practitioners to supply requested medical information. This language is identical to the language in proposed new § 476.130(b) applicable to written beneficiary complaints, including the same 10-calendar day timeframe for practitioners and providers to respond to requests for medical information and the QIO's right to request even earlier receipt when the QIO preliminarily determines that a concern may be serious enough to qualify as a gross and flagrant or substantial quality of care concern. Although the decreased timeframe is not related to the goal of providing

beneficiaries with more timely resolution of their complaints (because beneficiaries will not be getting results of these reviews), we still believe there is ample justification to warrant the reduced timeframe. Providers and practitioners will benefit from the faster resolution of these reviews and the increased focus on identifying and resolving impediments to improved health care (particularly in cases involving potential serious concerns). These improvements will ultimately benefit patients. Additionally, as with written beneficiary complaints, the timeframes are comparable to models typically used by vendors. We also considered that, as with written beneficiary complaints, the QIOs currently use shorter timeframes where the beneficiaries impacted by the general quality of care review are still receiving care (concurrent review), compared to those situations where a beneficiary has already been discharged (retrospective review). Again, while we are not proposing the continued use of the concurrent and retrospective designations, we recognize that there are circumstances, even with general quality of care reviews, where decreased timeframes are necessary, including the 10-calendar day, or even shorter, timeframe.

As mentioned previously, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28119 through 28120), we included proposed changes to § 476.78 to add references to ''practitioners'' in parts of this section, which currently refer only to ''providers,'' in order to equalize the 30-day and 21-day timeframes for submitting records. We also proposed changes to § 476.90 to equalize the ramifications for not submitting records on time because we see no reason to differentiate between a provider's and a practitioner's records. While these proposed changes in the FY 2013 IPPS/LTCH PPS proposed rule have not been finalized, we are proposing here to modify the current general 30-day and 21-day timeframes in § 476.78(b) to reflect the new timeframes in §§ 476.130(b) and 476.160(b), which apply only to records submitted for purposes of beneficiary complaint and general quality reviews. We also are requesting public comment on whether changes similar to those we are proposing for beneficiary complaints and general quality of care reviews, including shortening of the 30-day and 21-day timeframes, should be incorporated more broadly into § 476.78(b) for requests for medical information in general, for any kind of QIO reviews, including nonquality related reviews. We are proposing to apply a shorter timeframe for all of a QIO's requests for records, without limiting this application to beneficiary complaints or general quality reviews in just one instance: Where secure transmissions of electronic versions of medical information are available. Our proposal regarding secure transmissions of electronic versions of medical information is discussed more fully later in this section.

We also are proposing new § 476.160(c), which would specify that the QIO peer reviewer will render the initial determination within 7 calendar days of the receipt of all medical information; this paragraph is substantially different from the proposed beneficiary complaint review procedures in proposed new § 476.130 in two areas. First, beneficiaries would not be provided any information regarding these reviews. Although we recognize that, at times, potential quality concerns a QIO identifies could impact a specific beneficiary, we believe that this type of review does not warrant any communication directly to the beneficiary. In fact, we believe that giving feedback of potentially poor care to an unknowing beneficiary could cause more anxiety than is warranted by the circumstances, and that is not our goal. We also recognize that, in many situations, the reviews could relate to or involve numerous beneficiaries. However, those beneficiaries may only be a sample of the beneficiaries potentially impacted. This is particularly true in those circumstances where the QIO is reviewing system-related aspects of care, and it will be incumbent upon the QIO to determine what medical information—and by extension the sample of beneficiaries receiving care—to be analyzed in completing these reviews.

Second, we are proposing that practitioners and providers not be given an opportunity to discuss the QIO's initial determination before it becomes final. The QIO's obligation to provide an opportunity for discussion is specific to the QIO's responsibility to review beneficiary complaints under section 1154(a)(14) of the Act. This same obligation is not dictated by section 1154(a)(1)(B) of the Act on which the QIO's authority to conduct general quality of care reviews is based. We believe that giving such an opportunity is not necessary, particularly because these discussions frequently become, in effect, an entirely new review by the QIO and not merely a discussion, and because we are already proposing at proposed new § 476.170(a) that the practitioner and/or provider be given the right to request a reconsideration of the QIO's initial determination. As with beneficiary complaint reviews, we are proposing that this right not be available until after July 31, 2014, to give us time to fully establish the process requirements and ensure that this right is meaningful for providers and practitioners.

In addition, under proposed new § 476.170(a)(1) through (a)(3), we are proposing requirements similar to those in § 476.140 regarding the timeframe for submitting a request for a reconsideration, the obligation of a practitioner and/or provider to be available to answer questions or supply information, as well as the QIO's obligation to offer the provider the opportunity to provide information as part of the reconsideration request. We also proposed provisions under proposed new § 476.170(b) concerning the QIO's issuance of its final decision. This includes the requirement that the QIO's decision be issued within 72 hours after receipt of the request for a reconsideration, or, if later, 72 hours after receiving any medical information or other records needed for such a reconsideration, the specific content of the final decision, and the right of the QIO to provide information to the provider or practitioner regarding opportunities for improving care given to beneficiaries based on the specific findings of its review. The information QIOs provide regarding potential improvements could include specific opportunities related to the practitioner's or provider's delivery of care and/or even broader improvements focusing on the community served by the practitioners and/or providers.

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

The QIO regulations at § 480.101(b) define any information that explicitly or implicitly identifies an individual patient as confidential information. Although provisions are included in 42 CFR Part 480 governing a practitioner's and/or provider's right to allow a QIO to use or disclose confidential information about the named practitioner or provider (§§ 480.105(b), 480.133(a)(2)(iii), and 480.140(d)), a similar right is not conveyed for beneficiaries. Thus, QIOs are prohibited from obtaining a beneficiary's authorization to use or disclose the beneficiary's confidential information, even in situations where a use or disclosure could be helpful to the beneficiary and his or her health care or even where the beneficiary specifically

asks the QIO to disclose the information.

One of the key challenges for the QIOs is identifying improvements in health care delivery systems. In fact, the ''patient-centeredness'' aim of the QIO's current scope of work requires more patient involvement, and the goal of many patient and family engagement efforts is to incorporate ''real-world person's'' experiences to demonstrate the compelling and urgent need for healthcare delivery reform. Additionally, beneficiaries have asked to participate in the QIO's work in a meaningful way. Unfortunately, we are often unable to accommodate these requests in light of the current regulatory restriction. We believe that this restriction, which was developed many years ago, is outdated, and that beneficiaries should be given the right to make choices regarding the use and disclosure of their confidential information.

As such, we are proposing new § 480.145 that will govern a beneficiary's right to authorize a QIO's use or disclosure of the beneficiary's confidential information. Under proposed § 480.145(a), we are proposing that a QIO may not use or disclose a beneficiary's confidential information without an authorization from the beneficiary and that the QIO's use or disclosure must be consistent with the authorization. In proposed § 480.145(b)(1) through (b)(6), we have listed those aspects of an authorization necessary to make the authorization valid. This includes the requirements that a specific and meaningful description of the confidential information be included, the name(s) of the QIO and QIO point of contact making the request to use or disclose the information, the name or other specific identification of the person, or class of persons to whom the QIO may make the requested use or disclosure, a description of the purpose(s) of the use or disclosure, the date or event upon which the authorization will expire, and the signature and date of the beneficiary authorizing the use and/or disclosure of the information. We also are proposing in § 480.145(c)(1) and (c)(2) that the authorization must contain a statement that the beneficiary maintains the right to revoke his or her authorization in writing and that the QIO must specify any exceptions to the right to revoke, as well as the process a beneficiary must use to revoke the authorization. In addition, at § 480.145(c)(3), we are proposing the requirement that the QIO convey to the beneficiary its inability to condition the review or other activities it is responsible for (such as beneficiary complaint reviews, medical necessity of a beneficiary's services, or discharge appeals) on the beneficiary's authorization. We also are proposing under § 480.145(c)(4) to make clear the consequences of authorizing the use or disclosure of information, and the fact that the QIO may be unable to protect the information from redisclosure. In § 480.145(d), we are proposing that an authorization must be written in plain language, and in § 480.145(e) that a QIO must provide the beneficiary with a copy of the signed authorization. Lastly, although we make reference to a beneficiary's right to revoke authorization in proposed § 480.145(c)(1), in paragraph (f) we are proposing a specific provision that will make clear that a beneficiary may revoke, in writing, an authorization at any time, except when the QIO has taken action in reliance upon the authorization.

We believe that these proposed changes appropriately relax some of the historical restraints on the QIO's use of a beneficiary's confidential information, enable QIOs to better meet the needs of Medicare beneficiaries, and give beneficiaries the opportunity to participate in efforts to improve the quality of their health care.

D. Secure Transmissions of Electronic Versions of Medical Information

When the QIO program regulations were first written in 1985, computers, along with digitally or electronically stored information, were still in their infancy. Thus, the QIO program regulations were written based on the perspective that most information sharing would be through the exchange of paper copies of medical records and other information. Since that time, we have seen great advances in the ability to electronically share data, whether through the use of mass storage devices (flash drives), the sending and receipt of electronic facsimiles, and even the use of email. At the same time, several laws, including HIPAA and the Federal Information Security and Management Act (FISMA), have been established to protect sensitive information. However, because the QIO program regulations have not undergone significant modification since they were originally adopted, the regulations do not account for electronic sharing of information and the QIOs' work is carried out within the context of exchanging paper copies of documents and information. At times, this creates additional work and costs because those providers and practitioners who have the ability to securely share electronic versions of medical records must actually print out the records and pay to have the paper copies mailed to the QIOs. To address these issues, we are proposing to revise existing § 476.78(b)(2) to add a new paragraph (iii) to make clear the QIOs' right to exchange secure transmissions of electronic versions of medical information, subject to a QIO's ability to support the exchange of the electronic version. We believe that this proposal would enable QIOs to receive and send medical information in a variety of formats, including through secure electronic faxes, and would reduce costs for providers and practitioners because they would no longer have to print and mail paper copies. In addition, to fully take advantage of the ability to receive and send electronic versions of medical information, we believe that a reduced timeframe is warranted for those instances where electronic versions are to be forwarded in response to requests from a QIO. Therefore, we are proposing under proposed § 476.78(b)(2)(iii) to require providers and practitioners to deliver electronic versions of medical information within 10 calendar days of the request from the QIO. As we noted previously, changes to existing § 476.78(b) have already been proposed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28119). As discussed earlier in this preamble, we are now proposing in this CY 2013 OPPS/ASC proposed rule additional changes to § 476.78 to take into account the different, more expedited timeframes we are proposing for medical records related to beneficiary complaint and general quality of care reviews. We also are requesting public comments in this proposed rule on whether additional changes should be made to § 476.78(b) to expand the different timeframes to cover medical records for all kinds of reviews. We also are requesting public comments on whether any modifications should be made to the reimbursement methodologies for paper copies described in § 476.78(c). We note that we are carrying forth in this proposed rule the proposed change to the section heading for § 476.78 that was included in the FY 2013 IPPS/LTCH PPS proposed rule, that is, the proposed change from ''Responsibilities of health care facilities'' to ''Responsibilities of providers and practitioners''.

E. Active Staff Privileges

In our efforts to ensure the QIO program is able to meet the needs of Medicare beneficiaries and improve the quality of health care moving forward, we have identified an aspect of the QIO program regulations that has become increasingly problematic for the QIOs.

Under existing § 476.98(a)(1), QIOs are required to use an individual with ''active staff privileges in one or more hospitals'' in making initial denial determinations. However, there is an accelerating trend toward generalist (family physicians/internists) physicians who provide care solely in the inpatient or outpatient care settings and a corresponding decline in the number of family practice physicians who provide any care in hospitals. In fact, many of these individuals do not provide any inpatient care and either have no hospital privileges or only ''courtesy'' privileges, which do not meet the definition in existing § 476.1 of ''active staff privileges.'' While we believe that the continued use of peer reviewers is necessary and vital to the success of the QIO program, the need to use physicians with ''active staff privileges'' is not. We believe that proposing to remove this requirement would increase the number of peer reviewers available for use by the QIOs, which, at times, has become particularly problematic for the QIOs. Therefore, in this proposed rule, we are proposing to remove the definition of ''active staff privileges'' under § 476.1 and to remove the phrase referring to using individuals ''with active staff privileges in one or more hospitals in the QIO area'' in making initial denial determinations under § 476.98(a)(1).

F. Proposed Technical Corrections

In addition to the proposed changes discussed above, we are proposing to make the following technical corrections to the QIO regulations:

• In 1989, several sections in 42 CFR Part 405 were redesignated to 42 CFR part 411 (54 FR 41746), but the cross-references to these sections in the QIO regulations was never made. Therefore, we are proposing to make the following reference changes:

+- Changing the reference ''§ 405.330(b)'' in existing § 476.71(b) to ''§ 411.400(b)'';

+- Changing the reference ''§ 405.332'' in § 476.74 to ''§ 411.402'';

+ Changing the references ''§ 405.310(g) or § 405.310(k)'' in § 476.86 to ''§ 411.15(g) or § 411.15(k)''.

• In 1999, 42 CFR parts 466, 473, and 476 were redesignated as 42 CFR parts 476, 478, and 480, respectively (64 FR 66236). Therefore, we are proposing to make changes to correct several cross-references to sections in these Parts:

+ Changing the reference ''§ 466.73(b)(3)'' in § 476.73 to ''§ 476.78(b)(3)''.

+ Changing the reference ''part 473'' in § 476.78(f) to ''part 478''.

+ Changing the reference ''part 473'' in § 476.94(c)(3) to ''part 478''.

+ Changing the reference ''§ 473.24'' in §§ 480.132 and 480.133 to ''§ 478.24''.

+ Changing the reference ''§ 466.98'' in § 478.28 to ''§ 476.98''.

+ Changing the reference to ''Part 478'' in §§ 478.15, 478.16, 478.20, 478.38, 478.42, and 478.48 to ''Part 473''.

+ Changing the reference ''§ 473.24'' in § 480.132 to ''§ 478.24''.

+ Changing the references ''Part 466'' and ''§ 473.24'' in § 480.133(b) to ''Part 476'' and ''§ 478.24'', respectively.

• We are proposing the deletion of several provisions in Part 476 regarding risk-basis contracts because risk-basis contracts previously under section 1876 of the Act no longer exist. As such, these provisions are obsolete and no longer used under the QIO program. Specifically, we are deleting the following sentence from § 476.70(a): ''Section 1154(a)(4) of the Act requires QIOs, or, in certain circumstances, non-QIO entities, to perform quality of care reviews of services furnished under risk-basis contracts by health maintenance organizations (HMOs) and competitive medical plans (CMPs) that are covered under subpart C of part 417 of this chapter.'' We are proposing to delete the following sentence from § 476.70(b): ''Section 466.72 of this part also applies, for purposes of quality of care review under section 1154(a)(4) of the Act, to non-QIO entities that enter into contracts to perform reviews of services furnished under risk basis contracts by HMOs and CMPs under subpart C of part 417 of this chapter.'' We are proposing to delete § 476.72—Review of the quality of care of risk-basis health maintenance organizations and competitive medical plans, in its entirety for the same reason.

• In § 476.70(a), we are proposing to change the word ''basis'' to ''bases'' to match the title of this section and to correctly denote that there is more than one statutory basis described in paragraph (a).

• We are proposing technical corrections to sections in Part 476 and 480 to accurately reflect the transition to Medicare administrative contractors (MACs) to process Medicare claims and conduct other actions. This transition is ongoing, and fiscal intermediaries and carriers still exist. However, we believe that the presence of MACs should be accounted for to accurately reflect current contractual relationships. As such, we are proposing to incorporate references to ''Medicare administrator contractors'' in the following sections, where appropriate:

+ § 476.1, in the definition of ''Preadmission Certification'';

+ § 476.71(c)(1);

+ § 476.73(a);

+ § 476.74(b) and (c)(1);

+ § 476.80 section heading, and §§ 476.80(a), (a)(1), (a)(2), (b)(1), (c), (c)(3)(ii), (d)(1), (d)(2), (e) paragraph heading, (e)(1), and (e)(2);

+ § 476.86(a)(2), (c) introductory text, (c)(1), and (d);

+ § 476.94(a)(1)(iv) and (d);

+ § 476.104(a); and

+ § 480.105(a).

• We are proposing a technical correction to § 480.139 by adding a paragraph ''(a)'' in front of ''(1)'' to the beginning of the text of the section to correct an inadvertent coding error.

• We are proposing to correct the statutory citation in § 480.132(b) by changing ''section 1154(a)(3)'' to ''section 1154(a)(2)''.

XIX. Files Available to the Public via the Internet

The Addenda of the proposed rules and the final rules with comment period will be published and available only via the Internet on the CMS Web site. To view the Addenda of this proposed rule pertaining to the proposed CY 2013 payments under the OPPS, go to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html* and select ''1589–P'' from the list of regulations. All Addenda for this proposed rule are contained in the zipped folder entitled ''2013 OPPS 1589–P Addenda'' at the bottom of the page.

To view the Addenda of this proposed rule pertaining to the proposed CY 2013 payments under the ASC payment system, go to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html* and select ''1589–P'' from the list of regulations. All Addenda for this proposed rule are contained in the zipped folder entitled ''Addenda AA, BB, DD1 and DD2'', and ''Addendum EE'' at the bottom of the page.

