DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 411, 416, 419, 489, and 495

[CMS-1525-P]

RIN 0938-AQ26

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Provider Agreement Regulations on Patient Notification Requirements

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) to implement applicable statutory requirements and changes arising from our continuing experience with this system. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the OPPS. These proposed changes would be applicable to services furnished on or after January 1, 2012.

In addition, this proposed rule would update the revised Medicare ambulatory surgical center (ASC) payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. In this proposed rule, we set forth the proposed relative payment weights and payment amounts for services furnished in ASCs, specific HCPCS codes to which these proposed changes would apply, and other proposed ratesetting information for the CY 2012 ASC payment

system. These proposed changes would be applicable to services furnished on or after January 1, 2012.

We are proposing to revise the requirements for the Hospital Outpatient Quality Reporting (IQR) Program, add new requirements for ASC Quality Reporting System, and make additional changes to provisions of the Hospital Inpatient Value-Based Purchasing (VBP) Program.

We also are proposing to allow eligible hospitals and CAHs participating in the Medicare Electronic Health Record (EHR) Incentive Program to meet the clinical quality measure reporting requirement of the EHR Incentive Program for payment year 2012 by participating in the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot.

In addition, we are proposing to make changes to the rules governing the whole hospital and rural provider exceptions to the physician self-referral prohibition for expansion of facility capacity and changes to provider agreement regulations on patient notification requirements.

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 [insert 60 days from date of display at the **Federal Register**.]

ADDRESSES: In commenting, please refer to file code CMS-1525-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-1525-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-1525-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, S.W.,

Washington, DC 20201.

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

b. For delivery in Baltimore, MD—

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

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

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 in this document.

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

FOR FURTHER INFORMATION, CONTACT:

Paula Smith, (410) 786-0378, Hospital outpatient prospective payment issues.

Char Thompson, (410) 786-0378, Ambulatory surgical center issues.

Michele Franklin, (410) 786-4533, and Jana Lindquist, (410) 786-4533, Partial hospitalization and community mental health center issues.

James Poyer, (410) 786-2261, Reporting of Hospital Outpatient Quality Reporting (OQR) and ASC Quality Reporting Program issues.

Teresa Schell, (410) 786-8651, Physician Ownership and Investment in Hospitals issues.

Georganne Kuberski, (410) 786-0799, Patient Notification Requirements issues.

James Poyer, (410) 786-2261, and Ernessa Brawley (410) 786-2075, Hospital Value-Based Purchasing (VBP) Program issues.

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 throughout the preamble of our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with this CY 2012 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.hhs.gov/HospitalOutpatientPPS. The Addenda relating to the ASC payment system are available at: http://www/cms.hhs.gov/ASC Payment/. For complete details on the availability of the Addenda referenced in this proposed rule, we refer readers to section XVII. 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

ACEP	American College of Emergency Physicians
AHA	American Hospital Association
AHIMA	American Health Information Management Association
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
AMP	Average Manufacturer Price
AOA	American Osteopathic Association
APC	Ambulatory Payment Classification
ARRA	American Recovery and Reinvestment Act of 2009, Pub. L. 111-5
ASC	Ambulatory Surgical Center
ASP	Average Sales Price
AWP	Average Wholesale Price
BBA	Balanced Budget Act of 1997, Pub. L. 105-33

BBRA	Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Pub. L. 106-113
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106-554
BLS	Bureau of Labor Statistics
CAH	Critical Access Hospital
CAP	Competitive Acquisition Program
CBSA	Core-Based Statistical Area
CCN	CMS Certification Number
CCR	Cost-to-Charge Ratio
CDC	Centers for Disease Control
CERT	Comprehensive Error Rate Testing
CLFS	Clinical Laboratory Fee Schedule
CMHC	Community Mental Health Center
CMS	Centers for Medicare & Medicaid Services
CPT	[Physicians'] Current Procedural Terminology, Fourth Edition, 2009, copyrighted by the American Medical Association
CQM	Clinical Quality Measure
CR	Cardiac Rehabilitation
CY	Calendar Year
DFO	Designated Federal official
DHS	Designated Health Service

DRA	Deficit Reduction Act of 2005, Pub. L. 109-171
DSH	Disproportionate Share Hospital
EACH	Essential Access Community Hospital
E/M	Evaluation and Management
EHR	Electronic Health Record
ESRD	End-Stage Renal Disease
FACA	Federal Advisory Committee Act, Pub. L. 92-463
FAR	Federal Acquisition Regulations
FDA	Food and Drug Administration
FFS	Fee-for-Service
FSS	Federal Supply Schedule
FY	Fiscal Year
GAO	Government Accountability Office
HAC	Hospital-Acquired Condition
HAI	Healthcare-Associated Infection
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems
HCERA	Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152
HCP	Healthcare Personnel
HCPCS	Healthcare Common Procedure Coding System
HCRIS	Hospital Cost Report Information System
HHA	Home Health Agency

HIPAA	Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191
HOPD	Hospital OutPatient Department
Hospital OQR	Hospital Outpatient Quality Reporting
ICR	Intensive Cardiac Rehabilitation
IDE	Investigational Device Exemption
IHS	Indian Health Service
I/OCE	Integrated Outpatient Code Editor
IOL	Intraocular Lens
IPPS	[Hospital] Inpatient Prospective Payment System
MAC	Medicare Administrative Contractor
MedPAC	Medicare Payment Advisory Commission
MIEA-TRHCA	Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006, Pub. L. 109-432
MIPPA	Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110-275
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173
MMEA	Medicare and Medicaid Extenders Act of 2010, Pub. L. 111-309
MMSEA	Medicare, Medicaid, and SCHIP Extension Act of 2007, Pub. L. 110-173
MPFS	Medicare Physician Fee Schedule
MSA	Metropolitan Statistical Area

NCCI	National Correct Coding Initiative
NHSN	National Healthcare Safety Network
NCD	National Coverage Determination
NQF	National Quality Forum
NTIOL	New Technology Intraocular Lens
OIG	[HHS] Office of the Inspector General
OMB	Office of Management and Budget
OPD	[Hospital] Outpatient Department
OPPS	[Hospital] Outpatient Prospective Payment System
OQR	Outpatient Quality Reporting
PBD	Provider-Based Department
PHP	Partial Hospitalization Program
PPI	Producer Price Index
PPS	Prospective Payment System
PR	Pulmonary Rehabilitation
PRA	Paperwork Reduction Act
QAPI	Quality Assessment and Performance Improvement
QIO	Quality Improvement Organization
RAC	Recovery Audit Contractor
RFA	Regulatory Flexibility Act
Hospital IQR	Hospital Inpatient Quality Reporting
Hospital OQR	Hospital Outpatient Quality Reporting

RHHI	Regional Home Health Intermediary
SBA	Small Business Administration
SCH	Sole Community Hospital
SDP	Single Drug Pricer
SI	Status Indicator
TEP	Technical Expert Panel
TOPs	Transitional Outpatient Payments
VBP	Value-Based Purchasing
WAC	Wholesale Acquisition Cost

In this document, we address two payment systems under the Medicare program: the Hospital Outpatient Prospective Payment System (OPPS) and the Ambulatory Surgical Center (ASC) payment system. In addition, we are proposing to make changes to the rules governing limitations on certain physician referrals to hospitals in which physicians have an ownership or investment interest, the provider agreement regulations on patient notification requirements, and the rules governing the Hospital Inpatient Value-Based Purchasing (VBP) Program. The provisions relating to the OPPS are included in sections I. through XII. and section XIV. and sections XVII. through XXI. of this proposed rule. Addenda A, B, C, D1, D2, E, L, M, and N, which relate to the OPPS, are referenced in section XVII. of this proposed rule and are available via the Internet on the CMS Web site at the URL indicated in section XVII. The provisions related to the ASC payment system are included in sections XIII., XIV., and XVII. through XXI. of this proposed rule. Addenda AA, BB, DD1, DD2, and EE, which relate to the ASC

payment system, are referenced in section XVII. of this proposed rule and are available via the Internet on the CMS Web site at the URL indicated in section XVII. The provisions relating to physician referrals to hospitals in which physicians have an ownership or investment interest and to the provider agreement regulations on patient notification requirements are included in section XV., and the provisions relating to the Hospital Inpatient VBP Program are included in section XVI. of this proposed rule.

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I. Background and Summary of the CY 2012 OPPS/ASC Proposed Rule

A. Legislative and Regulatory Authority for the Hospital Outpatient Prospective Payment System

When Title XVIII of the Social Security Act (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 Part 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; and most recently 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, and most recently the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111-309).)

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

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 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 median 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 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.

B. 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 Medicare Physician Fee Schedule (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 inpatient prospective payment system (IPPS). We set forth the services that are excluded from payment under the OPPS in 42 CFR 419.22 of the regulations.

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; critical access hospitals (CAHs); hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and Indian Health Service (IHS) hospitals.

C. 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/HospitalOutpatientPPS/. The CY 2011 OPPS/ASC final rule with comment period appears in the November 24, 2010 **Federal Register** (75 FR 71800). In that final rule with comment period, we revised the OPPS to update the payment weights and conversion factor for services payable under the CY 2011 OPPS on the basis of claims data from January 1, 2009, through December 31, 2009, and to implement certain provisions of the Affordable Care Act. In addition, we responded to public comments received on the provisions of the CY 2010 final rule with comment period (74 FR 60316) pertaining to the APC assignment of HCPCS codes identified in Addendum B to that rule with the new interim ("NI") comment indicator, and public comments received on the August 3, 2010 OPPS/ASC proposed rule for CY 2011 (75 FR 46170).

D. Advisory Panel on Ambulatory Payment Classification (APC) Groups

1. Authority of the Advisory Panel on Ambulatory Payment Classification (APC) Groups (the APC Panel)

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Pub. L. 106-113, and redesignated by section 202(a)(2) of Pub. L. 106-113, requires that we consult with an outside panel of experts to review the clinical integrity of the payment groups and their weights under the OPPS. The Act further specifies that the panel will act in an advisory capacity. The APC Panel, discussed under section I.D.2. of this proposed rule, fulfills these requirements. The APC Panel is not restricted to using data compiled by CMS, and it may use data collected or developed by organizations outside the Department in conducting its review.

2. Establishment of the APC Panel

On November 21, 2000, the Secretary signed the initial charter establishing the APC Panel. This expert panel, which may be composed of up to 15 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 APC 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 APC 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 APC 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 APC Panel membership and other information pertaining to the APC 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.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage.

3. APC Panel Meetings and Organizational Structure

The APC Panel first met on February 27 through March 1, 2001. Since the initial meeting, the APC Panel has held multiple meetings, with the last meeting taking place on February 28-March 1, 2011. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting and, when necessary, to solicit nominations for APC Panel membership and to announce new members.

The APC Panel has established an operational structure that, in part, includes the use of three subcommittees to facilitate its required APC 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 APC Panel and for recommending options for resolving them. The Visits and Observation Subcommittee reviews and makes recommendations to the APC Panel on all technical issues pertaining to observation services and hospital outpatient visits paid

under the OPPS (for example, APC configurations and APC 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 APC Panel during a scheduled APC Panel meeting, and the APC Panel recommended that the subcommittees continue at the February/March 2011 APC Panel meeting. We accept those recommendations of the APC Panel. All subcommittee recommendations are discussed and voted upon by the full APC Panel.

Discussions of the other recommendations made by the APC Panel at the February/March 2011 APC Panel meeting are included in the sections of this proposed rule that are specific to each recommendation. For discussions of earlier APC 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.

E. Summary of the Major Contents of this CY 2012 OPPS/ASC Proposed Rule

In this proposed rule, we set forth proposed changes to the Medicare hospital OPPS for CY 2012 to implement statutory requirements and changes arising from our continuing experience with the system. In addition, we set forth proposed changes to the revised Medicare ASC payment system for CY 2012, including proposed updated

payment weights, covered surgical procedures, and covered ancillary items and services based on the proposed OPPS update. In addition, we are proposing to make changes to the rules governing limitations on certain physician referrals to hospitals in which physicians have an ownership or investment interest, provider agreement regulations on patient notification requirements, and the rules governing the Hospital Inpatient Value-Based Purchasing (VBP) Program.

The following is a summary of the major changes that we are proposing to make for CY 2012:

1. Proposed Updates Affecting OPPS Payments

In section II. of this proposed rule, we set forth—

- The methodology used to recalibrate the proposed APC relative payment weights.
- The proposed changes to packaged services.
- The proposed update to the conversion factor used to determine payment rates under the OPPS. In this section, we are proposing changes in the amounts and factors for calculating the full annual update increase to the conversion factor.
- The proposed retention of our current policy to use the IPPS wage indices to adjust, for geographic wage differences, the portion of the OPPS payment rate and the copayment standardized amount attributable to labor-related cost.
- The proposed update of statewide average default CCRs.

- The proposed application of hold harmless transitional outpatient payments (TOPs) for certain small rural hospitals, extended by section 3121 of the Affordable Care Act.
- The proposed payment adjustment for rural SCHs.
- The proposed calculation of the hospital outpatient outlier payment.
- The calculation of the proposed national unadjusted Medicare OPPS payment.
- The proposed beneficiary copayments for OPPS services.

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

In section III. of this proposed rule, we discuss--

- The proposed additions of new HCPCS codes to APCs.
- The proposed establishment of a number of new APCs.
- Our analyses of Medicare claims data and certain recommendations of the APC Panel.
- The application of the 2 times rule and proposed exceptions to it.
- The proposed changes to specific APCs.
- The proposed movement of procedures from New Technology APCs to clinical APCs.

3. Proposed OPPS Payment for Devices

In section IV. of this proposed rule, we discuss the proposed pass-through payment for specific categories of devices and the proposed adjustment for devices furnished at no cost or with partial or full credit.

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

In section V. of this proposed rule, we discuss the proposed CY 2012 OPPS payment for drugs, biologicals, and radiopharmaceuticals, including the proposed payment for drugs, biologicals, and radiopharmaceuticals with and without pass-through status.

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

In section VI. of this proposed rule, we discuss the estimate of CY 2012 OPPS transitional pass-through spending for drugs, biologicals, and devices.

6. Proposed OPPS Payment for Hospital Outpatient Visits

In section VII. of this proposed rule, we set forth our proposed policies for the payment of clinic and emergency department visits and critical care services based on claims data.

7. Proposed Payment for Partial Hospitalization Services

In section VIII. of this proposed rule, we set forth our proposed payment for partial hospitalization services, including the proposed separate threshold for outlier payments for CMHCs.

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

In section IX. of this proposed rule, we discuss the procedures that we are proposing to remove from the inpatient list and assign to APCs for payment under the OPPS.

9. Proposed Policies on Supervision Standards for Outpatient Services in Hospitals and CAHs

In section X. of this proposed rule, we discuss proposed policy changes relating to the supervision of outpatient services furnished in hospitals and CAHs.

10. Proposed OPPS Payment Status and Comment Indicators

In section XI. of this proposed rule, we discuss our proposed changes to the definitions of status indicators assigned to APCs and present our proposed comment indicators.

11. OPPS Policy and Payment Recommendations

In section XII. of this proposed rule, we address recommendations made by the Medicare Payment Advisory Commission (MedPAC) in its March 2011 report to Congress, by the Office of Inspector General (OIG), and by the APC Panel regarding the OPPS for CY 2012.

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

In section XIII. of this proposed rule, we discuss the proposed updates of the revised ASC payment system and payment rates for CY 2012.

13. Reporting Quality Data for Annual Payment Rate Updates

In section XIV. of this proposed rule, we discuss the proposed measures for reporting hospital outpatient quality data for the OPD fee schedule increase factor for CY 2013 and subsequent calendar years; set forth the requirements for data collection and submission; and discuss the reduction to the OPPS OPD fee schedule increase factor for hospitals that fail to meet the Hospital OQR Program requirements. We also discuss

proposed measures for reporting ASC quality data for the annual payment update factor for CYs 2014, 2015, and 2016; and set forth the requirements for data collection and submission for the annual payment update.

14. Proposed Changes to EHR Incentive Program for Eligible Hospitals and CAHs Regarding Electronic Submission of Clinical Quality Measures (CQMs)

In section XIV.J. of this proposed rule, we are proposing to allow eligible hospitals and CAHs participating in the Medicare EHR Incentive Program to meet the CQM reporting requirement of the EHR Incentive Program for payment year 2012 by participating in the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot.

15. Proposed Changes to Provisions Relating to Physician Self-Referral Prohibition and Provider Agreement Regulations on Patient Notification Requirements

In section XV. of this proposed rule, we present our proposed exception process for expansion of facility capacity under the whole hospital and rural provider exceptions to the physician self-referral law, and proposed changes to the provider agreement regulations on patient notification requirements.

16. Additional Proposed Changes Relating to the Hospital Inpatient VBP Program

In section XVI. of this proposed rule, we present our proposed requirements for the FY 2014 Hospital Inpatient VBP Program.

17. Economic and Federalism Analyses

In sections XX. and XXI. of this proposed rule, we set forth an analysis of the regulatory and federalism impacts that the proposed changes would have on affected entities and beneficiaries.

F. Public Comments Received on the CY 2011 OPPS/ASC Final Rule with Comment Period

We received approximately 43 timely pieces of correspondence on the CY 2011 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 24, 2010 (75 FR 71800), 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 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 and revise the relative payment weights for APCs at least annually. 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 2012 OPPS, we are proposing to recalibrate the APC relative payment weights for services furnished on or after January 1, 2012, and before January 1, 2013 (CY 2012), using the same basic methodology that we described in the CY 2011 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. For the purpose of recalibrating the proposed APC relative payment weights for CY 2012, we used approximately 138 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, 2010, and before January 1, 2011. (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/HospitalOutpatientPPS/HORD/.)

Of the 138 million final action claims for services provided in hospital outpatient settings used to calculate the proposed CY 2012 OPPS payment rates for this proposed rule, approximately 105 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 105 million claims, approximately 3 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 102 million claims, we created approximately 100 million

single records, of which approximately 67 million were "pseudo" single or "single session" claims (created from approximately 23 million multiple procedure claims using the process we discuss later in this section). Approximately 888,000 claims were trimmed out on cost or units in excess of +/- 3 standard deviations from the geometric mean, yielding approximately 99 million single bills for median setting. 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 are proposing to only use claims (or portions of each claim) that are appropriate for ratesetting purposes. Ultimately, we were able to use for CY 2012 ratesetting some portion of approximately 94 percent of the CY 2010 claims containing services payable under the OPPS.

The proposed APC relative weights and payments for CY 2012 in Addenda A and B to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) were calculated using claims from CY 2010 that were processed before January 1, 2011, and continue to be based on the median hospital costs for services in the APC groups. 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 median costs underpinning the APC relative payment weights and the CY 2012 payment rates.

b. Proposed Use of Single and Multiple Procedure Claims

For CY 2012, in general, we are proposing to continue to use single procedure claims to set the medians on which the APC relative payment weights would be based, with some exceptions as discussed below in this section. We generally use single procedure claims to set the median 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 2011 OPPS/ASC final rule with comment period (75 FR 71811 through 71822). In addition, for CY 2008, we increased packaging and created the first composite APCs. We have continued our packaging policies and the creation of composite APCs for CY 2009, 2010, and 2011, and we are proposing to continue them for CY 2012. Increased packaging and creation of composite APCs also increased the number of bills that we were able to use for median calculation 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 to calculate APC median costs. We have continued the composite APCs for multiple imaging services for CYs 2010 and 2011, and we are proposing to continue to create them for CY 2012. We refer readers to section II.A.2.e. of this proposed rule for discussion of the use of claims to establish median 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 2012 OPPS. This methodology enabled us to create, for this proposed rule, approximately 67 million "pseudo" single procedure claims, including multiple imaging composite "single session" bills (we refer readers to

section II.A.2.e.(5) of the proposed rule for further discussion), to add to the approximately 33 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 to calculate median costs.

For CY 2012, we are proposing to bypass 460 HCPCS codes for CY 2012 that are identified in Addendum N to this proposed rule (which is referenced in section XVII. of this proposed rule and 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 2012, data available for the February 28-March 1, 2011 APC Panel meeting from CY 2010 claims processed through September 30, 2010, and CY 2009 claims data processed through June 30, 2010, used to model the payment rates for CY 2011) to determine whether it would be appropriate to propose to add additional codes to the previous year's bypass list. For CY 2012, we are proposing to continue to bypass all of the HCPCS codes on the CY 2011 OPPS bypass list because they continue to meet the established empirical criteria for the bypass list. We updated HCPCS codes on the CY 2011 bypass list that were mapped to new HCPCS codes for CY 2012 ratesetting by evaluating data for the replacement codes under the empirical criteria described below and also removing the HCPCS codes that we are proposing to be deleted for CY 2012, 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. None of these deleted codes were "overlap bypass codes" (those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs). We also are proposing to add to the bypass list for CY 2012 all HCPCS codes not on the CY 2011 bypass list that, using either the CY 2011 final rule data (CY 2009 claims) or the February 28-March 1, 2011 APC Panel data (first 9 months of CY 2010 claims), met the empirical criteria for the bypass list that are summarized below. The entire list proposed for CY 2012 (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 median 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.

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 would prevent continuing decline in the threshold's real value. For CY 2011, based on CY 2009 claims data, we proposed to apply the final market basket of 3.6 percent published in the CY 2009 OPPS/ASC final rule with comment period (73 FR 26584) to the $50 packaged cost threshold used in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60325). This calculation led us to a proposed packaged cost threshold for bypass list additions for CY 2011 of $50 ($51.80 rounded to $50). We

stated that we believe that applying the market basket from the year of claims data to the packaged cost threshold, rounded to the nearest $5 increment, would appropriately account for the effects of inflation when considering additions to the bypass list because the market basket increase percentage reflects the extent to which the price of inputs for hospital services has increased compared to the price of inputs for hospital services in the prior year. We are proposing for CY 2012, based on the same rationale described for the CY 2011 OPPS/ASC final rule with comment period (75 CFR 71812), to continue to update the packaged cost threshold by the market basket. By applying the final CY 2011 market basket increase of 1.85 percent to the prior non-rounded dollar threshold of $51.80 (75 FR 71812), we determined that the threshold increases for CY 2012 to $55 ($52.76 rounded to $55, the nearest $5 increment). Therefore, we are proposing to set the median packaged cost threshold on the CY 2010 claims at $55 for a code to be considered for addition to the CY 2012 OPPS bypass list.

- The code is not a code for an unlisted service.

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 2012 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 on the bypass list certain HCPCS codes 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 median 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 referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site).

Addendum N to this proposed rule includes the proposed list of bypass codes for CY 2012. The list of bypass codes contains codes that were reported on claims for services in CY 2010 and, therefore, includes codes that were in effect in 2010 and used for billing but were deleted for CY 2011. We retained these deleted bypass codes on the proposed CY 2012 bypass list because these codes existed in CY 2010 and were covered OPD services in that period, and CY 2010 claims data are used to calculate 2012 payment rates. Keeping these deleted bypass codes on the bypass list potentially allowed 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 2012 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 2012 bypass list because these codes were either deleted from the HCPCS before CY 2010 (and therefore were not covered OPD services in CY2010) or were not separately payable codes under the proposed CY 2012 OPPS because these codes are not used for ratesetting (and therefore would not need to be bypassed). None of these proposed deleted codes were "overlap bypass" codes.

TABLE 1.—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2012 BYPASS LIST

HCPCS Code	HCPCS Short Descriptor
29220	Strapping of low back
78350	Bone mineral, single photon
90816	Psytx, hosp, 20-30 min
90818	Psytx, hosp, 45-50 min
90826	Intac psytx, hosp, 45-50 min
99241	Office consultation
99242	Office consultation
99243	Office consultation
99244	Office consultation
99245	Office consultation
0144T	CT heart wo dye; qual calc

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

For CY 2012, 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 median costs on which the proposed CY 2012 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 2010 claims data from the most recent available hospital cost reports, in most cases, cost reports beginning in CY 2009. For the CY 2012 OPPS proposed rates, we used the set of claims processed during CY 2010. 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/HospitalOutpatientPPS/03_crosswalk.asp#TopOfPage.

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2010 (the year of the claims data we used to calculate the proposed CY 2012 OPPS payment rates). For CY 2010, the National Uniform Billing Committee added revenue codes 860 (Magnetoencephalography (MEG); general classification) and 861 (Magnetoencephalography (MEG)). For purposes of applying a CCR to charges reported under revenue codes 860 and 861, we are proposing to use nonstandard Medicare cost report cost center 3280 (Electrocardiogram (EKG) and Electroencephalography (EEG)) as the primary cost center and to use standard cost center 5400 (Electroencephalography (EEG)) as the secondary cost center. We believe that MEG, which evaluates brain activity, is similar to EEG, which also evaluates brain activity, and that the few hospitals that furnish MEG are likely to furnish it in the same department of the hospital in which they furnish EEG services. Therefore, we believe that the CCRs that we apply to the EEG revenue codes are more likely to result in a more accurate estimated cost for MEG than would the application of the hospital-specific overall ancillary CCR. For hospitals that report charges under revenue code 860 or 861 but do not report costs on their cost report under cost center 3280 or 5400, we are proposing to apply the hospital-specific overall CCR to the charges reported under revenue code 860 or 861 for purposes of estimating the cost of these services. We note that revenue codes with effective dates in

CY 2011 are not relevant to this process because these new revenue codes were not applicable to claims for services furnished during CY 2010.

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 is the calculation of median 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 2010 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 2009. For this proposed rule, we are using the most recently submitted cost reports to calculate the CCRs to be used to calculate median costs for the proposed CY 2012 OPPS payment rates. If the most recent 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 in this section II.A.1.c. 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 median costs for CY 2012.

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.

To explore this issue, in August 2006, we awarded a contract to RTI International (RTI) to study the effects of charge compression in calculating the IPPS cost-based relative weights, particularly with regard to the impact on inpatient diagnosis-related group (DRG) payments, and to consider methods to better capture the variation in cost

and charges for individual services when calculating costs for the IPPS relative weights across services in the same cost center. RTI issued a report in March 2007 with its findings on charge compression, which is available on the CMS Web site at: http://www.cms.gov/reports/downloads/Dalton.pdf. Although this report was focused largely on charge compression in the context of the IPPS cost-based relative weights, because several of the findings were relevant to the OPPS, we discussed that report in the CY 2008 OPPS/ASC proposed rule (72 FR 42641 through 42643) and discussed those findings again in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66599 through 66602).

In August 2007, we contracted with RTI to evaluate the cost estimation process for the OPPS relative weights because its 2007 report had concentrated on IPPS DRG cost-based relative weights. The results of RTI's analyses had implications for both the OPPS APC cost-based relative weights and the IPPS MS-DRG (Medicare severity) cost-based relative weights. The RTI final report can be found on RTI's Web site at: http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf. For a complete discussion of the RTI recommendations, public comments, and our responses, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527).

We addressed the RTI finding that there was aggregation bias in both the IPPS and the OPPS cost estimation of expensive and inexpensive medical supplies in the FY 2009 IPPS final rule. Specifically, we finalized our proposal for both the OPPS and

IPPS to create one cost center for "Medical Supplies Charged to Patients" and one cost center for "Implantable Devices Charged to Patients," essentially splitting the then current CCR for "Medical Supplies and Equipment" into one CCR for low-cost medical supplies and another CCR for high-cost implantable devices in order to mitigate some of the effects of charge compression. Accordingly, in Transmittal 20 of the Provider Reimbursement Manual, Part II (PRM-II), Chapter 36, Form CMS-2552-96, which was issued in July 2009, we created a new subscripted Line 55.01 on Worksheet A for the "Implantable Devices Charged to Patients" cost center. This new subscripted cost center, placed under the standard line for "Medical Supplies Charged to Patients," is available for use for cost reporting periods beginning on or after May 1, 2009. A subscripted cost center is the addition of a separate new cost center line and description which bears a logical relationship to the standard cost center line and is located immediately following a standard cost center line. Subscripting a cost center line adds flexibility and cost center expansion capability to the cost report. For example, Line 55 of Worksheet A on Form CMS 2552-96 (the Medicare hospital cost report) is "Medical Supplies Charged to Patients." The additional cost center, which isolates the costs of "Implantable Medical Supplies Charged to Patients", was created by adding subscripted Line 55.01 to Worksheet A and is defined as capturing the costs and charges billed with the following UB-04 revenue codes: 0275 (Pacemaker); 0276 (Intraocular lens); 0278 (other implants); and 0624 (FDA investigations devices) (73 FR 48458).

In preparation for the FY 2012 IPPS proposed rule and this CY 2012 OPPS proposed rule, we have assessed the availability of data in the "Implantable Devices

Charged to Patients" cost center. 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. The cost center for "Implantable Devices Charged to Patients" is effective for cost reporting periods beginning on or after May 1, 2009. We have checked the availability of CY 2009 cost reports in the December 31, 2010 quarter ending update of HCRIS, which is the latest upload of CY 2009 cost report data that we could use for this proposed rule. We have determined that there are only 437 hospitals that have completed the "Implantable Devices Charged to Patients" cost center (out of approximately 3,500 IPPS hospitals). We do not believe this is a sufficient amount of data from which to generate a meaningful analysis. Therefore, we are not proposing to use data from the "Implantable Devices Charged to Patients" cost center to create a distinct CCR for Implantable Devices Charged to Patients for use in calculating the OPPS relative weights for CY 2012. We will reassess the availability of data for the "Implantable Devices Charged to Patients" cost center for the CY 2013 OPPS rulemaking cycle. Because there is approximately a 3-year lag in the availability of cost report data for IPPS and OPPS ratesetting purposes in a given calendar year, we believe we may be able to use data from the revised Medicare hospital cost report form to estimate costs from charges for implantable devices for the CY 2013 OPPS relative weights. 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 (73 FR 48458 through 45467).

In the CY 2009 OPPS/ASC final rule with comment period, we indicated that we would be making some other OPPS-specific changes in response to the RTI report recommendations. Specifically, these changes included modifications to the cost reporting software and the addition of three new nonstandard cost centers. With regard to modifying the cost reporting preparation software in order to offer additional descriptions for nonstandard cost centers to improve the accuracy of reporting for nonstandard cost centers, we indicated that the change would be made for the next release of the cost report software. These changes have been made to the cost reporting software with the implementation of CMS Transmittal 21, under Chapter 36 of the PRM-II, available on the CMS Web site at: http://www.cms.hhs.gov/Manuals/PBM/, which is effective for cost reporting periods ending on or after October 1, 2009.

We also indicated that we intended to add new nonstandard cost centers for "Cardiac Rehabilitation," "Hyperbaric Oxygen Therapy," and "Lithotripsy." We note that, in January 2010, CMS issued Transmittal 21 which updated the PRM-II, Chapter 36, Form CMS-2552-96. One of the updates in this transmittal established nonstandard cost centers for "Cardiac Rehabilitation," "Hyperbaric Oxygen Therapy," and "Lithotripsy" for use on Worksheet A. These three new nonstandard cost centers became available for cost reporting periods ending on or after October 1, 2009, and are included in the revenue code to cost center crosswalk we are proposing to use for calculating payment rates for CY 2012 OPPS. Specifically, the nonstandard cost centers are: 3120 (Cardiac Catheterization Laboratory); 3230 (CAT Scan); 3430 (Magnetic Resonance Imaging (MRI)). The revenue code to cost center crosswalk that we are proposing to use for

purposes of estimating the median costs of items and services for the CY 2012 OPPS is available for review and continuous comment (outside of comment on this proposed rule) on the CMS Web site at:

http://www.cms.gov/HospitalOutpatientPPS/03_crosswalk.asp#TopOfPage

Furthermore, 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/LTCH PPS and CY 2009 OPPS/ASC proposed and final rules, RTI 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 also concluded that both the IPPS and OPPS relative weights would better estimate the costs of those services if CMS were to add standard costs centers for CT scans, MRI, 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, MRI, and cardiac catheterization.) The new standard cost centers for MRI, CT scans, 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. CMS issued the new

hospital cost report Form CMS-2552-10 on December 30, 2010. The new cost report form can be accessed at the CMS Web site at: https://www.cms.gov/Manuals/PBM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS021935&intNumPerPage=10 . Once at this Web site, users should double click on "Chapter 40."