XX. Collection of Information Requirements

A. Legislative Requirements for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and to solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and

approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comments on each of the issues outlined above as discussed below that contained information collection requirements.

B. Proposed Requirements in Regulation Text

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

Under 42 CFR 495.6(f)(9), we require eligible hospitals and CAHs participating in the Medicare EHR Incentive Program (which would include those participating in the proposed 2013 Medicare EHR Incentive Program Electronic Reporting Pilot) to successfully report hospital clinical quality measures (CQMs) to CMS in the manner specified by CMS. As discussed in section XV.K. of this proposed rule, although we are proposing that eligible hospitals and CAHs may continue to attest CQMs in 2013, they may also choose to participate in the proposed 2013 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs. We are proposing that eligible hospitals and CAHs participating in the 2013 Medicare EHR Incentive Program Electronic Reporting Pilot must submit CQM data on all 15 CQMs (listed in Table 10 of the final rule (75 FR 44418 through 44420) for the Medicare and Medicaid EHR Incentive Program) to CMS, via a secure transmission based on data obtained from the eligible hospital or CAH's certified EHR technology.

Eligible hospitals and CAHs are required to report on core and menu set criteria for Stage 1 meaningful use. The reporting of clinical quality measures is part of the core set. We estimate that it would take an eligible hospital or CAH 0.5 hour to submit the required CQM information via the proposed 2013 Medicare EHR Incentive Program Electronic Reporting Pilot. Therefore, the estimated total burden for all 4,922 Medicare eligible hospitals and CAHs participating in the reporting Pilot (3,620 acute care hospitals and 1,302 CAHs) is 2,461 hours.

We believe that an eligible hospital or CAH might assign a computer and information systems manager to submit the CQM information on its behalf. We estimate the cost burden for an eligible hospital or CAH to submit to the CQMs and hospital quality requirements is $30.21 (0.5 hour × $60.41 mean hourly rate for a computer and information systems manager based on the 2011 Bureau of Labor Statistics) and the total estimated annual cost burden for all eligible hospitals and CAHs to submit the required CQMs is $148,694 ($30.21 × 4,922 hospitals and CAHs). We are soliciting public comments on the estimated numbers of eligible hospitals and CAHs that may register for the Medicare EHR Incentive Program Electronic Reporting Pilot that would submit the CQM information via the proposed Electronic Reporting Pilot in FY 2013. We also are inviting comments on the type of personnel or staff that would most likely submit on behalf of eligible hospitals and CAHs.

C. Proposed 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 previously stated in section XIV. of the CY 2012 OPPS/ASC final rule with comment period, the Hospital OQR Program has been generally modeled after the quality data reporting program for the Hospital IQR Program. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72110 and 72111 through 72114) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74549 through 74554) for detailed discussions of the Hospital OQR Program information collection requirements we have previously finalized.

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

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

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766), we retained the 7 chart-abstracted measures we used in CY 2009 and adopted 4 new claims-based imaging measures for the CY 2010 payment determination, bringing the total number of quality measures for which hospitals had to submit data to 11 measures. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60637), we required hospitals to continue to submit data on the same 11 measures for the CY 2011 payment determination. The burden associated with the aforementioned data submission requirements is currently approved under OCN: 0938–1109. This approval expires on October 31, 2013.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72071 through 72094), we adopted measures for the CY 2012, CY 2013, and CY 2014 payment determinations.

For the CY 2012 payment determination, we retained the 7 chart-abstracted measures and the 4 claims-based imaging measures we used for the CY 2011 payment determination. We also adopted 1 structural HIT measure that tracks HOPDs' ability to receive laboratory results electronically, and 3 claims-based imaging efficiency measures. These actions bring the total number of measures for the CY 2012 payment determination for which hospitals must submit data to 15 measures. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72112 through 72113), we discussed the burden associated with these information collection requirements.

For the CY 2013 payment determination, we required that hospitals continue to submit data for all of the quality measures that we adopted for the CY 2012 payment determination. We also adopted 1 structural HIT measure assessing the ability to track clinical results between visits, 6 new chart-abstracted measures on the topics of HOPD care transitions and ED efficiency, as well as 1 chart-abstracted ED–AMI measure that we proposed for the CY 2012 payment determination but which we decided to finalize for the CY 2013 payment determination. These actions bring the total number of quality measures for the CY 2013 payment determination for which hospitals must submit data to 23 measures.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72071 through 72094), for the CY 2014 payment determination, we retained the CY 2013 payment determination measures, but did not adopt any additional measures. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72112 through 72113), we discussed the burden associated with

these information collection requirements.

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

In the CY 2011 OPPS/ASC final rule with comment period, we did not adopt any new measures for the CY 2014 payment determination. In the CY 2012 OPPS/ASC final rule with comment period, we added, for the CY 2014 payment determination, 1 chart-abstracted measure and 2 structural measures (including hospital outpatient volume data for selected outpatient surgical procedures). However, as discussed at 76 FR 74456, we did not implement public reporting of the claims-based OP: 15 Use of Brain Computed Tomography (CT) in the ED for Atraumatic Headache. Because this is a claims-based measure, hospitals continue to submit relevant claims to be paid, but these administrative data and any measure calculations from them are not being made publicly available as specified for required hospital outpatient hospital quality of care measure data under section 1833(t)(17)(E) of the Act. In addition, in section XV.C. of this proposed rule, we are confirming that, using a subregulatory process, we have suspended indefinitely data collection for one measure, OP–19: Transition Record with Specified Elements Received by Discharged Patients, and we are proposing to defer data collection for another, OP–24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting. Thus, if this proposal is finalized, for the CY 2014 and subsequent years payment determinations, there would be a total of 26 measures, with hospitals reporting data on only 23 of them. The complete measure set for the CY 2014 and subsequent years payment determinations would include the measures shown below; all measures were previously adopted.

MEASURES REQUIRED FOR HOSPITAL OQR PROGRAM CY 2014 AND SUBSEQUENT YEARS PAYMENT DETERMINATIONS

OP–1: Median Time to Fibrinolysis
OP–2: Fibrinolytic Therapy Received Within 30 Minutes
OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP–4: Aspirin at Arrival
OP–5: Median Time to ECG
OP–6: Timing of Antibiotic Prophylaxis
OP–7: Prophylactic Antibiotic Selection for Surgical Patients
OP–8: MRI Lumbar Spine for Low Back Pain
OP–9: Mammography Follow-up Rates
OP–10: Abdomen CT—Use of Contrast Material
OP–11: Thorax CT—Use of Contrast Material
OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data
OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery
OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)
OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache *
OP–16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of Arrival
OP–17: Tracking Clinical Results between Visits
OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
OP–19: Transition Record with Specified Elements Received by discharged ED Patients **
OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional
OP–21: ED—Median Time to Pain Management for Long Bone Fracture
OP–22: ED—Patient Left Without Being Seen
OP–23: ED—Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival
OP–24: Cardiac Rehabilitation Patient Referral from an Outpatient Setting ***
OP–25: Safety Surgery Checklist
OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures

Procedure category	Corresponding HCPCS Codes
Gastrointestinal	40000 through 49999, G0104, G0105, G0121, C9716, C9724, C9725, and 0170T
Eye	65000 through 68999, G0186, 0124T, 0099T, 0017T, 0016T, 0123T, 0100T, 0176T, 0177T, 0186T, 0190T, 0191T, 0192T, 76510, and 0099T
Nervous System	61000 through 64999, G0260, 0027T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, and 0062T
Musculoskeletal	20000 through 29999, 0101T, 0102T, 0062T, 0200T, and 0201T
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, and C9727
Genitourinary	50000 through 58999, 0193T, and 58805
Cardiovascular	33000 through 37999
Respiratory	30000 through 32999

* Information for OP–15 will not be reported in Hospital Compare in 2012. Public reporting for this measure would occur in July 2013 at the earliest.
** Data collection for OP–19 was suspended effective with January 1, 2012 encounters until further notice.
*** Data collection for OP–24 would be deferred from January 1, 2013 to January 1, 2014, and its first application toward a payment determination would be for CY 2015 rather than CY 2014.

We will calculate the seven claims-based measures using Medicare FFS claims data and do not require additional hospital data submissions. With the exception of OP–22, we are using the same data submission requirements related to the chart-abstracted quality measures that are submitted directly to CMS that we used for the CY 2011 and CY 2012 payment determinations. For the four structural measures, including the collection of data for all-patient volume for selected outpatient procedures, hospitals will enter data into a Web-based collection

tool during a specified collection period once annually. Under the Hospital OQR Program requirements, hospitals must complete and submit a notice of participation form for the Hospital OQR Program if they have not already done so or have withdrawn from participation. By submitting this document, hospitals agree that they will allow CMS to publicly report the measures for which they have submitted data under the Hospital OQR Program.

For the CY 2014 payment determination, the burden associated with these requirements is the time and effort associated with completing the notice of participation form, and collecting and submitting the data on the 23 measures. For the 12 chart-abstracted measures (including those measures for which data are submitted directly to CMS, as well as the OP–22 measure for which data will be submitted via a Web-based tool rather than via an electronic file), we estimate that there will be approximately 3,200 respondents per year. For hospitals to collect and submit the information on the chart-abstracted measures we estimate it will take 35 minutes per sampled case. Based upon the data submitted for the CY 2011 and CY 2012 payment determinations, we estimate there will be a total of 1,628,800 cases per year, approximately 509 cases per year per respondent. The estimated annual burden associated with the submission requirements for these chart-abstracted measures is 949,590 hours (1,628,800 cases per year × 0.583 hours per case).

For the chart-abstracted OP–22 measure plus the structural measures, excluding the all-patient volume for selected surgical procedures measure, we estimate that each participating hospital will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with these measures 1,603 hours (3,200 hospitals × 0.167 hours per measure × 3 measures per hospital).

For the collection of all-patient volume for selected outpatient surgical procedures, because hospitals must determine their populations for data reporting purposes and most hospitals are voluntarily reporting population and sampling data for Hospital OQR Program purposes, we believe the only additional burden associated with this requirement is the reporting of the data using the Web-based tool. We estimate that each participating hospital will spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with this measure 53 hours (3,200 hospitals × 0.167 hours per measure × 1 all-patient volume measure per hospital).

c. Hospital OQR Program Measures for CY 2015

In the CY 2012 OPPS/ASC final rule with comment period, for the CY 2015 payment determination, we retained the requirement that hospitals must complete and submit a notice of participation form in order to participate in the Hospital OQR Program. For the CY 2015 payment determination, we also retained the measures used for CY 2014 payment determination (including the measures adopted in the CY 2012 final rule with comment period) and did not add any additional measures.

For the CY 2015 payment determination, the burden associated with these requirements is the time and effort associated with completing the notice of participation form, collecting and submitting the data on the measures, and collecting and submitting all-patient volume data for selected outpatient surgical procedures. For the chart-abstracted measures, we estimate that there will be approximately 3,200 respondents per year. For hospitals to collect and submit the information on the chart-abstracted measures where data is submitted directly to CMS, we estimate it will take 35 minutes per sampled case. Based upon the data submitted for the CY 2011 and CY 2012 payment determinations, we estimate there will be a total of 1,628,800 cases per year, approximately 509 cases per year per respondent. The estimated annual burden associated with the aforementioned submission requirements for the chart-abstracted data is 949,590 hours (1,628,800 cases per year × 0.583 hours per case). For the structural measures, we estimate that each participating hospital will spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with these measures 1,603 hours (3,200 hospitals × 0.167 hours per hospital × 3 structural measures per hospital).

For the collection of all-patient volume data for selected outpatient surgical procedures, because hospitals must determine their populations for data reporting purposes and most hospitals are voluntarily reporting population and sampling data for Hospital OQR purposes, we believe the only additional burden associated with this requirement will be the reporting of the data using the Web-based tool. We estimate that each participating hospital will spend 10 minutes per year to collect and submit the data, making the estimated annual burden associated with this measure 53 hours (3,200 hospitals × 0.167 hours per hospital).

We invite public comment on the burden associated with the information collection requirements.

3. Proposed Hospital OQR Program Validation Requirements for CY 2014

In this proposed rule, we are proposing to retain the requirements related to data validation for CY 2014 that we adopted in the CY 2011 OPPS/ASC final rule with comment period (76 FR 74486) for CY 2013, and that we revised in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74553). While these requirements are subject to the PRA, they are currently approved under OCN: 0938–1109. This approval expires on October 31, 2013.

Similar to our approach for the CY 2013 Hospital OQR Program payment determination (76 FR 74484 through 74485), we are proposing to continue to validate data from randomly selected hospitals for the CY 2014 payment determination, selecting 450 hospitals. We note that, because hospitals would be selected randomly, every hospital participating in the Hospital OQR Program would be eligible each year for validation selection.

In the CY 2011 OPPS/ASC proposed rule and final rule with comment period (75 FR 46381 and 75 FR 72106, respectively), we discussed additional data validation conditions under consideration for CY 2013 and subsequent years. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485 and 76 FR 74553), we finalized a policy under which we will select for validation up to 50 additional hospitals based upon targeting criteria.

For each selected hospital (random or targeted), generally we will randomly select up to 48 patient encounters per year (12 per quarter) for validation purposes from the total number of cases that the hospital successfully submitted to the OPPS Clinical Warehouse during the applicable time period. However, if a selected hospital submitted less than 12 cases in one or more quarters, only those cases available would be validated.

The burden associated with the CY 2014 requirement is the time and effort necessary to submit validation data to a CMS contractor. We 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 must submit up to 48 cases for the affected year for review. All selected hospitals must comply with these requirements each year, which would

result in a total of up to 24,000 charts being submitted by the sampled hospitals. The estimated annual burden associated with the data validation process for CY 2014 is approximately 6,000 hours.

We are proposing to maintain the deadline of 45 days for hospitals to submit requested medical record documentation to a CMS contractor to support our validation process.

We invite public comment on the burden associated with these information collection requirements.

4. Proposed Hospital OQR Program Reconsideration and Appeals Procedures

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68779), we adopted a mandatory reconsideration process that applied to the CY 2010 payment decisions. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60654 through 60655), we continued this process for the CY 2011 payment update. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72106 through 72108), we continued this process for the CY 2012 payment update with some modifications. We eliminated the requirement that the reconsideration request form be signed by the hospital CEO to facilitate electronic submission of the form and reduce hospital burden. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74487 and 74488 and 76 FR 74553 and 74554), we specified that we were continuing this process for the CY 2013 and subsequent years' payment determinations. In this CY 2013 OPPS/ASC proposed rule, we are proposing to make one change to this process—to add a requirement that the CEO or designated personnel must sign the reconsideration request. 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, and/or appeals.

5. ASCQR Program Requirements

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

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74496 through 74504), we adopted five claims-based measures (four outcome and one process) to be used for the CY 2014 payment determination. We will collect quality measure data for the five claims-based measures by using QDCs placed on submitted claims beginning with services furnished from October 1, 2012 through December 31, 2012. The five outcome measures are:

- Patient Burns (NQF #0263)
- Patient Falls (NQF #0266)
- Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)
- Hospital Transfer/Admission (NQF #0265)
- Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264)

The first four measures listed above are outcome measures and the fifth measure is a process measure.

Approximately 71 percent of ASCs participate in Medical Event Reporting, which includes reporting on the first four claims-based measures listed above. Between January 1995 and December 2007, ASCs reported 126 events, an average of 8.4 events per year (Florida Medical Quality Assurance, Inc. and Health Services Advisory Group: Ambulatory Surgery Center Environmental Scan (July 2008) (Contract No. GS–10F–0096T)). Thus, we estimate the burden to report QDCs on this number of claims per year for the first four claims-based measures to be nominal due to the small number of cases (less than 1 case per month per ASC, or about 11.8 events per year).

For the remaining claims-based measure, Prophylactic IV Antibiotic Timing, we estimate the burden associated with submitting QDCs to be nominal, as few procedures performed by ASCs will require prophylactic antibiotic administration.

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

For the CY 2015 payment determination, we finalized the retention of the five measures we adopted for the CY 2014 payment determination, and we added two structural measures: Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures (76 FR 74504 through 74509). For the CY 2015 payment determination, we are proposing that the data collection period for claims-based measures would be for services furnished from January 1, 2013, through December 31, 2013, that are paid by the administrative contractor by April 30, 2014.

For the CY 2016 payment determination, we finalized the retention of the seven measures for the CY 2015 payment determination and added Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) (76 FR 74509). For the CY 2016 payment determination, we are proposing that the data collection period for claims-based measures would be for services furnished from January 1, 2014, through December 31, 2014, that are paid by the administrative contractor by April 30, 2015.

Based on our data for CY 2014 payment determinations above, extrapolating to 100 percent of ASCs reporting, there would be an average of 11.8 events per year. Thus, we estimate the burden to report QDCs on this number of claims per year for the first four claims-based measures to be nominal due to the small number of cases (approximately one case per month per ASC) for the CYs 2015 and CY 2016 payment determinations. We estimate the burden associated with submitting QDCs for the fifth measure to be nominal as well, as discussed above.

For the CY 2015 payment determination, for the structural measures, ASCs will enter required information using a Web-based collection tool between July 1, 2013 and August 15, 2013. For the Safe Surgery Checklist Use structural measure, we estimate that each participating ASC will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure 864 hours (5,175 ASCs $\times$ 1 measure $\times$ 0.167 hours per ASC).

For the ASC Facility Volume Data on Selected ASC Surgical Procedures structural measure, we estimate that each participating ASC will spend 10 minutes per year to collect and submit the required data, making the estimated annual burden associated with this measure, 864 hours (5,175 ASCs $\times$ 1 measure $\times$ 0.167 hours per ASC).

6. IRF QRP

In the FY 2012 IRF PPS final rule (76 FR 47873 through 47883), we finalized the initial reporting requirements of the IRF QRP, including two quality measures for CY 2012 reporting. These two quality measures are: (1) Percent of Residents with Pressure Ulcers that are New or Worsened (NQF # 0678); and (2) Urinary Catheter Associated Urinary Tract Infection (CAUTI) rate per 1,000 urinary catheter days, for Intensive Care Unit (ICU) Patients (NQF#0138).

We also established reporting mechanisms for these two measures in the FY 2012 IRF PPS final rule. IRFs were instructed to use the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI) (approved under OCN: 0938–0842) to collect pressure ulcer measure data on Medicare Part A, Part B, and Medicare Advantage beneficiaries, and they were to collect CAUTI measure data on all

patients and report that data to CDC's National Healthcare Safety Network (NHSN). The burden associated with this collection of information for IRFs was included in the FY 2012 IRF PPS final rule (76 FR 47884 through 47885).

Section XVII. of this proposed rule includes three proposals for the IRF QRP, which are: (1) A proposal to implement updates made by the NQF to the CAUTI measure which will affect the annual payment update in FY 2014; (2) a proposal that any measure selected for use in the IRF QRP would remain in effect until actively removed, suspended, or replaced; and (3) a proposal to implement policies regarding when notice-and-comment rulemaking will be used to update existing IRF QRP measures.

The first proposal, if finalized, would allow us to incorporate recent updates that were made to the CAUTI measure (NQF#0138) by the NQF. However, these changes will not affect the type or amount of data that IRFs will be required to collect and submit.

The second proposal involves the implementation of a policy that IRF quality measures will remain in effect until a measure is actively removed, suspended, or replaced. This policy, if implemented, would not add any additional information collection requirements for CY 2013 and beyond as discussed below.

The third proposal involves implementing a policy regarding when notice-and-comment rulemaking would be used to update existing IRF QRP measures that have been updated by the NQF. This proposal would likewise not cause any increased information collection requirements to IRFs.

a. Pressure Ulcer Measure

In this proposed rule, we are not proposing to make any changes in the way the pressure ulcer data are to be collected and submitted to CMS using the current version of the IRF–PAI. Therefore, the information collection burden that IRFs will incur for the reporting of pressure ulcer data will not differ from that which was stated in the FY 2012 IRF PPS final rule (76 FR 47884 through 47885). Likewise, the information collection burden will not differ from the burden estimate that is currently approved for the IRF–PAI under OCN: 0938–0842. It is important to note that, while the FY 2012 IRF PPS final rule mainly discusses the reporting requirement that will be incurred by IRFs for the FY 2014 payment determination, we do not anticipate that our proposals will cause an increase in the information collection requirements for subsequent fiscal years.

b. CAUTI Measure

As discussed above, the FY 2012 IRF PPS final rule adopted the ''Urinary Catheter Associated Urinary Tract Infection (CAUTI) rate per 1,000 urinary catheter days, for Intensive Care Unit (ICU) Patients'' (NQF #0138) measure for the IRF QRP. However, subsequent to the publication of the FY 2012 IRF PPS final rule, this measure was expanded to several non-ICU settings, including IRFs. The CDC also changed the way the CAUTI measure is calculated from an infection rate per 1,000 days to a standardized infection ratio (''SIR''). The SIR calculation is comprised of the actual rate of infection over the expected rate of infection.

These changes will not impact the type or amount of data that IRFs will be required to collect and submit. Therefore, the information collection estimates that are stated in the FY 2012 IRF PPS final rule (76 FR 47884 through 47885) for reporting CAUTI data remain unchanged for the FY 2014 payment determination as well as for subsequent years payment determinations.

XXI. 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.

XXII. 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)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated as an ''economically'' significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Contract with America Advancement Act of 1996 (Pub. L. 104–121). Accordingly, the rule has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this 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 outpatient prospective payment rates and the ASC payment rates for CY 2013. The proposed rule is necessary to propose changes to payment policies and rates for outpatient services furnished by hospitals and CMHCs for CY 2013. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the APC payment rates. 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 relative APC payment weights using claims data for services furnished on and after January 1, 2011, through and including December 31, 2011, and updated cost report information.

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 implementing these payment provisions. Also, we list the 23 drugs and biologicals in Table 22 of this proposed rule that we are

proposing to remove from pass-through payment status for CY 2013.

This proposed rule is also necessary to update the ASC payment rates for CY 2013, enabling CMS to propose changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC for CY 2013. Because the ASC payment rates are based on the OPPS relative payment weights for the majority of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, because the services provided in ASCs are identified by HCPCS codes that are reviewed and revised either quarterly or annually, depending on the type of code, it is necessary to update the ASC payment rates annually to reflect these changes to HCPCS codes. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC not less frequently than every 2 years. Sections 1833(i)(2)(D)(iv) and 1833(i)(7) of the Act authorize the Secretary to implement a quality reporting system for ASCs in a manner so as to provide for a reduction of 2.0 percentage points in any annual update with respect to the year involved for ASCs that fail to meet the quality reporting requirements. For CY 2013, there are no impacts associated with this payment reduction because it will not be applied until CY 2014.

3. Overall Impacts for OPPS and ASC Provisions

We estimate that the effects of the proposed OPPS payment provisions will 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 expenditures under the OPPS for CY 2013 compared to CY 2012 would be approximately $700 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate that the OPPS expenditures for CY 2013 would be approximately $4.571 billion relative to CY 2012. Because this proposed rule for the OPPS 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 the costs and benefits of this proposed rulemaking. Table 45 of this proposed rule displays the redistributional impact of the proposed CY 2013 changes in OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the proposed update change to the conversion factor and other proposed adjustments (but not including the effects of outlier payments, the pass-through estimates, and the application of the frontier State wage adjustment for CY 2013) would increase total OPPS payments by 2.1 percent in CY 2013. 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 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 total proposed change in payments between CY 2012 and CY 2013, considering all payments, including changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment outside of budget neutrality, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G) and 1833(t)(17) of the Act, would increase total estimated OPPS payments by 2.1 percent.

We estimate that the effects of the proposed ASC provisions in this proposed rule for the ASC payment system would result in expenditures exceeding $100 million in any 1 year. We estimate the total increase (from proposed changes in this proposed rule as well as enrollment, utilization, and case-mix changes) in expenditures under the ASC payment system for CY 2013 compared to CY 2012 to be approximately $211 million. Because this proposed rule for the ASC payment system 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 proposed rulemaking. Tables 46 and Table 47 of this proposed rule display the redistributional impact of the proposed CY 2013 changes on ASC payment, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Detailed Economic Analyses

a. Estimated Effects of Proposed OPPS Changes

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2013 policy changes on various hospital groups. We post on the CMS Web site our proposed hospital-specific estimated payments for CY 2013 with the other supporting documentation for this proposed rule. To view the proposed hospital-specific estimates, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At the Web site, select ''regulations and notices'' from the left side of the page and then select ''CMS–1589–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 45 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 individual proposed policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we do not make adjustments for future changes in variables such as service volume, service-mix, or number of encounters. In this proposed rule, as we have done in previous proposed rules, 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 45 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 scalar estimate. We now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 45 and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2012, we are paying CMHCs under APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) and APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs), and we are paying hospitals for partial hospitalization services under APC 0175 (Level I Partial Hospitalization (3 services) for hospital-based PHPs) and APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). For CY 2013, we are proposing to continue this APC payment structure and are basing payment fully on the geometric mean costs calculated using data for the type of provider for which rates are being set, that is, hospital or CMHC. We display separately the impact of this proposed policy on CMHCs, and we discuss its impact on hospitals as part of our discussion of the hospital impacts.

The estimated increase in the proposed 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 estimated IPPS market basket increase for FY 2013 is 3.0 percent (77 FR 27870). Section 1833(t)(3)(F)(i) of the Act reduces that 3.0 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.8 percentage points (which is also the proposed MFP adjustment for FY 2013 in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27870); and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act further reduce the market basket percentage increase by 0.1 percentage point, resulting in the OPD fee schedule increase factor of 2.1 percent, which we are using in the calculation of the proposed CY 2013 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index of 1.00. The amounts attributable to this frontier State wage index adjustment are incorporated in the proposed CY 2013 estimates in Table 45.

To illustrate the impact of the proposed CY 2013 changes, our analysis begins with a baseline simulation model that uses the CY 2012 relative payment weights, the FY 2012 final IPPS wage indices that include reclassifications, and the final CY 2012 conversion factor. Table 45 shows the estimated redistribution of the increase in payments for CY 2013 over CY 2012 payments to hospitals and CMHCs as a result of the following factors: APC reconfiguration and recalibration based on our historical methodology using median costs (Column 2); the marginal impact of basing the APC relative payment weights on geometric mean costs over basing them on median costs (Column 3); APC recalibration based on geometric mean costs (Column 4, the combined effect of Columns 2 and 3); the wage indices and the rural adjustment (Column 5); the combined impact of APC recalibration based on geometric mean costs, the wage indices and rural adjustment, and the OPD fee schedule increase factor update to the conversion factor (Column 6); the combined impact of APC recalibration based on geometric mean costs, the wage indices and rural adjustment, the conversion factor update, and the frontier State wage index adjustment (Column 7); and the estimated redistribution taking into account all payments for CY 2013 relative to all payments for CY 2012 (Column 8), 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 2013. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2012 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services would 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 2012 and CY 2013 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed OPPS rates for CY 2013 would have a positive effect for providers paid under the OPPS, resulting in a 2.1 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 still result in a 2.1 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 45 shows the total number of facilities (4,070), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2011 hospital outpatient and CMHC claims data to model CY 2012 and proposed CY 2013 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not accurately estimate CY 2012 or proposed CY 2013 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this 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 (3,853) 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 154 CMHCs at the bottom of the impact table and discuss that impact separately below.

Columns 2, 3, and 4: APC Recalibration

These columns show the combined effects of the proposed reconfiguration, recalibration, and other policies (such as setting payment for separately payable drugs and biologicals at ASP+6 under our CY 2013 proposal to apply the statutory default). Column 2 shows the reclassification effects if we were to base the relative payment weights on the median costs of services. Column 3 shows the marginal effects of using the geometric mean costs compared to the effects if we were to base the relative payment weights on the median costs of services, in other words the effects of our proposed policy change from medians to geometric means. Column 4 shows the combined effect of Columns 2 and 3, in other words the effect of our proposal to base the relative payment weights on geometric mean costs. It reflects the impacts of the proposed reclassification of services among APC groups and the proposed recalibration of APC relative payment weights, based on 12 months of CY 2011 OPPS hospital claims data and the most recent cost report data, and determining relative payment weights using the geometric mean costs of services. We modeled the effect of the proposed APC recalibration changes by varying only the relative payment weights (the final CY 2012 relative weights versus the proposed CY 2013 relative weights calculated using the service-mix and volume in the CY 2011 claims used for this proposed rule) and calculating the percent difference in the relative weight. Column 4 also reflects any proposed changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights.

Overall, we estimate that proposed changes in APC reassignment and recalibration across all services paid under the OPPS would slightly decrease payments to urban hospitals by 0.1 percent. However, the smallest urban hospitals would receive slight payment increases of 0.6 percent (hospitals with 0–99 beds), attributable to increased payments for partial hospitalization, group psychotherapy and cardiac rehabilitation monitoring services furnished in the hospital. Due to recalibration, we estimate that low volume urban hospitals billing fewer than 21,000 lines for OPPS services would experience increases ranging from 0.8 percent to 4.0 percent. The increase of 4.0 percent for urban hospitals billing fewer than 5,000 lines per year is similarly attributable to an increase in payment for partial hospitalization and group psychotherapy services furnished in the hospital.

Overall, we estimate that rural hospitals would experience a small increase of 0.3 percent as a result of proposed changes to the APC structure, with the largest increases going to the smallest hospitals both by number of beds (0.9 percent to those with less than 50 beds) and volume (2.5 percent to those with fewer than 5,000 lines). As a result of the recalibration, we estimate that rural hospitals that report 5,000 or more lines for OPPS services would experience payment increases ranging from 0.2 percent to 1.0 percent.

Classifying hospitals according to teaching status, we estimate that the APC recalibration would lead to small payment decreases of 0.1 to 0.2 percent for major and minor teaching hospitals, respectively. We estimate that nonteaching hospitals would experience an increase of 0.1 percent. Classifying hospitals by type of ownership suggests that voluntary, proprietary, and governmental hospitals would experience changes ranging from a decrease of 0.1 percent to an increase of 0.2 percent as a result of the proposed APC recalibration.

For most hospitals, we estimate insignificant impacts of our proposal to use geometric mean-based relative payment weights. Most providers would receive small increases in payments of up to 2.5 percent. We estimate that hospitals for which DSH payments are not available (mostly urban hospitals) would experience an increase of 6.1 percent. Hospitals for which DSH data are not available (non-IPPS hospitals) furnish a large number of psychiatric services and we believe that the estimated increase in payment is due to increased payment for partial hospitalization and group psychotherapy services, as well as for hemodialysis services furnished in the hospital.

Column 5: Proposed New Wage Indices and the Effect of the Proposed Rural and Cancer Hospital Adjustments

Column 5 demonstrates the combined budget neutral impact of APC recalibration using geometric means; the wage index update; the rural adjustment; and the cancer hospital adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indices for each year, and using a CY 2012 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indices.

Column 5 reflects the independent effects of the updated wage indices, including the application of budget neutrality for the rural floor policy on a nationwide basis. This column excludes the effects of the frontier State wage index adjustment, which is not budget neutral and is included in Column 7. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are not proposing to make any changes to the policy for CY 2013. Similarly, the differential impact between the CY 2012 cancer hospital payment adjustment and the proposed CY 2013 cancer hospital payment adjustment had no effect on the budget neutral adjustment to the conversion factor. We modeled the independent effect of updating the wage indices by varying only the wage indices, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the proposed CY 2013 scaled weights and a CY 2012 conversion factor that included a budget neutrality adjustment for the effect of changing the wage indices between CY 2012 and CY 2013. This column estimates the impact of applying the proposed FY 2013 IPPS wage indices for the CY 2013 OPPS without the influence of the frontier State wage index adjustment, which is not budget neutral. The frontier State wage index adjustment is reflected in the combined impact shown in Column 7. We are proposing to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2013, as described in section II.E.2. 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 updated 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 rural adjustment, urban hospitals would experience no change from CY 2012 to CY 2013, although urban hospitals would experience small changes ranging from increases of 0.2 percent (for large urban hospitals) to decreases of 0.2 percent (for other urban hospitals). Sole community hospitals would not be affected, but other rural hospitals would experience decreases of 0.3 percent. Urban hospitals in the New England and Pacific regions would experience the most significant payment

changes with a decrease of 1.2 percent in New England and an increase of 1.6 percent in the Pacific region. Overall, we estimate that rural hospitals would experience a decrease of 0.2 percent as a result of changes to the proposed wage index for CY 2013. Regionally, the changes would range from a decrease of 0.9 in rural Pacific States to an increase of 0.4 in rural New England States.

Column 6: All Proposed Budget Neutrality Changes Combined With the Proposed OPD Fee Schedule Increase

Column 6 demonstrates the cumulative impact of the budget neutral adjustments from Column 5 and the proposed OPD fee schedule increase factor of 2.1 percent. We estimate that for most hospitals, the addition of the proposed OPD fee schedule increase factor of 2.1 percent would mitigate the negative impacts created by the budget neutrality adjustments made in Column 5.

While most classes of hospitals would receive an increase that is more in line with the 2.1 percent overall increase after the proposed update is applied to the budget neutrality adjustments, urban hospitals that bill fewer than 11,000 lines, rural hospitals that bill fewer than 5,000 lines, and hospitals for which DSH information is not available would experience larger increases ranging from 4.1 percent to 8.3 percent. In particular, urban hospitals that report fewer than 5,000 lines would experience a cumulative increase, after application of the proposed OPD fee schedule increase factor and the budget neutrality adjustments, of 6.4 percent, largely as a result of proposed increases in payments to partial hospitalization and group psychotherapy services furnished in the hospital. Similarly, urban hospitals for which DSH data are not available would experience an increase of 8.1 percent, also largely as a result of proposed increases in payment for partial hospitalization, group psychotherapy and hemodialysis services furnished in hospitals.

Overall, we estimate that these proposed changes would increase payments to urban hospitals by 2.1 percent. We estimate that large urban hospitals and ''other'' urban hospitals would also experience increases of 2.3 and 1.9 percent, respectively. Urban hospitals in the Pacific region would experience an increase of 3.6 percent, largely as a result of the proposed change in wage index shown under column 3 and discussed above. We estimate that rural hospitals would experience a 2.3 percent increase as a result of the proposed OPD fee schedule increase factor and other budget neutrality adjustments.

Classifying hospitals by teaching status suggests that the proposed OPD fee schedule increase factor and the proposed budget neutrality adjustments would result in an increase of 2.1 percent for major teaching hospitals, 1.9 percent for minor teaching hospitals and 2.3 percent for nonteaching hospitals.

Classifying hospitals by type of ownership suggests that proprietary hospitals would experience an estimated increase of 2.3 percent, while voluntary hospitals would experience an estimated increase of 2.1 percent and government hospitals would experience an estimated increase of 2.1 percent.