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 Median Costs

In this section of this proposed rule, we discuss the use of claims to calculate proposed OPPS payment rates for CY 2012. The hospital OPPS page on the CMS Web site on which this proposed rule is posted provides an accounting of claims used in the development of the proposed payment rates at: http://www.cms.gov/HospitalOutpatientPPS. The accounting of claims used in the development of this proposed rule is included on the CMS Web site under supplemental materials for this CY 2012 OPPS/ASC proposed rule. 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 CMS Web site,

http://www.cms.gov/HospitalOutpatientPPS, 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 2010 claims that were used to calculate the proposed payment rates for the CY 2012 OPPS.

We used the methodology described in sections II.A.2.a. through II.A.2.e. of this proposed rule to calculate the median costs we use to establish the relative weights used in calculating the proposed OPPS payment rates for CY 2012 shown in Addenda A and B to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC median costs to scaled payment weights.

a. Claims Preparation

For this proposed rule, we used the CY 2010 hospital outpatient claims processed before January 1, 2011, to calculate the median costs of APCs that underpin the proposed relative weights for CY 2012. To begin the calculation of the relative weights for CY 2012, we pulled all claims for outpatient services furnished in CY 2010 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 105 million claims that contain hospital bill types paid under the OPPS.

1. Claims that were not bill types 12X, 13X (hospital bill types), 14x (laboratory specimen bill types), or 76X (CMHC bill types). Other bill types are not paid under the OPPS and, 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 (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 the CMS Web site: http://www.cms.gov/HospitalOutpatientPPS**.** Revenue codes that we do not use to set medians 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 mean and median cost and a per day 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 CY 2010 OPPS/ASC final rule with comment period (74 FR 60517), we first adopted a policy to redistribute some portion of total cost of packaged drugs and biologicals to the separately payable drugs and biologicals as acquisition and pharmacy

overhead and handling costs. As discussed further in section V.B.3. of this proposed rule, we are proposing to continue this policy for CY 2012. Therefore, we used the line-item cost data for drugs and biologicals for which we had a HCPCS code with ASP pricing information to calculate the ASP+X values, first for all drugs and biologicals with HCPCS codes, whether separately paid or packaged, and then for separately payable drugs and biologicals and for packaged drugs and biologicals, respectively, by taking the ratio of total claim cost for each group relative to total ASP dollars (per unit of each drug or biological HCPCS code's April 2011 ASP amount multiplied by total units for each drug or biological in the CY 2010 claims data). These values are ASP+11 percent (for all drugs and biologicals with HCPCS codes, whether separately paid or packaged), ASP-2 percent (for drugs and biologicals that are separately paid), and ASP+188 percent (for drugs and biologicals that have HCPCS codes and that are packaged), respectively. As we discuss in section V.B.3. of this proposed rule, we are proposing to redistribute $161 million of the total cost in our claims data for coded packaged drugs and biologicals with an ASP to payment for separately payable drugs and biologicals. We also are proposing to redistribute an additional $54 million from the cost of uncoded packaged drugs billed under pharmacy revenue code series 025X (Pharmacy (also see 063X, an extension of 025X)), 026X (IV Therapy), and 063X (Pharmacy – Extension of 025X). This total excludes the cost of diagnostic and therapeutic radiopharmaceuticals because they are not reported under pharmacy revenue codes or under the pharmacy cost center on the hospital cost report. Our CY 2012 proposal to redistribute $215 million in estimated costs from coded and uncoded packaged drugs to separately payable drugs represents the

$200 million in total packaged drug costs redistributed from the CY 2011 OPPS/ASC final rule with comment period (75 FR 71967), updated by the PPI for Pharmaceuticals for Human Use.

Redistributing a total of $161 million in pharmacy overhead cost from packaged drugs and biologicals reduces the $705 million cost of packaged drugs and biologicals with HCPCS codes and ASPs to $544 million, approximately a 23-percent reduction. Redistributing $54 million from the cost of uncoded packaged drugs and biologicals reduces the $502 million cost of uncoded drugs and biologicals to $448 million, approximately an 11-percent reduction. To implement our proposed CY 2012 policy to redistribute $161 million from the pharmacy overhead cost of coded packaged drugs and biologicals to separately payable drugs and biologicals and $54 million from the cost of uncoded packaged drugs, we multiplied the cost of each packaged drug or biological with a HCPCS code and ASP pricing information in our CY 2010 claims data by 0.77, and we multiplied all uncoded packaged pharmacy drug costs in our CY 2010 claims data, excluding those for diagnostic radiopharmaceuticals, by 0.89. We also added the redistributed $215 million to the total cost of separately payable drugs and biologicals in our CY 2010 claims data, which increased the relationship between the total cost for separately payable drugs and biologicals and ASP dollars for the same drugs and biologicals from ASP-2 percent to ASP+4 percent. 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 and pharmacy overhead for CY 2012.

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 proposed 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 proposed year, such as services newly proposed to come off the inpatient list for CY 2011 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 2012, we are proposing to continue the policy we implemented for CY 2011 to exclude line-item data for pass-through drugs and biologicals (status indicator "G" for CY 2010) and nonpass-through drugs and biologicals (status indicator "K" for CY 2010) 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 2011 OPPS/ASC final rule with comment period (75 FR 71828) 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 single bills used to determine the mean unit costs for use in the ASP+X calculation described in section V.B.3. of this proposed rule with comment period.

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

(1) Splitting Claims

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 2012, 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 2012, 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 2012 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 median costs for composite APCs from multiple procedure major claims is discussed in section II.A.2.e. of this proposed rule.

Specifically, we divided the remaining claims into the following five groups:

1. Single Procedure Major Claims: Claims with a single separately payable procedure (that is, status indicator "S," "T," "V," or "X," which includes codes with status indicator "Q3"); claims with one unit of a status indicator "Q1" code ("STVX-packaged") where there was no code with status indicator "S," "T," "V," or "X" on the same claim on the same date; or claims with one unit of a status indicator "Q2" code ("T-packaged") where there was no code with a status indicator "T" on the same claim on the same date.

2. Multiple Procedure Major Claims: Claims with more than one separately payable procedure (that is, status indicator "S," "T," "V," or "X," which includes codes with status indicator "Q3"), or multiple units of one payable procedure. These claims include those codes with a status indicator "Q2" code ("T-packaged") where there was no procedure with a status indicator "T" on the same claim on the same date of service but where there was another separately paid procedure on the same claim with the same date of service (that is, another code with status indicator "S," "V," or "X"). We also include, in this set, claims that contained one unit of one code when the bilateral modifier was appended to the code and the code was conditionally or independently bilateral. In these cases, the claims represented more than one unit of the service described by the code, notwithstanding that only one unit was billed.

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

4. Multiple Procedure Minor Claims: Claims with multiple HCPCS codes that are assigned status indicator "F," "G," "H," "K," "L," "R," "U," or "N;" claims that contain more than one code with status indicator "Q1" ("STVX-packaged") or more than one unit of a code with status indicator "Q1" but no codes with status indicator "S," "T," "V," or "X" on the same date of service; or claims that contain more than one code with status indicator "Q2" (T-packaged), or "Q2" and "Q1," or more than one unit of a code with status indicator "Q2" but no code with status indicator "T" on the same date of service.

5. Non-OPPS Claims: Claims that contain no services payable under the OPPS (that is, all status indicators other than those listed for major or minor status). These claims were excluded from the files used for the OPPS. Non-OPPS claims have codes paid under other fee schedules, for example, durable medical equipment 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 in this proposed rule. 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 used the bypass codes listed in Addendum N to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS 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 2012 "overlap bypass codes" are listed in Addendum N to this proposed rule (which is referenced in section XVII. of this proposed rule and 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 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 median cost. 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 examined the multiple procedure minor claims to determine whether we could create "pseudo" single procedure claims. Specifically, where the claim contained multiple codes with status indicator "Q1" ("STVX-packaged") on the same date of service or contained multiple units of a single code with status indicator "Q1," we selected the status indicator "Q1" HCPCS code that had the highest CY 2011 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 2011 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 2011 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 median 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 2011 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 2011 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 2011 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 2011 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 2011 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 2011 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 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 XI.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 CY 2012 OPPS.

c. Completion of Claim Records and Median Cost Calculations

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 XVII. 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 2 below that appeared on the claim without a HCPCS code into the cost of the single major procedure remaining on the claim.

As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66606), for the CY 2008 OPPS, we adopted an APC Panel recommendation that CMS should review the final list of packaged revenue codes for consistency with OPPS policy and ensure that future versions of the I/OCE edit accordingly. As we have in the past, we will continue to compare the final list of packaged revenue codes that we adopt for CY 2012 to the revenue codes that the I/OCE will package for CY 2012 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 2012, as we did for CY 2011, we reviewed the changes to revenue codes that were effective during CY 2010 for purposes of determining the charges reported with revenue codes but without HCPCS codes that we would propose to package for the CY 2012 OPPS. We believe that the charges reported under the revenue codes listed in Table 2 below continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes. Therefore, for CY 2012, 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 2 below for purposes of calculating the median costs on which the CY 2012 OPPS are based.

TABLE 2.—PROPOSED CY 2012 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

Revenue Code	Description
0279	Medical/Surgical Supplies and Devices; Other Supplies/Devices
0280	Oncology; General Classification
0289	Oncology; Other Oncology
0343	Nuclear Medicine; Diagnostic Radiopharmaceuticals
0344	Nuclear Medicine; Therapeutic Radiopharmaceuticals
0370	Anesthesia; General Classification
0371	Anesthesia; Anesthesia Incident to Radiology
0372	Anesthesia; Anesthesia Incident to Other DX Services
0379	Anesthesia; Other Anesthesia
0390	Administration, Processing and Storage for Blood and Blood Components; General Classification
0392	Administration, Processing and Storage for Blood and Blood Components; Processing and Storage
0399	Administration, Processing and Storage for Blood and Blood Components; Other Blood Handling
0621	Medical Surgical Supplies – Extension of 027X; Supplies Incident to Radiology
0622	Medical Surgical Supplies – Extension of 027X; Supplies Incident to Other DX Services
0623	Medical Supplies – Extension of 027X, Surgical Dressings
0624	Medical Surgical Supplies – Extension of 027X; FDA Investigational Devices
0630	Pharmacy – Extension of 025X; Reserved
0631	Pharmacy – Extension of 025X; Single Source Drug
0632	Pharmacy – Extension of 025X; Multiple Source Drug
0633	Pharmacy – Extension of 025X; Restrictive Prescription
0681	Trauma Response; Level I Trauma
0682	Trauma Response; Level II Trauma
0683	Trauma Response; Level III Trauma
0684	Trauma Response; Level IV Trauma
0689	Trauma Response; Other
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)

Revenue Code	Description
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 2012 OPPS.

For the remaining claims, we then standardized 60 percent of the costs of the claim (which we have previously determined to be the labor-related portion) for geographic differences in labor input costs. We made this adjustment by determining the wage index that applied to the hospital that furnished the service and dividing the cost for the separately paid HCPCS code furnished by the hospital by that wage index. The claims accounting that we provide for the proposed and final rule contains the formula we use to standardize the total cost for the effects of the wage index. As has been our policy since the inception of the OPPS, we 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 median costs.

In accordance with our longstanding practice, we also excluded 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 102 million claims were left. Using these 102

million claims, we created approximately 100 million single and "pseudo" single procedure claims, of which we used slightly more than 99.5 million single bills (after trimming out approximately 888,000 claims as discussed above in this section) in the proposed CY 2012 median development and ratesetting.

We used these claims to calculate the proposed CY 2012 median costs for each separately payable HCPCS code and each APC. The comparison of HCPCS code-specific and APC medians 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 cannot be considered comparable with respect to the use of resources if the highest median (or mean cost, if elected by the Secretary) for an item or service in the group is more than 2 times greater than the lowest median cost for an item or service within the same group (the 2 times 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 median 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 median 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 median. 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 median. Finally, we reviewed the median 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 median costs and for other reasons. The APC medians were recalculated after we reassigned the affected HCPCS codes. Both the HCPCS code-specific medians and the APC medians 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 median costs are calculated using variations of the process outlined above. Specifically, section II.A.2.d. of this proposed rule addresses the proposed calculation of single APC criteria-based median costs. Section II.A.2.e. of this proposed rule discusses the proposed calculation of composite APC criteria-based median costs. Section VIII.B. of this proposed rule addresses the methodology for calculating the proposed median costs for partial hospitalization services.

APC Panel Recommendations Regarding Data Development: At the February 28-March 1, 2011 APC Panel Meeting, we provided the APC Panel Data Subcommittee with a list of all APCs fluctuating by greater than 10 percent when comparing the CY 2011 OPPS final rule median costs based on CY 2009 claims processed through June 30, 2010, to those based on CY 2010 OPPS/ASC final rule data

(CY 2008 claims processed through June 30, 2009). We included explanatory data where possible to allow the Data Subcommittee to focus on APC median changes that required more investigation, based on its request (75 FR 71834). The APC Panel Data Subcommittee reviewed the fluctuations in the APC median costs but did not express particular concerns with the median cost changes.

We also provided the APC Panel Data Subcommittee with a summary of cost and CCR data related to the Myocardial Positron Emission Tomography (PET) imaging APC, APC 0307, as well as the associated diagnostic radiopharmaceutical, Rb82 rubidium, based on a request for data related to the decline in the APC median cost from the CY 2010 OPPS final rule to the CY 2011 OPPS proposed rule. The Data Subcommittee noted a decline in the CCRs associated with the HCPCS codes in APC 0307, as well as declines in the line-item costs of the associated diagnostic radiopharmaceutical.

At the February 28-March 1, 2011 APC Panel Meeting, the APC Panel made a number of recommendations related to the data process. The Panel's recommendations and our responses follow.

Recommendation 1: The Panel commends the CMS staff for responding to the data requests of the Data Subcommittee.

CMS Response to Recommendation 1: We appreciate this recommendation.

Recommendation 2: The Panel recommends that the work of the Data Subcommittee continue.

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

Recommendation 3: The Panel recommends that Agatha Nolen, D.Ph., M.S., F.A.S.H.P., serve as acting chairperson for the winter 2011 meeting of the Data Subcommittee.

CMS Response to Recommendation 3: We are accepting this recommendation.

d. Proposed Calculation of Single Procedure APC Criteria-Based Median 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 2012, we are proposing to use the standard methodology for calculating median costs for device-dependent APCs that was finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71834 through 71837). (We refer readers to sections II.D.6. and II.A.e.6. of this proposed rule for detailed explanations of the proposed nonstandard methodology regarding cardiac resynchronization therapy.) This methodology utilizes claims data that generally represent the full cost of the required

device. Specifically, we are proposing to calculate the median costs for device-dependent APCs for CY 2012 using only the subset of single procedure claims from CY 2010 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, supplier, or practitioner, 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 median costs for device-dependent APCs gives us the most appropriate median costs for device-dependent APCs in which the hospital incurs the full cost of the device.

Table 3 below lists the APCs for which we are proposing to use our standard device-dependent APC ratesetting methodology (as explained in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71834 through 71837)) for CY 2012. We note that there are five proposed device-dependent APC title changes and one proposed deletion for CY 2012. As discussed in detail in section II.A.2.d.(6) of this proposed rule, we are proposing to change the title of APC 0083 from "Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty" to "Level I Endovascular Revascularization of the Lower Extremity"; the title of APC 0229 from "Transcatheter

Placement of Intravascular Shunt 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." We also are proposing to change the title of APC 0040 from "Percutaneous Implantation of Neurostimulator Electrodes" to "Level I Implantation/Revision/Replacement of Neurostimulator Electrodes," and the title of APC 0061 from "Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electrodes" to "Level II Implantation/Revision/Replacement of Neurostimulator Electrodes," as discussed in section III.D.1. of this proposed rule. In addition, as discussed in section II.A.2.e.(6) of this proposed rule, we are proposing to delete APC 0418 (Insertion of Left Ventricular Pacing Electrode) for CY 2012.

As we discuss in detail in section III.D.6. of this proposed rule, we are proposing to limit the payment for services that are assigned to APC 0108 to the proposed IPPS standardized payment amount for MS-DRG 227 (Cardiac Defibrillator Implant without Cardiac Catheterization and without Medical Complications and Comorbidities) because we do not believe that it would be equitable to pay more under the OPPS for services assigned to APC 0108 than under the IPPS. In other words, we are proposing to pay APC 0108 at the lesser of the APC 0108 median cost or the IPPS standardized payment rate for MS-DRG 227. We are proposing to continue to apply the device edits and other standard features of the device-dependent APCs to APC 0108, but we are proposing to limit the payment amount under the OPPS to the amount of payment established for MS-DRG 227 under the IPPS.

We refer readers to Addendum A to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) for the proposed payment rates for these APCs for CY 2012.

TABLE 3.--PROPOSED CY 2012 DEVICE-DEPENDENT APCs

Proposed CY 2012 APC	Proposed CY 2012 Status Indicator	Proposed CY 2012 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	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

Proposed CY 2012 APC	Proposed CY 2012 Status Indicator	Proposed CY 2012 APC Title
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
0656	T	Transcatheter Placement of Intracoronary Drug-Eluting Stents
0674	T	Prostate Cryoablation
0680	S	Insertion of Patient Activated Event Recorders

*OPPS CY 2012 payment for APC 0108 is proposed to be paid at the lesser of the APC 0108 median cost or the standardized payment rate for MS-DRG 227 under the IPPS. We refer readers to section III.D.6. of this proposed rule for more information.

(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 2012, 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 median costs upon which the proposed CY 2012 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe the hospital-specific, blood-specific CCR methodology best responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We believe that continuing with this methodology in CY 2012 would result in median 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 referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) for the proposed CY 2012 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) Allergy Tests (APCs 0370 and 0381)

We are proposing to continue with our methodology of differentiating single allergy tests ("per test") from multiple allergy tests ("per visit") by assigning these services to two different APCs to provide accurate payments for these tests in CY 2012. Multiple allergy tests are currently assigned to APC 0370 (Allergy Tests), with a median

cost calculated based on the standard OPPS methodology. For CY 2012, we are proposing to continue to use the standard OPPS methodology to set the APC payment rate for APC 0370, which has a proposed APC median cost of approximately $97 based on 283 claims.

We provided billing guidance in CY 2006 in Transmittal 804 (issued on January 3, 2006) specifically clarifying that hospitals should report charges for the CPT codes that describe single allergy tests to reflect charges "per test" rather than "per visit" and should bill the appropriate number of units (as defined in the CPT code descriptor) of these CPT codes to describe all of the tests provided. Services assigned to APC 0381 (Single Allergy Tests) reflect the CPT codes that describe single allergy tests in which CPT instructions direct providers to specify the number of tests performed, whereas the procedures in APC 0370 describe multiple allergy tests per encounter; therefore, for these procedures, only one unit of the service is billed even if multiple tests are performed. Our CY 2010 claims data available for this proposed rule for APC 0381 do not reflect improved and more consistent hospital billing practices of "per test" for single allergy tests. The median cost of APC 0381 calculated for this proposed rule according to the standard single claims OPPS methodology, is approximately $51, significantly higher than the CY 2011 OPPS/ASC final rule median cost of approximately $33 that was calculated according to the "per unit" methodology, and greater than we would expect for these procedures that are to be reported "per test" with the appropriate number of units. Some claims for single allergy tests still appear to provide charges that represent a "per visit" charge, rather than a "per test" charge. Therefore, consistent with our

payment policy for single allergy tests since CY 2006, we calculated a proposed "per unit" median cost for APC 0381, based upon 601 claims containing multiple units or multiple occurrences of a single CPT code. The proposed CY 2012 median cost for APC 0381 using the "per unit" methodology is approximately $34. For a full discussion of the "per unit" methodology for APC 0381, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66737).

(4) Hyperbaric Oxygen Therapy (APC 0659)

Since the implementation of OPPS in August 2000, the OPPS has recognized HCPCS code C1300 (Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval) for hyperbaric oxygen therapy (HBOT) provided in the hospital outpatient setting. In the CY 2005 final rule with comment period (69 FR 65758 through 65759), we finalized a "per unit" median cost calculation for APC 0659 (Hyperbaric Oxygen) using only claims with multiple units or multiple occurrences of HCPCS code C1300 because delivery of a typical HBOT service requires more than 30 minutes. We observed that claims with only a single occurrence of the code were anomalies, either because they reflected terminated sessions or because they were incorrectly coded with a single unit. In the same rule, we also established that HBOT would not generally be furnished with additional services that might be packaged under the standard OPPS APC median cost methodology. This enabled us to use claims with multiple units or multiple occurrences. Finally, we also used each hospital's overall CCR to estimate costs for HCPCS code C1300 from billed charges rather than the CCR for the respiratory therapy or other departmental cost centers. Our rationale for using the hospital's overall CCR can

be found in the CY 2005 OPPS final rule with comment period (69 FR 65758 through 65759). The public comments on the CY 2005 OPPS proposed rule effectively demonstrated that hospitals report the costs and charges for HBOT in a wide variety of cost centers. Since CY 2005, we have used this methodology to estimate the median cost for HBOT. The median costs of HBOT using this methodology have been relatively stable for several years.

For CY 2012, we are proposing to continue using the same methodology to estimate a "per unit" median cost for HCPCS code C1300. This methodology results in a proposed APC median cost of approximately $107 using 370,519 claims with multiple units or multiple occurrences for HCPCS code C1300 for CY 2012.

(5) Payment for Ancillary Outpatient Services When Patient Expires (APC 0375)

In the November 1, 2002 final rule with comment period (67 FR 66798), we discussed the creation of the new HCPCS modifier "–CA" to address situations where a procedure on the OPPS inpatient list must be performed to resuscitate or stabilize a patient (whose status is that of an outpatient) with an emergent, life-threatening condition, and the patient dies before being admitted as an inpatient. HCPCS modifier "-CA" is defined as a procedure payable only in the inpatient setting when performed emergently on an outpatient who expires prior to admission. In Transmittal A-02-129, issued on January 3, 2003, we instructed hospitals on the use of this modifier. For a complete description of the history of the policy and the development of the payment methodology for these services, we refer readers to the CY 2007 OPPS final rule with comment period (71 FR 68157 through 68158).

For CY 2012, we are proposing to continue to use our established ratesetting methodology for calculating the median cost of APC 0375 (Ancillary Outpatient Services When Patient Expires) and to continue to make one payment under APC 0375 for the services that meet the specific conditions for using HCPCS modifier "–CA." That is, we are proposing to calculate the relative payment weight for APC 0375 by using all claims reporting a status indicator "C" (inpatient procedures) appended with HCPCS modifier "-CA." For the history and detailed explanation of the methodology, we refer readers to the CY 2004 OPPS final rule (68 FR 63467 through 63468), We continue to believe that this established ratesetting methodology results in the most appropriate aggregate median cost for the ancillary services provided in these unusual clinical situations.

We believe that hospitals are reporting the HCPCS modifier "–CA" according to the policy initially established in CY 2003. We note that the claims frequency for APC 0375 has been relatively stable over the past few years. We note that the median cost for APC 0375 has decreased based on the CY 2010 OPPS claims data used for the development of the proposed rates for CY 2012 compared to that for CY 2011. Variation in the median cost for APC 0375 is expected because of the small number of claims and because the specific cases are grouped by the presence of the HCPCS modifier "-CA" appended to an inpatient only procedure and not according to the standard APC criteria of clinical and resource homogeneity. Cost variation for APC 0375 from year to year is anticipated and acceptable as long as hospitals continue judicious reporting of the HCPCS modifier "-CA." Table 4 below shows the number of claims, and the median costs for APC 0375 for CYs 2007, 2008, 2009, 2010, and 2011, and the proposed median

cost for APC 0375 for CY 2012. For CY 2012, we are proposing a median cost of approximately $5,711 for APC 0375 based on 155 claims.

TABLE 4.--CLAIMS FOR ANCILLARY OUTPATIENT SERVICES WHEN PATIENT EXPIRES (–CA MODIFIER) FOR CYs 2007 THROUGH 2012

Prospective Payment Year	Number of Claims	APC Median Cost
CY 2007	260	$3,549
CY 2008	183	$4,945
CY 2009	168	$5,545
CY 2010	182	$5,911
CY 2011	168	$6,304
CY 2012	155	$5,711*

*Proposed median cost.

(6) 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 code book 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 new 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 most recent cost report data to create simulated medians for 12 of the 16 new separately payable codes for CY 2011. Because the endovascular revascularization CPT codes are 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 median costs, we selected claims that we believe meet 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 median 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 71842), we developed these criteria based on our clinicians' understanding of services that were reported by 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 median 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 displayed their final CY 2011 APC assignments and CPT median costs (75 FR 71845). We noted that because these CPT codes are new for CY 2011, they are 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 the new year and subject to public comment. We

specifically requested public comment on our methodology for simulating the median costs for these new CY 2011 CPT codes in addition to public comments on the payment rates themselves (75 FR 71845).

At its February 28-March 1, 2011 meeting, the APC Panel recommended that CMS provide data to allow the Panel to investigate and monitor the APC weights for the lower extremity revascularization procedures in light of CPT coding changes for CY 2011. We are accepting the APC Panel's recommendation and will provide additional data to the Panel at an upcoming meeting.

For CY 2012, we are proposing to continue with the CY 2011 methodology that was described previously in this section in determining the APC assignments for the CPT codes that describe endovascular revascularization of the lower extremity. The predecessor endovascular revascularization CPT codes were in existence prior to CY 2011 and were assigned to APCs based on claims data and cost report data. Given that these data are available for the services described by the predecessor endovascular revascularization CPT codes, we are proposing to continue for CY 2012 to use the existing hospital outpatient claims and cost report data from the previous endovascular revascularization CPT codes to simulate an estimated median cost for the new endovascular revascularization CPT codes in determining the appropriate APC assignments. As has been our practice since the implementation of the OPPS in 2000, we review our latest claims data for ratesetting and, if necessary, revise the APC assignments for the upcoming year. In this case, review of the procedures with significant claims data in APC 0083 showed a 2 times rule violation. Specifically, APC 0083, as it was initially

configured, showed that the range of the CPT median costs for the procedures with significant claims data was approximately between $3,252 (for CPT code 35476 (Transluminal balloon angioplasty, percutaneous; venous)) and $7,174 (for CPT code 37221 (Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed)), resulting in a 2 times rule violation. Because of its median cost, we believe that CPT code 37221 would be more appropriately placed in APC 0229, which had an initial estimated median cost of approximately $8,606, based on the clinical and resource characteristics of other procedures also assigned to APC 0229. Therefore, for CY 2012, we are proposing to revise the APC assignment for CPT code 37221, from APC 0083 to APC 0229, to accurately reflect the cost and clinical feature of the procedure. This proposed reassignment of CPT code 37221 from APC 0083 to APC 0029 eliminates the 2 times rule violation for APC 0083 noted above. Based on this reconfiguration, the CY 2010 claims data available for this proposed rule were used to calculate a median cost of approximately $4,683 for APC 0083, approximately $8,218 for APC 0229, and approximately $14,556 for APC 0319. All three proposed median costs for CY 2012 are significantly greater than the CY 2011 OPPS/ASC final rule median costs of approximately $3,740 for APC 0083, approximately $7,940 for APC 0229, and approximately $13,751 for APC 0319.

In addition, we are proposing to revise the APC titles for APCs 0083, 0229, and 0319 to better describe the procedures assigned to these APCs. Specifically, we are proposing to revise the APC title for APC 0083 from “Coronary or Non-Coronary

Angioplasty and Percutaneous Valvuloplasty" to "Level I Endovascular Revascularization of the Lower Extremity"; for APC 0229, from "Transcatheter Placement of Intravascular Shunt and Stents" to "Level II Endovascular Revascularization of the Lower Extremity"; and for APC 0319, from "Endovascular Revascularization of the Lower Extremity" to "Level III Endovascular Revascularization of the Lower Extremity."

We are soliciting public comments on the proposed status indicators and APC assignments for the endovascular revascularization of the lower extremity CPT codes. Table 5 below lists the endovascular revascularization of the lower extremity CPT codes along with their proposed status indicator and APC assignments for CY 2012.

TABLE 5.—PROPOSED APCs TO WHICH ENDOVASCULAR REVASCULARIZATION OF THE LOWER EXTREMITY CPT CODES WOULD BE ASSIGNED FOR CY 2012

CY 2011 HCPCS Code	CY 2011 Short Descriptor	CY 2011 SI	CY 2011 APC	Proposed CY 2012 SI	Proposed CY 2012 APC
37220	Iliac revasc	T	0083	T	0083
37221	Iliac revasc w/stent	T	0083	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	Tibper revasc w/ather add-on	T	0229	T	0229
37234	Revsc opn/prq tib/pero stent	T	0083	T	0083
37235	Tib/per revasc stnt & ather	T	0083	T	0083

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

For CY 2011, the AMA CPT Editorial Panel deleted 19 non-congenital cardiac catheterization-related CPT codes and replaced them with 20 new CPT codes in the Cardiac Catheterization and Injection-Related section of the 2011 CPT Code Book to describe more precisely the specific services provided during cardiac catheterization procedures. In particular, the CPT Editorial Panel deleted 19 non-congenital cardiac catheterization-related CPT codes from the 93500 series and created 14 new CPT codes in the 93400 series and 6 in the 93500 series. We discussed these coding changes in detail in the CY 2011 OPPS/ASC final rule with comment period, 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 (75 FR 71846 through 71849). As discussed in the 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 medians 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 median 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 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 congenital catheterization-related CPT codes in APC 0080, to calculate CPT level median costs and the median cost for APC 0080 of approximately $2,698. We noted that, because the CPT codes listed in Table 11 are new for CY 2011, they were identified with comment indicator "NI" in Addendum B of 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 median 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 are proposing to continue with the CY 2011 methodology in determining the APC assignments for the cardiac catheterization CPT codes. The predecessor cardiac catheterization CPT codes were in existence prior to CY 2011 and

were assigned to APC 0080 based on claims data and cost report data. Given that these data are available for the services described by the predecessor cardiac catheterization CPT codes, for CY 2012, we are proposing to continue to use the existing hospital outpatient claims and cost report data from the predecessor cardiac catheterization CPT codes to simulate an estimated median cost for the new cardiac catheterization CPT codes in determining the appropriate APC assignments. As has been our practice since the implementation of the OPPS in 2000, we review our latest claims data for ratesetting and, if necessary, revise the APC assignments for the upcoming year. Based on analysis of the CY 2010 claims data available for this proposed rule, the proposed median cost for APC 0080 is approximately $2,822 for CY 2012, which is slightly greater than the median cost of approximately $2,698 for the CY 2011 OPPS/ASC final rule with comment period. For CY 2012, we are not proposing any changes to the CY 2011 APC assignments of any of the codes assigned to APC 0080 because the claims data available for this proposed rule support continuation of these APC assignments.

We are soliciting public comments on the proposed status indicators and the APC assignments for the CY 2012 cardiac catheterization CPT codes. Table 6 below lists the CY 2011 cardiac catheterization CPT codes along with their proposed status indicators, APC assignments, and payment rates for CY 2012.