Column 7: 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 2.1 percent OPD fee schedule increase factor, and the non-budget 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 6). This column differs from Column 6 solely based on application of the non-budget neutral frontier State wage index adjustment.

In general, we estimate that all facilities and all hospitals would experience a combined increase of 0.1 percent due to the frontier wage index. The index would only affect hospitals in the West North Central and Mountain regions. Urban hospitals in those regions would experience increases of 0.9 percent (West North Central) and 0.4 percent (Mountain) that are attributable to the frontier wage index, and rural hospitals would experience increases of 1.1 percent (West North Central) and 2.2 percent (Mountain) that are attributable to the frontier State wage index.

Column 8: All Proposed Changes for CY 2013

Column 8 depicts the full impact of the proposed CY 2013 policies on each hospital group by including the effect of all the proposed changes for CY 2013 and comparing them to all estimated payments in CY 2012. Column 8 shows the combined budget neutral effects of Columns 2 through 5; the proposed OPD fee schedule increase; the impact of the frontier State wage index adjustment; the proposed change in the fixed-dollar outlier threshold from $2,025 to $2,400 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 XV. of this proposed rule); and the impact of increasing the estimate of the percentage of total OPPS payments dedicated to transitional pass-through payments. Of the 101 hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2012 update (and assumed, for modeling purposes, to be the same number for CY 2013), we included 9 hospitals in our model because they had both CY 2011 claims data and recent cost report data. We estimate that the cumulative effect of all proposed changes for CY 2013 would increase payments to all providers by 2.1 percent for CY 2013. We modeled the independent effect of all proposed changes in Column 8 using the final relative payment weights for CY 2012 and the proposed relative payment weights for CY 2013. We used the final conversion factor for CY 2012 of $70.016 and the proposed CY 2013 conversion factor of $71.537 discussed in section II.B. of this proposed rule in this model.

Column 8 contains simulated outlier payments for each year. We used the one year charge inflation factor used in the FY 2013 IPPS/LTCH PPS proposed rule of 6.80 percent (1.0680) to increase individual costs on the CY 2011 claims, and we used the most recent overall CCR in the April 2012 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2012. Using the CY 2011 claims and a 6.80 percent charge inflation factor, we currently estimate that outlier payments for CY 2012, using a multiple threshold of 1.75 and a proposed fixed-dollar threshold of $2,025 should be approximately 1.03 percent of total payments. The estimated current outlier payments of 1.03 percent are incorporated in the CY 2013 comparison in Column 8. We used the same set of claims and a charge inflation factor of 14.06 percent (1.1406) and the CCRs in the April 2012 OPSF, with an adjustment of 0.9790, to reflect relative changes in cost and charge inflation between CY 2011 and CY 2013, to model the proposed CY 2013 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a proposed fixed-dollar threshold of $2,400.

We estimate that the anticipated change in payment between CY 2012 and CY 2013 for the hospitals failing to meet the Hospital OQR Program requirements would be negligible. Overall, we estimate that facilities would experience an increase of 2.1 percent under this proposed rule in CY

2013 relative to total spending in CY 2012. This projected increase (shown in Column 8) of Table 45 reflects the proposed 2.1 percent OPD fee schedule increase factor, with proposed 0.04 percent for the change in the pass-through estimate between CY 2012 and CY 2013, less 0.03 percent for the difference in estimated outlier payments between CY 2012 (1.03 percent) and CY 2013 (1.0 percent), less 0.04 percent due to the section 508 wage adjustment, less 0.1 percent due to the frontier adjustment in CY 2012, plus 0.1 percent due to the proposed frontier State wage index adjustment. When we exclude cancer and children's hospitals (which are held harmless to their pre-BBA amount) and CMHCs, the estimated increase continues to be 2.1 percent after rounding. We estimate that the combined effect of all proposed changes for CY 2013 would increase payments to urban hospitals by 2.1 percent, with large urban hospitals experiencing an estimated 2.2 percent increase and ''other'' urban hospitals experiencing an estimated 1.9 percent increase. We estimate that urban hospitals that bill less than 5,000 lines of OPPS services would experience an increase of 6.0 percent, largely attributable to the proposed increase in payment for partial hospitalization and group psychotherapy services furnished in the hospital. We estimate that urban hospitals that bill 11,000 or more lines of OPPS services would experience increases between 1.9 percent and 3.0 percent, while urban hospitals that report between 5,000 and 10,999 lines would experience an increase of 4.2 percent.

Overall, we estimate that rural hospitals would experience a 2.2 percent increase as a result of the combined effects of all proposed changes for CY 2013. We estimate that rural hospitals that bill less than 5,000 lines of OPPS services would experience an increase of 4.2 percent and that rural hospitals that bill 5,000 or more lines of OPPS services would experience increases ranging from 2.2 to 2.8 percent.

Among teaching hospitals, we estimate that the impacts resulting from the combined effects of all proposed changes would include an increase of 2.0 percent for major teaching hospitals and 2.3 percent for nonteaching hospitals. Minor teaching hospitals would experience an increase of 1.9 percent.

In our analysis, we also have stratified hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 2.0 percent, proprietary hospitals would experience an increase of 2.3 percent, and governmental hospitals would experience an increase of 2.1 percent.

TABLE 45—ESTIMATED IMPACT OF THE PROPOSED CY 2013 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM

	Number of hospitals	APC recalibration (median)	Impact of basing weights using geometric mean	APC recalibration (Geo mean)	New wage index and provider adjustments	Combine (cols 4, 5) with market basket update	Column 6 with frontier wage index adjustment	All changes
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
ALL FACILITIES*	4,070	0.0	0.0	0.0	0.0	2.1	2.2	2.1
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,853	0.0	0.0	0.0	0.0	2.1	2.2	2.1
URBAN HOSPITALS	2,907	−0.1	0.0	−0.1	0.0	2.1	2.2	2.1
LARGE URBAN (GT 1 MILL.)	1,592	0.0	0.0	0.0	0.2	2.3	2.3	2.2
OTHER URBAN (LE 1 MILL.)	1,315	−0.1	0.0	−0.1	−0.2	1.9	2.1	1.9
RURAL HOSPITALS	946	0.2	0.1	0.3	−0.2	2.3	2.5	2.2
SOLE COMMUNITY	384	0.3	0.1	0.4	0.0	2.5	3.0	2.5
OTHER RURAL	562	0.1	0.2	0.3	−0.3	2.1	2.1	2.0
BEDS (URBAN)								
0–99 BEDS	1,000	0.4	0.2	0.6	0.0	2.7	2.8	2.8
100–199 BEDS	831	0.1	0.1	0.2	0.1	2.3	2.4	2.3
200–299 BEDS	457	−0.1	0.0	−0.1	0.1	2.0	2.2	2.0
300–499 BEDS	415	−0.2	0.0	−0.2	0.1	2.0	2.1	2.0
500 + BEDS	204	−0.1	−0.1	−0.2	−0.1	1.8	1.8	1.8
BEDS (RURAL)								
0–49 BEDS	353	0.5	0.4	0.9	−0.2	2.8	3.1	2.8
50–100 BEDS	352	0.4	0.1	0.5	−0.1	2.5	2.7	2.4
101–149 BEDS	138	0.0	0.1	0.1	−0.5	1.7	1.9	1.8
150–199 BEDS	55	0.1	0.1	0.2	−0.3	2.1	2.7	2.2
200 + BEDS	48	−0.2	0.0	−0.1	0.3	2.2	2.2	2.1
VOLUME (URBAN)								
LT 5,000 Lines	573	1.9	2.1	4.0	0.2	6.4	6.5	6.0
5,000–10,999 Lines	135	1.2	1.1	2.4	−0.3	4.1	4.5	4.2
11,000–20,999 Lines	213	0.5	0.3	0.8	0.1	3.0	3.0	3.0
21,000–42,999 Lines	474	0.2	0.1	0.3	0.2	2.6	2.7	2.6
42,999–89,999 Lines	698	−0.1	0.0	0.0	0.1	2.2	2.2	2.1
GT 89,999 Lines	814	−0.1	0.0	−0.2	0.0	2.0	2.1	1.9
VOLUME (RURAL)								
LT 5,000 Lines	63	1.4	1.1	2.5	−0.3	4.3	7.2	4.2
5,000–10,999 Lines	69	0.2	0.7	1.0	−0.9	2.2	2.4	2.2
11,000–20,999 Lines	157	0.3	0.6	0.9	−0.2	2.8	3.1	2.8
21,000–42,999 Lines	292	0.4	0.2	0.6	−0.3	2.4	2.7	2.4
GT 42,999 Lines	365	0.1	0.1	0.2	−0.1	2.2	2.4	2.2
REGION (URBAN)								
NEW ENGLAND	148	0.2	0.0	0.2	−1.2	1.1	1.1	1.1
MIDDLE ATLANTIC	345	−0.1	−0.1	−0.2	−0.2	1.8	1.8	1.6
SOUTH ATLANTIC	450	−0.1	−0.1	−0.1	−0.4	1.5	1.5	1.6
EAST NORTH CENT	469	−0.1	0.0	−0.1	0.3	2.3	2.3	2.2
EAST SOUTH CENT	173	−0.2	−0.1	−0.3	−0.7	1.1	1.1	1.1
WEST NORTH CENT	185	0.0	0.0	0.1	0.5	2.7	3.6	2.8
WEST SOUTH CENT	494	−0.1	0.1	0.0	−0.2	1.9	1.9	2.0

TABLE 45—ESTIMATED IMPACT OF THE PROPOSED CY 2013 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM—Continued

	Number of hospitals	APC recalibration (median)	Impact of basing weights using geometric mean	APC recalibration (Geo mean)	New wage index and provider adjustments	Combine (cols 4, 5) with market basket update	Column 6 with frontier wage index adjustment	All changes
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
MOUNTAIN	203	0.1	0.0	0.1	−0.1	2.1	2.5	2.1
PACIFIC	393	−0.2	0.1	0.0	1.6	3.6	3.6	3.5
PUERTO RICO	47	0.3	0.1	0.3	0.3	2.7	2.7	2.8
REGION (RURAL)								
NEW ENGLAND	25	0.4	0.0	0.4	0.4	2.9	2.9	2.8
MIDDLE ATLANTIC	67	0.3	0.0	0.3	0.2	2.6	2.6	2.4
SOUTH ATLANTIC	161	0.0	0.1	0.2	−0.4	1.9	1.9	1.9
EAST NORTH CENT	126	0.2	0.1	0.3	0.3	2.7	2.7	2.5
EAST SOUTH CENT	174	−0.1	0.1	0.0	−0.3	1.7	1.7	1.8
WEST NORTH CENT	99	0.4	0.1	0.5	−0.3	2.3	3.4	2.3
WEST SOUTH CENT	200	0.3	0.4	0.8	−0.3	2.6	2.6	2.6
MOUNTAIN	65	0.4	0.0	0.4	0.1	2.6	4.8	2.9
PACIFIC	29	0.4	0.1	0.5	−0.9	1.7	1.7	1.6
TEACHING STATUS								
NON-TEACHING	2,878	0.0	0.1	0.1	0.0	2.3	2.4	2.3
MINOR	687	−0.1	0.0	−0.2	−0.1	1.9	2.1	1.9
MAJOR	288	0.0	−0.1	−0.1	0.1	2.1	2.1	2.0
DSH PATIENT PERCENT								
0	17	0.9	−0.1	0.8	−0.1	2.8	2.8	2.9
GT 0–0.10	365	0.1	−0.1	0.0	0.0	2.1	2.2	2.1
0.10–0.16	375	0.1	0.0	0.0	−0.1	2.0	2.1	1.9
0.16–0.23	742	0.0	0.0	0.0	0.0	2.1	2.3	2.0
0.23–0.35	1,018	−0.1	0.0	−0.1	0.0	2.0	2.1	2.0
GE 0.35	748	−0.1	0.1	0.0	0.1	2.2	2.2	2.1
DSH NOT AVAILABLE **	588	2.1	4.0	6.1	0.0	8.3	8.3	8.2
URBAN TEACHING/DSH								
TEACHING & DSH	886	−0.1	−0.1	−0.1	0.0	1.9	2.0	1.9
NO TEACHING/DSH	1,453	0.0	0.0	0.0	0.1	2.2	2.3	2.2
NO TEACHING/NO DSH	17	0.9	−0.1	0.8	−0.1	2.8	2.8	2.9
DSH NOT AVAILABLE **	551	2.1	3.7	5.9	0.1	8.1	8.1	8.0
TYPE OF OWNERSHIP								
VOLUNTARY	2,042	0.0	0.0	−0.1	0.0	2.1	2.2	2.0
PROPRIETARY	1,254	0.0	0.2	0.2	0.0	2.3	2.4	2.3
GOVERNMENT	557	0.0	0.0	0.1	−0.1	2.1	2.1	2.1
CMHCs	154	0.8	−6.9	−6.2	−0.4	−4.4	−4.4	−4.4

Column (1) shows total hospitals and/or CMHCs.

Column (2) shows the impact of changes resulting from the reclassification of HCPCS codes among APC groups, the use of median costs in developing relative payment weights, and the proposed recalibration of APC weights based on CY 2011 hospital claims data.

Column (3) shows the estimated impact of basing the CY 2013 OPPS proposed payments on geometric mean costs, by comparing estimated CY 2013 payments under the proposal for a geometric mean cost based system to those under a median based OPPS.

Column (4) shows the impact of changes resulting from the reclassification of HCPCS codes among APC groups, the use of geometric mean costs in developing the CY 2013 proposed OPPS relative payment weights, and the proposed recalibration of APC weights based on CY 2011 hospital claims data.

Column (5) shows the budget neutral impact of updating the wage index by applying the FY 2013 hospital inpatient wage index. The rural adjustment is 7.1 percent in both years so its budget neutrality factor is 1. Similarly, the differential in estimated cancer hospital payments for the proposed adjustment is minimal and thus results in a budget neutrality factor of 1.

Column (6) shows the impact of all budget neutrality adjustments and the proposed addition of the 2.1 percent OPD fee schedule increase factor (3.0 percent reduced by 0.8 percentage points for the proposed productivity adjustment and further reduced by 0.1 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).

Column (7) shows the non-budget neutral impact of applying the frontier State wage adjustment in CY 2013, after application of the CY 2013 proposed OPD fee schedule increase factor.

Column (8) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adds estimated outlier payments. This column also shows the expiration of section 508 wages on March 30, 2012, and the application of the frontier State wage adjustment for CY 2012 and 2013.

* These 4,070 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

(3) Estimated Effects of Proposed OPPS Changes on CMHCs

The last line of Table 45 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2012, CMHCs are paid under two APCs for these services: APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs) and APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs). In contrast, hospitals are paid for partial hospitalization services under APC 0175 (Level I Partial Hospitalization (3 services) for hospital-based PHPs) and APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). We first implemented these four APCs for CY 2011. We adopted payment rates for each APC based on the cost data derived from claims and cost reports for the provider type to which the APC is specific and provided a transition to CMHC rates based solely on CMHC data for the two CMHC PHP per diem rates. For CY 2013, we are proposing to continue the provider-specific APC structure that we adopted for CY 2011 and to base payment fully on the data for the type of provider furnishing the service. We modeled the impact of this APC policy assuming that CMHCs will continue to provide the same number of days of PHP care, with each day having either 3 services or 4 or more services, as seen in the CY 2011 claims data used for this proposed rule. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the

beneficiary. Because the relative payment weights for APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs) decline in CY 2013 using geometric mean-based relative payment weights as opposed to median-based relative payment weights, we estimate that there would be a 4.4 percent decrease in payments to CMHCs (shown in Columns 3 and 4).

Column 5 shows that the estimated impact of adopting the proposed CY 2013 wage index values would result in a small decrease of 0.4 percent to CMHCs. We note that all providers paid under the OPPS, including CMHCs, would receive a proposed 2.1 percent OPD fee schedule increase factor. Column 6 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2013 and the proposed CY 2013 wage index updates, results in an estimated decrease of 4.4 percent. Column 7 shows that adding the proposed frontier State wage adjustment would result in no change to the cumulative 4.4 percent decrease. Column 8 shows that adding the proposed changes in outlier and pass-through payments would result in no change to the 4.4 percent decrease in payment for CMHCs. This reflects all proposed changes to CMHCs for CY 2013.

(4) Estimated Effect of Proposed OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary share of payment would increase for services for which the OPPS payments would rise and would decrease for services for which the OPPS payments would fall. For example, for a service assigned to Level IV Needle Biopsy/Aspiration Except Bone Marrow (APC 0037) in the CY 2012 OPPS, the national unadjusted copayment is $227.35, and the minimum unadjusted copayment is $215.00, 20 percent of the national unadjusted payment rate of $1,074.99. For CY 2013, the proposed national unadjusted copayment for APC 0037 is $227.35, the same amount as the national unadjusted copayment in effect for CY 2012. The proposed minimum unadjusted copayment for APC 0037 is $224.34 or 20 percent of the proposed CY 2013 national unadjusted payment rate for APC 0037 of $1,121.70. The minimum unadjusted copayment would increase for CY 2013 compared to CY 2012 because the payment rate for APC 0037 would increase for CY 2013. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.H. of this 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 2012 hospital inpatient deductible is $1,156. The amount of the CY 2013 hospital inpatient deductible is not available at the time of publication of this 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 2011 claims. We estimate, using the claims of the 4,070 hospitals and CMHCs on which our modeling is based, that total beneficiary liability for copayments would decrease as an overall percentage of total payments, from 22.1 percent in CY 2012 to 21.6 percent in CY 2013 due largely to changes in service-mix.

(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 XIV. 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 $700 million in additional program payments for OPPS services furnished in CY 2013. The effect on the Medicaid program is expected to be limited to increased copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We refer readers to our discussion of the impact on beneficiaries in section XXII.A. of this 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 Our Proposal To Base the APC Relative Payment Weights on Geometric Mean Costs Rather Than Median Costs

As described in section II.A.2.f. of this proposed rule, we are proposing to base the CY 2013 relative payment weights on which OPPS payments are calculated using geometric mean costs rather than median costs. We are proposing to establish this policy based on public stakeholder comments, the improvements we have made to the data process to obtain more data and additional accuracy in estimating cost, and the other reasons described in the geometric mean based relative payment weights section.

In developing this proposal, we considered another alternative, which was to continue basing the relative payment weights based on median costs. As discussed in the geometric mean based weights section, medians have historically served as a good measure of central tendency and continue to do so. In the initial establishment of the OPPS, we selected medians as the measure of central tendency on which to base the weights for a number of reasons. Those included statistical bases such as medians' resistance to outlier observations and their impact as well as reasons surrounding the practical implementation of the OPPS as a new payment system. While some of those reasons for selecting medians continue to apply, others are now less relevant because of changes we have made in our data process, or no longer apply because of factors such as actual development of a working payment system. We have made a number of changes to the OPPS to address some of the challenges in arriving at better estimates of service cost, including trims, more specific application of cost to charge ratios in estimating cost, modeling changes to better simulate payment mechanisms, and methods of obtaining additional claims data through what is already available such as the bypass list.

We believe that those changes have helped to improve the relative costs on which the payment system is based. We also believe that geometric mean costs would better incorporate the range of costs associated with providing a service, and thus would represent one such additional improvement. Therefore, in order to improve the accuracy at which we arrive at service costs used to set relative payment weights, to be responsive to stakeholder concerns regarding the degree to which OPPS payment appropriately reflects service cost, and the other reasons described in section II.A.2.f of this proposed rule, we are proposing to establish the CY 2013 OPPS relative payment weights based on geometric means rather than continuing our historical practice of modeling costs using median costs.

• Alternatives Considered for Payment of Drugs and Biologicals That Do Not Have Pass-Through Status

We are proposing to pay for separately payable drugs and biologicals at ASP+6 percent, based on section 1833(t)(14)(A)(iii)(II) of the Act, also referred to as the statutory default. As detailed in greater depth in section V.B.3 of this proposed rule, this payment will represent the combined payment for both the acquisition and pharmacy overhead costs of separately payable drugs and biologicals.

We considered three alternatives for payment for drugs and biologicals that do not have pass-through status for CY 2013 (separately payable drugs and biologicals). The first alternative we considered was to use the standard methodology, as described in the CY 2006 OPPS/ASC final rule with comment period (70 FR 68642). We compared the estimated aggregate cost of separately payable drugs and biologicals in our claims data to the estimated aggregate ASP dollars for separately payable drugs and biologicals, using the ASP as a proxy for average acquisition cost, to calculate the estimated percent of ASP that would serve as the best proxy for the combined acquisition and pharmacy overhead costs of separately payable drugs and biologicals, but without redistribution of estimated pharmacy overhead costs. Under this methodology, without a redistribution of overhead costs from packaged drugs to separately payable drugs, using April 2012 ASP information and costs derived from CY 2011 OPPS claims data, we estimated the combined acquisition and overhead costs of separately payable drugs and biologicals to be ASP+0 percent. As discussed in section V.B.3. of this proposed rule, we also determined that the combined acquisition and overhead costs of packaged drugs are 311 percent of ASP.

We did not choose this alternative because we believe that this analysis indicates that hospital charging practices reflected in our standard drug payment methodology have the potential to ''compress'' the calculated costs of separately payable drugs and biologicals to some degree when there is no redistribution of estimated pharmacy overhead costs. Further, we recognize that the attribution of pharmacy overhead costs to packaged or separately payable drugs and biologicals through our standard drug payment methodology of a combined payment for acquisition and pharmacy overhead costs depends, in part, on the treatment of all drugs and biologicals each year under our annual drug packaging threshold. Changes to the packaging threshold may result in changes to payment for the overhead cost of drugs and biologicals that do not reflect actual changes in hospital pharmacy overhead cost for those products.

The second alternative we considered was to propose to continue our overhead adjustment methodology for CY 2013 and redistribute $270 million in overhead costs from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals. Using this approach, we adjusted the CY 2011 pharmacy overhead redistribution amount of $200 million using the PPI for Pharmaceuticals for Human Use, resulting in a redistribution amount of $270 million and a payment rate for separately payable drugs of ASP+6 percent. We did not choose this alternative because of the reasons discussed below and in further detail in section V.B.3 of this proposed rule.

The third option that we considered, and the one that we are proposing for CY 2013, is to pay for separately payable drugs and biologicals administered in the hospital outpatient department, at ASP+6 percent based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act, which requires an alternative methodology for determining payment rates for SCODs wherein, if hospital acquisition cost data are not available, payment shall be equal (subject to any adjustment for overhead costs) to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary. We are proposing that this ASP+6 percent payment amount for separately payable drugs and biologicals represents the combined acquisition and pharmacy overhead payment for drugs and biologicals for CY 2013.

As described in further detail in section V.B.3 of this proposed rule, we chose this alternative because we are uncertain about the full cost of pharmacy overhead and acquisition cost, due to the limitations of the submitted hospital charge and claims data for drugs. We believe that the continued use of our current drug payment methodologies may not appropriately account for average acquisition and pharmacy overhead cost and therefore could result in future payment rates that are not appropriate.

Therefore, we are proposing to pay for separately payable drugs and biologicals based on the statutory default at the physician's office Part B payment rates, as established in 1842(o) and 1847A of the Act, at ASP+6 percent. We believe that paying for separately payable drugs and biologicals at ASP+6 percent based on the statutory default is appropriate at this time as it yields increased predictability in payment for drugs and biologicals under the OPPS while appropriately paying for drugs at a level consistent with payment amounts yielded by our methodology of the past 7 years.

b. Estimated Effects of ASC Payment System Proposals

On August 2, 2007, we published in the **Federal Register** the final rule for the revised ASC payment system, effective January 1, 2008 (72 FR 42470). In that final rule, we adopted the methodologies to set payment rates for covered ASC services to implement the revised payment system so that it would be designed to result in budget neutrality as required by section 626 of Public Law 108–173; established that the OPPS relative payment weights would be the basis for payment and that we would update the system annually as part of the OPPS rulemaking cycle; and provided that the revised ASC payment rates would be phased in over 4 years.

ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIV. of this proposed rule, we set the proposed CY 2013 ASC relative payment weights by scaling the proposed CY 2013 OPPS relative payment weights by the proposed ASC scaler of 0.9331. 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 46 and 47 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which currently is the CPI–U) after application of any quality reporting reduction be reduced by a productivity adjustment. The Affordable Care Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). Because the ASCQR Program would not affect payment rates until CY 2014, there would be no reduction to the CPI–U for failure to meet the requirements of the ASCQR Program for CY 2013. We calculated the proposed CY 2013 ASC conversion factor by adjusting the CY 2012 ASC conversion

factor by 1.0002 to account for changes in the proposed pre-floor and pre-reclassified hospital wage indices between CY 2012 and CY 2013 and by applying the proposed CY 2013 MFP-adjusted CPI–U update factor of 1.3 percent (projected CPI–U update of 2.2 percent minus a projected productivity adjustment of 0.9 percent). The proposed CY 2013 ASC conversion factor is $43.190.

(1) Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2013 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2011 and CY 2013 with precision. We believe that the net effect on Medicare expenditures resulting from the proposed CY 2013 changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

(2) Estimated Effects of ASC Payment System Proposals 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 2013 payments would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the proposed CY 2013 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2011 claims data. Table 46 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2012 payments to estimated CY 2013 payments, and Table 47 shows a comparison of estimated CY 2012 payments to estimated CY 2013 payments for procedures that we estimate would receive the most Medicare payment in CY 2012.

Table 46 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 46.

- Column 1—*Surgical Specialty or Ancillary Items and Services Group* indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—*Estimated CY 2012 ASC Payments* were calculated using CY 2011 ASC utilization (the most recent full year of ASC utilization) and CY 2012 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2012 ASC payments.
- Column 3—*Estimated CY 2013 Percent Change* is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that would be attributable to proposed updates to ASC payment rates for CY 2013 compared to CY 2012.

As seen in Table 46, we estimate that the proposed update to ASC rates for CY 2013 would result in a 1 percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 3 percent increase in aggregate payment amounts for digestive system procedures, and a 5 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 2013 update are variable. For instance, we estimate that, in the aggregate, payment for integumentary system procedures, respiratory system procedures, and cardiovascular systems procedures would decrease by 2 percent, whereas auditory system procedures would increase by 1 percent under the proposed CY 2013 rates.

An estimated increase in aggregate payment for the specialty group does not mean that all procedures in the group would experience increased payment rates. For example, the proposed estimated increase for CY 2013 for nervous system procedures is likely due to an increase in the proposed ASC payment weight for some of the high volume procedures, such as CPT code 63685 (Insrt/redo spine n generator) where estimated payment would increase by 10 percent for CY 2013.

Also displayed in Table 46 is a separate estimate of Medicare ASC payments for the group of separately payable covered ancillary items and services. The payment estimates for the covered surgical procedures include the costs of packaged ancillary items and services. We estimate that aggregate payments for these items and services would remain unchanged for CY 2013.

TABLE 46—ESTIMATED IMPACT OF THE PROPOSED CY 2013 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2013 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical specialty group	Estimated CY 2012 ASC payments (in millions)	Estimated CY 2013 percent change
(1)	(2)	(3)
Total	$3,430	1
Eye and ocular adnexa	1,448	1

TABLE 46—ESTIMATED IMPACT OF THE PROPOSED CY 2013 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2013 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP—Continued

Surgical specialty group	Estimated CY 2012 ASC payments (in millions)	Estimated CY 2013 percent change
(1)	(2)	(3)
Digestive system	715	3
Nervous system	436	5
Musculoskeletal system	430	−1
Genitourinary system	159	0
Integumentary system	129	−2
Respiratory system	45	−2
Cardiovascular system	31	−2
Ancillary items and services	21	0
Auditory system	11	1
Hematologic & lymphatic systems	5	0

Table 47 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 2013. The table displays 30 of the procedures receiving the greatest estimated CY 2012 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2012 program payment.

- Column 1—CPT/*HCPCS code*.
- Column 2—*Short Descriptor* of the HCPCS code.
- Column 3—*Estimated CY 2012 ASC Payments* were calculated using CY 2011 ASC utilization (the most recent full year of ASC utilization) and the CY 2012 ASC payment rates. The estimated CY 2012 payments are expressed in millions of dollars.
- Column 4—*Estimated CY 2013 Percent Change* reflects the percent differences between the estimated ASC payment for CY 2012 and the estimated payment for CY 2013 based on the proposed update.

TABLE 47—ESTIMATED IMPACT OF THE PROPOSED CY 2013 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS code *	Short descriptor	Estimated CY 2012 ASC payments (in millions)	Estimated CY 2013 percent change
(1)	(2)	(3)	(4)
66984	Cataract surg w/iol, 1 stage	$1,076	1
43239	Upper GI endoscopy, biopsy	156	3
45380	Colonoscopy and biopsy	144	3
45385	Lesion removal colonoscopy	92	3
45378	Diagnostic colonoscopy	89	3
66982	Cataract surgery, complex	83	1
64483	Inj foramen epidural l/s	72	6
62311	Inject spine l/s (cd)	68	6
66821	After cataract laser surgery	55	6
63650	Implant neuroelectrodes	39	−1
15823	Revision of upper eyelid	39	−1
G0105	Colorectal scrn; hi risk ind	38	3
64493	Inj paravert f jnt l/s 1 lev	35	6
29827	Arthroscop rotator cuff repr	32	−6
64721	Carpal tunnel surgery	31	0
G0121	Colon ca scrn not hi rsk ind	30	3
29881	Knee arthroscopy/surgery	30	0
63685	Insrt/redo spine n generator	28	10
64590	Insrt/redo pn/gastr stimul	25	10
29880	Knee arthroscopy/surgery	24	0
45384	Lesion remove colonoscopy	23	3
43235	Uppr gi endoscopy diagnosis	23	3
52000	Cystoscopy	19	6
28285	Repair of hammertoe	19	0
62310	Inject spine c/t	18	6
26055	Incise finger tendon sheath	17	−4
29826	Shoulder arthroscopy/surgery	17	0
67042	Vit for macular hole	17	−1
67904	Repair eyelid defect	17	−3
50590	Fragmenting of kidney stone	17	−4

* Note that HCPCS codes we are proposing to delete for CY 2013 are not displayed in this table.

(3) Estimated Effects of ASC Payment System Proposals on Beneficiaries

We estimate that the proposed CY 2013 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 2013. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions would be if the ASC coinsurance amount exceeds the inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the inpatient deductible.) Furthermore, the additions to the ASC list of covered surgical procedures will provide beneficiaries access to more surgical procedures in ASCs. Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the revised ASC payment system, depending on the particular service and the relative payment amounts for that service in the physician's office compared to the ASC. However, for those additional procedures that we are proposing to designate as office-based in CY 2013, the beneficiary coinsurance amount would be no greater than the beneficiary coinsurance in the physician's office because the coinsurance in both settings is 20 percent (except for certain preventive services where the coinsurance is waived in both settings).

(4) Alternative ASC Payment Policies Considered

Alternatives to the changes we are proposing to make to the ASC payment system and the reasons that we have chosen specific options are discussed throughout this proposed rule. Some of the major ASC issues discussed in this proposed rule and the options considered are discussed below.

• Alternatives Considered for the Annual Update to ASC Payments for Inflation

Section 1833(i)(2)(C)(i) of the Act requires that, ''if the Secretary has not updated amounts established'' under the revised ASC payment system in a calendar year, the payment amounts ''shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.'' The statute, therefore, does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually under the revised payment system, we are not compelled to increase the ASC payment amounts by the CPI–U. Nonetheless, we adopted a policy, which we codified at § 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years. While we believe the CPI–U is appropriate to apply to update the ASC payment system, the CPI–U is highly weighted for housing and transportation and may not best reflect inflation in the cost of providing ASC services. Therefore, as alternatives to using the CPI–U to update ASC payment rates for inflation, in developing this proposed rule, we considered using: (1) The hospital market basket, which is used to update OPPS rates for inflation; (2) the PE component of the MEI update, which is used to update the MPFS payment rates for inflation; or (3) the average of the hospital market basket update and the PE component of the MEI update.

We did not select the use of any of the above alternatives to using the CPI–U to update ASC payments for inflation because, until we have more information regarding the cost inputs of ASCs, we are not confident that any of the alternatives are a better proxy for ASC cost inputs than the CPI–U.

• Alternatives Considered for Office-Based Procedures

According to our existing policy for the ASC payment system, we designate as office-based those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years and that we determine are predominantly performed in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure HCPCS code and/or, if appropriate, the clinical characteristics, utilization, and volume of related HCPCS codes. We establish payment for procedures designated as office-based at the lesser of the MPFS nonfacility practice expense payment amount or the ASC rate developed according to the standard methodology of the ASC payment system.

In developing this proposed rule, we reviewed CY 2011 utilization data for all surgical procedures added to the ASC list of covered surgical procedures in CY 2008 or later years and for those procedures for which the office-based designation is temporary in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74406 through 74408). Based on that review and as discussed in section XIV.C.1.b. of this proposed rule, we are proposing to newly designate 6 surgical procedures as permanently office-based, to make temporary office-based designations for 6 procedures in CY 2013 that were designated as temporarily office-based for CY 2012, and to make temporary office-based designations for 2 procedures that are proposed as new ASC covered surgical procedures for CY 2013. We considered two alternatives in developing this policy.

The first alternative we considered was to make no change to the procedure payment designations. This would mean that we would pay for the 6 procedures we proposed to designate as permanently office-based and the 8 procedures we proposed to designate as temporarily office-based at an ASC payment rate calculated according to the standard ratesetting methodology of the ASC payment system. We did not select this alternative because our analysis of the data and our clinical review indicated that all 6 procedures we proposed to designate as permanently office-based, as well as the 8 procedures that we proposed to designate temporarily as office-based, are considered to be predominantly performed in physicians' offices. Consistent with our final policy adopted in the August 2, 2007 final rule (72 FR 42509 through 42513), we were concerned that making payments at the standard ASC payment rate for the 6 procedures we proposed to designate as permanently office-based and the 8 procedures we proposed to designate as temporarily office-based could create financial incentives for the procedures to shift from physicians' offices to ASCs for reasons unrelated to clinical decisions regarding the most appropriate setting for surgical care. Further, consistent with our policy, we believe that when adequate data become available to make permanent determinations about procedures with

temporary office-based designations, maintaining the temporary designation is no longer appropriate.