TABLE 6.—PROPOSED APCs TO WHICH NON-CONGENITAL CARDIAC CATHETERIZATION CPT CODES WOULD BE ASSIGNED FOR CY 2012

CY 2011 HCPCS Code	CY 2011 Short Descriptor	CY 2011 SI	CY 2011 APC	Proposed CY 2012 SI	Proposed CY 2012 APC
93451	Right heart cath	T	0080	T	0080
93452	Left hrt cath w/ventrclgrphy	T	0080	T	0080
93453	R&l hrt cath w/ventriclgrphy	T	0080	T	0080
93454	Coronary artery angio s&i	T	0080	T	0080
93455	Coronary art/grft angio s&i	T	0080	T	0080
93456	R hrt coronary artery angio	T	0080	T	0080
93457	R hrt art/grft angio	T	0080	T	0080
93458	L hrt artery/ventricle angio	T	0080	T	0080
93459	L hrt art/grft angio	T	0080	T	0080
93460	R&l hrt art/ventricle angio	T	0080	T	0080
93461	R&l hrt art/ventricle angio	T	0080	T	0080
93462	L hrt cath trnsptl puncture	T	0080	T	0080
93463	Drug admin & hemodynmic meas	N	NA	N	NA
93464	Exercise w/hemodynamic meas	N	NA	N	NA
93563	Inject congenital card cath	N	NA	N	NA
93564	Inject hrt congntl art/grft	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

(8) Cranial Neurostimulator and Electrodes (APC 0318)

For CY 2011, the AMA CPT Editorial Panel created a new CPT code 64568 (Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator) and indicates that it describes the services formerly included in the combinations of (1) CPT code 64573 (Incision for implantation of neurostimulator electrodes; cranial nerve) and CPT code 61885 (Insertion or replacement of cranial

neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array); or (2) CPT code 64573 and CPT code 61886 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays). As we discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71850), our standard process for assigning new CPT codes to APCs is to assign the code to the APC that we believe contains services that are comparable with respect to clinical characteristics and resources required to furnish the service. A new CPT code is given a comment indicator of "NI" to identify it as a new interim APC assignment for the first year and the APC assignment for the new code is then open to public comment. In some, but not all, cases, we are able to use the existing data from established codes to simulate an estimated median cost for the new code to guide us in the assignment of the new code to an APC. For CY 2011, in the case of the new neurostimulator electrode and pulse generator implantation CPT code, we were able to use the existing CY 2009 claims and most current cost report data to create a simulated median cost.

Specifically, to estimate the hospital costs of CPT code 64568 based on its CY 2011 descriptor, we used CY 2009 claims and the most recent cost report data, using the single and "pseudo" single claims within this data set to simulate the definition of this service. We selected claims with CPT code 64573 on which CPT code 61885 or 61886 was also present and consistent with the description of the new CPT code 64568. We treated the summed costs on these claims as if they were a single procedure claim for CPT code 64568. We created an estimated median cost of approximately $22,562 for

CPT code 64568 from 298 single claims to set a final payment rate for CY 2011 for the new code. We created APC 0318 (Implantation of Cranial Neurostimulator Pulse Generator and Electrode) for CY 2011, to which CPT code 64568 is the only procedure assigned. APC 0225 (Implantation of Neurostimulator Electrodes, Cranial Nerve), which contained only the predecessor CPT code 64573, was deleted effective January 1, 2011. We noted that, because CPT code 64568 is new for CY 2011, it was identified with comment indicator "NI" in Addendum B of the CY 2011 OPPS/ASC final rule with comment period to identify it as subject to public comment. We specifically requested public comment on our methodology for simulating the median costs for this new CY 2011 CPT code, in addition to public comments on the payment rate itself (75 FR 71850).

For CY 2012, we are proposing to use the same methodology we used in CY 2011 to estimate the hospital costs of CPT code 64568. We created an estimated median cost of approximately $24,267 for CPT code 64568 from 332 single claims to set a proposed payment rate for APC 0318 for CY 2012. We are proposing to maintain CPT code 64568 as the only code assigned to APC 0318 for CY 2012. We continue to request public comment on our proposed methodology for simulating the median cost for this CPT code introduced in CY 2011, in addition to public comments on the proposed payment rate itself.

(9) Brachytherapy Sources

(A) Background

Section 1833(t)(2)(H) of the Act, as added by section 621(b)(2)(C) of Pub. L. 108-173 (MMA), mandated the creation of additional groups of covered OPD

services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) ("brachytherapy sources") separately from other services or groups of services. The additional groups must reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished and include separate groups for palladium-103 and iodine-125 sources.

Section 1833(t)(16)(C) of the Act, as added by section 621(b)(1) of Pub. L. 108-173, established payment for brachytherapy sources furnished from January 1, 2004 through December 31, 2006, based on a hospital's charges for each brachytherapy source furnished adjusted to cost. Under section 1833(t)(16)(C) of the Act, charges for the brachytherapy sources may not be used in determining any outlier payments under the OPPS for that period in which payment is based on charges adjusted to cost. Consistent with our practice under the OPPS to exclude items paid at cost from budget neutrality consideration, these items were excluded from budget neutrality for that time period as well.

Subsequent to the MMA, various amendments to the Act were made that resulted in the extension of the payment period for brachytherapy sources based on a hospital's charges adjusted to cost through December 31, 2009. The CY 2011 OPPS/ASC final rule with comment period summarizes these amendments to the Act and our proposals to pay for brachytherapy sources at prospective payment rates based on their source specific median costs from CY 2007 through CY 2009 (75 FR 71977 through 71981).

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60533 through 60537), we adopted for CY 2010 the general OPPS prospective payment methodology

for brachytherapy sources, consistent with section 1833(t)(2)(C) of the Act, with payment rates based on source-specific median costs. For CY 2011, we continued to use the general OPPS prospective payment methodology for brachytherapy sources, consistent with section 1833(t)(2)(C) of the Act (75 FR 71980). We also finalized our proposals to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537 and 75 FR 71980) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was superseded by section 142 of Pub. L. 110-275). That policy is intended to enable us to assign future 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, for CYs 2010 and 2011, we finalized proposals 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 (75 FR 71980 through 71981 and 75 FR 60537). Hospitals could receive outlier payments for brachytherapy sources if the costs of furnishing brachytherapy sources meet the criteria for outlier payment. In addition, as noted in the CY 2010 and CY 2011 OPPS/ASC final rules with comment period (74 FR 60534 and 75 FR 71978 and 71979, respectively), implementation of prospective payments for brachytherapy sources provided opportunities for eligible hospitals to receive additional payments in CY 2010 and

CY 2011 under certain circumstances through the 7.1 percent rural adjustment, as described in section II.E. of this final rule with comment period.

(B) Proposed OPPS Payment Policy

As we have stated previously (72 FR 66780, 73 FR 41502, 74 FR 60533 through 60534, and 75 FR 71978), 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 median 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 eliminating some of the extremely high and low payment amounts resulting from 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.

For CY 2012, we are proposing to use the median costs from CY 2010 claims data for setting the proposed CY 2012 payment rates for brachytherapy sources, as we are proposing for most other items and services that will be paid under the CY 2012 OPPS. 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). The proposed payment methodology for NOS sources would provide payment to a hospital for new sources and, at the same time, encourage interested parties to quickly bring new sources to our attention so that specific coding and payment could be established.

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, 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. In addition, as noted in the CY 2010 and CY 2011 OPPS/ASC final rules with comment period (74 FR 60534 and 75 FR 71978 through 71979, respectively), implementation of prospective payments for brachytherapy sources would provide opportunities for eligible hospitals to receive additional payments in CY 2012 under certain circumstances through the 7.1 percent rural adjustment, as described in section II.E. of this proposed rule.

Therefore, we are proposing to pay for brachytherapy sources at prospective payment rates based on their source-specific median costs for CY 2012. We refer readers to Addendum B to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) for the proposed CY 2012 payment rates for brachytherapy sources, identified with status indicator "U." For more detailed discussion of the legislative history surrounding brachytherapy sources and our proposed and final policies for CY 2004 through CY 2011, we refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 71977 through 71981).

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

e. Proposed Calculation of Composite APC Criteria-Based Median 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 APC policies for extended assessment and management services, low dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, and multiple imaging 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).

For CY 2012, we are proposing to continue, with some modifications, our established composite APC policies for extended assessment and management, LDR prostate brachytherapy, cardiac electrophysiologic evaluation and ablation, mental health

services, and multiple imaging 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), and II.A.2.e.(5), respectively, of this proposed rule. We also are proposing to create a new composite APC for cardiac resynchronization therapy services, as discussed in section II.A.2.e.(6) of this proposed rule.

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

For CY 2012, 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 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 two composite APCs as appropriate.

As defined for the CY 2008 OPPS, composite APC 8002 describes an encounter for care provided to a patient that includes a high level (Level 5) clinic visit or direct referral for observation services in conjunction with observation services of substantial duration (72 FR 66648 through 66649). Composite APC 8003 describes an encounter for care provided to a patient that includes a high level (Level 4 or 5) Type A emergency department visit, a high level (Level 5) Type B emergency department visit, or critical care services in conjunction with observation services of substantial duration. HCPCS

code G0378 (Observation services, per hour) is assigned status indicator "N," signifying that its payment is always packaged. As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66648 through 66649), the Integrated Outpatient Code Editor (I/OCE) evaluates every claim received to determine if payment through a composite APC is appropriate. If payment through a composite APC is inappropriate, the I/OCE, in conjunction with the OPPS Pricer, determines the appropriate status indicator, APC, and payment for every code on a claim. The specific criteria that must be met for the two extended assessment and management composite APCs to be paid are provided below in the description of the claims that were selected for the calculation of the proposed CY 2012 median costs for these composite APCs. We are not proposing to change these criteria for the CY 2012 OPPS.

When we created composite APCs 8002 and 8003 for CY 2008, we retained as general reporting requirements for all observation services those criteria related to physician order and evaluation, documentation, and observation beginning and ending time as listed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66812). These are more general requirements that encourage hospitals to provide medically reasonable and necessary care and help to ensure the proper reporting of observation services on correctly coded hospital claims that reflect the full charges associated with all hospital resources utilized to provide the reported services. We also issued guidance clarifying the correct method for reporting the starting time for observation services (sections 290.2.2 through 290.5 in the Medicare Claims Processing Manual (Pub. 100-4), Chapter 4, through Transmittal 1745, Change Request 6492, issued May 22, 2009 and

implemented July 6, 2009). We are not proposing to change these reporting requirements for the CY 2012 OPPS.

For CY 2012, we are proposing to continue the extended assessment and management composite APC payment methodology for APCs 8002 and 8003. 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 are proposing to calculate the median costs for APCs 8002 and 8003 using all single and "pseudo" single procedure claims for CY 2010 that meet the criteria for payment of each composite APC.

Specifically, to calculate the proposed median costs for composite APCs 8002 and 8003, we selected single and "pseudo" single procedure claims that met each of the following criteria:

1. Did not contain a HCPCS code to which we have assigned status indicator "T" that is reported with a date of service 1 day earlier than the date of service associated with HCPCS code G0378. (By selecting these claims from single and "pseudo" single claims, we had already assured that they would not contain a code for a service with status indicator "T" on the same date of service.);

2. Contained eight or more units of HCPCS code G0378; and

3. Contained one of the following codes:

● In the case of composite APC 8002, HCPCS code G0379 (Direct referral of patient for hospital observation care) on the same date of service as HCPCS code G0378; or CPT code 99205 (Office or other outpatient visit for the evaluation and management of a new patient (Level 5)); or CPT code 99215 (Office or other outpatient visit for the

evaluation and management of an established patient (Level 5)) provided on the same date of service or one day before the date of service for HCPCS code G0378.

- In the case of composite APC 8003, CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes); or HCPCS code G0384 (Level 5 hospital emergency department visit provided in a Type B emergency department) provided on the same date of service or one day before the date of service for HCPCS code G0378. (As discussed in detail in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68684), we added HCPCS code G0384 to the eligibility criteria for composite APC 8003 for CY 2009.)

As discussed further in section VII. of this proposed rule, and consistent with our CY 2008, CY 2009, CY 2010, and CY 2011 final policies, when calculating the median costs for the clinic, Type A emergency department visit, Type B emergency department visit, and critical care APCs (0604 through 0617 and 0626 through 0630), we utilize our methodology that excludes those claims for visits that are eligible for payment through the two extended assessment and management composite APCs, that is APC 8002 or APC 8003. We believe that this approach results in the most accurate cost estimates for APCs 0604 through 0617 and 0626 through 0630 for CY 2012.

At its February 28-March 1, 2011 meeting, the APC Panel recommended that CMS consider expanding the extended assessment and management composite APCs for CY 2012. We are accepting this recommendation.

Consistent with our acceptance of the APC Panel's recommendation, we have examined various ways of potentially expanding the current extended assessment and management composite APCs to further limit the possibility that total beneficiary copayments would exceed the inpatient deductible during extended observation encounters. At this time, we have decided not to pursue for CY 2012 the expanded extended assessment and management composite APCs that we analyzed because, while the composites that we modeled would serve to further limit the number of beneficiaries with copayments that exceeded the inpatient deductible, the modeled composites also had the effect of possibly increasing copayments by a small amount for the majority of beneficiaries undergoing extended observation. In addition, expanded assessment and management composite APCs do not address certain concerns about extended observation services raised by stakeholders at CMS' observation listening session last year (that is, observation time not counting towards the 3-day prior hospitalization requirement for the skilled nursing facility benefit). We will continue our efforts to model other composite structures for a possible new extended assessment and management composite structure for CY 2013.

In summary, for CY 2012, we are proposing to continue to include composite APCs 8002 and 8003 in the OPPS. We are proposing to continue the extended assessment and management composite APC payment methodology and criteria that we

finalized for CYs 2009, 2010, and 2011. We also are proposing to calculate the median costs for APCs 8002 and 8003 using the same methodology that we used to calculate the medians for composite APCs 8002 and 8003 for the CY 2008 OPPS (72 FR 66649). That is, we used all single and "pseudo" single procedure claims from CY 2010 that met the criteria for payment of each composite APC and applied the standard packaging and trimming rules to the claims before calculating the proposed CY 2012 median costs. The proposed CY 2012 median cost resulting from this methodology for composite APC 8002 is approximately $395, which was calculated from 16,770 single and "pseudo" single bills that met the required criteria. The proposed CY 2012 median cost for composite APC 8003 is approximately $735, which was calculated from 225,874 single and "pseudo" single bills that met the required criteria.

(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). Generally, the component services represented by both codes are provided in the same operative session in the same hospital on the same date of service to the Medicare beneficiary being treated with LDR

brachytherapy for prostate cancer. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66653), OPPS payment rates for CPT code 77778, in particular, had fluctuated over the years. We were frequently informed by the public that reliance on single procedure claims to set the median costs for these services resulted in 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 (that is, a multiple procedure claim).

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 median 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. In uncommon occurrences in which the services are billed individually, hospitals have continued to receive separate payments for the individual services. 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 2012, we are proposing to continue paying for LDR prostate brachytherapy services using the composite APC methodology proposed and implemented for CY 2008 through CY 2011. That is, we are proposing to use CY 2010 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 2011 practice, we are proposing not to use the claims that meet these criteria in the calculation of the median 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. The median costs for APCs 0163 and 0651 would 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 median cost upon which to base the composite APC payment rate.

Using partial year CY 2010 claims data available for this CY 2012 proposed rule, we were able to use 556 claims that contained both CPT codes 55875 and 77778 to calculate the median cost upon which the proposed CY 2012 payment for composite

APC 8001 is based. The proposed median cost for composite APC 8001 for CY 2012 is approximately $3,364. This is an increase compared to the CY 2011 final median cost for this composite APC of approximately $3,195 based on 849 single bill claims from a full year of CY 2009 claims data. The proposed CY 2012 median cost for this composite APC is slightly less than $3,555, the sum of the proposed median costs for APCs 0163 and 0651 ($2,658 + $897), the APCs to which CPT codes 55875 and 77778 map if one service is billed on a claim without the other. We believe the proposed CY 2012 median cost for composite APC 8001 of approximately $3,364, calculated from claims we believe to be correctly coded, would result in a reasonable and appropriate payment rate for this service in CY 2012.

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

Cardiac electrophysiologic evaluation and ablation services frequently are performed in varying combinations with one another during a single episode of care in the hospital outpatient setting. Therefore, 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)). As a result, there would never be many single bills for cardiac electrophysiologic evaluation and ablation services, and those that are reported as single bills would often represent atypical cases or incorrectly coded claims. As described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66655 through 66659),

the APC Panel and the public expressed persistent concerns regarding the limited and reportedly unrepresentative single bills available for use in calculating the median costs for these services according to our standard OPPS methodology.

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. Calculating a composite APC for these services allowed us to utilize many more claims than were available to establish the individual APC median costs for these services, and we also saw this composite APC as an opportunity to advance our stated goal of promoting hospital efficiency through larger payment bundles. In order to calculate the median 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 2012, 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 2011. Consistent with our CY 2008 through CY 2011 practice, we are proposing not to use the claims that meet the composite payment criteria in the calculation of the median costs for APC 0085 and APC 0086, to which the CPT codes in both groups A and B for composite APC 8000 are otherwise assigned. Median costs for APCs 0085 and 0086 would continue to be calculated using single procedure claims. We continue to believe that the composite APC methodology for cardiac electrophysiologic evaluation and ablation services is the most efficient and effective way to use the claims data for the majority of these services and best represents the hospital resources associated with performing the common combinations of these services that are clinically typical. Furthermore, this approach creates incentives for efficiency by providing a single payment for a larger bundle of major procedures when they are performed together, in contrast to continued separate payment for each of the individual procedures.

For CY 2012, using a partial year of CY 2010 claims data available for this proposed rule, we were able to use 11,156 claims containing a combination of group A and group B codes and calculate a proposed median cost of approximately $11,598 for composite APC 8000. This is an increase compared to the CY 2011 final median cost for this composite APC of approximately $10,673 based on a full year of CY 2009 claims data. We believe the proposed median cost of $11,598 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.

Table 7 below list the groups of procedures upon which we based proposed composite APC 8000 for CY 2012.

TABLE 7.—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 2011 CPT Code	Proposed Single Code CY 2012 APC	Proposed CY 2012 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

Codes Used in Combinations: At Least One in Group A and One in Group B	CY 2011 CPT Code	Proposed Single Code CY 2012 APC	Proposed CY 2012 SI (Composite)
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 2012, 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 treatment for CY 2012. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy. We continue to believe that the costs associated with administering a partial hospitalization program represent the most resource-intensive of all outpatient mental health treatment. Therefore, we do not believe that we should pay more for a day of individual mental health services under the OPPS than the partial hospitalization per diem payment.

As discussed in detail in section VIII. of this proposed rule, for CY 2012, we are proposing to continue using a provider-specific two tiered payment approach for partial hospitalization services that distinguishes payment made for services furnished in a CMHC from payment made for services furnished in a hospital. Specifically, we are

proposing one APC for partial hospitalization program days with three services furnished in a CMHC (APC 0172, (Level I Partial Hospitalization (3 services) for CMHCs) and one APC for days with four or more services furnished in a CMHC (APC 0173, Level II Partial Hospitalization (4 or more services) for CMHCs). We are proposing that the payment rates for these two APCs be based upon the median per diem costs calculated using data only from CMHCs. Similarly, we are proposing one APC for partial hospitalization program days with three services furnished in a hospital (APC 0175, Level I Partial Hospitalization (3 services) for Hospital-Based PHPs), and one APC for days with four or more services furnished in a hospital (APC 0176, Level II Partial Hospitalization (4 or more services) for Hospital-Based PHPs). We are proposing that the payment rates for these two APCs be based on the median per diem costs calculated using data only from hospitals.

Because our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment rate for the most resource-intensive of all outpatient mental health treatment, we are proposing to continue to set the CY 2012 payment rate for APC 0034 (Mental Health Services Composite) at the same rate as we are proposing for APC 0176, which is the maximum partial hospitalization per diem payment. We believe this APC payment rate would provide the most appropriate payment for composite APC 0034, taking into consideration the intensity of the mental health services and the differences in the HCPCS codes for mental health services that could be paid through this composite APC compared with the HCPCS codes that could be paid through partial hospitalization

APC 0176. 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, we are proposing that those specified mental health services would be assigned to APC 0034. We are proposing that APC 0034 would have the same payment rate as APC 0176 and that the hospital would continue to be paid one unit of APC 0034. The I/OCE currently determines, and we are proposing for CY 2012 that it would continue to determine, whether to pay these specified mental health services individually or to 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.

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

Prior to CY 2009, hospitals received a full APC payment for each imaging service on a claim, regardless of how many procedures were performed during a single session using the same imaging modality. Based on extensive data analysis, we determined that this practice neither reflected nor promoted the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). As a result of our data analysis, and in response to ongoing recommendations from MedPAC to improve payment accuracy for imaging services under the OPPS, we expanded the composite APC model developed in CY 2008 to multiple imaging services. 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. 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 13 of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71859 through 71860).

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.

Hospitals continue to use the same HCPCS codes to report imaging procedures, and the I/OCE determines when combinations of imaging procedures qualify for composite APC payment or map to standard (sole service) APCs for payment. 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).

At its February 2010 meeting, the APC Panel recommended that CMS continue providing analysis on an ongoing basis of the impact on beneficiaries of the multiple imaging composite APCs as data become available. In the CY 2011 OPPS/ASC proposed rule, we indicated that we were accepting this recommendation and would provide the requested analysis to the APC Panel at a future meeting (75 FR 46212). At the February 28-March 1, 2011 APC Panel meeting, CMS staff provided an updated analysis of the multiple imaging composite APCs to the Panel, comparing partial year CY 2010 imaging composite cost and utilization data to comparable CY 2009 data in order to meet the APC Panel request that we provide analysis of the impact on beneficiaries of the multiple imaging composite APCs.

For CY 2012, we are proposing to continue paying for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite payment methodology. The proposed CY 2012 payment

rates for the five multiple imaging composite APCs (APC 8004, APC 8005, APC 8006, APC 8007, and APC 8008) are based on median costs calculated from the partial year CY 2010 claims available for this 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 median costs, we used the same methodology that we used to calculate the final CY 2011 median costs for these composite APCs. That is, we removed any HCPCS codes in the OPPS imaging families that overlapped with codes on our bypass list ("overlap bypass codes") to avoid splitting claims with multiple units or multiple occurrences of codes in an OPPS imaging family into new "pseudo" single claims. The imaging HCPCS codes that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC median costs appear in Table 9 of this proposed rule. (We note that, consistent with our proposal in section II.A.1.b. of this proposed rule to add CPT code 71550 (Magnetic resonance (eg, proton) imaging, chest (eg, for evaluation of hilar and mediastinal lymphadenopathy); without contrast material(s)) to the list of bypass codes for CY 2012, we also are proposing to add CPT code 71550 to the list of proposed OPPS imaging family services overlapping with HCPCS codes on the proposed CY 2012 bypass list.) We integrated the identification of imaging composite "single session" claims, that is, claims with multiple imaging procedures within the same family on the same date of service, into the creation of "pseudo" single procedure claims to ensure that claims were split in the "pseudo" single process into accurate reflections of either a composite "single session" imaging service or a standard sole imaging service resource cost. Like all single

bills, the new composite "single session" claims were for the same date of service and contained no other separately paid services in order to isolate the session imaging costs. Our last step after processing all claims through the "pseudo" single process was to reassess the remaining multiple procedure claims using the full bypass list and bypass process in order to determine if we could make other "pseudo" single bills. That is, we assessed whether a single separately paid service remained on the claim after removing line-items for the "overlap bypass codes."

As discussed in detail in section III.D.2. of this proposed rule, we are proposing to establish two APCs to which we would propose to assign the codes created for CY 2011 by the AMA's CPT Editorial Board for combined abdominal and pelvis CT services. Specifically, we are proposing to create new APC 0331 (Combined Abdominal and Pelvis CT Without Contrast), to which we are proposing to assign CPT code 74176 (Computed tomography, abdomen and pelvis; without contrast material); and we are proposing to create new APC 0334 (Combined Abdominal and Pelvis CT With Contrast), to which we are proposing to assign CPT codes 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)) and 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions) for the CY 2012 OPPS. As noted and listed in section III.D.2. of this proposed rule, we selected claims of predecessor codes of new CPT codes 74176, 74177, and 74178 to calculate the costs of proposed new APCs 0331 and 0334, respectively. Therefore, we are proposing not to use

those claims listed in Table 21 in section III.D.2. of this proposed rule in calculating the costs of APCs 8005 and 8006.

We were able to identify 1 million "single session" claims out of an estimated 2 million potential composite cases from our ratesetting claims data, or approximately half of all eligible claims, to calculate the proposed CY 2012 median costs for the multiple imaging composite APCs. We list in Table 8 below the HCPCS codes that would be subject to the proposed multiple imaging composite policy, the approximate proposed median costs for the imaging composite APCs, and their respective families for CY 2012. The HCPCS codes listed in Table 8 are assigned status indicated "Q3"" in Addendum B to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) to identify their status as potentially payable through a composite APC. Their proposed composite APC assignment is identified in Addendum M to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site). Table 9 below lists the OPPS imaging family services that overlap with HCPCS codes on the proposed CY 2012 bypass list.

TABLE 8.—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs

Family 1 – Ultrasound	
Proposed CY 2012 APC 8004 (Ultrasound Composite)	**Proposed CY 2012 Approximate APC Median Cost = $197**
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 2012 APC 8005 (CT and CTA without Contrast Composite)*	**Proposed CY 2012 Approximate APC Median Cost = $445**
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 2012 APC 8006 (CT and CTA with Contrast Composite)	**Proposed CY 2012 Approximate APC Median Cost = $744**
70487	Ct maxillofacial w/dye
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o&w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye

71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o&w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o&w/dye
73206	Ct angio upr extrm w/o&w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o&w/dye
73706	Ct angio lwr extr w/o&w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
74177	Ct angio abd&pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
***** If a "without contrast" CT or CTA procedure is performed during the same session as a "with contrast" CT or CTA procedure, the I/OCE will assign APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
Proposed CY 2012 APC 8007 (MRI and MRA without Contrast Composite)*	**Proposed CY 2012 Approximate APC Median Cost = $718**
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 2012 APC 8008 (MRI and MRA with Contrast Composite)	**Proposed CY 2012 Approximate APC Median Cost = $1,032**
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
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 8007.	

TABLE 9.--PROPOSED OPPS IMAGING FAMILY SERVICES OVERLAPPING WITH HCPCS CODES ON THE PROPOSED CY 2012 BYPASS LIST

Family 1 – Ultrasound	
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76775	Us exam abdo back wall, lim
76776	Us exam k transpl w/Doppler
76856	Us exam, pelvic, complete
76870	Us exam, scrotum
76857	Us exam, pelvic, limited
Family 2 - CT and CTA with and without Contrast	
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
Family 3 - MRI and MRA with and without Contrast	
70336	Magnetic image, jaw joint
70544	Mr angiography head w/o dye
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 (APCs 0108, 0418, 0655, and 8009)

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." CRT performed by the implantation of a pacemaker along with a pacing electrode is referred to as "CRT–P."

CRT-D procedures are described by combinations of CPT codes for the insertion of pulse generators and the insertion of the leads associated with ICDs, along with the insertion of the pacing electrode. For the implantation of a pulse generator, hospitals may use CPT code 33240 (Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator), which is the only CPT code assigned to APC 0107 (Insertion of Cardioverter-Defibrillator) for CY 2011. For the implantation of a pulse generator and leads, hospitals may use CPT code 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator), which is the only CPT code assigned to APC 0108 (Insertion/Replacement /Repair of Cardioverter-Defibrillator Leads) for CY 2011.

For CRT-P, hospitals may use CPT codes 33206 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial) and 33207 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); ventricular), which are assigned to APC 0089 (Insertion/Replacement of Permanent Pacemaker and

Electrodes) for CY 2011. Hospitals also may use CPT code 33208 (Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular), for the implantation of a pacemaker with leads, which is assigned to APC 0655 (Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker).

When CRT-P is provided, hospitals would report CPT code 33206, 33207, or 33208 codes for ICD or pacemaker insertion, along with CPT code 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (including upgrade to dual chamber system)), for implantation of the pacing electrode, which is assigned to APC 0418 (Insertion of Left Ventricular Pacing Electrode) for CY 2011.

A number of commenters who responded to prior OPPS proposed rules, as well as public presenters to the APC Panel, have recommended that CMS establish new composite APCs for CRT-D, citing significant fluctuations in the median cost for CPT code 33225 and the payment rate for APC 0418. The commenters and presenters have pointed out 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 single or pseudo single claims upon which to calculate an accurate median cost. These commenters and presenters also asserted that claims data for these services demonstrate that the percentage of single claims available for use in CRT ratesetting is very low compared to the total number of claims submitted for CRT–D or CRT–P services. The APC Panel at its February and August 2009 meetings recommended that CMS evaluate the implications of the creation of a new composite APC for CRT-D and

recommended that CMS reconsider creating a composite APC or group of composite APCs for CRT-D and CRT-P. While we did not propose any new composite APCs for CY 2010 or CY 2011, we accepted both of these APC Panel recommendations (75 FR 71852).

In response to the APC Panel recommendations and the comments we have received, we have evaluated the implications of creating four composite APCs for CRT, which would include the ICD and pacemaker insertion procedures listed previously in this section (described by CPT codes 33240, 33249, 33206, 33207, and 33208) performed in combination with the insertion of a pacing electrode (described by CPT code 33225). Table 10 below outlines the four potential composite APCs that we modeled. Specifically, we provide a description of each potential composite APC, the combination of CPT codes that we used to define the potential composite APC, the frequency of claims that met the definition of the potential composite APC that could be used to calculate a median cost for the potential composite APC, and the median cost calculated for the potential composite APC. Table 10 below contains the results from our calculations for the four potential composite APCs using CY 2010 claims data available for this proposed rule, that is, those claims processed between January 1 and December 31, 2010.

TABLE 10.—POTENTIAL COMPOSITE APCs

Potential Composite APC	Description	Component APCs	CPT Codes	CY 2010 Frequency	CY 2012 Payment Estimate
A	Cardiac Resynchronization Therapy - ICD Pulse Generator and Leads	0418 0107	33225 33240	21	$35,623
B	Cardiac Resynchronization Therapy - ICD Pulse Generator	0418 0108	33225 33249	2,358	$38,854
C	Cardiac Resynchronization Therapy - Pacemaker Pulse Generator, and Leads (Atrial or Ventricular)	0418 0089	33225 33206 33207	84	$17,306
D	Cardiac Resynchronization Therapy - Pacemaker Pulse Generator, and Leads (Atrial and Ventricular)	0418 0655	33225 33208	314	$18,705

For CY 2012, under the authority of section 1833(t)(1)(B) of the Act, we are proposing to create a new composite APC 8009 (Cardiac Resynchronization Therapy with Defibrillator Composite), listed as potential composite APC "B" in Table 10 above, for CRT-D services. This proposed composite APC is the only modeled composite in the study as shown above in Table 10, with significant claims volume, and would combine a procedure currently in APC 0418 with a procedure currently in APC 0108 (Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads) when performed on the same date of service. Specifically, we are proposing to create composite APC 8009,

which would be used when CPT 33249 and CPT 33225 are performed on the same day, in order to recognize the inherent challenges in calculating accurate median costs for CPT code 33225 based on single procedure claims utilized in standard OPPS ratesetting methodology, and to address commenters' concerns regarding the fluctuations in median costs for APC 0418. We believe a composite payment methodology is appropriate for these services and would result in more accurate payment for these services because such a methodology is specifically designed to provide payment for two or more procedures when they are provided in the same encounter, thus enabling us to use more claims data and to use claims data that more accurately represents the full cost of the services when they are furnished in the same encounter. We also believe that there is sufficient claims volume for CPT 33249 and CPT 33225 provided in the same encounter to warrant creation of the composite APC. In addition, we believe that the claims volume for CPT 33249 and CPT 33225 is sufficient to demonstrate that these services are commonly performed together. While the other combinations of CRT procedures listed in Table 10 may also be performed together, we are not proposing to implement composite APCs for these services because of the low frequency with which CPT code 33225 is reported with other CPT codes for ICD and pacemaker insertion in the claims data. As we have stated previously (74 FR 60392), because of the complex claims processing and ratesetting logic involved, in the past, we have explored composite APCs only for combinations of services that are commonly performed together. Because of the low frequency of the other combinations of CRT procedures listed in Table 10, we do not consider them to be commonly performed together.

Under the authority of section 1833(t)(2)(E) of the Act, we also are proposing to cap the payment rate for composite APC 8009 at the most comparable Medicare-severity diagnosis-related group (MS-DRG) payment rate established under the IPPS that would be provided to acute care hospitals for providing CRT-D services to hospital inpatients. Specifically, we are proposing to pay APC 8009 at the lesser of the APC 8009 median cost or the IPPS payment rate for MS-DRG 227 (Cardiac Defibrillator Implant without Cardiac Catheterization without Major Complication or Comorbidity), as adopted in the FY 2012 IPPS/LTCH PPS final rule. We would establish the OPPS payment amount at the FY 2012 IPPS standardized payment amount for MS-DRG 227. In the FY 2012 IPPS/LTCH proposed rule, this amount is $26,364.93. We calculated the standardized payment rate for MS-DRG 227 ($26,364.93) by multiplying the normalized weight from Table 5 of the FY 2012 IPPS/LTCH PPS proposed rule (5.1370) by the sum of the nonlablor and labor-related shares of the proposed FY 2012 IPPS operating standardized amount (nonwage-adjusted) ($5,132.36) which were obtained from Table 1B. For further detail on the calculation of the IPPS proposed FY 2012 payments rates, we refer readers to the FY 2012 IPPS / LTCH PPS proposed rule (76 FR 26028 through 26029).

We consider the standardized payment rate for MS-DRG 227 to represent appropriate payment for a comparable package of services furnished to outpatients. We believe that, because this MS-DRG includes defibrillator implantation for those inpatients without major complications or comorbidities, it represents the payment made for hospital inpatients who are most similar to patients who would receive CRT-D on an outpatient basis, because hospital outpatients are generally less sick than hospital

inpatients and because patients who had complications or comorbitities would be most likely to be admitted to inpatient status to receive CRT-D therapy. Similar to the proposed payment rate for composite APC 8009, the proposed payment rate for MS-DRG 227 includes the device costs associated with CRT-D along with the service costs associated with CPT codes 33249 and 33225, which are the procedures that are reported for implanting those devices. We believe that we should not pay more for these services under the proposed OPPS composite APC payment than under the IPPS because the OPPS payment would, by definition, include fewer items and services than the corresponding IPPS MS-DRG payment. For example, the IPPS MS-DRG payment includes payment for drugs and diagnostic tests that would be separately payable under the OPPS. A payment cap is necessary, therefore, to ensure that we do not create an inappropriate payment incentive to provide CRT-D services in one setting of care over another by paying more for CRT-D in the outpatient setting compared to the inpatient setting. We also believe that limiting payment for CRT-D services under the OPPS to the IPPS MS-DRG payment will ensure appropriate and equitable payment to hospitals because patients who receive these services in the hospital outpatient setting are not as sick as patients who have been admitted to receive this same service in the hospital inpatient setting. Therefore, we expect it would be less costly to provide care for these patients, who would also spend less time in the facility. For more detail and how this payment rate was calculated, we refer readers to section III. D. 6 of this proposed rule.

In order to ensure that hospitals correctly code for CRT services in the future, we are proposing to create claim processing edits that would return claims to providers

unless CPT code 33225 is billed in conjunction with one of the following CPT codes, as specified by AMA in the CPT code book:

- 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).

Finally, in order to reduce the extent to which payment rates for the two services currently assigned to APC 0418, described by CPT codes 33224 and 33225, might continue to fluctuate, we also are proposing to move CPT 33225 from APC 0418 to APC 0108. We believe that moving these codes to APCs that have higher volumes of services to which they are more similar in clinical characteristics and median costs will increase the stability of the payments for these services from year to year. In general, a higher volume of services across multiple procedures within an APC results in more stable APC median costs and, therefore, in the payment rate from one year to the next. We also are proposing to change the name of APC 0108 from "Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads" to "Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes." Similarly, we are proposing to move CPT 33224 from APC 0418 to APC 0655 and to change the name of APC 0655 from "Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker" to "Insertion/Replacement/Conversion of a Permanent Dual

Chamber Pacemaker or Pacing Electrode." We believe that moving CPT code 33224 into APC 0655 will promote stability in payment for CPT code 33224 because CPT code 33224 would then be in an APC with similar median costs but with a higher volume of services and, therefore, will benefit from the stability in APC median cost and payment rate that generally results as the volume of services within an APC increases. Because these proposed actions would result in APC 0418 containing no CPT codes, we are proposing to delete APC 0418.

In summary, for CY 2012, we are proposing to create a composite for CRT-D services billed with CPT code 33225 and CPT code 33249 on the same date of service (Composite APC 8009 (Cardiac Resynchronization Therapy - ICD Pulse Generator and Leads)), for which we are proposing that payment would be capped at the IPPS payment rate for MS-DRG 227. In other words, we would pay APC 8009 at the lesser of the APC 8009 median cost or the IPPS standardized payment for MS-DRG 227. We also are proposing to implement claims processing edits that would return to providers incorrectly coded claims on which a pacing electrode insertion (CPT code 33225) is billed without an ICD or pacemaker insertion. Finally, we are proposing to delete APC 0418, and to redistribute its component CPT codes (33225 and 33224) to APCs 0108 and 0655. The proposed changes would all be made in a budget neutral manner, in the same way that payment for other composite APCs and the reassignment of codes to APCs are budget neutral within the OPPS. We refer readers to section II.A.4 of this proposed rule for a discussion of the scaling of payment weights for budget neutrality.

3. Proposed Changes to Packaged Services

a. Background

The OPPS, like other prospective payment systems, relies on the concept of averaging, where the payment may be more or less than the estimated cost of providing a service or bundle of services for a particular patient, but with the exception of outlier cases, the payment is adequate to ensure access to appropriate care. Packaging payment for multiple interrelated services into a single payment creates 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. Packaging also encourages hospitals to negotiate carefully 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 carefully scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the stability of payment for services over time. Finally, packaging also may reduce the importance of refining service-specific payment because there is more opportunity for hospitals to average payment across higher cost cases requiring many ancillary services and lower cost cases requiring fewer ancillary services. For these reasons, packaging payment for 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 assign status indicator "N" to those HCPCS codes 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 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 when one or more separately paid primary services with the status indicator of "S," "T," "V," or "X" are furnished in the hospital outpatient encounter. A "T-packaged code" describes a code whose payment is packaged when 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 XI.A.1. of this proposed rule and Addenda D1 (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) with other Addenda, for a complete listing of proposed status indicators and the meaning of each.

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."

Hospitals include HCPCS codes and charges for packaged services on their claims, and the estimated costs associated with those packaged services are then added to the costs of separately payable procedures on the same claims in establishing payment rates for the separately payable services. We encourage hospitals to report all HCPCS codes that describe packaged services that were provided, unless the CPT Editorial Panel or CMS provide 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 our Medicare beneficiaries.

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 into the payment for the primary diagnostic or therapeutic modality to which we believe these items and services are typically ancillary and supportive. The seven categories are: (1) guidance services; (2) image processing services; (3) intraoperative services; (4) imaging supervision and interpretation services; (5) diagnostic radiopharmaceuticals; (6) contrast media; and (7) observation services. We specifically chose these categories of HCPCS codes for packaging because we believe that the items and services described

by the codes in these categories are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support.

In addition, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66650 through 66659), we finalized additional packaging for the CY 2008 OPPS, which included the establishment of new composite APCs for CY 2008, specifically APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite), APC 8001 (LDR Prostate Brachytherapy Composite), APC 8002 (Level I Extended Assessment & Management Composite), and APC 8003 (Level II Extended Assessment & Management Composite). In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569), we expanded the composite APC model to one new clinical area—multiple imaging services. We created five multiple imaging composite APCs for payment in CY 2009 that incorporate statutory requirements to differentiate between imaging services provided with contrast and without contrast as required by section 1833(t)(2)(G) of the Act. The multiple imaging composite APCs are: (1) APC 8004 (Ultrasound Composite); (2) APC 8005 (CT and CTA without Contrast Composite); (3) APC 8006 (CT and CTA with Contrast Composite); (4) APC 8007 (MRI and MRA without Contrast Composite); and (5) APC 8008 (MRI and MRA with Contrast Composite). We discuss composite APCs in more detail in section II.A.2.e. of this proposed rule.

We recognize that decisions about packaging and bundling payment involve a balance between ensuring that payment is adequate to enable the hospital to provide

quality care and establishing incentives for efficiency through larger units of payment. Therefore, we invite public comments regarding our packaging proposals for the CY 2012 OPPS.

b. Packaging Issues

(1) CMS Presentation of Findings Regarding Expanded Packaging at the February 28-March 1, 2011 APC Panel Meeting

In deciding whether to package a service or pay for a code separately, we have historically considered a variety of factors, including whether the service is normally provided separately or in conjunction with other services; how likely it is for the costs of the packaged code to be appropriately mapped to the separately payable codes with which it was performed; and whether the expected cost of the service is relatively low.

As discussed in section I.D. of this proposed rule, the APC Panel advises CMS on the clinical integrity of payment groups and their weights, and the APC Panel has had a Packaging Subcommittee that is now renamed the Subcommittee for APC Groups and Status Indicator (SI) Assignments to reflect that its function has expanded to include assisting CMS with assignment of HCPCS codes to APCs. As part of its function, the APC Panel studies and makes recommendations on issues pertaining to services that are not separately payable under the OPPS, but whose payments are bundled or packaged into APC payments. The APC Panel has considered packaging issues at several earlier meetings. For discussions of earlier APC Panel meetings and recommendations, we refer readers to previously published hospital OPPS/ASC proposed and final rules on the CMS Web site at: http://www.cms.gov/HospitalOutpatientPPS/HORD/list.asp.

(2) Packaging Recommendations of the APC Panel at its February 28-March 1, 2011 Meeting

During the February 28-March 1, 2011 APC Panel meeting, the APC Panel accepted the report of the Subcommittee for APC Groups and Status Indicator (SI) Assignment, heard several public presentations related to packaged services, discussed the deliberations of the subcommittee, and made five recommendations related to packaging and to the function of the subcommittee. The Report of the February 28-March 1, 2011 meeting of the APC Panel may be found at the website at: http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

To summarize, the APC Panel made five recommendations regarding the packaging of payment under the CY 2012 OPPS. Below we present each of these five packaging recommendations and our responses to those recommendations. One recommendation that evolved from the discussions of the APC Groups and Status Indicator Subcommittee that is specific to HCPCS codes is discussed in section III.D. of this proposed rule.

APC Panel Recommendation 4: That HCPCS code 31627 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s])) continue to be assigned a status indicator of "N." The Panel further recommended that CMS continue to collect claims data for HCPCS code 31627.

CMS Response to Recommendation 4: HCPCS code 31627 was new for CY 2010, and we assigned a new interim status indicator of "N" in our CY 2010 OPPS/ASC final rule with comment period based on our policy of packaging guidance and intraoperative services that are ancillary and dependent upon an independent separately paid procedure. At the APC Panel's February 2010 meeting, the manufacturer of the electromagnetic navigation bronchoscopy (ENB) technology, one of several technologies that can be used to perform the service described by HCPCS code 31627, asserted that use of the ENB technology during a bronchoscopy procedure enables access to distal lesions that are otherwise not accessible without use of the ENB technology. The manufacturer also stated that without separate payment for the ENB technology, hospitals would likely not adopt the technology and the population that would likely benefit from the ENB technology would not have access to this technology. In response to the manufacturer's presentation at the February 2010 Panel meeting, the APC Panel asked CMS to consider whether HCPCS code 31627 should be packaged or paid separately; and if it should be paid separately, the APC Panel asked CMS to investigate the appropriate APC assignment. The report of the February 2010 APC Panel meeting is available at http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

We stated in the CY 2011 OPPS/ASC proposed rule (75 FR 46223) that we considered and analyzed the information available to us for HCPCS code 31627 and believed that the code described a procedure that is supportive of and ancillary to the

primary diagnostic or therapeutic modality. Therefore, we proposed to package payment for HCPCS code 31627. We stated that, by proposing to package payment for this procedure, we would be treating it in the same manner as similar computer-assisted, navigational diagnostic procedures that are supportive of and ancillary to a primary diagnostic or therapeutic modality.

At its August 23-24, 2010 meeting, the APC Panel listened to discussions regarding whether HCPCS code 31627 should remain packaged for CY 2011. After hearing presentations from the public, the APC Panel recommended that CMS continue to package payment for HCPCS code 31627 into payment for the major separately paid procedure with which it is performed and asked that CMS bring claims data on the cost of HCPCS code 31627 to the APC Panel's winter 2011 meeting for review. After consideration of all of the information provided by commenters on this issue, and hearing the discussion of the issue by the APC Panel at its August 23-24, 2010 meeting, we accepted the APC Panel's recommendation to continue to package payment for HCPCS code 31627 into the payment for the major separately paid procedure with which it is reported for CY 2011. In addition, we also accepted the APC Panel's recommendation that CMS bring claims data [for HCPCS code 31627 to the winter 2011 APC Panel meeting. The report of the August 2010 APC Panel meeting is available at http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

At its meeting on February 28-March 1, 2011, the APC Panel listened to a public presentation in which the manufacturer of the ENB technology requested that HCPCS

code 31627 be paid separately on the basis that the cost of the technology is substantially higher than the OPPS payment for APC 0076 (Level I Endoscopy Lower Airway), the APC to which most bronchoscopy codes are assigned and into which payment for HCPCS code 31627 is packaged. The manufacturer stated that if CMS does not pay HCPCS code 31627 separately, hospitals will not furnish the procedure to hospital outpatients.

In response to the request of the APC Panel at its August 2010 meeting, we presented the available data on HCPCS code 31627 that could be derived from the hospital outpatient claims that were paid under the OPPS for services on and after January 1, 2010 through and including September 30, 2010, as processed through the CMS common working file by December 31, 2010. Specifically, using the limited set of APC Panel data, CMS found that 119 hospitals billed for 573 units of HCPCS code 31627, and that HCPCS code 31627 had a median cost of approximately $329 per unit. We also found that HCPCS code 31627 is reported on 0 to 4 percent of the claims for bronchoscopy codes with which CPT guidance states that it is permissible to report HCPCS code 31627, with the exception of HCPCS code 31626 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple). HCPCS code 31627 was reported on approximately 52% of claims for HCPCS code 31626 in the APC Panel data. The APC Panel considered this information in its formulation of Recommendation 4 that CMS continue to package payment for HCPCS code 31627 into the payment for the bronchoscopy code with which HCPCS code 31627 is reported. Subsequent to the APC Panel meeting, examination and

analysis of the CY 2012 proposed rule data found that 149 hospitals reported 867 units of HCPCS code 31627, and that HCPCS code 31627 has a proposed rule median cost of approximately $344 per unit.

After considering the public presentation and the information presented by CMS staff, the APC Panel recommended that HCPCS code 31627 continue to be assigned a status indicator of "N." The Panel further recommended that CMS continue to collect claims data for HCPCS code 31627. We are proposing to accept both of the APC Panel's recommendations for the CY 2012 OPPS. Specifically, we are proposing to assign HCPCS code 31627 to status indicator "N" for the CY 2012 OPPS and, therefore, are proposing to package payment for the procedure into payment for the bronchoscopy to which we believe that it is ancillary and supportive. As with all packaged items and services, the cost we calculate for CPT code 31627 will be added to the costs on the single bill for the bronchoscopy code with which the service reported by CPT code 31627 is furnished, and therefore, the cost of CPT code 31627 will be incorporated into the payment for the APC to which that bronchoscopy code is assigned. We continue to believe that HCPCS code 31627, for which there are several different technologies, describes a service that is supportive and ancillary to the primary bronchoscopy procedure with which it must be reported, as defined by CPT. HCPCS code 31627 describes a computer assisted image guided navigation service that is not furnished without a bronchoscopy. As defined by CPT, HCPCS code 31627 may only be furnished in addition to a bronchocsopy service and therefore we believe that it is ancillary and supportive to the bronchsocopy service with which it must be reported. We agree to

provide further claims information on HCPCS code 31627 to the APC Panel when it becomes available.

APC Panel Recommendation 5: That CMS consider a more appropriate APC assignment for HCPCS code 31626 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers), the most common code with which HCPCS code 31627 was billed in 2010.

CMS Response to Recommendation 5: We are accepting this recommendation, and therefore are proposing to reassign HCPCS code 31626 (which has a proposed CY 2012 APC median cost of approximately $2,708) from APC 0076 (which has a proposed CY 2012 APC median cost of approximately $751) to APC 0415 (Level II Endoscopy Lower Airway), which has a proposed CY 2012 APC median cost of approximately $2,007. We agree with the APC Panel that it appears that the proposed APC median cost of HCPCS code 31626 of $2,708 justifies placement in an APC that has a median cost that is more similar to the APC median cost for this code. We believe that APC 0415 is the most appropriate clinically similar APC because the proposed CY 2012 median cost for APC 0415 of $2,007 is more similar in clinical resource for HCPCS code 31626 than the proposed CY 2012 median cost for APC 0076 of $715.

APC Panel Recommendation 6: That Judith Kelly, R.H.I.T., R.H.I.A., C.C.S., continue to chair the APC Groups and Status Indicator (SI) Assignments Subcommittee for 2011.

CMS Response to Recommendation 6: We are accepting the APC Panel's recommendation that Judith Kelly, R.H.I.T., R.H.I.A., C.C.S. continue to chair the APC Groups and Status Indicator Assignments Subcommittee for 2011.

APC Panel Recommendation 7: That CMS furnish the results of its investigation of claims that contain the following unconditionally packaged codes without separately paid procedures:

- HCPCS code G0177 (Training and educational services related to the care and treatment of patient's disabling mental health problems per session (45 minutes or more));
- HCPCS code G0378 (Hospital observation service, per hour);
- HCPCS code 75940 (Percutaneous placement of IVC filter, radiological supervision and interpretation);
- HCPCS code 76937 (Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting (List separately in addition to code for primary procedure)).

CMS Response to Recommendation 7: We are accepting the APC Panel's recommendation that CMS furnish the results of its investigation of claims that contain the unconditionally packaged codes: HCPCS code G0177, HCPCS code G0378, HCPCS code 75940, and HCPCS code 76937 at a future APC Panel meeting.

APC Panel Recommendation 8: That the work of the APC Groups and Status Indicator (SI) Assignments Subcommittee continue.

CMS Response to Recommendation 8: We are accepting the APC Panel's recommendation that the work of the APC Groups and Status Indicator Assignments Subcommittee continue.

(3) Other Packaging Proposals for CY 2012

The HCPCS codes for which we are proposing that payment be packaged into payment for the separately paid procedures with which the codes are reported either unconditionally (for which we are proposing to continue to assign status indicator "N"), or conditionally (for which we are proposing to continue to assign status indicators "Q1", "Q2", or "Q3") are displayed in Addendum B of this proposed rule (which is referenced in section XVIII. of this proposed rule and available via the Internet on the CMS Web site). The supporting documents for this CY 2012 OPPS/ASC proposed rule, including but not limited to Addendum B, are available at www.cms.hhs.gov/HospitalOutpatientPPS/HORD. To view the proposed status indicators by HCPCS code in Addendum B, select CMS 1525-P and then select the folder labeled "2012 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.

The proposed continuation of our standard policy regarding packaging of drugs and biologicals, implantable biologicals, contrast agents and diagnostic radiopharmaceuticals is discussed in section V.B. of this proposed rule. We note that an implantable biological that is surgically inserted or implanted through a surgical incision

or a natural orifice is commonly referred to throughout this proposed rule as an "implantable biological."

The proposed creation of a new composite APC for CY 2012 for payment of the insertion of cardiac resynchronization devices is discussed in section II.A.2.e.(6) of this proposed rule.

4. Proposed Calculation of OPPS Scaled Payment Weights

Using the APC median costs discussed in sections II.A.1. and II.A.2. of this proposed rule, we calculated the proposed relative payment weights for each APC for CY 2012 shown in Addenda A and B to this proposed rule (which are referenced in section XVIII. of this proposed rule and available via the Internet on the CMS Web site). 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 to APC 0606 (Level 3 Clinic Visits) because we deleted APC 0601 as part of the reconfiguration of the clinic visit APCs. We selected APC 0606 as the base because APC 0606 was the mid-level clinic visit APC (that is, Level 3 of five levels). Therefore, for CY 2012, to maintain consistency in using a median for calculating unscaled weights representing the median cost of some of the most frequently provided services, we are proposing to continue to use the median cost of the mid-level

clinic visit APC (APC 0606) to calculate unscaled weights. Following our standard methodology, but using the proposed CY 2012 median cost for APC 0606, for CY 2012 we assigned APC 0606 a relative payment weight of 1.00 and divided the median cost of each APC by the proposed median 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 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 2012 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 2011 scaled relative weights to the estimated aggregate weight using the proposed CY 2012 unscaled relative weights. For CY 2011, we multiplied the CY 2011 scaled APC relative weight applicable to a service paid under the OPPS by the volume of that service from CY 2010 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 2012, we performed the same process using the proposed CY 2012 unscaled weights rather than scaled weights. We then calculated the weight scaler by dividing the CY 2011 estimated aggregate weight by the proposed CY 2012 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/HospitalOutpatientPPS/. We included payments to CMHCs in our comparison of estimated unscaled weight in CY 2012 to estimated total weight in CY 2011 using CY 2010 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we adjusted the unscaled relative weights for purposes of budget neutrality. The proposed CY 2012 unscaled relative payment weights were adjusted by multiplying them by a proposed weight scaler of 1.4647 to ensure that the proposed CY 2012 relative weights are budget neutral.

Section 1833(t)(14) of the Act provides the payment rates for certain "specified covered outpatient drugs." That section 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 specified covered outpatient drugs (as discussed in section V.B.3. of this proposed rule) was included in the proposed budget neutrality calculations for the CY 2012 OPPS.

The proposed scaled relative payment weights listed in Addenda A and B to this proposed rule (which are referenced in section XVII. of this proposed rule and 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 2012 IPPS/LTCH PPS proposed rule (76 FR 25949), consistent with current law, based on IHS Global Insight, Inc.'s first quarter 2011 forecast of the FY 2012 market basket increase, we proposed that the FY 2012 IPPS market basket update would be 2.8 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(ii) of the Act, as added by section 3401(i) of the Pub. L. 111-148 and as amended by section 10319(g) of such law and further amended by section 1105(e) of Pub. L. 111-152, provide adjustments to the OPD fee schedule update for CY 2012.

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 section 1833(t)(3)(F) of the Act. Specifically, section 1833(t)(3)(F)(i) of the Act requires that 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 for 2012 and subsequent years. 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"). We refer readers to the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25949 through 25951) for a discussion of the calculation of the MFP adjustment. The proposed MFP adjustment for FY 2012 is estimated to be 1.2 percentage points.

We are proposing to reduce the OPD fee schedule increase factor for CY 2012 by the proposed MFP adjustment of 1.2 percentage points for FY 2012. Since the OPD fee schedule increase factor is based on the IPPS hospital inpatient market basket percentage increase, we believe that it is appropriate to apply the same MFP adjustment that is used to reduce the IPPS market basket increase to the OPD fee schedule increase factor. Consistent with the FY 2012 IPPS/LTCH PPS proposed rule, we are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data, if appropriate, to determine the FY 2012 market basket update and MFP adjustment in the CY 2012 final rule. We believe that it is appropriate to apply the MFP adjustment, which is calculated on a fiscal year basis, to the OPD fee schedule increase factor, which is used to update the OPPS payment rates on a calendar year basis, because we believe that it is appropriate for the numbers associated with both components of the calculation (the underlying OPD fee schedule increase factor and the productivity adjustment) to be aligned so that changes in market conditions are aligned.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the adjustment described in

subparagraph (G) for each of 2010 through 2019. For CY 2012, section 1833(t)(3)(G)(ii) of the Act provides a 0.1 percentage point reduction to the OPD fee schedule increase factor under subparagraph (C)(iv). Therefore, we are proposing to apply a 0.1 percentage point reduction to the OPD fee schedule increase factor.

We note that section 1833(t)(F) of the Act provides that application of this subparagraph may result in the increase factor under subparagraph (C)(iv) being less than 0.0 for a year, and may result in payment rates under the payment system under this subsection for a year being less than such payment rates for the preceding year. As described in further detail below, we are proposing an OPD fee schedule increase factor of 1.5 percent for the CY 2012 OPPS (2.8 percent, which is the proposed estimate of the hospital market basket increase, less the proposed 1.2 percentage points MFP adjustment, less the 0.1 percentage point additional adjustment).

We are proposing to revise 42 CFR 419.32 to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2012, 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 0.1 percentage point for CY 2012. We also are proposing to amend §419.32 (iv)(A) to indicate that the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act is further reduced by the adjustments necessary to satisfy the requirements in sections 1833(t)(3)(F) and (t)(3)(G) of the Act.

Hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of additional 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. For a complete discussion of the Hospital OQR requirements and the payment reduction for hospitals that fail to meet those requirements, we refer readers to section XIV. of this proposed rule.

To set the OPPS conversion factor for CY 2012, we are proposing to increase the CY 2011 conversion factor of $68.876 by 1.5 percent. In accordance with section 1833(t)(9)(B) of the Act, we are proposing to further adjust the conversion factor for CY 2012 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 a proposed overall budget neutrality factor of 1.0003 for wage index changes by comparing total estimated payments from our simulation model using the FY 2012 IPPS proposed wage indices to those payments using the current (FY 2011) IPPS wage indices, as adopted on a calendar year basis for the OPPS. For CY 2012, we are not proposing to make a change to our rural adjustment policy. Therefore, the proposed budget neutrality factor for the rural adjustment would be 1.0000. For CY 2012, we are proposing a cancer hospital payment adjustment policy, as discussed in section II.F. of this proposed rule, and, therefore, we applied a proposed budget neutrality adjustment of 0.9927 to adjust the conversion factor for that proposed policy. We calculated the proposed cancer hospital budget neutrality factor of 0.9927 by comparing total estimated payments from our

simulation model for CY 2012 including the proposed payment adjustment for cancer hospitals to total estimated payments from our simulation model for CY 2012 without the proposed payment adjustment for cancer hospitals.

For this proposed rule, we estimate that pass-through spending for both drugs and biologicals and devices for CY 2012 would equal approximately $64.5 million, which represents 0.15 percent of total projected CY 2012 OPPS spending. Therefore, the conversion factor would also be adjusted by the difference between the 0.15 percent estimate of pass-through spending for CY 2011 and the 0.15 percent estimate of CY 2012 pass-through spending. Finally, estimated payments for outliers remain at 1.0 percent of total OPPS payments for CY 2012.

The proposed OPD fee schedule increase factor of 1.5 percent for CY 2012 (that is, the estimate of the hospital market basket increase of 2.8 percent less the 1.2 percentage points MFP adjustment and less the 0.1 percentage point adjustment which are necessary in order to comply with the requirements of the Affordable Care Act), the required proposed wage index budget neutrality adjustment of approximately 1.0003, the proposed cancer hospital payment adjustment of 0.9927, and the proposed adjustment of 0.00 percent of projected OPPS spending for the difference in the pass-through spending result in a proposed conversion factor for CY 2012 of $69.420, which reflects the full OPD fee schedule increase, after including the adjustments necessary to comply with the requirements of the Affordable Care Act.

To calculate the proposed CY 2012 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the Hospital OQR Program for the

full CY 2012 payment update, we are proposing to make all other adjustments discussed above, but would use a proposed reduced OPD fee schedule update factor of -0.5 percent (that is, the proposed OPD fee schedule increase factor 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 resulted in a proposed reduced conversion factor for CY 2012 of $68.052 for those hospitals that fail to meet the Hospital OQR requirements (a difference of -$1.368 in the proposed conversion factor relative to those hospitals that met the Hospital OQR requirements).

In summary, for CY 2012, we are proposing to use a conversion factor of $69.420 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using median costs. We are proposing to amend §419.32(b)(1)(iv)(B) by adding a new paragraph (3) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2012 in order to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(ii) of the Act. We also are proposing to amend §419.32(b)(1)(iv)(A) to indicate that the hospital inpatient market basket percentage increase is reduced by the adjustments described in §419.32(b)(1)(iv)(B). We are proposing to use a reduced conversion factor of $68.052 in the calculation of payments for hospitals that fail to comply with the Hospital OQR requirements to reflect the reduction to the OPD fee schedule increase factor that is required by section 1833(t)(17) of the Act for these hospitals.

C. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust, for geographic wage differences, the portion of the OPPS payment rate, which includes the copayment standardized amount, that is attributable to labor and labor-related cost. 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 2012 OPPS. We refer readers to section II.H. of this proposed rule for a description and example of how the proposed wage index for a particular hospital is used to determine the proposed payment for the hospital.

As discussed in section II.A.2.c. of this proposed rule, for estimating national median APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same proposed FY 2012 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 would also apply to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule, 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 contains provisions that affect the proposed FY 2012 IPPS wage index values, including revisions to the reclassification wage comparability criteria that were finalized in the FY 2009 IPPS final rule (73 FR 48568 through 48570), and the application of rural floor budget neutrality on a national, rather than State-specific, basis through a uniform, national adjustment to the area wage index (76 FR 26021). In addition, section 10324 of the Affordable Care Act requires CMS to establish an adjustment to create a wage index floor of 1.00 for hospitals located in States determined to be frontier States.

Section 10324 specifies that, for services furnished beginning CY 2011, the wage adjustment factor applicable to any hospital outpatient department that is located in a

frontier State (as defined in section 1886(d)(3)(E)(iii)(II) of the Act) may not be less than 1.00. Further, section 10324 states that this adjustment to the wage index for these outpatient departments should not be made in a budget neutral manner. As such, for the CY 2012 OPPS, we are proposing to continue to adjust the FY 2012 IPPS wage index, as adopted on a calendar year basis for the OPPS, for all hospitals paid under the OPPS, including non-IPPS hospitals (providers that are not paid under the IPPS) located in a frontier State, to 1.00 in instances where the proposed FY 2012 wage index (that reflects Medicare Geographic Classification Review Board (MGCRB) reclassifications, the application of the rural floor, and the rural floor budget neutrality adjustment) for these hospitals is less than 1.00. Similar to our current policy for HOPDs that are affiliated with multicampus hospital systems, we fully expect that the HOPD would receive a wage index based on the geographic location of the specific inpatient hospital with which it is associated. Therefore, if the associated hospital is located in a frontier State, the wage index adjustment applicable for the hospital would also apply for the affiliated HOPD. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160) 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 2012 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 (out-migration adjustment). We refer readers to the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25880 through 25888) for a detailed discussion of all proposed changes to the FY 2012 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 3137 of the Affordable Care Act extended, through FY 2010, section 508 reclassifications as well as certain special exceptions. The most recent extension of the provision was included in section 102 of the Medicare and Medicaid Extender Act, which extends, through FY 2011, section 508 reclassifications as well as certain special exceptions. The latest extension of these provisions expires on September 30, 2011, and will no longer be applicable effective with FY 2012. As we did for CY 2010, we revised wage index values for certain special exception hospitals from January 1, 2011 through December 31, 2011, 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 effective date under OPPS for all other non-section 508 and non-special exception providers is July 1, 2011, instead of April 1, 2011, so that these providers may also receive a full 6 months of payment under the revised wage index comparable to IPPS.