The second alternative we considered and the one we are proposing for CY 2013 is to designate 6 additional procedures as permanently office-based for CY 2013 and to designate 8 procedures as temporarily office-based in CY 2013. We chose this alternative because our claims data and clinical review indicate that these procedures would be considered to be predominantly performed in physicians' offices. We believe that designating these procedures as office-based, which results in the CY 2013 ASC payment rate for these procedures potentially being capped at the CY 2013 physicians' office rate (that is, the MPFS nonfacility practice expense payment amount), if applicable, is an appropriate step to ensure that Medicare payment policy does not create financial incentives for such procedures to shift unnecessarily from physicians' offices to ASCs, consistent with our final policy adopted in the August 2, 2007 final rule.

c. Effects of the Proposed Revisions to the QIO Regulations

In section XVIII. of this proposed rule, we discuss our proposed changes to the QIO program regulations, including: Adding provisions for processing beneficiary complaints that will give beneficiaries more information about the QIO's review process, which includes a new alternative dispute resolution option (immediate advocacy); giving QIOs the authority to send and receive secure transmissions of electronic versions of health information; conveying beneficiaries the right to authorize the QIOs' use and disclosure of confidential information; and removing outdated regulatory provisions that will enable QIOs to give more information regarding the results of reviews. We believe the proposed changes will improve the QIO program, give beneficiaries better information regarding review activities and reduce burden for both providers and practitioners.

The QIO program requests approximately 62,400 medical records each year for the Hospital IQR and Hospital OQR Programs combined (38,400 for inpatient and 24,000 for outpatient). For the Hospital IQR Program, the average number of pages per medical record is 289 pages, and for the Hospital OQR Program, the average number of pages is 74. Reimbursement is made at a rate of $0.12 per page for PPS hospitals, which includes the costs of toner, paper, and labor associated with the copying of paper medical records. We also note that the labor associated with copying the medical records can be considerable. In fact, many providers and practitioners store health information electronically, and these same providers and practitioners are forced to print hard copies of the information for shipment to the QIOs. Sometimes this may entail using the ''print screen'' function to create the record to be shipped. On average, the cost of shipping the records is approximately $32.35 per shipment, with approximately 5,200 shipments being made. The shipping amount takes into consideration that, for some QIO review activities, multiple records are shipped at one time, which can involve the use of several boxes.

Under our proposal, by example, assuming all hospitals operate under a PPS, should all hospitals transfer health information on a digital versatile device (DVD), the costs associated with the toner and paper would be replaced by the costs of a DVD. In fact, numerous medical records could be copied to a single DVD. Moreover, the labor in copying the records would be substantially reduced because, for example, rather than copying the average 289 pages related to a Hospital IQR Program review, the file could be electronically transferred to a DVD for shipping. We estimate that the $0.12 per page rate could be reduced by as much as $0.07 per page. Based on the overall average number of pages for the Hospital IQR Program and Hospital OQR Program, respectively, reducing the per page rate to $0.05 per page would save $901,152 ((11,097,600 pages × $0.12 = $1,331,712) + (1,776,000 pages × $0.12 = $213,120) − (11,097,600 pages × $0.05 = $554,880) − (1,776,000 pages × $0.05 = $88,800)).

The proposed changes also would reduce the costs associated with mailing the records. For the Hospital IQR Program, hospitals sometimes need to ship as many as four or five large boxes of medical records. By comparison, a single DVD can house multiple medical records and even if multiple DVDs were required, all the DVDs could be mailed in a single envelope at a significantly lower costs. Potentially, the per envelope mailing cost could be as low as $5 compared to the per shipment average cost of $32.35. Thus, if all records were shipped on DVDs, the program would save $142,220 ($168,220 − $26,000).

The proposed changes allowing the sending and receiving of electronic versions of health information also would reduce costs for other QIO review activities. QIOs request approximately 100,000 medical records in completing other review activities, including but not limited to requests related to the processing of general quality of care reviews, written beneficiary complaint reviews, medical necessity reviews, and expedited discharge appeal reviews. The average number of pages associated with each of these reviews varies greatly, and we have estimated an overall average of approximately 175 pages per request. The reimbursement rate for requests associated with these activities is $0.12 per page for PPS providers and $0.15 per page for practitioners and non-PPS providers. Assuming an overall average number of 175 pages for each record, we estimate that the total number of pages requested is approximately 17,500,000. Assuming that approximately 75 percent (13,125,000) of the pages are from practitioners and non-PPS providers, with the remaining 25 percent (4,375,000) from PPS providers, based on the $0.12 or $0.15 per page reimbursement rate, we estimate that the total costs would be approximately $1,968,750 and $525,000, respectively. If all these requests were fulfilled using a DVD or other electronic means, we estimate that the cost per page could be reduced to approximately $0.05 per page for PPS providers and $0.06 per page for practitioners and non-PPS providers. Thus, the estimated savings related to PPS providers would be approximately $306,250 ($525,000 − $218,750) and the estimated savings related to practitioners and non-PPS providers would be approximately $1,181,250 ($1,968,750 − $787,500).

With regard to mailing, we also believe the proposed changes would significantly reduce the costs for other QIO review activities. Moreover, unlike the Hospital IQR and Hospital OQR Programs, the number of medical records requested for these other QIO review activities more closely mirrors the actual number of shipments made. For example, on average, the QIOs request 100,000 medical records related to these other activities, and we estimate that this equates to approximately 82,000 shipments. We estimate that there is a corresponding decrease in the cost per shipment ($7 per shipment compared to $32.35 per shipment for the Hospital IQR and OQR Programs). If DVDs were used instead of paper copies of the medical records, we estimate saving of $164,000 (82,000 × $7 − 82,000 × $5).

Beginning with the QIOs' most recent scope of work, which began August 1, 2011, QIOs began offering immediate advocacy to Medicare beneficiaries for the resolution of certain types of oral complaints. We believe that cost savings

will be realized as a result. In developing this new proposed process, we had several goals. One of these goals was to create a way for Medicare beneficiaries to obtain resolutions of complaints much faster than the traditional peer review process, which usually take over 158 days to complete because, inevitably, various timeframes throughout the review process are not met (for example, providers and practitioners sometimes take more time that allowed to respond to medical record requests or the opportunity for discussion). By comparison, we believe that immediate advocacy normally can be completed within 2 calendar days. However, this proposed process could result in reductions of more than merely a reduction in days. Because immediate advocacy is completed without reviewing a beneficiary's medical record, QIOs would save the costs associated with requesting the records, which includes the labor, supplies (toner and paper), and mailing of the records. Moreover, although there may be some variation among QIOs, immediate advocacy would typically be carried out by a nurse or social worker, and, thus, the QIO can avoid the more expensive costs associated with the use of a physician reviewer.

In addition, for a traditional complaint review, the QIO's peer reviewer completes three separate and distinct reviews (the interim initial determination, the final initial determination, and the reconsideration determination), each time reviewing the medical information and providing his/her conclusion about the quality of care provided. Moreover, the provider and/or practitioner who is the subject of the complaint will be brought into the complaint process each time to respond to the conclusions. With immediate advocacy, the nurse or social work would be involved once, early in the process, with the primary role being to listen to the beneficiary's concerns and then coordinate a resolution with the provider or practitioner, instead of merely reviewing information contained in the beneficiary's medical information. Not only would this process enable beneficiaries to obtain resolution of complaints quicker, but it would decrease the amount of time and energy practitioners and providers would devote to responding to the complaints. This is especially true for certain types of complaints where the issues involved are not even documented in the medical information the physician reviewers would review in the traditional complaint process. Typically, we have estimated a total cost per case of $960 for each case processed using the traditional peer review process. We estimate that, for those instances where immediate advocacy is used, the average cost per case would be approximately $87. On average, QIOs complete approximately 3,500 complaint reviews each year, and we estimate that approximately 10 percent of these reviews (350) would be resolved using immediate advocacy instead of the traditional peer review process. This would result in savings of $305,550 each year (($960 × 350 = $336,000) − ($87 × 350 = $30,450)).

The technical changes to the QIO regulations under section XVIII.F. of this proposed rule that we are proposing to improve the regulations reflect CMS' commitment to the general principles of the President's Executive Order on Regulatory Reform, Executive Order 13563 (January 18, 2011).

Below is a table summarizing the savings associated with both of these provisions.

Provision	Savings per year
Authority to transmit information electronically	$2,388,622 total per year.
Quality Reporting Information (Copying)	901,152.
Quality Reporting Information (Mailing)	142,220.
Other QIO Activities (Copying)	1,181,250.
Other QIO Activities (Mailing)	164,000.
Immediate Advocacy	305,550 total per year.
Total Savings	2,694,172 per year.

d. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget Web Site at: *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*, we have prepared three accounting statements to illustrate the impacts of this proposed rule. The first accounting statement, Table 48 below, illustrates the classification of expenditures for the CY 2013 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2013 OPD fee schedule increase, based on the FY 2013 President's Budget. The second accounting statement, Table 49 below, illustrates the classification of expenditures associated with the proposed 1.3 percent CY 2013 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs in the FY 2013 President's Budget. The third accounting statement, Table 50 below, illustrates the estimated impact based on the proposed provisions allowing QIOs to securely send and receive electronic versions of health information as well as the use of alternative dispute resolution process called immediate advocacy. Lastly, the three tables classify all estimated impacts as transfers.

TABLE 48—ACCOUNTING STATEMENT: CY 2013 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2012 TO CY 2013 ASSOCIATED WITH THE PROPOSED CY 2013 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$700 million.
From Whom to Whom	Federal Government to outpatient hospitals and other providers who received payment under the hospital OPPS.
Total	$700 million.

TABLE 49—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2012 TO CY 2013 AS A RESULT OF THE PROPOSED CY 2013 UPDATE TO THE REVISED ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$40 million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.
Total	$40 million.

TABLE 50—ACCOUNTING STATEMENT: CY 2013 ESTIMATED SAVINGS TO MEDICARE FROM THE PROPOSED REVISIONS OF THE QIO REGULATIONS

Category	Transfers
Annualized Monetized Transfers	−$2.7 million.
From whom to Whom	Federal Government to Medicare Providers.
Total	−$2.7 million.

e. Effects of Proposed Requirements for the Hospital OQR Program

In section XVI. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68758 through 68781), section XVI. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60629 through 60655), section XVI. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72110), and section XVI. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74451 through 74492), we discussed the requirements for subsection (d) hospitals to report quality data under the Hospital OQR Program in order to receive the full OPD fee schedule increase factor for CY 2010, CY 2011, and CYs 2012 through 2014, respectively. In section XV. of this proposed rule, we are proposing to adopt additional policies affecting the Hospital OQR Program.

We determined that 114 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor for CY 2012. Most of these hospitals (106 of the 114) received little or no OPPS payment on an annual basis and did not participate in the Hospital OQR Program. We estimate that 106 hospitals may not receive the full OPD fee schedule increase factor in CY 2014. We are unable at this time to estimate the number of hospitals that may not receive the full OPD fee schedule increase factor in CY 2015.

In section XVI.E.3.a. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60647 through 60650), for the CY 2011 payment update, as part of the validation process, we required hospitals to submit paper copies of requested medical records to a designated contractor within the required timeframe. Failure to submit requested documentation could result in a 2.0 percentage point reduction to a hospital's CY 2011 OPD fee schedule increase factor, but the failure to attain a validation score threshold would not.

In section XVI.D.3.b of the CY 2011 OPPS/ASC final rule with comment period, we finalized our proposal to validate data submitted by 800 hospitals of the approximately 3,200 participating hospitals for purposes of the CY 2012 Hospital OQR Program payment determination. We stated our belief that this approach was suitable for the CY 2012 Hospital OQR Program because it would: Produce a more reliable estimate of whether a hospital's submitted data have been abstracted accurately; provide more statistically reliable estimates of the quality of care delivered in each selected hospital as well as at the national level; and reduce overall hospital burden because most hospitals would not be selected to undergo validation each year. We adopted a threshold of 75 percent as the threshold for the validation score because we believed this level was reasonable for hospitals to achieve while still ensuring accuracy of the data. Additionally, this level is consistent with what we adopted in the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program)) (75 FR 50225 through 50229). As a result, we believed that the effect of our validation process for CY 2012 would be minimal in terms of the number of hospitals that would not meet all program requirements.

In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to validate data submitted by up to 500 of the approximately 3,200 participating hospitals for purposes of the CY 2013 Hospital OQR Program payment determination. Under our policy for CY 2011, CY 2012, and CY 2013, we stated that we would conduct a measure level validation by assessing whether the measure data submitted by the hospital matches the independently reabstracted measure data.

In this proposed rule, for CY 2014 and subsequent years payment determinations, we are proposing some modifications to administrative requirements in extending a deadline to submit a Notice of Participation as well as to extraordinary circumstance waiver or extension and reconsideration processes to broaden the scope of personnel who can sign these requests. However, we are not proposing any modifications to our validation requirements. We expect these proposals to have minimal impact on the program.

As stated above, we are unable to estimate the number of hospitals that may not receive the full OPD fee schedule increase factor in CY 2015. We also are unable to estimate the number of hospitals that would fail the validation documentation submission requirement for the proposed CY 2015 payment update.

The validation requirements for CY 2014 would result in medical record documentation for approximately 6,000 cases per quarter for CY 2014, being submitted to a designated CMS contractor. We will pay for the cost of sending this medical record documentation to the designated CMS contractor at the rate of 12 cents per page for copying and approximately $1.00 per case for postage. We have found that an outpatient medical chart is generally up to 10 pages. Thus, as a result of validation requirements effective for CY 2014, we estimate that we will have expenditures of approximately $13,200 per quarter for CY 2014. Because we will pay for the

data collection effort, we believe that a requirement for medical record documentation for 7,300 total cases for up to 500 hospitals for CY 2014 represents a minimal burden to Hospital OQR Program participating hospitals.

We are proposing to maintain a 45-day timeframe for hospitals to submit requested medical record documentation to meet our validation requirement. The total burden would be a maximum of 12 charts for each of the four quarters that must be copied and mailed within a 45-day period after the end of each quarter.

f. Effects of the Proposed EHR Electronic Reporting Pilot

Under section XV.K. of this proposed rule, we are proposing to allow eligible hospitals and CAHs that are participating in the EHR Incentive Program to meet the CQM reporting requirement of the program for payment year 2013 by participating in the Medicare EHR Incentive Program Electronic Reporting Pilot. This proposal would facilitate the use of an electronic infrastructure that supports the use of EHRs by hospitals and CAHs to meet the requirements in various CMS programs and reduce reporting burden simultaneously. Through this pilot, we have encouraged hospitals and CAHs to take steps toward the adoption of EHRs that will allow for reporting of clinical quality data from EHRs to a CMS data repository. We expect that the submission of quality data through EHRs will provide a foundation for establishing the capacity of hospitals to send, and for CMS, in the future, to receive, quality measures via hospital EHRs for the Hospital IQR Program's measures. Hospitals that choose to participate in the EHR Incentive Program by means of this pilot for the purpose of meeting the CQM reporting requirement of Meaningful Use will be taking those first steps toward reporting clinical quality data in such a way.

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

g. Effects of Proposals for the ASCQR Program

In section XVI. of this proposed rule, for the ASCQR Program, we are seeking public comment on our approach for future measures selection and development as well as proposing certain measures for future inclusion in the ASCQR Program measure set. For the CY 2015 payment determination and subsequent year payment determinations, we are proposing requirements regarding the dates for submission, payment, and completeness for claims-based measures. We also are proposing how the payment rates would be reduced for ASCs that fail to meet program requirements beginning in CY 2014 and are clarifying our policy on updating measures.

We are unable at this time to estimate the number of ASCs that may not receive the full ASC annual payment update in CYs 2014, 2015, and 2016. However, we do not expect our proposals to significantly affect the number of facilities that do not receive a full annual payment update.

h. Effects of Proposed Updates to the IRF QRP

In section XVII. of this proposed rule, we discuss our proposals to retain the measures that were finalized for the IRF QRP for the previous annual payment determination year, for all subsequent annual payment determination years, unless we propose otherwise. Specifically, we are proposing to apply this policy to the two quality measures that were previously finalized in the FY 2012 IRF PPS final rule. We are proposing to use the CAUTI measure that was previously finalized in the FY 2012 IRF PPS final rule with revisions which were made by the NQF after publication of the FY 2012 IRF PPS final rule. We are proposing to apply the revised CAUTI measure to the 2012 reporting period and each subsequent reporting period thereafter.

These proposed changes would not impose any additional burden on IRFs, nor would they result in any increase in costs.

B. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals, ASCs and CMHCs are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of $34.5 million or less in any single year. Most ASCs and most CMHCs are considered small businesses with total revenues of $10 million or less in any single year. 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 705 small rural hospitals.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $139 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

D. Conclusion

The changes we are proposing will affect all classes of hospitals paid under the OPPS and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS will experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2013. Table 45 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 2.1 percent increase in payments for all services paid under the OPPS in CY 2013, after considering all 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 2013. We estimate that hospitals for whom DSH data are not available (non-IPPS, largely urban hospitals) would experience an increase of 8.2 percent due to increased payments for partial hospitalization, group psychotherapy and hemodialysis

services. CMHCs would see an overall decrease in payment of 4.4 percent as a result of a decrease in their estimated costs.

The proposed updates to the ASC payment system for CY 2013 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 changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 46 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted CPI–U update factor of 1.3 percent for CY 2013.

XXIII. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have examined the OPPS and ASC provisions included in this 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 45 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 2.1 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 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 476

Health care, Health professional, Health record, Peer Review Organization (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 478

Administrative practice and procedure, Health care, Health professions, Peer Review Organizations (PRO), Reporting and recordkeeping requirements.

42 CFR Part 480

Health care, Health professions, Health records, Peer Review Organizations (PRO), Privacy, Reporting and recordkeeping requirements.

42 CFR Part 495

Computer technology, Electronic health records, Electronic transactions, Health, Health care. Health information technology, Health insurance, Health records, Hospitals, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR chapter IV as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

1. The authority citation for Part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and1395hh).

2. Section 416.160 is amended by revising paragraph (a)(1) to read as follows:

§ 416.160 Basis and scope.

(a) * * *

(1) Section 1833(i)(2)(D) of the Act requires the Secretary to implement a revised payment system for payment of surgical services furnished in ASCs. The statute requires that, in the year such system is implemented, the system shall be designed to result in the same amount of aggregate expenditures for such services as would be made if there was no requirement for a revised payment system. The revised payment system shall be implemented no earlier than January 1, 2006, and no later than January 1, 2008. The statute provides that the Secretary may implement a reduction in any annual update for failure to report on quality measures as specified by the Secretary. The statute also requires that, for CY 2011 and each subsequent year, any annual update to the ASC payment system, after application of any reduction in the annual update for failure to report on quality measures as specified by the Secretary, be reduced by a productivity adjustment. There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, of the revised payment system.

* * * * *

3. Section 416.171 is amended by—

a. Redesignating paragraph (a)(2)(iii) as paragraph (a)(2)(iv) and revising the redesignated paragraph (a)(2)(iv).

b. Adding paragraph (a)(2)(iii).

The revision and addition read as follows:

§ 416.171 Determination of payment rates for ASC services.

(a) * * *

(2) * * *

(iii) For CY 2014 and subsequent calendar years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(ii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(iv) *Productivity adjustment.* (A) For calendar year 2011 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(ii) of this section, after application of any reduction under paragraph (a)(2)(iii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(B) The application of the provisions of paragraph (a)(2)(iv)(A) of this section may result in the update being less than zero percent for a year, and may result in payment rates for a year being less than the payment rates for the preceding year.

* * * * *

4. Section 416.195 is amended by revising paragraphs (a)(2) and (a)(4) introductory text, to read as follows:

§ 416.195 Determination of membership in new classes of new technology IOLs.

(a) * * *

(2) The IOL shall have a new lens characteristic in comparison to currently available IOLs. The FDA-approved labeling shall contain a claim of a specific clinical benefit imparted by the new lens characteristic.

* * * * *

(4) Any specific clinical benefit referred to in paragraph (a)(2) of this section must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved outcome. Improved outcomes include:

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

5. The authority citation for Part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395(t), and 1395hh).

6. Section 419.2 is amended by revising paragraph (b) heading and introductory text to read as follows:

§ 419.2 Basis of payment.

* * * * *

(b) *Determination of hospital outpatient prospective payment rates: Packaged costs.* The prospective payment system establishes a national payment rate, standardized for geographic wage differences, that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis. In general, these packaged costs include, but are not limited to, the following items and services, the payments for which are packaged into the payments for the related procedures or services.

* * * * *

7. Section 419.31 is amended by revising paragraphs (a)(1), (b), and (c)(2) to read as follows:

§ 419.31 Ambulatory payment classification (APC) system and payment weights.

(a) * * *

(1) CMS classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. Except as specified in paragraph (a)(2) of this section, items and services within a group are not comparable with respect to the use of resources if the highest geometric mean cost for an item or service within the group is more than 2 times greater than the lowest geometric mean cost for an item or service within the group.

* * * * *

(b) *APC weighting factors.* (1) Using hospital outpatient claims data from calendar year 1996 and data from the most recent available hospital cost reports, CMS determines the geometric mean costs for the services and procedures within each APC group.

(2) CMS assigns to each APC group an appropriate weighting factor to reflect the relative geometric mean costs for the services within the APC group compared to the geometric mean costs for the services in all APC groups.

(c) * * *

(2) CMS standardizes the geometric mean costs determined in paragraph (b)(1) of this section by adjusting for variations in hospital labor costs across geographic areas.

8. Section 419.32 is amended by:

a. Revising paragraph (b)(1)(iv)(A).

b. Removing ''and'' from the end of paragraph (b)(1)(iv)(B)(*2*).

c. Removing the period from the end of paragraph (b)(1)(iv)(B)(*3*) and adding ''; and'' in its place.

d. Adding paragraph (b)(1)(iv)(B)(*4*).

The revision and addition read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv)(A) For calendar year 2003 and subsequent years, by the OPD fee schedule increase factor, which, subject to the adjustments specified in paragraph (b)(1)(iv)(B) of this section and §§ 419.43(h)(1) and (h)(2), if applicable, is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(B) * * *

(*4*) For calendar year 2013, a multifactor productivity adjustment (as determined by CMS) and 0.1 percentage point.

* * * * *

9. Section 419.70 is amended by—

a. Revising paragraph (d)(2) introductory text.

b. Adding paragraph (d)(7).

The revision and addition read as follows:

§ 419.70 Transitional adjustments to limit decline in payments.

* * * * *

(d) * * *

(2) *Temporary treatment for small rural hospitals on or after January 1, 2006.* For covered hospital outpatient services furnished in a calendar year from January 1, 2006 through December 31, 2012, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 95 percent of that difference for services furnished during CY 2006, 90 percent of that difference for services furnished during CY 2007, and 85 percent of that difference for services furnished during CYs 2008, 2009, 2010, 2011, and 2012 if the hospital—

* * * * *

(7) *Temporary treatment of sole community hospitals on or after January 1, 2012 through December 31, 2012.* (i) For covered hospital outpatient services furnished on or after January 1, 2012 through December 31, 2012, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 85 percent of that difference if the hospital—

(A) Is a sole community hospital as defined in § 412.92 of this chapter or is an essential access community hospital as described under § 412.109 of this chapter; and

(B) Has 100 or fewer beds as defined in § 412.105(b) of this chapter, except as provided in paragraph (d)(7)(ii) of this section.

(ii) For covered hospital outpatient services furnished on or after January 1, 2012 through February 29, 2012, the bed size limitation under paragraph (d)(7)(i)(B) of this section does not apply.

* * * * *

PART 476—UTILIZATION AND QUALITY CONTROL REVIEW

10. The authority citation for Part 476 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

11. Section 476.1 is amended by—

a. Removing the definition of ''Active staff privileges''.

b. Adding definitions of ''Appointed representative'', ''Authorized representative'', ''Beneficiary complaint'', ''Beneficiary complaint review'', ''Beneficiary representative'', ''General quality of care review'', ''Gross and flagrant violation'', ''Immediate advocacy'', ''Quality improvement initiative'', ''Quality of care concern'', ''Quality of care review'', ''Significant quality of care concern'', and ''Substantial violation in a substantial number of cases''.

c. Revising the definition of ''Preadmission certification''.

The additions and revisions read as follows:

§ 476.1 Definitions.

* * * * *

Appointed representative means an individual appointed by a Medicare beneficiary to represent the beneficiary in the beneficiary complaint review process.

Authorized representative means an individual authorized, under State or other applicable law, to act on behalf of a Medicare beneficiary. An authorized representative has all of the rights and responsibilities of a Medicare beneficiary throughout the processing of a beneficiary complaint.

Beneficiary complaint means a complaint by a Medicare beneficiary or a Medicare beneficiary's representative alleging that the quality of Medicare covered services received by the beneficiary did not meet professionally recognized standards of care. A complaint may consist of one or more quality of care concerns.

Beneficiary complaint review means a review conducted by a QIO in response to the receipt of a written beneficiary complaint to determine whether the quality of Medicare covered services provided to the beneficiary was consistent with professionally recognized standards of health care.

Beneficiary representative means an individual identified as an authorized or appointed representative of a Medicare beneficiary.

* * * * *

General quality of care review means a review conducted by a QIO to determine whether the quality of Medicare covered services provided to a Medicare beneficiary was consistent with professionally recognized standards of health care. A general quality of care review may be carried out as a result of a referral to the QIO or a QIO's identification of a potential concern during the course of another review activity or through the analysis of data.

Gross and flagrant violation means a violation of an obligation resulting from inappropriate or unnecessary services, services that do not meet recognized professional standards of care, or services that are not supported by evidence of medical necessity or quality as required by the QIO. The violation must have occurred in one or more instances that present an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations.

* * * * *

Immediate advocacy means an informal alternative dispute resolution process used to quickly resolve an oral complaint a Medicare beneficiary or his or her representation has regarding the quality of Medicare covered health care received. This process involves a QIO representative's direct contact with the provider and/or practitioner.

* * * * *

Preadmission certification means a favorable determination, transmitted to the hospital and the fiscal intermediary or the Medicare administrative contractor, approving the patient's admission for payment purposes.

* * * * *

Quality improvement initiative means any formal activity designed to serve as a catalyst and support for quality improvement that uses proven methodologies to achieve these improvements. The improvements may relate to safety, health care, health and value and involve providers, practitioners, beneficiaries, and/or communities.

Quality of care concern means a concern that care provided did not meet a professionally recognized standard of health care. A general quality of care review or a beneficiary complaint review may cover a single or multiple concerns.

Quality of care review means a review conducted by a QIO to determine whether the quality of Medicare covered services provided to beneficiaries was consistent with professionally recognized standards of health care. A quality of care review can either be a beneficiary complaint review or a general quality of care review.

* * * * *

Significant quality of care concern means a determination by the QIO that the quality of care provided to a Medicare beneficiary did not meet the standard of care and, while not a gross and flagrant or substantial violation of the standard, represents a noticeable departure from the standard that could reasonably be expected to have a negative impact on the health of a beneficiary.

Substantial violation in a substantial number of cases means a pattern of providing care that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the QIO.

* * * * *

12. Section 476.70 is revised to read as follows:

§ 476.70 Statutory bases and applicability.

(a) *Statutory bases.* Sections 1154, 1866(a)(1)(F), and 1886(f)(2) of the Act require that a QIO review those services furnished by physicians, other health care professionals, providers and suppliers as specified in its contract with the Secretary.

(b) *Applicability.* The regulations in this subpart apply to review conducted by a QIO and its subcontractors.

13. Section 476.71 is amended by—

a. Revising paragraph (a)(2).

b. In paragraph (b), removing the reference ''§ 405.330(b)'' and adding in its place the reference ''§ 411.400(b) of this chapter''.

c. Revising paragraph (c)(1).

The revisions read as follows:

§ 476.71 QIO review requirements.

(a) * * *

(2) Whether the quality of the services meets professionally recognized standards of health care, as determined through the resolution of oral beneficiary complaints as specified in § 476.110, written beneficiary complaints as specified in § 476.120, or the completion of general quality of care reviews as specified in § 476.160.

* * * * *

(c) * * *

(1) The QIO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare administrative contractor, fiscal intermediary, or carrier if it determines that the information submitted by the hospital was incorrect.

* * * * *

§ 476.72 [Removed]

14. Section 476.72 is removed.

§ 476.73 [Amended]

15. In § 476.73—

a. In paragraph (a), the phrase ''and Medicare fiscal intermediaries and carriers.'' is removed and the phrase '', Medicare administrative contractors, fiscal intermediaries, and carriers.'' is added in its place.

b. In paragraph (b)(1), the reference ''§ 466.78(b)(3) of this part'' is removed and the reference ''§ 476.78(b)(3)'' is added in its place.

§ 476.74 [Amended]

16. In § 476.74—

a. In paragraph (b), the phrase ''appropriate Medicare fiscal intermediary or carrier'' is removed and the phrase ''appropriate Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

b. In paragraph (c)(1), the phrase ''Medicare fiscal intermediaries and

carriers'' is removed, and the phrase ''Medicare administrative contractors, fiscal intermediaries, and carriers'' is added in its place.

c. In paragraph (e), the reference ''§ 405.332'' is removed and the reference ''§ 411.402'' is added in its place.

17. Section 476.78 is amended by—

a. Revising the section heading.

b. Revising paragraphs (b)(2)(i) and (b)(2)(ii).

c. Adding paragraph (b)(2)(iii).

The revisions and addition read as follows:

§ 476.78 Responsibilities of providers and practitioners.

* * * * *

(b) * * *

(2) * * *

(i) Except as provided under §§ 476.130(b) and 476.160(b), relating to beneficiary complaint reviews and general quality of care reviews, photocopy and deliver to the QIO all required information within 30 calendar days of a request.

(ii) Except as provided under §§ 476.130(b) and 476.160(b), relating to beneficiary complaint reviews and general quality of care reviews, deliver all required medical information to the QIO within 21 calendar days from the date of the request in those situations where a potential ''serious reportable event'' has been identified or where other circumstances as deemed by the QIO warrant earlier receipt of all required medical information. For purposes of this paragraph (b)(2)(iii), a ''serious reportable event'' is defined as a preventable, serious and unambiguous adverse event that should never occur.

(iii) Secure transmission of an electronic version of medical information, subject to the QIO's ability to support receipt and transmission of the electronic version. Providers and practitioners must deliver electronic versions of medical information within 10 calendar days of the request.

* * * * *

18. In § 476.80—

a. The section heading is revised to read as set forth below.

b. In paragraphs (b)(1) introductory text and (c)(1) (two places), the phrase ''Medicare fiscal intermediaries and carriers'' is removed and the phrase ''Medicare administrative contractors, fiscal intermediaries, and carriers'' is added in its place.

c. In paragraph (a) introductory text, the phrase ''Medicare fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

d. In paragraphs (a)(1), (a)(2) introductory text (two places), (c)(3)(ii), (d)(1), and (d)(2), the phrase ''fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

e. In paragraph (e), in the paragraph heading and in paragraphs (e)(1) and (e)(2), the phrase ''fiscal intermediary'' is removed and the phrase ''Medicare administrative contractor or fiscal intermediary'' is added in its place.

The revision reads as follows:

§ 476.80 Coordination with Medicare administrative contractors, fiscal intermediaries, and carriers.

* * * * *

§ 476.86 [Amended]

19. In § 476.86—

a. In paragraph (a)(1)(iii), the reference ''§ 405.310(g) or § 405.310(k)'' is removed and the reference ''§ 411.15(g) or § 411.15(k)'' is added in its place.

b. In paragraph (a)(2), the phrase ''Medicare fiscal intermediaries or carriers'' is removed and the phrase ''Medicare administrative contractors, fiscal intermediaries, or carriers'' is added in its place.

c. In paragraph (c) introductory text, the phrase ''Medicare fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

d. In paragraph (c)(1), the phrase ''fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

e. In paragraph (d), the phrase ''Medicare fiscal intermediaries and carriers'' is removed and the phrase ''Medicare administrative contractors, fiscal intermediaries, and carriers'' is added in its place.

f. In paragraph (e), the phrase ''intermediaries and carriers'' is removed and the phrase ''Medicare administrative contractors, fiscal intermediaries, and carriers'' is added in its place.

g. In paragraph (f), the reference ''part 473'' is removed and the reference ''part 478'' is added in its place.

§ 476.94 [Amended]

20. In § 476.94—

a. In paragraph (a)(1)(iv), the phrase ''fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

b. In paragraph (d), the phrase ''Medicare fiscal intermediary or carrier'' is removed and the phrase ''Medicare administrative contractor, fiscal intermediary, or carrier'' is added in its place.

c. In paragraph (c)(3) introductory text, the reference ''part 473'' is removed and the reference ''part 478'' is added in its place.

§ 476.98 [Amended]

21. In § 476.98, in paragraph (a)(1), the phrase ''with active staff privileges in one or more hospitals in the QIO area'' is removed.

22. Section 476.104 is amended by revising paragraph (a) to read as follows:

§ 476.104 Coordination of activities.

* * * * *

(a) Medicare administrative contractors, fiscal intermediaries, and carriers.

* * * * *

23. New §§ 476.110, 476.120, 476.130, 476.140, 476.150, 476.160, 476.170 are added to subpart C to read as follows:

Subpart C—Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations (QIOs)

Sec.

* * * * *

476.110 Use of immediate advocacy to resolve oral beneficiary complaints.

476.120 Submission of written beneficiary complaints.

476.130 Beneficiary complaint review procedures.

476.140 Beneficiary complaint reconsideration procedures.

476.150 Abandoned complaints and reopening rights.

476.160 General quality of care review procedures.

476.170 General quality of care reconsideration procedures.

* * * * *

§ 476.110 Use of immediate advocacy to resolve oral beneficiary complaints.

(a) *Immediate advocacy.* A QIO may offer the option of resolving an oral complaint through the use of immediate advocacy if:

(1) The complaint is received not later than 6 months from the date on which the care giving rise to the complaint occurred.

(2) After initial screening of the complaint, the QIO makes a preliminary determination that—

(i) The complaint is unrelated to the clinical quality of health care itself but relates to items or services that accompany or are incidental to the medical care and are provided by a practitioner and/or provider; or

(ii) The complaint, while related to the clinical quality of health care received by the beneficiary, does not rise to the level of being a gross and flagrant, substantial, or significant quality of care concern.

(3) The beneficiary agrees to the disclosure of his or her name to the involved provider and/or practitioner.

(4) All parties orally consent to the use of immediate advocacy.

(5) All parties agree to the limitations on redisclosure set forth in § 480.107 of this subchapter.

(b) *Discontinuation of immediate advocacy.* The QIO or either party may discontinue participation in immediate advocacy at any time.

(1) The QIO must inform the parties that immediate advocacy will be discontinued; and

(2) The beneficiary must be informed of his or her right to submit a written complaint in accordance with the procedures in § 476.120.