For purposes of the OPPS, we are proposing to continue our policy in CY 2012 to allow 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 2012 IPPS/LTCH PPS proposed rule (and made available via the Internet on the CMS Web site at: http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp) identifies counties eligible for the proposed out-migration adjustment and providers proposed to receive the adjustment for FY 2012. We note that, beginning with FY 2012, we proposed under the IPPS that 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 2012 IPPS/LTCH PPS proposed rule (76 FR 25885) for more detailed discussion on the proposed Lugar redesignation waiver for the out-migration adjustment). As we have done in prior years, we are reprinting 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 2012 OPPS. Addendum L is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site.

As stated earlier in this section, our longstanding policy for OPPS has been to adopt the final wage index used in IPPS. Therefore, for calculating proposed OPPS payments in CY 2012, we use the proposed FY 2012 IPPS wage indices. However,

section 1833(t)(2)(D) of the Act confers broad discretionary authority upon the Secretary in determining the wage adjustment factor used under the OPPS. Specifically, this provision provides that "subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions . . . ." In other prospective payment systems, we do not adopt the adjustments applied to the IPPS wage index, such as the outmigration adjustment, reclassifications, and the rural floor. For the OPPS, using the hospital IPPS wage index as the source of an adjustment factor for geographic wage differences has in the past been both reasonable and logical, given the inseparable, subordinate status of the outpatient department within the hospital overall.

However, in recent years, we have become concerned that hospitals converting status significantly inflates wage indexes across a State, in a manner that was not intended by the Congress. In the FY 2008 IPPS final rule (72 FR 47324 and 47325), we discussed a situation where a CAH may have converted back to IPPS status in order to increase the rural floor.

The FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26060) shows the impact of the CAH conversion. Hospitals in one State can expect an approximate 8-percent increase in IPPS payments due to the conversion and resulting increase of the rural floor. Our concern is that the manipulation of the rural floor is of sufficient magnitude that it requires all hospital wage indexes to be reduced approximately 0.62 percent as a result of

nationwide budget neutrality for the rural floor (or more than a 0.4 percent total payment reduction to all IPPS hospitals).

In addition to the CAH conversion, we recently received two requests from urban hospitals to convert to rural hospital status under section 1886(d)(8)(E) of the Act, which would inflate other States' rural floors, through the conversion of what would otherwise be urban hospitals to rural status. While we recognize that conversions from urban-to-rural status are permitted under section 1886(d)(8)(E) of the Act, we do not believe Congress anticipated individual urban to rural conversion allowing payment redistributions of this magnitude.

We believe the above discussions demonstrate that, as a result of hospital actions not envisioned by Congress, the rural floor is resulting in significant disparities in wage index and, in some cases, resulting in situations where all hospitals in a State receive a wage index higher than that of the single highest wage index urban hospital in the State. As stated above, the statute does not require the Secretary to use the IPPS wage adjustment factor to wage adjust OPPS payments and copayments, nor to apply to OPPS payment and copayment calculation the same adjustment that the law requires be applied to the IPPS wage adjustment factor.

We are considering adopting a policy that would address situations where IPPS wage index adjustments, such as the rural floor, are resulting in significant fluctuations in the wage index. One option would be to not apply the rural floor wage index at all in the OPPS where the rural floor is set by a snall number of hospitals and results in a rural floor that benefits all hospitals in the State. Alternatively, we could apply within State

rural budget neutrality to the OPPS wage index as we did for both the IPPS and OPPS wage index beginning in FY 2009. We are seeking public comment on whether to: (1) adopt the IPPS wage index for the OPPS in its entirety including the rural floor, geographic reclassifications and all other wage index adjustments; (2) adopt the IPPS wage index for the OPPS in its entirety except when a small number of hospitals set the rural floor for the benefit of all other hospitals in the State; (3) adopt the IPPS wage index for the OPPS in its entirety except apply rural floor budget neutrality within each State instead of nationally; or (4) adopt another decision rule for when the rural floor should not be applied in the OPPS when we have concerns about disproportionate impact.

We also are requesting public comments on an option that we are considering adopting for both the IPPS and the OPPS, where we would determine the applicable rural wage index floor using only data from those hospitals geographically rural under OMB and the Census Bureau's MSA designations, and without including wage data associated with hospital reclassified from urban to rural status under section 1886(d)(8)(E) of the Act. Such a policy would eliminate the incentive to reclassify from urban to rural status primarily to increase rural floors across a State, and would ensure that the rural floor is based upon hospitals located in rural areas.

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 2012 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/HospitalOutpatientPPS/. At this link, readers will find a link to the proposed FY 2012 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 2012 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 2012, 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 2012 OPPS relative weights. Table 11 below lists the proposed CY 2012 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 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 corresponding to the year of the majority of cost reports used to calculate the overall CCRs. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66680 through 66682) and prior OPPS rules for a more detailed discussion of our established methodology for calculating the statewide average default CCRs, including the hospitals used in our calculations and our trimming criteria.

For this CY 2012 OPPS/ASC proposed rule, approximately 87 percent of the submitted cost reports utilized in the default ratio calculations represented data for cost reporting periods ending in CY 2009 and 13 percent were for cost reporting periods

ending in CY 2008. 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 2011 and CY 2012 are modest and the few significant changes are associated with areas that have a small number of hospitals.

Table 11 below lists the proposed statewide average default CCRs for OPPS services furnished on or after January 1, 2012.

TABLE 11.–-PROPOSED CY 2012 STATEWIDE AVERAGE CCRs

State	Urban/Rural	Proposed CY 2012 Default CCR	Previous Default CCR (CY 2011 OPPS Final rule)
ALASKA	RURAL	0.487	0.479
ALASKA	URBAN	0.321	0.315
ALABAMA	RURAL	0.213	0.212
ALABAMA	URBAN	0.191	0.193
ARKANSAS	RURAL	0.225	0.223
ARKANSAS	URBAN	0.274	0.282
ARIZONA	RURAL	0.236	0.231
ARIZONA	URBAN	0.193	0.202
CALIFORNIA	RURAL	0.189	0.195
CALIFORNIA	URBAN	0.202	0.205
COLORADO	RURAL	0.345	0.350
COLORADO	URBAN	0.225	0.233
CONNECTICUT	RURAL	0.356	0.356
CONNECTICUT	URBAN	0.292	0.291

State	Urban/Rural	Proposed CY 2012 Default CCR	Previous Default CCR (CY 2011 OPPS Final rule)
DISTRICT OF COLUMBIA	URBAN	0.301	0.313
DELAWARE	RURAL	0.280	0.279
DELAWARE	URBAN	0.347	0.362
FLORIDA	RURAL	0.183	0.185
FLORIDA	URBAN	0.170	0.172
GEORGIA	RURAL	0.241	0.246
GEORGIA	URBAN	0.214	0.220
HAWAII	RURAL	0.320	0.356
HAWAII	URBAN	0.306	0.308
IOWA	RURAL	0.297	0.252
IOWA	URBAN	0.272	0.288
IDAHO	RURAL	0.416	0.419
IDAHO	URBAN	0.378	0.384
ILLINOIS	RURAL	0.245	0.251
ILLINOIS	URBAN	0.240	0.239
INDIANA	RURAL	0.298	0.302
INDIANA	URBAN	0.268	0.270
KANSAS	RURAL	0.282	0.286
KANSAS	URBAN	0.209	0.215
KENTUCKY	RURAL	0.223	0.220
KENTUCKY	URBAN	0.245	0.244
LOUISIANA	RURAL	0.256	0.256
LOUISIANA	URBAN	0.226	0.235
MARYLAND	RURAL	0.280	0.284
MARYLAND	URBAN	0.251	0.256
MASSACHUSETTS	URBAN	0.320	0.314
MAINE	RURAL	0.440	0.460
MAINE	URBAN	0.460	0.450
MICHIGAN	RURAL	0.313	0.312
MICHIGAN	URBAN	0.314	0.320
MINNESOTA	RURAL	0.482	0.483
MINNESOTA	URBAN	0.326	0.311
MISSOURI	RURAL	0.248	0.258
MISSOURI	URBAN	0.267	0.264
MISSISSIPPI	RURAL	0.226	0.229
MISSISSIPPI	URBAN	0.186	0.182

State	Urban/Rural	Proposed CY 2012 Default CCR	Previous Default CCR (CY 2011 OPPS Final rule)
MONTANA	RURAL	0.434	0.444
MONTANA	URBAN	0.398	0.399
NORTH CAROLINA	RURAL	0.256	0.254
NORTH CAROLINA	URBAN	0.264	0.264
NORTH DAKOTA	RURAL	0.322	0.351
NORTH DAKOTA	URBAN	0.429	0.360
NEBRASKA	RURAL	0.323	0.328
NEBRASKA	URBAN	0.252	0.259
NEW HAMPSHIRE	RURAL	0.323	0.323
NEW HAMPSHIRE	URBAN	0.292	0.290
NEW JERSEY	URBAN	0.221	0.221
NEW MEXICO	RURAL	0.266	0.277
NEW MEXICO	URBAN	0.286	0.307
NEVADA	RURAL	0.242	0.269
NEVADA	URBAN	0.169	0.178
NEW YORK	RURAL	0.410	0.415
NEW YORK	URBAN	0.350	0.375
OHIO	RURAL	0.324	0.327
OHIO	URBAN	0.241	0.241
OKLAHOMA	RURAL	0.248	0.260
OKLAHOMA	URBAN	0.220	0.208
OREGON	RURAL	0.302	0.306
OREGON	URBAN	0.327	0.340
PENNSYLVANIA	RURAL	0.270	0.275
PENNSYLVANIA	URBAN	0.200	0.210
PUERTO RICO	URBAN	0.490	0.505
RHODE ISLAND	URBAN	0.287	0.284
SOUTH CAROLINA	RURAL	0.222	0.222
SOUTH CAROLINA	URBAN	0.217	0.227
SOUTH DAKOTA	RURAL	0.309	0.316
SOUTH DAKOTA	URBAN	0.253	0.251
TENNESSEE	RURAL	0.212	0.221
TENNESSEE	URBAN	0.201	0.204
TEXAS	RURAL	0.239	0.245

State	Urban/Rural	Proposed CY 2012 Default CCR	Previous Default CCR (CY 2011 OPPS Final rule)
TEXAS	URBAN	0.210	0.216
UTAH	RURAL	0.385	0.386
UTAH	URBAN	0.359	0.362
VIRGINIA	RURAL	0.238	0.241
VIRGINIA	URBAN	0.257	0.263
VERMONT	RURAL	0.415	0.411
VERMONT	URBAN	0.365	0.365
WASHINGTON	RURAL	0.366	0.367
WASHINGTON	URBAN	0.317	0.327
WISCONSIN	RURAL	0.407	0.412
WISCONSIN	URBAN	0.327	0.334
WEST VIRGINIA	RURAL	0.283	0.291
WEST VIRGINIA	URBAN	0.335	0.337
WYOMING	RURAL	0.385	0.393
WYOMING	URBAN	0.302	0.296

E. Proposed OPPS Payments to Certain Rural and Other Hospitals

1. Hold Harmless Transitional Payment Changes Made by Pub. L. 110-275 (MIPPA)

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 transitional corridor payments are temporary payments for most providers and were intended to ease their transition from the prior reasonable cost-based payment system to the OPPS system. There are two exceptions to this provision, cancer hospitals and children's hospitals, and those hospitals receive the transitional corridor payments on a permanent basis. Section 1833(t)(7)(D)(i) of the Act

originally provided for transitional corridor payments to rural hospitals with 100 or fewer beds for covered OPD services furnished before January 1, 2004. However, section 411 of Pub. L. 108-173 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 transitional corridor payments 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 transitional corridor payments under section 1833(t)(7)(D)(i) of the Act, as amended by section 411 of Pub. L. 108-173, for rural hospitals having 100 or fewer beds and SCHs located in rural areas expired on December 31, 2005.

Section 5105 of Pub. L. 109-171 reinstituted 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. When the OPPS payment was less than the provider's pre-BBA amount, the amount of payment was increased by 95 percent of the amount of the difference between the two amounts for CY 2006, by 90 percent of the amount of that difference for CY 2007, and by 85 percent of the amount of that difference for CY 2008.

For CY 2006, we implemented section 5105 of Pub. L. 109-171 through Transmittal 877, issued on February 24, 2006. In the Transmittal, we did not specifically address whether TOPs apply to essential access community hospitals (EACHs), which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act. Accordingly,

under the statute, EACHs are treated as SCHs. In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010), we stated that EACHs were not eligible for TOPs under Pub. L. 109-171. However, we stated they were eligible for the adjustment for rural SCHs. In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68228), we updated §419.70(d) of our regulations to reflect the requirements of Pub. L. 109-171.

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

For CY 2009, we revised our regulations at §§419.70(d)(2) and (d)(4) and added a new paragraph (d)(5) to incorporate the provisions of section 147 of Pub. L. 110-275. In addition, we made other technical changes to §419.70(d)(2) to more precisely capture our

existing policy and to correct an inaccurate cross-reference. We also made technical corrections to the cross-references in paragraphs (e), (g), and (i) of §419.70.

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

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60425), we stated that, effective for services provided on or after January 1, 2010, rural hospitals and SCHs (including EACHs) having 100 or fewer beds would no longer be eligible for TOPs, in accordance with section 147 of Pub. L. 110-275. However, subsequent to issuance of the CY 2010 OPPS/ASC final rule with comment period, section 3121(a) of the Affordable Care Act 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, with section 3121(b) of the Affordable Care Act removing 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 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 one 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). 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 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 one year the hold harmless provision for an SCH (as defined in section 1886(d)(5)(D)(iii) of the Act (including EACHs) removing 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 is increased by 85 percent of the amount of the difference between the two payments. We are proposing to revise our regulations at §419.70(d) to conform the regulation text to the self-implementing provisions of section 108 of the MMEA described above.

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

In CY 2007, we became aware that we did not specifically address whether the adjustment applies to EACHs, which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act. Thus, under the statute, EACHs are treated as SCHs. Therefore, in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised §419.43(g) to clarify that EACHs are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, three hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Pub. L. 105-33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outliers and copayment. As 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 2011. 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 2012 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 (75 FR 46232). We intend to reassess the 7.1 percent adjustment in the near future by examining differences between urban and rural hospitals' costs using updated claims, 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 Transitional Outpatient Payments (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. Almost all of the 11 cancer hospitals receive TOPs each year. The volume weighted average payment-to-cost ratio (PCR) for the cancer hospitals is 0.83, or outpatient payment with TOPs to cancer hospitals is 83 percent of reasonable cost.

Section 3138 of the Affordable Care Act 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 ambulatory payment classification (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 to reflect these higher costs. Cancer hospitals described in section 1886(d)(1)(B)(v) of the Act remain eligible for TOPs (which are not budget neutral) and outlier payments (which are budget neutral).

2. Study of Cancer Hospitals' Costs Relative to Other Hospitals

It has been our standard analytical approach to use a combination of explanatory and payment regression models to assess the costliness of a class of hospitals while controlling for other legitimate influences of costliness, such as ability to achieve economies of scale, to ensure that costliness is due to the type of hospital and to identify appropriate payment adjustments. We used this approach in our CY 2006 OPPS final rule with comment period to establish the 7.1 percent payment adjustment for rural SCHs (70 FR 68556 through 68561). In our discussion for the CY 2006 OPPS proposed rule, we stated that a simple comparison of unit costs would not be sufficient to assess the costliness of a class of hospitals because the costs faced by individual hospitals, whether

urban or rural, are a function of many varying factors, including local labor supply and the complexity and volume of services provided (70 FR 42699).

In constructing our analysis of cancer hospitals' costs with respect to APC groups relative to other hospitals, we considered whether our standard analytical approach to use a combination of explanatory and payment regression models would lead to valid results for this particular study, or whether we should develop a different or modified analytic approach. We note that the analyses presented in the CY 2006 OPPS proposed and final rules were designed to establish an adjustment for a large class of rural hospitals. In contrast, section 3138 of the Affordable Care Act is specifically limited to identifying an adjustment for 11 cancer hospitals to the extent their costs with respect to APC groups exceeded those costs incurred by other hospitals furnishing services under section 1833(t) of the Act. With such a small sample size (11 out of approximately 4,000 hospitals paid under the OPPS), we were concerned that the standard explanatory and payment regression models used to establish the rural hospital adjustment would lead to imprecise estimates of payment adjustments for this small group of hospitals. Further, section 3138 of the Affordable Care Act specifies explicitly that cost comparisons between classes of hospitals must include the cost of drugs and biologicals. In our CY 2006 analysis of rural hospitals, we excluded the cost of drugs and biologicals in our model because the extreme units associated with proper billing for some drugs and biologicals can bias the calculation of a service mix index, or volume weighted average APC relative weight, for each hospital (70 FR 42698). Therefore, we chose not to pursue our standard

combination of explanatory and payment regression modeling to determine a proposed cancer hospital adjustment.

As discussed in the CY 2011 OPPS/ASC proposed rule (75 FR 46235), while we chose not to use our standard models to calculate a proposed cancer hospital adjustment, we determined it still would be appropriate to construct our usual provider-level analytical dataset consisting of variables related to assessing costliness with respect to APC groups, including average cost per unit for a hospital and the hospital's average APC relative weight as an indicator of the hospital's resource intensity, as measured by the APC relative weights. We used these variables to calculate univariate statistics that describe the costliness with respect to APC groups and related aspects of cancer hospitals and other hospitals paid under the OPPS. While descriptive statistics cannot control for the myriad factors that contribute to observed costs, we believed that stark differences in cost between cancer hospitals and other hospitals paid under the OPPS that would be observable by examining descriptive univariate statistics would provide some indication of relative costliness. We began our analysis of the cancer hospitals by creating an analytical dataset of hospitals billing under the OPPS for CY 2009 (a total of 3,933) that were included in our claims dataset for establishing the CY 2011 OPPS proposed APC relative weights. This analytical dataset included the 3,933 OPPS hospitals' total estimated cost (including packaged cost), total lines, total discounted units as modeled for CY 2011 OPPS payment, and the average weight of their separately payable services (total APC weight divided by total units) as modeled for the CY 2011 OPPS. We then summarized estimated utilization and payment for each hospital ("hospital-level"). These files consist of hospital-level aggregate costs (including the cost of packaged items and services), total estimated discounted units under the modeled proposed CY 2011 OPPS, total estimated volume of number of occurrences of separately payable HCPCS codes under the modeled proposed CY 2011 OPPS, and total relative weight of separately payable services under the modeled proposed CY 2011 OPPS. After summarizing modeled payment to the hospital-level, we removed 48 hospitals in Puerto Rico from our dataset because we did not believe that their cost structure reflected the costs of most hospitals paid under the OPPS and because they could bias the calculation of hospital-weighted statistics. We then removed an additional 66 hospitals with a cost per unit of more than 3 standard deviations from the geometric mean

(mean of the natural log) because including outliers in hospital-weighted descriptive statistics also could bias those statistics. This resulted in a dataset with 11 cancer hospitals and 3,808 other hospitals.

We included the following standard hospital-level variables that describe hospital costliness in our analysis file: outpatient cost per discounted unit under the modeled CY 2011 OPPS (substituting a cost per administration, rather than a cost per unit, for drugs and biologicals); each hospital's proposed CY 2011 wage index as a measure of relative labor cost; the service mix index, or volume-weighted average proposed CY 2011 APC relative weight (including a simulated weight for drugs and biologicals created by dividing the CY 2010 April ASP-based payment amount at ASP+6 percent appearing in Addendum A and B of the proposed rule by the proposed conversion factor of $68.267); outpatient volume based on number of occurrences of HCPCS codes in the CY 2009 claims data; and number of beds. We used these variables because they are key indicators of costliness with respect to APC groups under the modeled OPPS system, and they allowed us to assess the relative costliness of classes of hospitals under the proposed CY 2011 OPPS. A hospital's service mix index is a measure of resource intensity of the services provided by the hospital as measured by the proposed CY 2011 OPPS relative weights, and standardizing the cost per discounted unit by the service mix index creates an adjusted cost per unit estimate that reflects the remaining relative costliness of a hospital remaining after receiving the estimated payments that we proposed to make under the CY 2011 OPPS. In short, if a class of hospitals demonstrates higher cost per unit after standardization by service mix, it is an early indication that the class of hospitals may be significantly more costly in the regression models. We used these data to calculate the descriptive univariate statistics for cancer hospitals appearing in Table 12 below. We note that because drugs and biologicals are such a significant portion of the services that the cancer hospitals provide, and because section 3138 of the Affordable Care Act explicitly requires us to consider the cost of drugs and biologicals, we included the cost of these items in our total cost calculation for each hospital, counting each occurrence of a drug in the modeled proposed CY 2011 data (based on units in CY 2009 claims data). That is, we sought to treat each administration of a drug or biological as one unit.

In reviewing these descriptive statistics, we observed that cancer hospitals had a standardized cost per discounted unit of $150.12 compared to a standardized cost per discounted unit of $94.14 for all other

hospitals. That is, cancer hospitals' average cost per discounted unit remained high even after accounting for payment under the modeled proposed CY 2011 payment system, which is not true for all other hospitals. Observing such differences in standardized cost per discounted unit led us to conclude that cancer hospitals are more costly with respect to APC groups than other hospitals furnishing services under the OPPS, even without the inferential statistical models that we typically employ.

TABLE 12.—MEANS AND STANDARD DEVIATIONS FOR KEY VARIABLES BY CANCER AND NON-CANCER OPPS HOSPITALS

Variable	Cancer Hospitals		Non-Cancer Hospitals	
	Mean	Standard Deviation	Mean	Standard Deviation
Outpatient Cost per Unit*	$344.20	(64.68)	$264.11	(165.86)
Unit Cost Standardized by Service Mix Wage Indices	$150.12	(31.64)	$94.14	(81.19)
Wage Index	1.10	(0.13)	0.98	(0.16)
Service Mix Index *	2.19	(0.26)	3.18	(2.25)
Outpatient Volume	192,197	(186,063)	34,578	(43,094)
Beds	173	(162.33)	173	(171.46)
Number of Hospitals	11		3,808	

* Includes drugs and biologicals based on per administration rather than per unit.

3. CY 2011 Proposed Payment Adjustment for Certain Cancer Hospitals

Having reviewed the cost data from the standard analytic database and determined that cancer hospitals are more costly with respect to APC groups than other hospitals furnishing services under the OPPS system, we decided to examine hospital cost report data from Worksheet E, Part B (where TOPs are calculated on the Hospital and Hospital Health Care Complex Cost Report each year) in order to determine whether our findings were further supported by cost report data and to determine an appropriate proposed payment adjustment methodology for CY 2011 based on cost report data. Analyses on our standard analytic database and descriptive statistics presented in Table 12 above did

not consider TOPs in assessing costliness of cancer hospitals relative to other hospitals furnishing services under section 1833(t) of the Act. There were several reasons for this. One, TOPs have no associated relative weight that could be included in an assessment of APC-based payment. TOPs are paid at cost report settlement on an aggregate basis, not on a per service basis, and we would have no way to break these payments down into a relative weight to incorporate these retrospective aggregate payments in the form of a relative weight. In addition, section 3138 of the Affordable Care Act requires that any cancer adjustment be made within the budget neutral system, and TOPs are not part of the budget neutral payment system. The cost report data we selected for the analysis were limited to the OPPS-specific payment and cost data available on Worksheet E, Part B. These data include aggregate OPPS payments, including outlier payments and the cost of medical and other health services. These aggregate measures of cost and payment also include the cost and payment for drugs and biologicals and other adjustments that we typically include in our regression modeling, including wage index adjustment and rural adjustment, if applicable. While these cost report data cannot provide an estimate of cost per unit after controlling for other potential factors that could influence cost per unit, we used this aggregate cost and payment data to examine the cancer hospitals' OPPS PCR and OPPS PCR with TOPs, and compare these to the OPPS PCR for other hospitals. PCRs calculated from the most recent cost report data available at the time of the CY 2011 OPPS/ASC proposed rule also indicated that costs relative to payments at cancer hospitals were higher than those at other hospitals paid under the OPPS (that is, cancer hospitals have lower PCRs). In order to calculate PCRs for hospitals paid under

the OPPS (including cancer hospitals), we used the same extract of cost report data from the Hospital Cost Report Information System (HCRIS) that we used to calculate the CCRs that were used to estimate median costs for the CY 2011 OPPS. We limited the dataset to the hospitals with CY 2009 claims data that we used to model the CY 2011 proposed APC relative weights.

We estimated that, on average, the OPPS payments to the 11 cancer hospitals, not including TOPs, were approximately 62 percent of reasonable cost (that is, we calculated a PCR of 0.615 for the cancer hospitals), whereas we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 87 percent of reasonable cost (resulting in a PCR of 0.868). When TOPS were included in the calculation of the PCR, cancer hospitals, as a group, received payments that were approximately 83 percent of reasonable cost, which was still lower than the average PCR of other OPPS hospitals of approximately 87 percent of reasonable cost.

Based on our findings that cancer hospitals, as a class, have a significantly lower volume weighted average PCR than the volume weighted PCR of other hospitals furnishing services under the OPPS and our findings that the cancer hospitals cost per discounted unit standardized for service mix remains much higher than the standardized cost per discounted unit of all other hospitals, we proposed an adjustment for cancer hospitals to reflect these higher costs, effective January 1, 2011. For purposes of calculating a proposed adjustment, we chose to rely on this straightforward assessment of payments and costs from the cost report data because of the concerns outlined above with

respect to the small number of hospitals, and because of the challenges associated with accurately including drug and biological costs in our standard regression models. We believed that an appropriate adjustment would redistribute enough payments from other hospitals furnishing services under the OPPS to the cancer hospitals to give cancer hospitals a PCR that was comparable to the average PCR for other hospitals furnishing services under the OPPS. Therefore, we proposed a hospital-specific payment adjustment determined as the percentage of additional payment needed to raise each cancer hospital's PCR to the weighted average PCR for other hospitals furnishing services under the OPPS (0.868) in the CY 2011 dataset. This would be accomplished by adjusting each cancer hospital's OPPS payment by the percentage difference between the hospital's individual PCR (without TOPs) and the weighted average PCR of the other hospitals furnishing services under the OPPS. This cancer hospital payment adjustment proposed for CY 2011 would have resulted in an estimated aggregate increase in OPPS payments to cancer hospitals of 41.2 percent and a net increase in total payments, including TOPs, of 5 percent for CY 2011.

4. Proposed CY 2011 Cancer Hospital Payment Adjustment That Was Not Finalized

The public comments associated with the cancer hospital adjustment that we proposed for CY 2011 are detailed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71886 through 71887). Many commenters urged CMS to consider TOPs when calculating the cancer hospital payment adjustment stating that the proposed methodology results, largely, in a change in the form of outpatient payments to cancer hospitals by shifting payment from hold harmless payment under the TOPs provision to

APC payments. Noting that the majority of cancer care provided in the country is provided by the non-cancer hospitals that would experience a payment reduction under the CY 2011 proposal, commenters also suggested that the associated budget neutral payment reduction of 0.7 percent was not appropriate or equitable to other OPPS hospitals. Commenters also expressed concern that the proposed payment adjustment would increase beneficiary copayments. That is, they believed that the proposed cancer hospital adjustment would increase APC payments and, because beneficiary copayment is a percentage of the APC payment, Medicare beneficiaries seeking services at the 11 designated cancer hospitals would experience higher copayments due to the proposed methodology. These commenters strongly encouraged CMS to implement the adjustment in a way that does not increase beneficiary copayments. These commenters also indicated that CMS should have taken into account the concentration of outpatient services at the designated cancer hospitals, as compared to other OPPS hospitals, and adjust the PCR benchmark higher. The commenters argued that other PPS hospitals have the ability to improve their Medicare margins through other payment systems, but that cancer hospitals receive the majority of their Medicare payments through the OPPS. One commenter suggested that the CMS analysis was inadequate to conclude that costs are higher in cancer hospitals and that an adjustment is warranted. As indicated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71887), because the many public comments we received identified a broad range of very important issues and concerns associated with the proposed cancer hospital payment adjustment, we

determined that further study and deliberation was necessary and, therefore, we did not finalize the CY 2011 proposed payment adjustment for certain cancer hospitals.

5. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2012

During our deliberations that occurred subsequent to the CY 2011 OPPS/ASC final rule, we reconfirmed that TOPs could not be included when establishing the PCR target given the current statutory language in section 1833(t)(18) of the Act that was to capture costliness with respect to APC groups. Specifically, section 1833(t)(18)(A) of the Act requires the Secretary to determine if, under the OPPS, costs incurred by cancer hospitals with respect to APC groups exceed those costs incurred by other hospitals furnishing services under the OPPS. As discussed in the CY 2011 OPPS/ASC proposed rule and final rule with comment period, TOPs payments are not paid on a service specific basis, and we have no way to break these payments down into a relative weight that could be included in an assessment of an APC-based payment. Because section 1833(t)(18)(A) of the Act ties the assessment of the costs incurred by the 11 cancer hospitals to APC groups, we cannot include TOPs, which are not tied to APC groups, in such assessment. In addition, section 1833(t)(7)(D)(ii) of the Act (the hold harmless provision for cancer hospitals) provides that this adjustment is applied for covered OPD services for which the "PPS amount" is less than the "pre-BBA" amount. The "PPS amount" means, with respect to covered OPD services, "the amount payable under this title [Title 18] for such services (determined without regard to this paragraph) . . ." (See section 1833(t)(7)(E) of the Act). Under this provision, the cancer adjustment must be included in the calculation of the "PPS amount" because it is an integral component of

"the amount payable under this title." Further, we note that the Affordable Care Act requires that any cancer hospital payment adjustment be made within the budget neutral system. We note that TOPs are not part of the budget neutral payment system.

In addition, we have revisited the issue of whether payments associated with the cancer hospital payment adjustment can be excluded from the amount of payment on which the copayment amount is determined. We continue to believe that the statute requires such payment to be included in the amount of payment upon which the copayment amount is determined. Specifically, section 1833(t)(8) of the Act sets forth the methodology for calculating the copayment amount under section 1833(t). Section 1833(t)(8)(A) of the Act states the following: "Except as provided in subparagraphs (B) and (C), the copayment amount under this subsection is the amount by which the amount described in paragraph (4)(B) exceeds the amount of payment determined under paragraph (4)(C)." We note that the amount in paragraph (4)(B) incorporates the amount calculated under subparagraph (A) of section 1833(t)(4) of the Act which provides that the "medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year is adjusted for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E)." The reference to "factors computed under paragraphs. . . (2)(E)" includes a cancer hospital payment adjustment because it is required to be provided under paragraph (2)(E). Therefore, the statute is clear that the cancer hospital payment adjustment is a component of the payment amount upon which the beneficiary copayment is determined.

Finally, though commenters suggested that CMS take into account the cancer hospitals' significant Medicare outpatient concentration relative to that of other OPPS hospitals when establishing an appropriate PCR benchmark, we believe it is inappropriate to incorporate the payments associated with other Medicare payment systems when determining a payment adjustment under the OPPS.

After a thorough review and deliberation of the issues associated with the cancer hospital payment adjustment proposed for CY 2011, we continue to believe a straightforward and appropriate method to adjust payments of cancer hospitals described in section 1886(d)(1)(B)(v) of the Act in order to reflect their higher costs with respect to APC groups is to propose to redistribute enough payments from other hospitals furnishing services under the OPPS to the cancer hospitals to give each cancer hospital a PCR that is comparable to the weighted average PCR for other hospitals furnishing services under section 1833(t) of the Act. Therefore, as explained in more detail below, for services furnished on and after January 1, 2012, we are proposing that, for a cancer hospital with an individual PCR (as determined by the Secretary) below the weighted average PCR for other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary) (Target PCR), we would make a hospital-specific payment adjustment by adjusting the wage-adjusted OPPS payment for covered OPD services (except for devices receiving pass-through status as defined in 42 CFR 419.66) by the percent difference between the hospital's individual PCR and the weighted average PCR of other hospitals furnishing services under section 1833(t) of the Act in the CY 2012 dataset. With respect to such hospitals, for devices receiving pass-through status as

defined in 42 CFR 419.66 which are furnished on and after January 1, 2012, , we are proposing a zero percent adjustment. For a cancer hospital with an individual PCR (as determine by the Secretary) above the weighted average PCR for other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary), we are proposing a zero percent adjustment for covered hospital outpatient services furnished on and after January 1, 2012.

In order to calculate PCRs for hospitals furnishing services under the OPPS (including cancer hospitals) for the proposed CY 2012 cancer hospital payment adjustment, we used the same extract of cost report data from HCRIS, as discussed in section II.A of this proposed rule, used to estimate median costs for the proposed CY 2012 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 data set to the hospitals with CY 2010 claims data that we use to model the impact of the CY 2012 proposed APC relative weights (4,009 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled proposed CY 2012 OPPS. The cancer hospitals in this dataset largely had cost report data from cost reporting periods ending in FY 2009 and FY 2010. The cost report data for the other hospitals were from cost report periods with fiscal year ends ranging from 2008 to 2010. We then removed the cost report data for 47 hospitals from Puerto Rico from our data set 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 206

hospitals with cost report data that were not complete (missing OPPS payments, including outliers, missing aggregate cost data, or 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 final analytic file of 3,756 hospitals with cost report data. We believe that the costs and PPS payments reported on Worksheet E, Part B, for the hospitals included in our CY 2012 modeling should be sufficiently accurate for assessing hospital's relative costliness because all of the key elements that we believe are necessary for the analysis (payment and cost) are contained on this worksheet.

Using this smaller dataset of cost report data, we estimate that, on average, the OPPS payments to the 11 cancer hospitals, not including TOPs, are approximately 65 percent of reasonable cost (that is, we calculated a PCR of 0.647 for the cancer hospitals), whereas, we estimate that, on average, the OPPS payments to other hospitals furnishing services under the OPPS are approximately 90 percent of reasonable cost (resulting in a PCR of 0.901). Individual cancer hospitals' OPPS PCRs range from approximately 0.56 to approximately 0.82.

As indicated above, we are proposing that, for a cancer hospital with an individual PCR below the weighted average PCR for other hospitals furnishing services under the OPPS in the CY 2012 dataset, we would make a hospital-specific payment adjustment by adjusting the wage-adjusted OPPS payment for covered OPD services (except devices receiving pass-through status because these items and services are always paid at the estimated full cost and, therefore, no payment adjustment is necessary) furnished on and after January 1, 2012, by the percent difference between the hospital's individual PCR

and the weighted average PCR of other hospitals furnishing services under the OPPS in the CY 2012 dataset. This proposed methodology would result in the proposed percentage payment adjustments for the 11 cancer hospitals appearing in Table 13 below. In addition, we note that we are proposing to amend 42 CFR 419.43 by adding a new paragraph (i). Proposed new paragraph(i)(1) would specify that CMS provides for a payment adjustment for covered hospital outpatient services furnished on or after January 1, 2012, by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act. Proposed new paragraph (i)(2) would specify how the amount of the payment adjustment to cancer hospitals is established. Proposed new paragraph (i)(3) would specify that this payment adjustment would be budget neutral, consistent with section 1833(t)(18)(B) of the Act. Proposed new paragraph (i)(4) would specify the services or groups that are excluded from qualifying for the cancer hospital payment adjustment. In the event that a cancer hospital has a PCR that is higher than the weighted average PCR for other OPPS hospitals furnishing services under the OPPS, we are proposing that the specific hospital would receive a zero percent adjustment. We believe that this would indicate that the cancer hospital's costs do not exceed the costs incurred by other hospitals furnishing services under the OPPS and, therefore, a payment adjustment above zero percent would not be necessary.

We note that the proposed payment adjustment for all cancer hospitals would result in an estimated aggregate increase in OPPS payments to cancer hospitals of 39 percent for CY 2012 and an estimated net increase in total payments, including TOPs, of 9 percent, based on cost report data. The dataset of hospital cost report data that we

used to model this proposed payment adjustment for cancer hospitals is available under supporting documentation for this proposed rule on the CMS Web site at: *http://www.cms.gov/HospitalOutpatientPPS/HORD/*.

TABLE 13.--PROPOSED CY 2012 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS WITHOUT REGARD TO TOPs AND OUTLIER PAYMENTS

Provider Number	Hospital Name	Percent Increase Without TOPs or Outlier Payment
050146	City of Hope Helford Clinical Research Hospital	10.1%
050660	USC Kenneth Norris Jr. Cancer Hospital	15.7%
100079	University of Miami Hospital & Clinic	27.6%
100271	H. Lee Moffitt Cancer Center & Research Institute	21.6%
220162	Dana-Farber Cancer Institute	54.4%
330154	Memorial Hospital for Cancer and Allied Diseases	39.4%
330354	Roswell Park Cancer Institute	24.3%
360242	James Cancer Hospital & Solove Research Institute	30.1%
390196	Hospital of the Fox Chase Cancer Center	15.3%
450076	University of Texas M. D. Anderson Cancer Center	61.8%
500138	Seattle Cancer Care Alliance	43.7%
Proposed Aggregate Payment Adjustment		**39.3%**

Because section 7101 of the Affordable Care Act expanded the 340B drug program to include certain cancer hospitals, we believe that the PCRs and any cancer hospital payment adjustment should be recalculated annually. The 340B drug program allows certain hospitals to purchase certain outpatient drugs at reduced prices. The Affordable Care Act provision was effective for drugs purchased on or after January 1,

2010. Inclusion of cancer hospitals in the 340B drug program should lower drug costs at these cancer hospitals going forward and, therefore, may cause significant changes in each cancer hospital's PCR compared to the previous year's calculation. Therefore, we are proposing to recalculate the PCR of each cancer hospital and the weighted average PCR of the other hospitals furnishing services under 1833(t) on an annual basis in order to determine an appropriate hospital specific payment adjustment to cancer hospitals each year.

We note that the changes made by section 3138 of the Affordable Care Act do not affect the existing statutory provisions that provide for outlier payment for all hospitals paid under the OPPS, including cancer hospitals and TOPs for cancer hospitals. Because outlier payments are made within budget neutrality, outlier payments are assessed after all budget neutral payments for an individual service have been made, including the cancer hospital payment adjustment. The TOPs are assessed after all payments have been made for a cost reporting period. Further, both outlier payments and TOPs serve as a safety net for hospitals, although outliers are budget neutral and TOPs are not, and TOPs are limited to certain hospitals. Outliers and TOPs are assessed after final payments have been made. If this proposed payment adjustment is finalized, we estimate that there would be no cancer hospitals that would continue to receive TOPs. We are proposing to update the hospital-specific cancer hospital payment adjustments in Table 13 using the more recent cost reports that will become available for the CY 2012 OPPS/ASC final rule with comment period.

G. Proposed Hospital Outpatient Outlier Payments

1. Background

Currently, the OPPS pays outlier payments on a service-by-service basis. For CY 2011, the outlier threshold is 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 outliers 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. 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 (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 2010 OPPS payment, using available CY 2010 claims and the revised OPPS expenditure estimate for the Presidential Budget for FY 2012, is approximately 1.11 percent of the total aggregated OPPS payments. Therefore, for CY 2010, we

estimate that we paid at 0.11 percent above the CY 2010 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 2010 claims data and CY 2011 payment rates, we currently estimate that the aggregate outlier payments for CY 2011 would be approximately 1.06 percent of the total CY 2011 OPPS payments. The difference between 1.0 percent and 1.06 percent is reflected in the regulatory impact analysis in section XX. of this proposed rule. We note that we provide estimated CY 2012 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.hhs.gov/HospitalOutpatientPPS/.

2. Proposed Outlier Calculation

We are proposing for CY 2012 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, specifically 0.14 percent, 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 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 propose rule.

To ensure that the estimated CY 2012 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 $2,100 fixed-dollar threshold. This proposed threshold reflects the methodology discussed below in this section, as well as the proposed APC recalibration for CY 2012.

We calculated the proposed fixed-dollar threshold for this proposed rule using largely the same methodology as we did in CY 2011 (75 FR 71887 through 71889). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2011 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 2010 claims to model the

CY 2012 OPPS. In order to estimate the proposed CY 2012 hospital outlier payments for this proposed rule, we inflated the charges on the CY 2010 claims using the same inflation factor of 1.0908 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26024). We used an inflation factor of 1.0444 to estimate CY 2011 charges from the CY 2010 charges reported on CY 2010 claims. The methodology for determining this charge inflation factor is discussed in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26024). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors are appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we are proposing to apply the same CCR inflation adjustment factor that we are proposing to apply for the FY 2012 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2012 OPPS outlier payments that determine the fixed-dollar threshold. Specifically, for CY 2012, we are proposing to apply an adjustment of 0.9850 to the CCRs that were in the April 2011 OPSF to trend them forward from CY 2011 to CY 2012. The methodology for calculating this proposed adjustment is discussed in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26024 through 26025).

Therefore, to model hospital outlier payments for this CY 2012 OPPS/ASC proposed rule, we applied the overall CCRs from the April 2011 OPSF file after adjustment (using the proposed CCR inflation adjustment factor of 0.9850 to approximate CY 2012 CCRs) to charges on CY 2010 claims that were adjusted (using the proposed charge inflation factor of 1.0908 to approximate CY 2012 charges). We simulated aggregated CY 2012 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 2012 OPPS payments. We estimate that a proposed fixed-dollar threshold of $2,100, combined with the proposed multiple threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. 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 $2,100 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 requirements. For hospitals that fail to meet the Hospital OQR 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 XIV. of this proposed rule.

3. 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 proposed 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, as we have previously discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68596), we are not proposing to 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 proposed conversion factor calculated in accordance with section II.B. of this proposed rule and the proposed 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 referenced in section XVII. of this proposed rule and 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 referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) was calculated by multiplying the proposed CY 2012 scaled weight for the APC by the proposed CY 2012 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 Outpatient Quality Reporting (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 XVI.D. 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 referenced in section XVII. of this proposed rule and 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 2012 OPPS fee schedule increase factor of 1.50 percent.

Step 1. Calculate 60 percent (the labor-related portion) of the proposed 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 2012 under the IPPS, reclassifications through the MGCRB, section 1886(d)(8)(B) "Lugar" hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in §412.103 of the regulations, and hospitals designated as urban under section 601(g) of Pub. L. 98-21. We note that the reclassifications of hospitals under section 508 of Pub. L. 108-173, as extended by sections 3137 and 10317 of the Affordable Care Act, expired on September 30, 2010. Section 102 of the Medicare and Medicaid Extenders Act of 2010 extends Section 508 and certain additional special exception hospital reclassifications from October 1, 2010 through September 30, 2011. Therefore, these reclassifications will not apply to the CY 2012 OPPS. (For further discussion of the changes to the FY 2012 IPPS wage indices, as applied to the CY 2012 OPPS, we refer readers to section II.C. of this proposed rule.) We are proposing to continue applying a wage index floor of 1.00 to frontier states, in accordance with section 10324 of the Affordable Care Act.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Pub. L. 108-173. Addendum L to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) contains the qualifying counties and the associated proposed wage index increase developed for the FY 2012 IPPS and listed as Table 4J in the FY 2012 IPPS/LTCH PPS proposed rule and available via the Internet on the CMS Web site at: http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp. 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 a SCH, set forth in the regulations at §412.92, or an EACH, which is considered to be a 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 proposed total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071

We have provided examples below of the calculation of both the proposed full and reduced national unadjusted payment rates that would apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined above. For purposes of this example, we 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 2012 full national unadjusted payment rate for APC 0019 is $338.51. The proposed reduced national unadjusted payment rate for a hospital

that fails to meet the Hospital OQR Program requirements is $331.74. This reduced rate is calculated by multiplying the reporting ratio of 0.980 by the full unadjusted payment rate for APC 0019.

The proposed FY 2012 wage index for a provider located in CBSA 35644 in New York is 1.3190. The proposed labor-related portion of the full national unadjusted payment is $267.90 (.60 * $338.51 *1.3190). The proposed labor-related portion of the reduced national unadjusted payment is $262.54 (.60 * $331.74 * 1.3190). The proposed nonlabor-related portion of the full national unadjusted payment is $135.40 (.40 * $338.51). The proposed nonlabor-related portion of the reduced national unadjusted payment is $132.70 (.40 * $331.74). The sum of the labor-related and nonlabor-related portions of the full national adjusted payment is $403.30 ($267.90 + $135.40). The sum of the reduced national adjusted payment is $395.24 ($262.54 + $132.70).

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, for all services paid

under the OPPS in CY 2010, and in calendar years thereafter, the percentage is 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 final rule (75 FR 72013).

2. Proposed OPPS Copayment Policy

For CY 2012, 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, 2012, are shown in Addenda A and B to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site). As discussed in section XIV.E. of this proposed rule, for CY 2012, the proposed Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would 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.

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, $67.71 is 20 percent of the full national unadjusted payment rate of $338.51. For APCs with only a minimum unadjusted copayment in Addenda A and B of this proposed rule (which are referenced in section XVII. of this proposed rule and 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, 2012, are shown in Addenda A and B to this proposed rule

(which are referenced in section XVII. of this proposed rule and 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 2012 OPD fee schedule increase factor discussed in section XIV.E. 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: (1) Category I CPT codes, which describe medical services and 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. 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 comments on these new codes and finalize our proposals related to these codes through our annual rulemaking process. In Table 14 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. We note that because of the timing of the publication of this proposed rule, the codes that will be implemented through the July 2011 OPPS quarterly update are not included in Addendum B of this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site), while those codes based upon the April 2011 OPPS quarterly update are included in Addendum B.

TABLE 14.—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April l, 2011	Level II HCPCS Codes	April 1, 2011	CY 2012 OPPS/ASC proposed rule	CY 2012 OPPS/ASC final rule with comment period
July 1, 2011	Level II HCPCS Codes	July 1, 2011	CY 2012 OPPS/ASC proposed rule	CY 2012 OPPS/ASC final rule with comment period
	Category I (certain vaccine codes) and III CPT codes	July 1, 2011	CY 2012 OPPS/ASC proposed rule	CY 2012 OPPS/ASC final rule with comment period
October 1, 2011	Level II HCPCS	October 1, 2011	CY 2012	CY 2013

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
	Codes		OPPS/ASC final rule with comment period	OPPS/ASC final rule with comment period
January 1, 2012	Level II HCPCS Codes	January 1, 2012	CY 2012 OPPS/ASC final rule with comment period	CY 2013 OPPS/ASC final rule with comment period
	Category I and III CPT Codes	January 1, 2012	CY 2012 OPPS/ASC final rule with comment period	CY 2013 OPPS/ASC final rule with comment period

This process is discussed in detail below. We have separated our discussion into two sections based on whether we are proposing to solicit public comments in this CY 2012 OPPS/ASC proposed rule or whether we will be soliciting public comments in the CY 2012 OPPS/ASC final rule with comment period. We note that we sought public comment in the CY 2011 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2011. We also sought public comments in the CY 2011 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2010. These new codes, with an effective date of October 1, 2010, or January 1, 2011, 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 2011 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 2011 OPPS/ASC final rule with comment period. We will respond

to public comments and finalize our proposed OPPS treatment of these codes in the CY 2012 OPPS/ASC final rule with comment period.

1. Proposed Treatment of New Level II HCPCS Codes and Category I CPT Vaccine Codes and Category III CPT Codes for Which We Are Soliciting Public Comments in this CY 2012 Proposed Rule

Through the April 2011 OPPS quarterly update CR (Transmittal 2174, Change Request 7342, dated March 18, 2011) and the July 2011 OPPS quarterly update CR (Transmittal 2234, Change Request 7443, dated May 27, 2011), we recognized several new HCPCS codes for separate payment under the OPPS. Effective April 1 and July 1 of CY 2011, we made effective a total of 22 new Level II HCPCS codes and 14 Category III CPT codes. Specifically, 5 new Level II HCPCS codes were effective for the April 2011 update and another 17 new Level II HCPCS codes were effective for the July 2011 update for a total of 22. Fourteen new Category III CPT codes were effective for the July 2011 update. Of the 22 new Level II HCPCS codes, we recognized for separate payment 16 of these codes, and of the 14 new Category III CPT codes, we recognized for separate payment 12 of these codes, for a total of 28 new HCPCS codes that are recognized for separate payment for CY 2012.

Through the April 2011 OPPS quarterly update CR, we allowed separate payment for each of the five new Level II HCPCS codes. Specifically, as displayed in Table 15 below, we provided separate payment for the following HCPCS codes:

- HCPCS code C9280 (Injection, eribulin mesylate, 1 mg)
- HCPCS code C9281 (Injection, pegloticase, 1 mg)

- HCPCS code C9282 (Injection, ceftaroline fosamil, 10 mg)
- HCPCS code Q2040 (Injection, incobotulinumtoxin A, 1 unit)
- HCPCS code C9729 (Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with ligamentous resection, discectomy, facetectomy and/or foraminotomy, when performed) any method under indirect image guidance, with the use of an endoscope when performed, single or multiple levels, unilateral or bilateral; lumbar)

We note that HCPCS code Q2040 replaced HCPCS code C9278 (Injection, incobotulinumtoxin A, 1 unit) beginning April 1, 2010. HCPCS code C9278 was effective January 1, 2011, and deleted March 30, 2011, because it was replaced with HCPCS code Q2040. HCPCS code C9278 was assigned to pass-through status beginning January 1, 2011, when the code was implemented. Because HCPCS code Q2040 describes the same drug as HCPCS code C9278, we are continuing its pass-through status and assigning the HCPCS Q-code to the same APC and status indicator as its predecessor HCPCS C-code, as shown in Table 15 below. Specifically, HCPCS code Q2040 is assigned to APC 9278 and status indicator "G."

We are proposing to assign the Level II HCPCS codes listed in Table 15 to the specific proposed APCs and status indicators set forth in this proposed rule.

TABLE 15.—LEVEL II HCPCS CODES WITH A CHANGE IN OPPS STATUS INDICATOR OR NEWLY IMPLEMENTED IN APRIL 2011

CY 2011 HCPCS Code	CY 2011 Long Descriptor	Proposed CY 2012 Status Indicator	Proposed CY 2012 APC
C9280	Injection, eribulin mesylate, 1 mg	G	9280

CY 2011 HCPCS Code	CY 2011 Long Descriptor	Proposed CY 2012 Status Indicator	Proposed CY 2012 APC
C9281	Injection, pegloticase, 1 mg	G	9281
C9282	Injection, ceftaroline fosamil, 10 mg	G	9282
C9729	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with ligamentous resection, discectomy, facetectomy and/or foraminotomy, when performed) any method under indirect image guidance, with the use of an endoscope when performed, single or multiple levels, unilateral or bilateral; lumbar	T	0208
Q2040*	Injection, incobotulinumtoxin A, 1 unit	G	9278

*Level II HCPCS code C9278 was deleted March 31, 2011, and replaced with HCPCS code Q2040 effective April 1, 2011.

Through the July 2011 OPPS quarterly update CR, which included HCPCS codes that were made effective July 1, 2011, we allowed separate payment for 11 of the 17 new Level II HCPCS codes. Specifically, as displayed in Table 16 of this proposed rule, we provided separate payment for the following HCPCS codes:

- HCPCS code C9283 (Injection, acetaminophen, 10 mg)
- HCPCS code C9284 (Injection, ipilimumab, 10 mg)
- HCPCS code C9285 (Lidocaine 70 mg/tetracaine 70 mg, per patch)
- HCPCS code C9365 (Oasis Ultra Tri-Layer matrix, per square centimeter)
- HCPCS code C9406 (Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries)
- HCPCS code C9730 (Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle, 1 lobe)

- HCPCS code C9731 (Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle, 2 or more lobes)
- HCPCS code Q2041 (Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco)
- HCPCS code Q2042 (Injection, hydroxyprogesterone caproate, 1 mg)
- HCPCS code Q2043 (Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion)
- HCPCS code Q2044 (Injection, belimumab, 10 mg)

We note that two of the Level II HCPCS Q-codes that were made effective July 1, 2011, were previously described by a HCPCS J-code and a C-code that were assigned to pass-through status under the hospital OPPS. Specifically, HCPCS code Q2041 replaced HCPCS code J7184 (Injection, von willebrand factor complex (human), Wilate, per 100 iu vwf:rco) beginning July 1, 2011. HCPCS code J7184 was assigned to pass-through status when it was made effective January 1, 2011; however, the code is "Not Payable by Medicare" because HCPCS code J7184 is replaced with HCPCS code Q2041 effective July 1, 2011. Therefore, HCPCS code J7184 was reassigned to status indicator "E" effective July 1, 2011. Because HCPCS code J7184 describes the same drug as HCPCS code Q2041, we continued its pass-through status and assigned HCPCS code Q2041 to status indicator "G" effective July 1, 2011. However, because the dosage descriptor for HCPCS code Q2041 is not the same as HCPCS code J7184, we reassigned

HCPCS code Q2041 to a new APC to maintain data consistency for future rulemaking. Specifically, HCPCS code Q2041 was assigned to APC 1352 effective July 1, 2011. In addition, HCPCS code Q2043 replaced HCPCS code C9273 (Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion) beginning July 1, 2011. HCPCS code C9273 was assigned to pass-through status when it was made effective October 1, 2010. Because HCPCS code Q2043 describes the same product as HCPCS code C9273, we continued its pass-through status and assigned HCPCS code Q2043 to status indicator "G" as well as assigned it to the same APC, specifically APC 9273, effective July 1, 2011.

Of the 17 HCPCS codes that were made effective July 1, 2011, we did not recognize for separate payment 6 HCPCS codes that describe durable medical equipment (DME) because DME is paid under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule and not the OPPS. These codes are listed in Table 16 below, and are assigned to either status indicator "Y" or "A" effective July 1, 2011.

Table 16 below includes a complete list of the Level II HCPCS codes that were made effective July 1, 2011, with their proposed status indicators, APC assignments, and payment rates for CY 2012.

TABLE 16.—NEW LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2011

CY 2011 HCPCS Code	CY 2011 Long Descriptor	Proposed CY 2012 Status Indicator	Proposed CY 2012 APC	Proposed CY 2012 Payment Rate
C9283	Injection, acetaminophen, 10 mg	G	9283	$0.11
C9284	Injection, ipilimumab, 1 mg	G	9284	$127.20
C9285	Lidocaine 70 mg/tetracaine 70 mg, per patch	G	9285	$13.57
C9365	Oasis Ultra Tri-Layer matrix, per square centimeter	G	9365	$10.60
C9406	Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries	G	9406	$1,908.00
C9730	Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle, 1 lobe	T	0415	$1,971.77
C9731	Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle, 2 or more lobes	T	0415	$1,971.77
K0741	Portable gaseous oxygen system, rental, includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing, for cluster headaches	Y	NA	NA
K0742	Portable oxygen contents, gaseous, 1 month's supply = 1 unit, for cluster headaches, for initial months supply or to replace used contents	Y	NA	NA
K0743	Suction pump, home model, portable, for use on wounds	Y	NA	NA
K0744	Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 square inches or less	A	NA	NA
K0745	Absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 square inches but less than or equal to 48 square inches	A	NA	NA
K0746	Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 square inches	A	NA	NA
Q2041	Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco	G	1352	$0.88
Q2042	Injection, hydroxyprogesterone caproate, 1 mg	K	1354	$2.90

CY 2011 HCPCS Code	CY 2011 Long Descriptor	Proposed CY 2012 Status Indicator	Proposed CY 2012 APC	Proposed CY 2012 Payment Rate
Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion	G	9273	$32,860.00
Q2044	Injection, belimumab, 10 mg	G	1353	$39.15

For CY 2012, 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 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. Through the July 2011 OPPS quarterly update CR, we allow separate payment for 12 of the 14 new Category III CPT codes effective July 1, 2011. Specifically, as displayed in Table 17 of this proposed rule, we allow separate payment for the following CPT codes:

- CPT code 0263T (Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest)

- CPT code 0264T (Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest)

- CPT code 0265T (Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy)
- CPT code 0267T (Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed))
- CPT code 0268T (Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed))
- CPT code 0269T (Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed))
- CPT code 0270T (Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed))
- CPT code 0271T (Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed))
- CPT code 0272T (Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with

interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day))

- CPT code 0273T (Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming)

- CPT 0274T (Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic)

- CPT 0275T (Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar) (As published in the July 2011 OPPS quarterly update CR, CPT code 0275T replaced Level II HCPCS code C9729 effective July 1, 2011.)

We note that Category III CPT codes 0262T (Implantation of catheter-delivered prosthetic pulmonary valve, endovascular approach) and 0266T (Implantation or

replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)) are assigned to status indicator "C" (Inpatient Procedures) under the hospital OPPS beginning July 1, 2011. We believe these procedures should only be paid when provided in the inpatient setting because of the clinical circumstances under which these procedures are performed. There are no new Category I Vaccine CPT codes for the July 2011 update.

Table 17 below lists the Category III CPT codes that were implemented in July 2011 for which we are proposing to allow separate payment, along with their proposed status indicators, proposed APC assignments, and proposed payment rates for CY 2012.

TABLE 17.—CATEGORY III CPT CODES IMPLEMENTED IN JULY 2011

CY 2011 CPT Code	CY 2011 Long Descriptor	Proposed CY 2012 Status Indicator	Proposed CY 2012 APC	Proposed CY 2012 Payment Rate
0262T	Implantation of catheter-delivered prosthetic pulmonary valve, endovascular approach	C	NA	NA
0263T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest	S	0112	$2,166.33
0264T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest	S	0112	$2,166.33

0265T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy	S	0112	$2,166.33
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	C	NA	NA
0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	T	0687	$1,496.15
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	S	0039	$14,743.58
0269T	Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	T	0221	$2,567.33
0270T	Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	T	0687	$1,496.15
0271T	Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	T	0688	$2,003.33
0272T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values,	S	0218	$80.78

	with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day)			
0273T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming	S	0218	$80.78
0274T	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic	T	0208	$3,535.92
0275T	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar	T	0208	$3,535.92

We are soliciting public comments on the CY 2012 proposed status indicators and the proposed APC assignments and payment rates, if applicable, for the Level II HCPCS codes and the Category III CPT codes that are newly recognized in April or July 2011 through the respective OPPS quarterly update CRs. These codes are listed in Tables 15, 16, and 17 of this proposed rule. We are proposing to finalize their status indicators and their APC assignments and payment rates, if applicable, in the CY 2012 OPPS/ASC final

rule with comment period. Because the July 2011 OPPS quarterly update CR is issued close to the publication of this proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2011 OPPS quarterly update CR could not be included in Addendum B to this proposed rule, but these codes are listed in Tables 16 and 17, respectively. We are proposing to incorporate these codes into Addendum B to the CY 2012 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 2011 OPPS update CR and displayed in Table 15 are included in Addendum B to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS website), where their proposed CY 2012 payment rates also are shown.

2. Proposed Process for New Level II HCPCS Codes and Category I and Category III CPT Codes for Which We Will Be Soliciting Public Comments on the CY 2012 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. All

of these codes are flagged with comment indicator "NI" in Addendum B to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. 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 2012. Specifically, for CY 2012, we are proposing to include in Addendum B (which is available via the Internet on the CMS Web site) to the CY 2012 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2012 (including the Category III CPT codes that were released by the AMA in July 2011) that would be incorporated in the January 2012 OPPS quarterly update CR and the new Level II HCPCS codes, effective October 1, 2011, or January 1, 2012, that would be released by CMS in its October 2011 and January 2012 OPPS quarterly update CRs. These codes would be flagged with comment indicator "NI" in Addendum B to the CY 2012 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim OPPS payment status for CY 2012. Their status indicators and their APC assignments and payment rates, if applicable, would be open to public comment in the CY 2012 OPPS/ASC final rule with comment period and would be finalized in the CY 2013 OPPS/ASC final rule with comment period. We note that the Category III CPT codes that were released by the AMA in July 2011 that are subject to comment in this CY 2012 OPPS/ASC proposed rule, and are listed in Table 17, will not

be assigned to comment indicator "NI" in Addendum B because comments about these codes will be addressed in the CY 2012 OPPS/ASC final rule with comment period.

B. Proposed OPPS Changes – Variations within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in §419.31 of the regulations. We use Level I and Level II HCPCS codes to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices.

We have packaged into payment for each procedure or service within an APC group the costs associated with those items or services that are directly related to, and supportive of, performing the main independent procedures or furnishing the services. Therefore, we do not make separate payment for these packaged items or services. For example, packaged items and services include: (1) use of an operating, treatment, or procedure room; (2) use of a recovery room; (3) observation services; (4) anesthesia;

(5) medical/surgical supplies; (6) pharmaceuticals (other than those for which separate payment may be allowed under the provisions discussed in section V. of this proposed rule); (7) incidental services such as venipuncture; and (8) 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 2011 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, and multiple imaging 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 median cost of the services included in that APC, relative to the hospital median 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; the Act further requires us to repeat this process on a basis that is not less often than annually. Section 1833(t)(9)(A) of the Act also requires the Secretary, beginning in CY 2001, to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights (the APC Panel recommendations for specific services for the CY 2012 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 median cost (or mean cost as elected by the Secretary) for an item or service in 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 (referred to as the "2 times rule"). We use the median cost of the item or service in implementing this provision. 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 median cost of the highest cost item or service within an APC group is more than 2 times greater than the median 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 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 median 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 median 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 median. 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 2012.

During the APC Panel's February 2011 meeting, we presented median cost and utilization data for services furnished during the period of January 1, 2010, through September 30, 2010, about which we had concerns or about which the public had raised concerns regarding their APC assignments, status indicator assignments, or payment rates. The discussions of most service-specific issues, the APC Panel recommendations, if any, and our proposals for CY 2012 are contained mainly in sections III.C. and III.D. of this proposed rule.

In addition to the assignment of specific services to APCs that we discussed with the APC Panel, we also identified APCs with 2 times violations that were not specifically discussed with the APC Panel but for which we are proposing changes to their HCPCS codes' APC assignments in Addendum B (available via the Internet) 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. We also are proposing to rename existing APCs or create new clinical APCs to complement proposed HCPCS code reassignments. In many cases, the proposed HCPCS code reassignments and associated APC reconfigurations for CY 2012 included in this proposed rule are related to changes in median costs of services that are observed in the CY 2010 claims data newly available for CY 2012 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 2012.

Addendum B to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) identifies with comment indicator "CH" those HCPCS codes for which we are proposing a change to the APC assignment or status indicator that were initially assigned in the April 2011 Addendum B update (via Transmittal 2174, Change Request 7342, dated March 18, 2011).

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 2012 based on the APC Panel recommendations that are discussed mainly in sections III.C. and III.D. of this proposed rule, the other proposed changes to status indicators and APC assignments as identified in Addendum B to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site), and the use of CY 2010 claims data to calculate the median costs of procedures classified in the APCs, we reviewed all the APCs to determine which APCs would not satisfy the 2 times rule. 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;
- 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 18 of this proposed rule lists 17 APCs that we are proposing to exempt from the 2 times rule for CY 2012 based on the criteria cited above and based on claims data processed from January 1, 2010, through September 30, 2010. For the final rule with comment period, we plan to use claims data for dates of service between January 1, 2010, and December 31, 2010, that were processed on or before June 30, 2011, and updated CCRs, if available. Based on our analysis of CY 2010 claims data in preparation for this proposed rule, we found 17 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 2012, and identified 17 APCs that meet the criteria for exception to the 2 times rule for this proposed rule. These proposed APC exceptions are listed in Table 18 below. For cases in which a recommendation by the APC Panel appeared to result in or allow a violation of the 2 times rule, we generally accepted the APC Panel's recommendation because those recommendations were based on explicit consideration of resource use, clinical homogeneity, hospital specialization, and the quality of the CY 2010 claims data used to determine the APC payment rates that we are

proposing for CY 2012. The proposed median 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/HospitalOutpatientPPS/01_overview.asp.