(c) *Confidentiality requirements.* All communications, written and oral, exchanged during the immediate advocacy process must not be redisclosed without the written consent of all parties.

(d) *Abandoned complaints.* If any party fails to participate or otherwise comply with the requirements of the immediate advocacy process, the QIO may determine that the complaint has been abandoned and—

(1) Inform the parties that immediate advocacy will be discontinued; and

(2) Inform the Medicare beneficiary of his or her right to submit a written complaint in accordance with the procedures in § 476.120.

§ 476.120 Submission of written beneficiary complaints.

(a) *Timeframe for submission of written complaints.* A QIO shall be responsible for conducting a review of any written complaint received from a Medicare beneficiary or a Medicare beneficiary's representative about the quality of health care if the complaint is received not later than 3 years from the date on which the care giving rise to the complaint occurred.

(1) A written complaint includes a complaint submitted electronically to the QIO.

(2) In those instances where a Medicare beneficiary contacts the QIO regarding a complaint but declines to submit the complaint in writing and immediate advocacy has not been offered, the QIO may complete a general quality of care review in accordance with § 476.160 if the QIO makes a preliminary determination that the complaint involves a potential gross and flagrant, substantial or significant quality of care concern.

(b) *New concerns raised by a Medicare beneficiary.* If a Medicare beneficiary raises new concerns relating to the same complaint after the completion of the interim initial determination in § 476.130(c), the concerns will be processed as a new complaint. The QIO may process new concerns raised after the receipt of the written complaint as part of the same complaint, provided they are received prior to the completion of the interim initial determination. Even if a concern is received before the interim initial determination, the QIO can address it as a separate complaint if the QIO determines that this is warranted by the circumstances.

§ 476.130 Beneficiary complaint review procedures.

(a) *Scope of the QIO review.* In completing its review, the QIO shall consider any information and materials submitted by the Medicare beneficiary or his or her representative and any information submitted by the provider and/or practitioner. All information obtained by the QIO that fits within the definition of ''confidential information'' under § 480.101 of this chapter, will be held by the QIO as confidential.

(1) The QIO's review will focus on the episode of care from which the complaint arose and address the specific concerns identified by the beneficiary and any additional concerns identified by the QIO. The QIO may separate concerns into different complaints if the QIO determine that the concerns relate to different episodes of care.

(2) The QIO will use evidence-based standards of care to the maximum extent practicable. If no standard of care exists, the QIO will use available norms, best practices and established guidelines to establish the standard that will be used in completing the review. The QIO's determination regarding the standard used is not subject to appeal.

(b) *Medical information requests.* Upon request by the QIO, a provider or practitioner must deliver all medical information requested in response to a Medicare beneficiary complaint within 10 calendar days of the request. A QIO is authorized to require the receipt of the medical information sooner if the QIO make a preliminary determination that the complaint involves a potential gross and flagrant or substantial quality of care concern as specified in 42 CFR Part 1004 and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(c) *Interim initial determination.* The QIO peer reviewer will complete the review and notify the practitioner and/or provider of its interim initial determination within 7 calendar days of the receipt of all medical information.

(1) A practitioner and provider will be notified by telephone of the opportunity to discuss the QIO's interim initial determination with the QIO in those situations where the peer reviewer determines that the quality of services does not meet professionally recognized standards of care for any concern in the complaint. The discussion must be held no later than 7 calendar days from the date of the initial offer.

(2) The interim initial determination becomes the final initial determination if the discussion is not completed timely as a result of the practitioner's and/or provider's failure to respond.

(3) Written statements in lieu of a discussion must be received no later than 7 calendar days from the date of the initial offer.

(4) In rare circumstances, the QIO may grant additional time to complete the discussion or submission of a written statement in lieu of a discussion.

(d) *Final initial determination.* The QIO must issue notification of its final initial determination in those cases in which the QIO has determined that care met professionally recognized standards, as well as in those cases in which the QIO determined that standards were not met and the opportunity for discussion has been completed. No later than 72 hours after completion of its review, or for cases in which the standard was not met, no later than 72 hours after the discussion or receipt of the provider's and/or practitioner's written statement, the QIO will notify (by telephone) the beneficiary and the provider/practitioner of its final initial determination and of the right to request a reconsideration of the QIO's final initial determination.

(1) Written notice of the QIO's final initial determination will be forwarded to all parties, unless either party requests a reconsideration of the final initial determination. If a reconsideration request is submitted, the QIO will notify the parties that a written decision will be issued once the reconsideration review is completed in accordance with § 476.140(b).

(2) If a reconsideration request is not received, the written decision will be issued within 72 hours after the QIO has contacted the parties, as described in

paragraph (d) of this section, and must include:

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns; and

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings, including references to medical information and, if held, the discussion with the involved practitioner and/or provider.

§ 476.140 Beneficiary complaint reconsideration procedures.

(a) *Right to request a reconsideration.* Beginning with complaints filed after July 31, 2014, a Medicare beneficiary, a provider, or a practitioner who is dissatisfied with a QIO's final initial determination may request a reconsideration by the QIO.

(1) The reconsideration request must be received by the QIO, in writing or by telephone, no later than noon of the calendar day following initial notification (whether by telephone or in writing) of the QIO's determination. In rare circumstances, the QIO may grant an additional calendar day. If the QIO is unable to accept a request, the request must be submitted by noon of the next day the QIO is available to accept a request.

(2) The Medicare beneficiary, or his or her representative, and the practitioner and/or provider must be available to answer any questions or supply any information that the QIO requests in order to conduct its reconsideration.

(3) The QIO must offer the Medicare beneficiary and the practitioner and/or provider an opportunity to provide further information. A Medicare beneficiary, a practitioner, and a provider may, but are not required to, submit evidence to be considered by the QIO in making its reconsideration decision.

(b) *Issuance of the QIO's final decision.* No later than 72 hours after receipt of the request for a reconsideration, or, if later, 72 hours after receiving any medical or other records needed for such reconsideration, the QIO must complete the review and notify the beneficiary and the practitioner/provider of its decision.

(1) The QIO's initial notification may be done by telephone, followed by the mailing of a written notice by noon of the next calendar day that includes—

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns;

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings; and

(iv) A statement that the letter represents the QIO's final determination and that there is no right to further appeal.

(2) The QIO may provide information to the beneficiary, practitioner, and provider regarding opportunities for improving the care given to patients based on the specific findings of its review and the development of quality improvement initiatives.

§ 476.150 Abandoned complaints and reopening rights.

(a) *Abandoned complaints.* If a Medicare beneficiary fails to participate or otherwise comply with the requirements of the beneficiary complaint review process and the QIO does not have sufficient information to complete its review, the QIO may determine that the complaint has been abandoned and—

(1) Inform the parties that its complaint review will be discontinued; and

(2) Inform the beneficiary of his or her right to resubmit a written complaint in accordance with the procedures in § 476.120.

(b) *Reopening complaint reviews.* A QIO may reopen a Medicare beneficiary complaint review using the same procedures that the QIO would use for reopening initial denial determinations and changes as a result of DRG validation, as described in § 476.96.

§ 476.160 General quality of care review procedures.

(a) *Scope of the QIO review.* A QIO may conduct a general quality of care review in accordance with section 1154(a)(1)(B) of the Act.

(1) A QIO may conduct general quality of care reviews based on—

(i) Concerns identified during the course of other QIO review activities;

(ii) Referrals from other sources, including but not limited to individuals, contractors, other Federal or State agencies; or

(iii) Analysis of data.

(2) The QIO's review will focus on all concerns identified by the QIO and/or identified by those who have referred or reported the concerns, with consideration being given to the episode of care related to the concerns.

(3) The QIO will use evidence-based standards of care to the maximum extent practicable. If no standard of care exists, the QIO must use available norms, best practices, and established guidelines to establish the standard that will be used in completing the review. The QIO's determination regarding the standard used is not subject to appeal.

(b) *Medical information requests.* Upon request by the QIO, a provider or practitioner must deliver all medical information requested within 10 calendar days of the request. A QIO is authorized to require the receipt of the medical information sooner if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial quality of care concern and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established time frame may result in the QIO taking action pursuant to § 476.90.

(c) *Initial determination.* The QIO peer reviewer will complete the review and notify the practitioner and/or provider within 7 calendar days of the receipt of all medical information.

§ 476.170 General quality of care reconsideration procedures.

(a) *Right to request a reconsideration.* Beginning with reviews initiated after July 31, 2014, a provider or practitioner who is dissatisfied with a QIO's initial determination may request a reconsideration by the QIO.

(1) The reconsideration request must be received by the QIO, in writing or by telephone, by no later than noon of the calendar day following initial notification (whether by telephone or in writing) of the QIO's determination. In rare circumstances, the QIO may grant an additional calendar day. If the QIO is unable to accept the request, the request must be submitted by noon of the next day the QIO is available to accept a request.

(2) The practitioner or provider must be available to answer any questions or supply any information that the QIO requests in order to conduct its reconsideration.

(3) The QIO must offer the practitioner or provider an opportunity to provide further information. A practitioner or provider may, but is not required to, submit evidence to be considered by the QIO in making its reconsideration decision.

(b) *Issuance of the QIO's final decision.* No later than 72 hours after receipt of the request for a reconsideration, or, if later, 72 hours after receiving any medical or other records needed for such reconsideration, the QIO must complete the review and notify the practitioner or provider of its decision.

(1) The QIO's initial notification may be done by telephone, followed by the

mailing of a written notice by noon the next calendar day that includes:

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns;

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings; and

(iv) A statement that the letter represents the QIO's final determination and that there is no right to further appeal.

(2) The QIO may provide information regarding opportunities for improving the care given to patients based on the specific findings of its review.

PART 478—RECONSIDERATIONS AND APPEALS

24. The authority citation for Part 478 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 478.15 [Amended]

25. In § 478.15(b), the reference ''§§ 473.18 through 473.36, and 473.48(a) and (c)'' is removed and the reference ''§§ 478.18 through 478.36 and § 478.48(a) and (c)'' is added in its place.

§ 478.16 [Amended]

26. In § 478.16, the reference ''§ 473.14(a)'' is removed and the reference ''§ 478.14'' is added in its place.

§ 478.20 [Amended]

27. In § 478.20—

a. In paragraph (a)(1), the reference ''§ 473.22'' is removed and the reference ''§ 478.22'' is added in its place.

b. In paragraph (b), the reference ''§ 473.22'' is removed and the reference ''§ 478.22'' is added in its place.

c. In paragraph (c), the reference ''§ 473.18(c)'' is removed and the reference ''§ 478.18(c)'' is added in its place.

§ 478.28 [Amended]

28. In § 478.28 (a), the reference ''§ 466.98'' is removed and the reference ''§ 476.98'' is added in its place.

§ 478.38 [Amended]

29. In § 478.38—

a. In paragraph (a), the reference ''§ 473.40'' is removed and the reference ''§ 478.40'' is added in its place.

b. In paragraph (b), the reference ''§ 473.48'' is removed and the reference ''§ 478.48'' is added in its place.

§ 478.42 [Amended]

30. In § 478.42—

a. In paragraph (a) introductory text, the reference ''§ 473.40'' is removed and the reference ''§ 478.40'' is added in its place.

b. In paragraph (b), the reference ''§ 473.22'' is removed and the reference ''§ 478.22'' is added in its place.

§ 478.48 [Amended]

31. In § 478.48—

a. In paragraph (a)(1), the reference ''§ 473.15'' is removed and the reference ''§ 478.15'' is added in its place.

b. In paragraph (a)(2) introductory text, the reference ''§ 473.15'' is removed and the reference ''§ 478.15'' is added in its place.

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE QUALITY IMPROVEMENT ORGANIZATION REVIEW INFORMATION

32. The authority citation for Part 480 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 480.105 [Amended]

33. In § 480.105(a), the phrase ''Medicare fiscal intermediaries'' is removed and the phrase ''Medicare administrative contractors or fiscal intermediaries'' is added in its place.

34. Section 480.107 is amended by adding a new paragraph (l) to read as follows:

§ 480.107 Limitations on redisclosure.

* * * * *

(l) Redisclosures of information that is confidential because it identifies the parties involved in immediate advocacy may occur if all parties have consented to the redisclosure, as provided for under § 476.110(c) of this chapter.

35. Section 480.132 is amended by—

a. Revising paragraph (a) introductory text, paragraph (a)(1)(iii), and paragraph (a)(2).

b. Revising paragraph (b)(1).

c. Revising paragraph (c).

d. Removing the undesignated text following paragraph (c)(3).

The revisions read as follows.

§ 480.132 Disclosure of information about patients.

(a) *General requirements for disclosure.* Except as specified in §§ 476.130(d) and 476.140(b) of this chapter and paragraph (b) of this section, a QIO must—

(1) * * *

(iii) Except as provided under paragraph (b) of this section, all other patient and practitioner identifiers have been removed.

(2) Make disclosure to the patient or the patient's representative within 14 calendar days of receipt of the request.

(b) * * *

(1) If a request for information is in connection with an initial denial determination under section 1154(a)(2) of the Act, the QIO must provide only the information used to support that determination in accordance with the procedures for disclosure of information related to determinations under § 478.24, including relevant practitioner identifiers.

* * * * *

(c) Manner of disclosure. (1) The QIO must disclose the patient information directly to the patient or the patient's representative when the representative has been authorized or appointed to receive that information.

(2) In identifying a representative, the QIO must follow pertinent State law requirements regarding the designation of health care representatives and agents. If the patient is unable to designate a representative and the identity of the representative is not already dictated by State law, the QIO must disclose the information to a person whom the QIO determines is responsible for the patient.

36. Section 480.133 is amended by—

a. Adding a new paragraph (a)(2)(iv).

b. In paragraph (b)(1), removing the reference to ''Part 466'' and adding the reference ''Part 476'' in its place; and removing the reference ''§ 473.24'' and adding the reference ''§ 478.24 of this subchapter'' is its place.

The addition reads as follows:

§ 480.133 Disclosure of information about practitioners, reviewers, and institutions.

(a) * * *

(2) * * *

(iv) A QIO is not required to obtain the consent of a practitioner or provider prior to the release of information to a beneficiary in connection with an initial denial determination or in providing a beneficiary with the QIO's findings in response to a beneficiary complaint. Information that must be specified in a QIO's final decision in a complaint review is specified in §§ 476.130(d) and 476.140(b) of this subchapter.

* * * * *

§ 480.139 [Amended]

37. Section 480.139 is amended by redesignating the existing paragraph (1) as paragraph (a)(1).

38. A new § 480.145 is added to read as follows:

§ 480.145 Beneficiary authorization of use of confidential information.

(a) Except as otherwise provided under this part, a QIO may not use or

disclose a beneficiary's confidential information without an authorization from the beneficiary. The QIO's use or disclosure must be consistent with the authorization.

(b) A valid authorization is a document that contains the following:

(1) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(2) The name or other specific identification of the QIO(s) and QIO point(s) of contact making the request to use or disclose the information.

(3) The name or other specific identification of the person(s), or class of persons, to whom the QIO(s) may disclose the information or allow the requested use.

(4) A description of each purpose of the requested use or disclosure. The statement ''at the request of the individual'' is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of purpose.

(5) An expiration date or an expiration event that relates to the beneficiary or the purpose of the use or disclosure. The statement ''end of the QIO research study,'' ''none,'' or similar language is sufficient if the authorization is for a use or disclosure of confidential information for QIO research, including for the creation and maintenance of a research database or research repository.

(6) Signature of the individual and date. If the authorization is signed by a beneficiary's representative, a description of such representative's authority to act for the beneficiary must also be provided.

(c) In addition to those items contained in paragraph (b) of this section, the authorization must contain statements adequate to place the individual on notice of all of the following:

(1) The individual's right to revoke the authorization in writing; and

(2) Any exceptions to the right to revoke and a description of how the individual may revoke the authorization;

(3) The ability or inability of the QIO to condition its review activities on the authorization, by stating either:

(i) That the QIO may not condition the review of complaints, appeals, or payment determinations, or any other QIO reviews or other tasks within the QIO's responsibility on whether the individual signs the authorization;

(ii) The consequences to the individual of a refusal to sign the authorization when the refusal will render the QIO unable to carry out an activity.

(4) The potential for information disclosed pursuant to the authorization to be subject to either appropriate or inappropriate redisclosure by a recipient, after which the information would no longer be protected by this subpart.

(d) The authorization must be written in plain language.

(e) If a QIO seeks an authorization from a beneficiary for a use or disclosure of confidential information, the QIO must provide the beneficiary with a copy of the signed authorization.

(f) A beneficiary may revoke an authorization provided under this section at any time, provided the revocation is in writing, except to the extent that the QIO has taken action in reliance upon the authorization.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

39. 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).

40. Section 495.8 is amended by revising paragraph (b)(2)(vi) to read as follows:

§ 495.8 Demonstration of meaningful use criteria.

* * * * *

(b) * * *

(2) * * *

(vi) Exception for Medicare eligible hospitals and CAHs for FY 2012 and 2013—Participation in the Medicare EHR Incentive Program Electronic Reporting Pilot. In order to satisfy the clinical quality measure reporting requirements of meaningful use, aside from attestation, a Medicare eligible hospital or CAH may participate in the Medicare EHR Incentive Program Electronic Reporting Pilot.

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(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 28, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: June 29, 2012.

Kathleen Sebelius,

Secretary.

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