TABLE 18.—PROPOSED APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2012

Proposed CY 2012 APC	Proposed CY 2012 APC Title
0016	Level IV Debridement & Destruction
0057	Bunion Procedures
0058	Level I Strapping and Cast Application
0060	Manipulation Therapy
0080	Diagnostic Cardiac Catheterization
0105	Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices
0235	Level I Posterior Segment Eye Procedures
0245	Level I Cataract Procedures without IOL Insert
0263	Level I Miscellaneous Radiology Procedures
0340	Minor Ancillary Procedures
0347	Level III Transfusion Laboratory Procedures
0367	Level I Pulmonary Test
0369	Level III Pulmonary Tests
0432	Health and Behavior Services
0604	Level 1 Hospital Clinic Visits
0660	Level II Otorhinolaryngologic Function Tests
0667	Level II Proton Beam Radiation Therapy

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"' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of "T" (Significant Procedure, Multiple Reduction Applies. 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 Medicare beneficiary projected utilization 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, we are proposing for CY 2012 to retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to a clinically appropriate APC. The flexibility associated with this policy allows us to move a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for reassignment have not been collected. Table 19 below lists the HCPCS codes and associated status indicators that we are proposing to reassign from a New Technology APC to a clinically appropriate APC or to a different New Technology APC for CY 2012.

Currently, in CY 2011, there are three procedures described by a HCPCS G-code 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 1506 (New Technology - Level VI ($400 - $500)); HCPCS code G0418 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41-60

specimens) is assigned to New Technology APC 1511 (New Technology - Level XI ($900 - $1,000)); 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 1513 (New Technology - Level XIII ($1,100-$1,200)).

Analysis of our hospital outpatient data for claims submitted for CY 2010 indicates that prostate saturation biopsy procedures are rarely performed on Medicare patients. For OPPS claims submitted from CY 2009 through CY 2010, our claims data show that there were only five claims submitted for HCPCS code G0417 in CY 2009 and only one in CY 2010 with a proposed median cost of approximately $532. Our claims data did not show any hospital outpatient claims for HCPCS codes G0418 and G0419 from either CY 2009 or CY 2010.

While we believe that these procedures will always be low volume, given the number of specimens being collected, we believe that we should continue their New Technology payments for another year for HCPCS codes G0417, G0418, and G0419 to see if more claims data become available. For CY 2012, we are proposing to revise the APC assignments for these procedures and continue the New Technology APC payments for HCPCS G-codes G0417, G0418, and G0419. Specifically, we are proposing to reassign HCPCS code G0417 from APC 1506 to APC 1505 (New Technology - Level V ($300 - $400)), HCPCS code G0418 from APC 1511 to APC 1506 (New Technology - Level VI ($400 - $500)), and HCPCS G0419 code from APC 1513 to APC 1508 (New Technology - Level VIII ($600 - $700)). We believe that the proposed revised APC assignments would more appropriately reflect the procedures described by these three

HCPCS G-codes, based on clinical and resource considerations. These procedures and their proposed APC assignments are displayed in Table 19.

TABLE 19.—PROPOSED REASSIGNMENT OF PROCEDURES ASSIGNED TO NEW TECHNOLOGY APCs FOR CY 2012

CY 2011 HCPCS Code	CY 2011 Short Descriptor	CY 2011 SI	CY 2011 APC	Proposed CY 2012 SI	Proposed CY 2012 APC
G0417	Sat biopsy prostate 21-40	S	1506	S	1505
G0418	Sat biopsy prostate 41-60	S	1511	S	1506
G0419	Sat biopsy prostate: >60	S	1513	S	1508

D. Proposed OPPS APC-Specific Policies

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

For CY 2011, we continued to assign CPT codes 63661 (Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed), 63662 (Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed), 63663 (Revision, including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed), and 63664 (Revision, including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed) to APC 0687 (Revision/Removal of Neurostimulator Electrodes), which had a CY 2011 final rule median cost of approximately $1,480. These codes were created effective for services performed on or after January 1, 2010, when the AMA CPT Editorial Board deleted CPT code 63660 (Revision or removal of spinal neurostimulator electrode percutaneous array(s) or plate/ paddle(s)) and created new CPT codes 63661, 63662, 63663, and 63664 to differentiate between revision and removal procedures, and to also differentiate between percutaneous leads (arrays) and surgical leads (plates/paddles).

As discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71913), we have received several comments objecting to the placement of CPT codes 63663 and 63664 in APC 0687 because, the commenter stated, these codes are used to report both revision and replacement of neurostimulator electrodes. The

commenters believed that the use of hospital resources is substantially greater when neurostimulator electrodes are being replaced rather than revised. We responded to these comments by stating that we did not have CY 2009 claims data on the cost of these codes upon which to make an assessment of whether there is a meaningful difference between the cost of revising the electrodes or replacing them, and that we were not convinced by the commenters stating that the use of the CPT codes for these services and the assignment of the codes for revision/replacement of neurostimulator electrodes to APC 0687 was inappropriate. We further stated that the OPPS is a payment system of averages in which the payment for a service is based on the estimated relative cost of the service, including a range of supply and other input costs, as well as other services in the same APC that are comparable in resource cost and clinical homogeneity. We noted that we expect that hospital charges for a service, which are derived from the cost of a service, can vary across individual patients. Therefore, we expect variability in the estimated cost of a service, across cases in a hospital and among hospitals, to be reflected at some level in the final APC relative payment weight. We indicated that we would examine estimated costs for these CPT codes in the CY 2010 claims data that we would use to model the CY 2012 proposed rule when these data became available.

At its February 28-March 1, 2011 meeting, the APC Panel recommended that CMS provide more data on CPT codes 63663, 63664, and 64569 (Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator) to determine whether they represent primarily device replacements or device revisions. We are accepting this

recommendation and have examined the CY 2010 claims data available for this proposed rule to compare the frequency of claims containing CPT codes 63663 or 63664 that were billed with HCPCS C1778 (Lead, neurostimulator (implantable)) or C1897 (Lead, neurostimulator test kit (implantable)) to the frequency of claims with CPT codes 63663 or 63664 billed without HCPCS codes C1778 and C1897, in order to determine whether they represent primarily device replacements or device revisions. We found that 61 percent of claims containing CPT codes 63663 or 63664 did not contain HCPCS code C1778 or C1897, while 39 percent of claims with CPT codes 63663 or 63664 did contain HCPCS code C1778 or C1897. Because the majority of the claims did not contain HCPCS code C1778 or C1897, these findings suggest that these CPT codes are used to describe mainly device revision procedures, although there are a significant number of cases of device replacement procedures in the claims data. We will present the requested data for CPT code 64569 at a future meeting of the APC Panel.

We also have completed an examination of the estimated costs for CPT codes 63661, 63662, 63663, and 63664 now that claims data for these CPT codes are available for the first time since they became effective on January 1, 2010. Based on the partial year claims data available for this proposed rule, the proposed median costs for CPT codes 63661 and 63662 are approximately $1,167 and $2,190, respectively. The claims data show a median cost of approximately $4,316 for CPT code 63663 and a median cost of approximately $4,883 for CPT code 63664, which constitute a 2 times rule violation within APC 0687.

In order to resolve the 2 times rule violation in APC 0687, we are proposing to move CPT codes 63663 and 63664 from APC 0687 to APC 0040 (Percutaneous Implantation of Neurostimulator Electrodes), which has a CY 2012 proposed median cost of approximately $4,516 that is more consistent with the median costs for CPT codes 63663 and 63664. We also are proposing to change the title of APC 0040 to "Level I Implantation/Revision/Replacement of Neurostimulator Electrodes" to reflect that the APC would include revision and replacement procedures beginning in CY 2012, and to change the title of APC 0061 from "Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electrodes" to "Level II Implantation/Revision/Replacement of Neurostimulator Electrodes" to be consistent with the APC 0040 title change. We believe that CPT codes 63661 and 63662 continue to be placed appropriately in APC 0687 because their CY 2012 proposed CPT median costs of approximately $1,167 and $2,190, respectively, are consistent with the overall proposed APC 0687 median cost of approximately $1,492 and because they describe only device removal procedures.

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

The AMA CPT Editorial Panel created three new codes for computed tomography (CT) of abdominal and pelvis that were effective January 1, 2011: CPT code 74176 (Computed tomography, abdomen and pelvis; without contrast material); CPT code 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)); and CPT code 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). As with all new CPT codes for CY 2011, these new codes were announced through the publication of the CY 2011 CPT in November 2010, effective on January 1, 2011.

In accordance with our longstanding policy, we made an interim APC assignment for each new code for CY 2011 based on our understanding of the resources required to furnish the service as the service was defined in the new code (75 FR 71898). Specifically, for CY 2011, we assigned new CPT code 74176 to APC 0332 (Computed Tomography Without Contrast), which has a CY 2011 payment rate of approximately $194; we assigned CPT code 74177 to APC 0283 (Computed Tomography With Contrast), which has a CY 2011 payment rate of $300; and we assigned CPT code 74178 to CPT code 0333 (Computed Tomography Without Contrast Followed by With Contrast), which has a CY 2011 payment rate of $334. For CY 2011, we also made these codes eligible for composite payment under the multiple imaging composite APC methodology when they are furnished with other CT procedures to the same patient on the same day.

As is our standard practice each year, our clinicians review each of the many CPT code changes that will be effective in the forthcoming year and make a decision regarding status indicator and/or APC assignment based on their understanding of the nature of the services furnished. We are unable to include a proposed status indicator and/or APC assignment in the proposed rule for codes that are not announced by the AMA CPT Editorial Board prior to the proposed rule. Therefore, in accordance with our longstanding policy, we include, in the final rule with comment period, an interim status

indicator and/or APC assignment for all new CPT codes that are announced by the AMA CPT Editorial Board subsequent to the OPPS/ASC proposed rule to enable payment to be made for new services as soon as the code is effective. In accordance with our longstanding practice, we identified the new codes for abdominal/pelvis CT for CY 2011 in Addendum B of the CY 2011 OPPS/ASC final rule with comment period as having new interim APC assignments by showing a comment indicator of "NI," and we provided a public comment period. As we do with all new CPT codes, we will respond to the public comments in the OPPS/ASC final rule with comment period for CY 2012. This longstanding process enables us to pay for new services as soon as the new CPT codes for them go into effect, despite the fact that they first become publicly available at the same time the final rule with comment period for the upcoming year is made public.

At its February 28-March 1, 2011 meeting, the APC Panel heard public presentations on this issue and recommended that CMS provide more data on the new CPT codes for combined abdomen and pelvis CT as soon as these data are available. We are accepting this recommendation, and we will provide claims data as soon as the data are available. We note that because these codes were effective January 1, 2011, the first available claims data for these codes will be the APC Panel claims data for the CY 2013 OPPS rulemaking. These data will be for dates of service January 1, 2011 through and including September 30, 2011, as processed through the Common Working File on or before September 30, 2011.

In general, stakeholders who provided comments on the interim assignment of these codes for CY 2011 stated that the most appropriate approach to establishing

payment for these new codes is 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 relative cost of the services under the OPPS if we were to establish payment rates for the codes for CY 2012 using claim data that reflect the combined cost of the two predecessor codes. They noted that when these services were reported in CY 2010 using two CPT codes, rather than a single code, the services that are being reported under CPT code 74176 were assigned to imaging composite APC 8005 (CT and CTA without Contrast) for which the CY 2010 payment was $419.45. Similarly, the services being reported under CPT code 74177 or CPT code 74178 were assigned to composite APC 8006 (CT and CTA with Contrast) for which the CY 2010 payment was $628.49. They indicated that they believed that simulating the median cost for CPT codes 74176, 74177, and 74178 using historic claims data from the predecessor codes in a manner similar to that used to create the composite APC medians would result in the best estimates of costs for these codes and, therefore, the most accurate payment rate for these codes.

After considering the presentations at the APC Panel meeting, the views of stakeholders who met with us to discuss this issue, and the comments in response to the CY 2011 final rule with public comment period, and after examining our claims data for the predecessor codes, we believe that establishment of payment rates for these services based on historic claims data for the combinations of predecessor codes that are now reported by CPT codes 74176, 74177, and 74178 would result in a more accurate and

appropriate payment for these services for CY 2012 because it would take into account the full cost of both services that are now reported by a single CPT code. We believe that the best way to secure the most appropriate payments for CY 2012 is to use the claims data from the predecessor codes under which the new codes were reported for CY 2010 to simulate median costs for the new codes and to create APCs that are appropriate to the services. To do so should reflect both the full cost of the service as reported by the new code and should also reflect the efficiencies of reporting the service represented by the single new code. Therefore, we are proposing to establish two APCs to which we would propose to assign the combined abdominal and pelvis CT services. Specifically, we are proposing to create new APC 0331 (Combined Abdominal and Pelvis CT Without Contrast), to which we are proposing to assign CPT code 74176 and for which we are proposing to base the CY 2012 OPPS payment rate on a median cost of approximately $417. We also are proposing to create new APC 0334 (Combined Abdominal and Pelvis CT With Contrast), to which we are proposing to assign CPT codes 74177 and 74178 for the CY 2012 OPPS and for which we are proposing to base the CY 2012 OPPS payment rate on a median cost of approximately $592. We are proposing to create two new APCs to which to assign these codes, rather than one, because CPT code 74176 is furnished without contrast, while CPT codes 74177 and 74178 are furnished with contrast. Section 1833(t)(2)(G) of the Act requires that services with contrast may not be assigned to APCs that contain services without contrast, and therefore, we could not assign CPT code 74176, which does not require contrast, to the same APC as CPT codes 74177 and 74178, which require contrast.

We are proposing to create new APC 0331 to which we would assign CPT code 74176 and to create new APC 0334 to which we would assign CPT codes 74177 and 74178 because the proposed methodology for simulating the median costs for CPT codes 74176, 74177, and 74178, which uses claims data for the predecessor codes is unique to these CPT codes. Therefore, we believe that it is appropriate to create APCs comprised only of services for which we calculated medians using claims data for the predecessor codes. To the extent this policy is finalized, we would reassess whether it continues to be appropriate to pay these codes under APCs 0331 and 0334 once the median costs for the proposed CY 2013 OPPS are calculated using our standard methodology, based on hospitals' CY 2011 charges for CPT codes 74176, 74177, and 74178.

To calculate the median costs for proposed APCs 0331 and 0334 for CY 2012, we selected claims that contained one unit of both of the predecessor CPT codes that appear in the CY 2011 CPT for CPT codes 74676, 74677, and 74678. The predecessor codes are limited to the codes in Table 20 below.

TABLE 20.--CPT CODES THAT WERE COMBINED TO CREATE NEW ABDOMINAL AND PELVIS CPT CODES FOR CY 2011

CPT Code	Descriptor
72192	Computed tomography, pelvis; without contrast material
72193	Computed tomography, pelvis; with contrast material(s)
72194	Computed tomography, pelvis; without contrast material, followed by contrast material(s) and further sections
74150	Computed tomography, abdomen; without contrast material
74160	Computed tomography, abdomen; with contrast material(s)
74170	Computed tomography, abdomen; without contrast material, followed by contrast material(s) and further sections

For purposes of selecting claims to be used to calculate simulated median costs, we selected only claims that contained one (and only one) unit of each of the predecessor codes in the allowed combinations identified in Table 21 below. We used only claims that contained one and only one unit of each of the code combinations because we believe that it represents the best simulation of the definition of the new codes. Where more than one unit of either or both codes were reported, the claim would be paid under an imaging composite APC, not under APC 0331 or 0334. For median calculation, claims that contained more than one unit of either or both codes were assigned to the applicable imaging composite APC. We refer readers to section II.A.2.e.5 of this proposed rule for discussion of the imaging composite APCs.

TABLE 21.--COMBINATIONS OF PREDECESSOR CPT CODES USED TO SIMULATE MEDIAN COSTS FOR THE COMBINED ABDOMINAL AND PELVIS CT CODES THAT ARE NEW FOR CY 2011

Combined Abdominal and pelvis CT code	Predecessor CT Abdomen without contrast	Predecessor CT Pelvis without contrast	Predecessor CT Abdomen with contrast	Predecessor CT Pelvis with contrast
74176	74150	72192	--	--
74177	--	--	74160	72193
74178	74150	--	--	72193
74178	74150	--	--	72194
74178	--	72192	74160	--
74178	--	--	74160	72194
74178	--	72192	74170	--
74178	--	--	74170	72193
74178	--	--	74170	72194

After we selected the claims that contained one and only one unit of each code in each combination, we deleted claims that contained other separately paid HCPCS codes if those codes did not appear on the bypass list (we refer readers to section II.A.1.b. of this proposed rule and to Addendum N, which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site). We bypassed the costs for codes that appeared on the bypass list to create simulated single procedure claims for CPT codes 74178, 74177, and 74178. Using the remaining simulated single procedure claims for the combined abdominal and pelvis CT services, we applied our standard trimming, packaging, and wage standardization methodology to calculate the median cost for each combined abdominal and pelvis CT code for the two proposed APCs. We refer readers to section II.A.2.c. of this proposed rule for discussion of our standard trimming, packaging, and wage standardization methodology.

We found that using this proposed methodology resulted in a simulated median cost for CPT code 74176 of approximately $417, and that, because we are proposing that CPT code 74176 would be the only HCPCS code assigned to APC 0331, the simulated median cost for APC 0331 also would be approximately $417. We found that using this proposed methodology, the simulated median cost for CPT code 74177 was approximately $570 and the simulated median cost for CPT code 74178 was approximately $638, and that the simulated median cost for proposed APC 0334 was approximately $592. We are proposing to use this simulation methodology to establish proposed median costs for proposed APCs 0331 and 0334 for the CY 2012 OPPS.

We also are proposing that, in cases where CPT code 74176 is reported with CT codes that describe CT services for other regions of the body other than the abdomen and pelvis in which contrast is not used, it would be assigned to imaging composite APC 8005 (CT and CTA Without Contrast), for which we are proposing a median cost of approximately $445 for the CY 2012 OPPS. In cases where CPT code 74177 or 74178 is reported with CT codes that describe CT services for regions of the body other than abdomen and pelvis in which contrast is used, we are proposing that the code would be assigned to APC 8006 (CT and CTA With Contrast), for which we are proposing a median cost of approximately $744 for the CY 2012 OPPS. We are proposing to assign CPT codes 74176 to imaging composite APC 8005 and to assign CPT codes 74177 and 74178 to imaging composite APC 8006 because the predecessor codes for CPT codes 74176, 74177 and 74178 (identified in Table 20), continue to be reported when either abdominal CT or pelvis CT (but not both) is furnished, and we are proposing to continue to assign them to imaging composite APCs 8005 and 8006. We believe that it would be inconsistent with our proposed imaging composite policy if we did not propose to assign CPT codes 74176, 74177, and 74178 to the applicable imaging composite APC for CY 2012. We refer readers to section II.A.2.e.(5) of this proposed rule for the discussion of the calculation of our proposed median costs for APCs 8005 and 8006 for CY 2012.

In summary, we are proposing to establish new APCs 0331 and 0334 to which we would assign the abdominal and pelvis CT codes that were created by the AMA CPT Editorial Panel for CY 2011 and to use the simulation methodology we describe above to establish simulated median costs on which we would base the CY 2012 payment rates

because we believe that to do so would result in relative payment weights for these new services that will more accurately reflect the resources required to furnish these services as defined by CPT than would be true of continued assignment of the codes to the single service APCs to which we made interim assignments for CY 2011. We note that claims and cost data for these services will be available for the CY 2013 OPPS rulemaking, and we will reassess the payment policy for these codes based on the cost data that are used to establish the CY 2013 OPPS median cost and payment rates.

3. Placement of Amniotic Membrane (APCs 0233 and 0244)

For the CY 2011 update, 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 created 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 carefully 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 65780 to APC 0244 (Corneal and Amniotic Membrane Transplant) with a CY 2011 payment rate of approximately $2,681. We assigned CPT code 65778 to APC 0239 (Level II Repair and Plastic Eye Procedures) with a payment rate of approximately $559, and CPT code 65779 to APC 0255 (Level II Anterior Segment Eye Procedures) with a payment rate of approximately $519. In addition, we assigned both 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 both codes were new codes for CY 2011 with an interim APC assignment subject to public comment. We will address any public comments on issues regarding these new codes in the CY 2012 OPPS/ASC final rule with comment period.

At the APC Panel at the February 28-March 1, 2011 meeting, a presenter requested the reassignment of both new CPT codes 65778 and 65779 to APC 0244, 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 new procedures described by CPT codes 65778 and 65779 are very similar to the procedure described by CPT code 65780.

The APC Panel recommended that CMS reassign both CPT codes 65778 and 65779 to APC 0233 (Level III Anterior Segment Eye Procedures), citing clinical similarity to procedures already in APC 0233. Based on clinical as well as resource similarity to the other procedures currently assigned to APC 0233, we are proposing to accept the APC Panel's recommendations to reassign CPT code 65778 from APC 0239 to APC 0233 and to reassign CPT code 65779 from APC 0255 to APC 0233. However, based upon our further review and analysis of the clinical characteristics of the procedure described by CPT code 65778, we also are proposing to conditionally package CPT code 65778. The service described by CPT code 65778 would rarely be provided as a separate, stand-alone service in the HOPD; it would almost exclusively be provided in addition to another procedure or service. Our medical advisors indicate 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. Given the characteristics of this procedure and its likely use in the HOPD, we are proposing to conditionally package CPT code 65778 for CY 2012 and reassign its status indicator from “T” to “Q2” to indicate that the procedure is packaged when it is billed on the same date with another procedure or service that is also assigned to status indicator “T.” Otherwise, separate payment would be made for the procedure.

In summary, for CY 2012, we are proposing to reassign CPT code 65778 from APC 0239 to APC 0233 with a conditionally packaged status, to reassign CPT code 65779 from APC 0255 to APC 0233, which has a proposed median cost of approximately $1,214, and to continue to assign CPT code 65780 to APC 0244, which has a proposed median cost of approximately $2,767.

As has been our practice since the implementation of the OPPS, we annually review all the items and services within an APC group to determine, with respect to comparability of the use of resources, for any 2 times violations. In making this determination, we review our claims data and determine whether we need to make changes to the current APC assignments for the following year. Because CPT codes 65778 and 65779 are new for CY 2011, and we have no claims data for the CY 2012 update, we will again reevaluate the status indicator and APC assignments for CPT codes 65778, 65779, and 65780 in CY 2012 for the CY 2013 OPPS rulemaking cycle. The amniotic membrane procedures and their CY 2012 proposed APC assignments are displayed in Table 22 below.

TABLE 22.--PROPOSED APC ASSIGNMENT FOR THE AMNIOTIC MEMBRANE PROCEDURES FOR CY 2012

CY 2011 HCPCS Code	CY 2011 Short Descriptor	CY 2011 SI	CY 2011 APC	Proposed CY 2012 SI	Proposed CY 2012 APC
65778	Cover eye w/membrane	T	0239	Q2	0233
65779	Cover eye w/membrane suture	T	0255	T	0233
65780	Ocular reconst transplant	T	0244	T	0244

4. Upper Gastrointestinal Services (APCs 0141, 0419, and 0422)

For CY 2011, there are two upper gastrointestinal (GI) procedure APCs, APC 0141 (Level I Upper GI Procedures), which has a CY 2011 national unadjusted payment rate of $611.73, and APC 0422 (Level II Upper GI Procedures), which has a CY 2011 national unadjusted payment rate of $1,148.75. In the CY 2011 OPPS/ASC proposed rule, we proposed to reconfigure APCs 0141 (Level I Upper GI Procedures) and APC 0442 (Level II Upper GI Procedures) by moving several CPT codes from APC 0141 to APC 0422. We received public comments on the proposed rule objecting to our proposal on the basis that the reconfiguration would reduce the median cost and, therefore, the payment for services to which APC 0422 was assigned and would not maintain the clinical homogeneity of these services. Instead commenters, including the applicable medical specialty societies, asked that we reconfigure APCs 0141 and 0422 to create three APCs by adding a new APC for upper GI procedures. They also recommended a HCPCS configuration that they believed would provide payment rates that would more accurately reflect the median costs of the services in APCs 0141 and 0422. We finalized our proposed changes to APCs 0141 and 0422 for CY 2011 without establishing a third APC for upper GI procedures for the reasons discussed in the CY 2011 OPPS/ASC final rule with public comment period (75 FR 71907).

However, when we developed the median costs for APCs 0141 and 0422 using CY 2010 claims data for discussion at the APC Panel meeting of February 28-March 1, 2011, we observed that there was a 2 times violation for APC 0141 that had not existed for CY 2010 OPPS. For the APC Panel meeting, we simulated the HCPCS and

APC median costs that would result from the reconfiguration that was recommended by the stakeholders in their comments on the CY 2011 OPPS/ASC final rule with comment period, and we discussed the results with the APC Panel. The APC Panel recommended that CMS create an intermediate level upper GI procedures APC (APC Panel Recommendation 13). The APC Panel recommendations and report may be found at the APC Panel Web site, located at: http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

For the reasons we discuss below, we are accepting the APC Panel recommendation to propose to establish three levels of upper GI procedure APCs and to propose to adopt the reconfiguration recommended by stakeholders because we believe that the proposed reconfiguration will provide payments that are more closely aligned with the median costs of the services. Creating an intermediate APC for upper GI procedures provides APC median costs that are more closely aligned with the median costs for the many CPT codes for upper GI procedures, and therefore, the APC median costs better reflect the resources required to provide these services as defined by the CPT codes for them. Moreover, the proposed reconfiguration resolves the 2 times rule violation that would result in APC 0141 if we were to apply the CY 2011 APC configuration to the CY 2012 proposed rule data. Therefore, we believe that we would need to propose to reassign HCPCS codes regardless of whether we created the intermediate APC for CY 2012. We believe that the proposed reconfiguration to create the intermediate APC is the most appropriate means of avoiding a 2 times violation that

would otherwise exist for CY 2012 and that the resulting median costs will provide payments that are more reflective of the relative costs of the services being furnished.

Therefore, for CY 2012, we are proposing to create new APC 0419 (Level II Upper GI Procedures), as recommended by the stakeholders, and we are proposing to reassign HCPCS codes previously assigned to APCs 0141 and 0422 to the three APC configuration. Table 23 below contains the proposed HCPCS reassignments for CY 2012 using the proposed three APC reconfiguration. We believe that this proposed reconfiguration classifies upper GI CPT codes in groups that demonstrate the best clinical and resource homogeneity. For APC 0141, we calculated a proposed rule median cost for CY 2012 of approximately $603. For proposed new APC 0419, we calculated a proposed rule median cost of approximately $904. For APC 0422, we calculated a proposed rule median cost of approximately $1,833.

TABLE 23.--PROPOSED RECONFIGURATION OF UPPER GI PROCEDURE CODES FOR CY 2012

APC	HCPCS	SI	Description	Median	Single Bill Frequency	Percent Single Bills	Total Frequency
0141			Level I Upper GI Procedures	$602.59			
	43831	T	Place gastrostomy tube	$0.00	0		0
	43510	T	Surgical opening of stomach	$186.33	1		1
	43999	T	Stomach surgery procedure	$238.68	1,732		2,128
	43204	T	Esoph scope w/sclerosis inj	$361.50	2		6
	43761	T	Reposition gastrostomy tube	$496.12	361		602
	43235	T	Uppr gi endoscopy diagnosis	$538.38	70,885	20	124,837

APC	HCPCS	SI	Description	Median	Single Bill Frequency	Percent Single Bills	Total Frequency
	43200	T	Esophagus endoscopy	$592.17	1,016		5,513
	43239	T	Upper gi endoscopy biopsy	$618.39	260,422	73	516,015
	43202	T	Esophagus endoscopy biopsy	$619.63	461		1,244
	43248	T	Uppr gi endoscopy/guide wire	$621.09	16,548	5	37,741
	43234	T	Upper gi endoscopy exam	$644.39	510		872
	43247	T	Operative upper GI endoscopy	$656.88	5,028	1	16,489
	43236	T	Uppr gi scope w/submuc inj	$660.41	3,369	1	8,141
	43600	T	Biopsy of stomach	$666.46	5		14
	43243	T	Upper gi endoscopy & inject	$748.56	161		326
	43241	T	Upper GI endoscopy with tube	$782.08	164		462
	43499	T	Esophagus surgery procedure	$2,158.45	528		1,375
0419			Level II Upper GI Procedures	$903.97			
	91111	T	Esophageal capsule endoscopy	$730.21	69		79
	43250	T	Upper GI endoscopy/tumor	$730.67	949	1	3,083
	43201	T	Esoph scope w/submucous inj	$760.79	99		256
	43251	T	Operative upper GI endoscopy	$793.29	2,976	3	10,936
	43237	T	Endoscopic us exam esoph	$796.01	369		696
	43259	T	Endoscopic ultrasound exam	$811.70	13,234	15	21,312
	43246	T	Place gastrostomy tube	$814.37	15,205	17	20,923
	43231	T	Esoph endoscopy w/us exam	$822.22	346		455

APC	HCPCS	SI	Description	Median	Single Bill Frequency	Percent Single Bills	Total Frequency
	43244	T	Upper GI endoscopy/ligation	$875.56	5,100	6	6,916
	43215	T	Esophagus endoscopy	$881.45	220		858
	43255	T	Operative upper GI endoscopy	$882.09	3,810	4	7,517
	43458	T	Dilate esophagus	$890.28	145		1,305
	43217	T	Esophagus endoscopy	$890.36	24		104
	49446	T	Change g-tube to g-j perc	$891.78	389		681
	43205	T	Esophagus endoscopy/ligation	$894.22	121		142
	43249	T	Esoph endoscopy dilation	$897.83	19,351	22	50,173
	49440	T	Place gastrostomy tube perc	$899.69	1,770	2	2,823
	43245	T	Uppr gi scope dilate strictr	$919.77	2,489	3	5,401
	43226	T	Esoph endoscopy dilation	$925.45	741	1	1,138
	43240	T	Esoph endoscope w/drain cyst	$953.86	32		85
	49441	T	Place duod/jej tube perc	$976.70	136		232
	43220	T	Esoph endoscopy dilation	$1,011.56	593	1	908
	43232	T	Esoph endoscopy w/us fn bx	$1,017.09	351		425
	44100	T	Biopsy of bowel	$1,028.66	5		22
	43238	T	Uppr gi endoscopy w/us fn bx	$1,115.06	383		539
	43242	T	Uppr gi endoscopy w/us fn bx	$1,125.47	12,260	14	16,443
	43258	T	Operative upper GI endoscopy	$1,138.38	5,654	6	10,278
	43227	T	Esoph endoscopy repair	$1,405.46	25		39
	43830	T	Place gastrostomy tube	$1,721.16	150		288

APC	HCPCS	SI	Description	Median	Single Bill Frequency	Percent Single Bills	Total Frequency
0422			Level III Upper GI Procedures	$1,833.15			
	43216	T	Esophagus endoscopy/lesion	$1,416.11	12		31
	43870	T	Repair stomach opening	$1,651.04	95	4	153
	43257	T	Uppr gi scope w/thrml txmnt	$1,724.95	46	2	62
	43228	T	Esoph endoscopy ablation	$1,829.56	2,518	93	3,022
	C9724	T	EPS gast cardia plic	$5,957.92	38	1	69

5. Pulmonary Rehabilitation (APC 0102)

Section 144(a)(1) of Pub. L. 110–275 (MIPPA) added section 1861(fff) to the Act to provide Medicare Part B coverage and payment for a comprehensive program of pulmonary rehabilitation services furnished to beneficiaries with chronic obstructive pulmonary disease, effective January 1, 2010. Accordingly, in the CY 2010 OPPS/ASC final rule with comment period, we established a policy to pay for pulmonary rehabilitation services furnished as a part of the comprehensive pulmonary rehabilitation program benefit (74 FR 60567). There was and continues to be no single CPT code that fully and accurately describes the comprehensive pulmonary rehabilitation benefit provided in section 1861(fff) of the Act. Moreover, there were no alphanumeric HCPCS codes that described the comprehensive pulmonary rehabilitation benefit in effect for CY 2008 (on which the CY 2010 OPPS was based) or CY 2009 (on which the CY 2011 OPPS was based). Therefore, for CY 2010, we created new HCPCS code G0424 (Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per

session, up to two sessions per day) and assigned the code to APC 0102 (Level II Pulmonary Treatment), which we also created for CY 2010 OPPS. Because none of the pulmonary treatment codes for which there were charges for CY 2008 or CY 2009 accurately described the comprehensive pulmonary rehabilitation service for which MIPPA provided coverage, we did not assume that the charge reported on any one of the previously existing HCPCS codes under which pulmonary treatments were reported would represent the full charge for the comprehensive pulmonary rehabilitation service.

Instead, for the CY 2010 OPPS, which was based on claims for services in CY 2008, we calculated a median "per session" cost that we simulated from historical hospital claims data for pulmonary therapy services that were billed in combination with one another, much like we create composite APC median costs by summing the costs of multiple procedures that are typically provided on the same date. Our methodology for calculating the "per session" median cost that we used as the basis for the CY 2010 OPPS payment rate for HCPCS code G0424 and APC 0102 is discussed in detail in the CY 2010 OPPS final rule with comment period (74 FR 60567 through 60570).

Specifically, to simulate the "per session" median cost of new HCPCS code G0424 from claims data for existing services, we used only claims that contained at least one unit of HCPCS code G0239 (Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring), the group code that is without limitation on time duration, and one unit of HCPCS code G0237 (Therapeutic procedures to increase strength or endurance of respiratory muscles, one on one, face to face, per 15 minutes (includes monitoring) or

HCPCS code G0238 (Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, one on one, face to face, per 15 minutes (includes monitoring), the individual, face-to-face codes that report 15 minutes of service, on the same date of service. We reasoned that patients in a pulmonary rehabilitation program would typically receive individual and group services in each session of approximately 1 hour in duration. This was consistent with public comments that suggested that pulmonary rehabilitation is often provided in group sessions in the HOPD, although patients commonly require additional one-on-one care in order to fully participate in the program. We note that our use of "per session" claims reporting one unit of HCPCS code G0237 or G0238 and one unit of HCPCS code G0239 in this simulation methodology was also consistent with our overall finding of approximately 2.4 service units of the HCPCS G-codes per day on a single date of service, usually consisting of both individual and group services, for patients receiving pulmonary therapy services in the HOPD based upon CY 2008 claims. We concluded that the typical session of pulmonary rehabilitation would be 1 hour based on public comments that indicated that a session of pulmonary rehabilitation is typically 1 hour and based on our findings that the most commonly reported HCPCS code for pulmonary treatment is HCPCS code G0239, which has no time definition for this group service.

We included all costs of the related tests and assessment services (CPT codes 94620 (Pulmonary stress testing; simple (e.g., 6-minute walk test, prolonged exercise test for bronchospasm with pre- and post-spirometry and oximetry)); 94664 (Demonstration and/or evaluation of patient utilization of an aerosol generator, nebulizer, metered dose

inhaler or IPPB device); and 94667 (Manipulation chest wall, such as cupping, percussion and vibration to facilitate lung function; initial demonstration and/or evaluation), and all CPT codes for established patient clinic visits, on the same date of service as the HCPCS G-codes in the claims we used to simulate the median cost for HCPCS code G0424. After identifying these "per session" claims, which we believe to represent 1 hour of care, we summed the costs on them and calculated the median cost for the set of selected claims. In light of the cost and clinical similarities of pulmonary rehabilitation and the existing services described by HCPCS codes G0237, G0238, and G0239 and the CPT codes for related assessments and tests, and the significant number of "per session" hospital claims we found, we believed that the simulated median cost for HCPCS code G0424, constructed to include the costs of these services where furnished, was our best estimate of the expected hospital cost of a pulmonary rehabilitation session, given that we did not have hospital charges for the comprehensive pulmonary rehabilitation service provided by MIPPA for which we created HCPCS code G0424.

We used the resulting simulated median "per session" cost of approximately $50 as the basis for the payment for pulmonary rehabilitation service for CY 2010, the first year in which the comprehensive pulmonary rehabilitation benefit was covered. For CY 2011, which was based on claims for services furnished in CY 2009, we continued to assign HCPCS code G0424 to APC 0102 and to apply the simulation methodology that we used in CY 2010 to claims for services in CY 2009 to calculate a median "per session" cost simulated from historical hospital claims data for similar pulmonary therapy services for the CY 2011 OPPS. The CY 2011 OPPS final rule median cost of

approximately $62 resulted in a national unadjusted payment rate for CY 2011 of approximately $63.

For the CY 2012 OPPS, however, we have a very robust set of claims for HCPCS code G0424 on which hospitals reported the charges for the comprehensive pulmonary rehabilitation service for which MIPPA provided the pulmonary rehabilitation benefit beginning on January 1, 2010. Specifically, the CY 2012 OPPS proposed rule data, based on CY 2010 claims, contained a total frequency of 393,056 lines of HCPCS code G0424, of which we were able to use 391,901 single procedure bills or almost 100 percent of the claims submitted for HCPCS code G0424. This is an extremely robust volume of single procedure bills containing charges for HCPCS code G0424 on which to base a median cost. In general, we have found that higher volumes of single bills both in absolute numbers and as a percentage of total frequency provide very stable estimates of hospital costs.

Therefore, we are proposing that the payment rate for HCPCS code G0424 and, therefore, for APC 102, would be based on the median cost for the service as derived from claims for services furnished in CY 2010 and the most current available cost report information, using our longstanding process for estimating the median cost of a service described by a HCPCS code. We refer readers to section II. of this proposed rule for a description of our longstanding standard process for calculating the median costs on which the OPPS payment rates are based. Using our standard median calculation process for HCPCS code G0424 results in a proposed median cost of approximately $38 for HCPCS code G0424 and, therefore, for APC 0102. Given that the volume of claims in

the CY 2012 OPPS proposed rule data is so robust for HCPCS code G0424, we believe that the proposed median cost we calculated for HCPCS code G0424 is a valid reflection of the relative cost of the comprehensive pulmonary rehabilitation service described by HCPCS code G0424 and that the proposed median cost for HCPCS code G0424 is an appropriate basis on which to establish the proposed national unadjusted payment rate for APC 0102.

We recognize that there is a significant difference between our simulated median cost for CY 2011 and the CY 2012 proposed rule median cost of approximately $38 that is derived from application of our standard median calculation process to hospital claims data for CY 2010. We believe that this difference arises because the median simulation methodology we used for CY 2010 and CY 2011 selected claims that contained multiple procedures and packaged the costs of numerous services into the "per session" cost for the simulated code where numerous services appeared on the same date of service. Our simulation methodology assumed that hospitals would include the charges for these additional services in their CY 2010 charges for HCPCS code G0424 because the services are included in the definition of comprehensive pulmonary rehabilitation.

In response to the CY 2012 OPPS proposed median of approximately $38 for HCPCS code G0424, we looked at our claims data in more depth. We found that 1,048 hospitals, approximately 25 percent of hospitals paid under the OPPS, reported HCPCS code G0424 and that the median line item median cost (exclusive of packaging) was approximately $38, virtually no different from the median cost per unit that we derived from the single bills. We also examined the charges that were submitted for HCPCS

code G0424 in CY 2010 and the CCRs that were applied to the charges for HCPCS code G0424 to calculate the estimated median cost for the code for this CY 2012 proposed rule. We also looked at the revenue codes under which charges for HCPCS code G0424 were reported and the percentage of cost that was associated with packaged costs, such as oxygen, drugs, and medical supplies. We found that the median line item charge for HCPCS code G0424 in the CY 2012 proposed rule data was approximately $150 and that the median CCR was 0.29. We also found that the most frequently reported revenue code for HCPCS code G0424 was revenue code 410 (Respiratory therapy), approximately 108,000 single bills, and with revenue code 948 (Pulmonary Rehabilitation), approximately 81,000 single bills, being the second most commonly reported revenue code for HCPCS code G0424. We found that only 0.02 percent of the cost of HCPCS code G0424 was packaged cost (for example, oxygen, drugs, and supplies). In general, our detailed examination of total and line item charges for pulmonary rehabilitation, the CCRs used to reduce the charges to estimated costs on the single bills, the revenue codes reported, and the absence of packaging on the single bills supports the proposed median cost of $38 per unit as a valid estimate of the relative cost of one unit of HCPCS code G0424.

In summary, our examination of the claims and cost data for HCPCS code G0424 causes us to believe that the proposed median cost that we calculated from claims data for HCPCS code G0424 was calculated correctly according to our longstanding standard median cost calculation methodology. Therefore, we are proposing to base the CY 2012 OPPS payment rate for HCPCS code G0424 and APC 0102 on the median cost that we

derive from applying our standard median calculation methodology to the CY 2010 charges and cost data for HCPCS code G0424.

6. Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes (APC 0108)

For CY 2011, only HCPCS code 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator) is assigned to APC 0108 (Insertion/Replacement/Repair of Cardioverter Defibrillator Leads). HCPCS code 33249, and therefore APC 0108, has a CY 2011 OPPS median cost of $26,543.91 on which the CY 2011 national unadjusted payment rate is based. For CY 2011, there are two HCPCS codes assigned to APC 0418: CPT code 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (including upgrade to dual chamber system) (List separately in addition to code for primary procedure)), and CPT code 33224 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or pacing cardioverter-defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of generator)). APC 0418 is titled "Insertion of left ventricular pacing electrode" for CY 2011. APC 0418 has a CY 2011 median cost of $10,516.97 on which the CY 2011 payment rate for HCPCS codes 33225 and 33224 are based. Both APCs 0108 and 0418 are device-dependent APCs for which the criteria and process used for calculating the median costs are discussed in section II.A.2.d.1. of this proposed rule.

In the CY 2010 claims data used for this CY 2012 proposed rule, HCPCS code 33249 has a median cost of approximately $27,020 based on 6,139 single bills; HCPCS code 33225 has a median cost of approximately $34,018 based on 458 single bills, and HCPCS code 33224 has a median cost of approximately $12,418 based on 201 single bills. We are proposing to retain HCPCS code 33249 in APC 0108 but to reassign HCPCS code 33225 to APC 0108 on the basis that these codes are similar in clinical characteristics and median cost. We are proposing to revise the title of APC 0108 to read "Insertion/Replacement/Repair of AICD Leads, Generator, and Pacing Electrodes" for CY 2012. Under our standard methodology, using CY 2010 claims data, we calculated a median cost of approximately $27,361 for APC 0108.

We also are proposing to assign HCPCS code 33224 to APC 0655 because it is similar in clinical characteristics and median costs to the other services in APC 0655, and to revise the title of APC 0655 to read "Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker or Pacing Electrode." We are proposing a CY 2012 OPPS median cost for APC 0655 of approximately $9,785 upon which we are proposing to base the CY 2012 OPPS payment rate. We are proposing the changes to the titles of APCs 0108 and 0655 to better describe the proposed content of the APCs. Because the reassignment of HCPCS code 33225 to APC 0108 and HCPCS 33244 to APC 0655 would result in APC 0418 containing no HCPCS codes, we are proposing to delete APC 0418.

As we discuss in detail in section III.D. of this proposed rule, we are proposing that HCPCS codes 33249 and 33225 would be paid under APC 0108 only if they are not

reported on the same date of service. We are proposing that, when HCPCS codes 33249 and 33225 are reported on the same date of service, they would be paid through proposed new composite APC 8009 (Cardiac Resynchronization Therapy with Defibrillator Composite) and that the payment rate for proposed composite APC 8009 would be limited to the proposed IPPS standardized payment amount for MS-DRG 227 (Cardiac Defibrillator Implant without Cardiac Catheterization and without Medical Complications and Comorbidities), which is currently estimated to be $26,364.93. In other words, we are proposing to pay APC 8009 at the lesser of the APC 8009 median cost or the IPPS standardized payment rate for MS-DRG 227. We calculated the standardized payment rate for MS-DRG 227 ($26,364.93) by multiplying the normalized weight from Table 5 of the FY 2012 IPPS/LTCH PPS proposed rule (5.1370) by the sum of the nonlabor and labor-related shares of the proposed FY 2012 IPPS operating standardized amount (nonwage-adjusted) labor-related share $3,182.06 + nonlabor-related share $1,950.30 = $5,132.36) which were obtained from Table1B. For further detail on the calculation of the IPPS proposed FY 2012 payment rates, we refer readers to the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 26028 through 26029).

In addition, under the authority of section 1833(t)(2)(E) of the Act, which gives the Secretary the authority to make adjustments to ensure equitable payments, we are proposing to limit the payment for services that are assigned to APC 0108, to the proposed IPPS standardized payment amount for MS-DRG 227. In other words, we are proposing to pay APC 0108 at the lesser of the APC 0108 median cost or the IPPS standardized payment rate for MS-DRG 227. We believe that MS-DRG 227 is the most

comparable DRG to APC 0108 because, like APC 0108, MS-DRG 227 includes implantation of a defibrillator in patients who do not have medical complication or comorbidities. If we were to base payment for APC 0108 on our calculated median cost of approximately $27,361, it would result in a payment under the CY 2012 OPPS that would exceed our proposed standardized payment under the IPPS for MS-DRG 227 of $26,364.93. We do not believe that it would be equitable to pay more for the implantation of a cardioverter defibrillator or implantation of a left ventricular pacing electrode for an outpatient encounter, which, by definition, includes fewer items and services than an inpatient stay during which the patient has the same procedure. In contrast, the amount Medicare would pay for an inpatient stay includes continuous skilled nursing care, room and board, all medications, and all diagnostic tests for an average of 3 days.

We believe that limiting OPPS payment for the services described by HCPCS codes 33249 and 33225 to the IPPS MS-DRG payment will ensure sufficient, appropriate, and equitable payment to hospitals because patients who receive these services in the hospital outpatient setting are not as sick as patients who have been admitted to receive this same service in the hospital inpatient setting. Therefore, we expect it would be less costly to care for these patients as outpatients, who would also spend less time in the facility and receive fewer services. In addition, we believe that a payment cap is necessary to ensure that we do not create an inappropriate payment incentive to implant ICDs and left ventricular leads in one setting of care over another by paying more in the outpatient setting compared to the inpatient setting.

We are proposing to continue all other standard policies that apply to device-dependent procedures, including the procedure-to-device edits that were established beginning in the CY 2005 OPPS for claims processing and median calculation; and calculation of and application of device offset amounts when pass-through devices are used and when an "FB" or "FC" modifier is attached to the line for either CPT code 33249 or 33225. However, for CY 2012, we are proposing that if the APC 0108 median cost that we will calculate for the CY 2012 OPPS/ASC final rule exceeds the FY 2012 IPPS standardized payment rate for MS-DRG 227, as adopted in the FY 2012 IPPS/LTCH PPS final rule, we would establish the OPPS payment amount at the IPPS standardized payment rate for MS-DRG 227 for FY 2012. In the FY 2012 IPPS/LTCH PPS proposed rule, this amount is $26,364.93. If the median cost for APC 0108 as calculated using the CY 2012 OPPS/ASC final rule data is less than the FY 2012 IPPS standardized payment rate for MS-DRG 227, we would base the payment for APC 0108 on the CY 2012 OPPS/ASC final rule median cost ofr APC 0108. These proposed changes would be made in a budget neutral manner, in the same way that payment for other APCs is budget neutral within the OPPS.

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. The date on which a pass-through category is in effect 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 is one new device category eligible for pass-through payment, described by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (implantable), which we announced in the October 2010 OPPS Update (Transmittal 2050, Change Request 7117, dated September 17, 2010). There are no categories for which we proposed expiration of pass-through status in CY 2011. If we create new device categories for pass-through payment status during the remainder of CY 2011, we will propose future expiration dates in accordance with the statutory requirement that they be eligible for pass-through payments for at least 2, but not more

than 3, years from the date on which pass-through payment for any medical device described by the category may first be made.

b. Proposed CY 2012 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 category C1749 was established for pass-through payments on October 1, 2010, 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 2012. Therefore, we are proposing an expiration date for pass-through payment for device category C1749 of December 31, 2012. Therefore, under our proposal, beginning January 1, 2013, device category C1749 will no longer be eligible for pass-through payments.

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

a. Background

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). We deduct from the pass-through payments for identified device categories eligible for pass-through payments 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, as required by section 1833(t)(6)(D)(ii) of the Act. 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 2011 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/HospitalOutpatientPPS/01_overview.asp. 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).

As of CY 2009, the costs of implantable biologicals without pass-through status are packaged into the payment for the procedures in which they are inserted or implanted because implantable biologicals without pass-through status are not separately paid (73 FR 68633 through 68636). For CY 2010, we finalized a new policy to specify 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; also referred to as "implantable biologicals") 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. As a result, for CY 2010,

we included implantable biologicals in our calculation of the device APC offset amounts (74 FR 60476). We calculated and set the device APC offset amount for a newly established device pass-through category, which could include a newly eligible implantable biological, beginning in CY 2010 using the same methodology we have historically used to calculate and set device APC offset amounts for device categories eligible for pass-through payment (72 FR 66751 through 66752), with one modification. Because implantable biologicals are considered devices rather than drugs for purposes of pass-through evaluation and payment under our established policy, the device APC offset amounts include the costs of implantable biologicals. For CY 2010, we also finalized a policy to utilize the revised device APC offset amounts to evaluate whether the cost of an implantable biological 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. Further, for CY 2010, we no longer used the "policy-packaged" drug APC offset amounts for evaluating the cost significance of implantable biological pass-through applications under review and for setting the APC offset amounts that would apply to pass-through payment for those implantable biologicals, effective for new pass-through status determinations beginning in CY 2010 (74 FR 60463).

For CY 2011, we continued our policy that the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly

approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only.

b. Proposed CY 2012 Policy

We are proposing to continue our policy, for CY 2012, 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 would 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 2012, 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 2012 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, as we first finalized and implemented for CY 2010.

In addition, we are proposing to update, on the CMS Web site at http://www.cms.gov/HospitalOutpatientPPS, the list of all procedural APCs with the final CY 2012 portions of the APC payment amounts that we determine are associated with the cost of devices so that this information is available for use by the public in developing potential CY 2012 device pass-through payment applications and by CMS in reviewing those applications.

In summary, for CY 2012, consistent with the policy established for CY 2010, we are proposing to continue the following policies related to pass-through payment for devices: (1) treating 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 on or after January 1, 2010, as devices for purposes of the OPPS pass-through evaluation process and payment methodology; (2) including implantable biologicals in calculating the device APC offset amounts; (3) using the device APC offset

amounts to evaluate whether the cost of a device (defined to include implantable biologicals) 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; and (4) reducing device pass-through payments based on device costs already included in the associated procedural APCs, when we determine that device costs associated with the new category are already packaged into the existing APC structure.

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

1. Background

In recent years, there have been several field actions on and recalls of medical devices as a result of implantable device failures. In many of these cases, the manufacturers have offered devices without cost to the hospital or with credit for the device being replaced if the patient required a more expensive device. In order to ensure that payment rates for procedures involving devices reflect only the full costs of those devices, our standard ratesetting methodology for device-dependent APCs uses only claims that contain the correct device code for the procedure, do not contain token charges, do not contain the "FB" modifier signifying that the device was furnished without cost or with a full credit, and do not contain the "FC" modifier signifying that the device was furnished with partial credit. As discussed in section II.A.2.d.(1) of this proposed rule, we are proposing to continue to use our standard ratesetting methodology for device-dependent APCs for CY 2012.

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 reduce the OPPS payment for the implantation procedure by 100 percent of the device offset for no cost/full credit cases when both a specified device code is present on the claim and the procedure code maps to a specified APC. Payment for the implantation procedure is reduced by 50 percent of the device offset for partial credit

cases when both a specified device code is present on the claim and the procedure code maps to a specified APC. Beneficiary copayment is based on the reduced payment amount when either the "FB" 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. 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 2012, 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. Because the APC payments for the related services are specifically constructed to ensure that the full cost of the device is included in the payment, we continue to believe it is appropriate to reduce the APC payment in cases in which the hospital receives a device without cost, with full credit, or with partial credit, in order to provide equitable payment in these cases. (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.) Moreover, the payment for these devices comprises a large part of the APC payment on which the beneficiary copayment is based, and we continue to believe it is equitable that the beneficiary cost sharing reflects the reduced costs in these cases.

For CY 2012, 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. As we stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71925), 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 2012 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 2011 continue to meet the criteria for CY 2012, and to determine whether other APCs to which the policy did not apply in CY 2011 would meet the criteria for CY 2012. Based on the CY 2010 claims data available for this proposed rule, we are not proposing any changes to the APCs and devices to which this policy applies. However, as discussed in section II.A.2.e.(6) of this proposed rule, we are proposing to delete APC 0418 (Insertion of Left Ventricular Pacing Electrode) for CY 2012 and, therefore, are proposing to remove this APC from the list of APCs to which the no cost/full credit and partial credit device adjustment policy would apply in CY 2012.

Table 24 below lists the proposed APCs to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2012 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 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 25 below lists the proposed devices to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2012. In the CY 2012 OPPS/ASC final rule with comment period, 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 2012, consistent with the three selection criteria discussed earlier in this section, based on the final CY 2010 claims data available for the final rule with comment period.

We are proposing, for CY 2012, that OPPS payments for implantation procedures to which the "FB" modifier is appended be reduced by 100 percent of the device offset for no cost/full credit cases when both a device code listed in Table 25 below, is present on the claim and the procedure code maps to an APC listed in Table 24 below. We are also 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 25 is present on the claim and the procedure code maps to an APC listed in Table 24. 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 24.—PROPOSED APCs TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY IN CY 2012

Proposed CY 2012 APC	Proposed CY 2012 APC Title	Proposed CY 2012 Device Offset Percentage for No Cost/ Full Credit Case	Proposed CY 2012 Device Offset Percentage for Partial Credit Case
0039	Level I Implantation of Neurostimulator Generator	85%	43%
0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	54%	27%

Proposed CY 2012 APC	Proposed CY 2012 APC Title	Proposed CY 2012 Device Offset Percentage for No Cost/ Full Credit Case	Proposed CY 2012 Device Offset Percentage for Partial Credit Case
0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes	64%	32%
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	71%	35%
0090	Insertion/Replacement of Pacemaker Pulse Generator	73%	37%
0106	Insertion/Replacement of Pacemaker Leads and/or Electrodes	43%	21%
0107	Insertion of Cardioverter-Defibrillator	88%	44%
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	87%	43%
0227	Implantation of Drug Infusion Device	81%	40%
0259	Level VII ENT Procedures	83%	41%
0315	Level II Implantation of Neurostimulator Generator	88%	44%
0318	Implantation of Cranial Neurostimulator Pulse Generator and Electrode	86%	43%
0385	Level I Prosthetic Urological Procedures	61%	30%
0386	Level II Prosthetic Urological Procedures	70%	35%
0425	Level II Arthroplasty or Implantation with Prosthesis	60%	30%
0648	Level IV Breast Surgery	44%	22%
0654	Insertion/Replacement of a permanent dual chamber pacemaker	74%	37%

Proposed CY 2012 APC	Proposed CY 2012 APC Title	Proposed CY 2012 Device Offset Percentage for No Cost/ Full Credit Case	Proposed CY 2012 Device Offset Percentage for Partial Credit Case
0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	73%	37%
0680	Insertion of Patient Activated Event Recorders	72%	36%

TABLE 25.—PROPOSED DEVICES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY IN CY 2012

CY 2012 Device HCPCS Code	CY 2012 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

CY 2012 Device HCPCS Code	CY 2012 Short Descriptor
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 2012 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 referenced in section XVII. of this proposed rule and available via the Internet.

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. As we noted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68633), the Part B drug CAP program was postponed beginning in CY 2009 (Medicare Learning Network (MLN) Matters Special Edition 0833, available via the Web site: http://www.cms.gov). As of publication of this proposed rule, the postponement of the Part B drug CAP program remains in effect, and there is no effective CAP program rate for pass-through drugs and biologicals as of January 1, 2009. Consistent with what we indicated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71928), if the program is reinstituted during CY 2012 and Part B drug CAP rates become available, we would again use the Part B drug CAP rate for pass-through drugs and biologicals if they are a part of the Part B drug CAP program. Otherwise, we would continue to use the rate that would be paid in the physician's office setting for all drugs and biologicals with pass-through status.

This methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64, which 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.hhs.gov/McrPartBDrugAvgSalesPrice.

For CYs 2005, 2006, and 2007, we estimated the OPPS pass-through payment amount for drugs and biologicals to be zero based on our interpretation that the "otherwise applicable Medicare OPD fee schedule" amount was equivalent to the amount to be paid for pass-through drugs and biologicals under section 1842(o) of the Act (or section 1847B of the Act, if the drug or biological is covered under a competitive acquisition contract). We concluded for those years that the resulting difference between these two rates would be zero. For CYs 2008 and 2009, we estimated the OPPS pass-through payment amount for drugs and biologicals to be $6.6 million and $23.3 million, respectively. For CY 2010, we estimated the OPPS pass-through payment estimate for drugs and biologicals to be $35.5 million. For CY 2011, we estimated the OPPS pass-through payment for drugs and biologicals to be $15.5 million. Our proposed OPPS pass-through payment estimate for drugs and biologicals in CY 2012 is $19 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.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp.

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

We are proposing that the pass-through status of 19 drugs and biologicals would expire on December 31, 2011, as listed in Table 26 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, 2011. These drugs and biologicals were approved for pass-through status on or before January 1, 2010. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through status, specifically diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals, 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 for CY 2012), 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+4 percent for CY 2012, as discussed further in section V.B.3. of this proposed rule). Section V.B.2.d. of this proposed rule discusses the packaging of all nonpass-through contrast agents, diagnostic radiopharmaceuticals, and implantable biologicals.

TABLE 26.—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS WILL EXPIRE DECEMBER 31, 2011

Proposed CY 2012 HCPCS Code	CY 2012 Long Descriptor	Proposed CY 2012 SI	Proposed CY 2012 APC
A9582	Iodine I-123 iobenguane, diagnostic, per study dose, up to 15 millicuries	N	N/A
A9583	Injection, gadofosveset trisodium, 1 ml	N	N/A
C9250	Human plasma fibrin sealant, vapor-heated, solvent-detergent (Artiss), 2ml	K	9250
C9360	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters	K	9360
C9361	Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 centimeter length	N	N/A
C9362	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc	N	N/A
C9363	Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter	K	9363
C9364	Porcine implant, Permacol, per square centimeter	N	N/A
J0598	Injection, C-1 esterase inhibitor (human), Cinryze, 10 units	K	9251
J0641	Injection, levoleucovorin calcium, 0.5 mg	K	1236
J0718	Injection, certolizumab pegol, 1 mg	K	9249
J1680	Injection, human fibrinogen concentrate, 100 mg	K	1290
J2426	Injection, paliperidone palmitate, 1 mg	K	9255
J2562	Injection, plerixafor, 1 mg	K	9252
J7312	Injection, dexamethasone intravitreal implant, 0.1 mg	K	9256
J8705	Topotecan, oral, 0.25 mg	K	1238
J9155	Injection, degarelix, 1 mg	K	1296
J9328	Injection, temozolomide, 1 mg	K	9253

Proposed CY 2012 HCPCS Code	CY 2012 Long Descriptor	Proposed CY 2012 SI	Proposed CY 2012 APC
Q0138	Injection, Ferumoxytol, for treatment of iron deficiency anemia, 1 mg	K	1297

3. Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2012

We are proposing to continue pass-through status in CY 2012 for 33 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, 2011. These drugs and biologicals, which were approved for pass-through status between April 1, 2010 and July 1, 2011, are listed in Table 27 below. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through April 1, 2011, are assigned status indicator "G" in Addenda A and B, which are referenced in section XVIII of this proposed rule and available via the Internet.

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 (or, if the drug or biological is covered under a CAP 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 the year established under such section as calculated and adjusted by the Secretary) 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 2012, the amount that drugs and biologicals receive under section 1842(o) of the Act. Thus, for CY 2012, 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 2012. Therefore, the difference between ASP+4 percent that we are proposing to pay for nonpass-through separately payable drugs under the CY 2012 OPPS and ASP+6 percent would be the CY 2012 pass-through payment amount for these drugs and biologicals. 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 procedures. We note that we are proposing to expire pass-through status for the remaining three implantable biologicals approved on or before January 1, 2010, under pass-through status as a drug or biological. Therefore, as described in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60476) and as proposed in this proposed rule, implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) would be evaluated under the device pass-through process and paid according to the device payment methodology. Payment for nonpass-through implantable biologicals would continue to be packaged into the payment for the associated procedure as described in section V.B.2.d. of this proposed rule.

In addition, we are proposing to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2012 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). If the Part B drug CAP is reinstated during CY 2012, and a drug or biological that has been granted pass-through status for CY 2012 becomes covered under the Part B drug CAP, we are proposing to provide pass-though payment at the Part B drug CAP rate and to make the adjustments to the payment rates for these drugs and biologicals on a quarterly basis, as appropriate. As is our standard methodology, we annually review new permanent HCPCS codes and delete temporary HCPCS C-codes if an alternate permanent HCPCS code is available for purposes of OPPS billing and payment.

In CY 2012, as is consistent with our CY 2011 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 2012, 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 V.B.2.d. of this proposed rule, over the last 4 years, we implemented a policy whereby payment for all nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals 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 2012. As stated earlier, pass-through payment is the difference between the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a CAP 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 the year established under such section as calculated and adjusted by the Secretary) 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 are 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 2011, 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 2012. The separate OPPS payment to a hospital for the pass-through diagnostic radiopharmaceutical or contrast agent, after taking into account any applicable payment offset for the item due to the device or "policy-packaged" APC offset policy, is the item's pass-through payment, which 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 the proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site).

The 33 drugs and biologicals that we are proposing to continue on pass-through status for CY 2012 or that have been granted pass-through status as of July 2011 are displayed in Table 27. We note that, for CY 2010 and the first two quarters of CY 2011, HCPCS code J1572 (Injection, immune globulin, (flebogamma/flebogamma dif),

intravenous, non-lyophilized (e.g. liquid), 500 mg) was assigned a status indicator of "K," meaning that this product was paid separately as a nonpass-through separate payable drug. Beginning on July 1, 2011, HCPCS code J1572 is assigned a status indicator of "G" and will be given pass-through status for at least 2, but not more than 3, years. The payment rate reflecting a pass-through payment amount of ASP+6 percent is not included in Addenda A and B of this proposed rule because these Addenda solely reflect codes and prices effective as of the second quarter of CY 2011, or April 2011.

TABLE 27.—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN CY 2012

Proposed CY 2012 HCPCS Code	CY 2012 Long Descriptor	Proposed CY 2012 SI	Proposed CY 2012 APC
C9270	Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg	G	9270
C9272	Injection, denosumab, 1 mg	G	9272
C9274	Crotalidae polyvalent immune fab (ovine), 1 vial	G	9274
C9275	Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose	G	9275
C9276	Injection, cabazitaxel, 1 mg	G	9276
C9277	Injection, alglucosidase alfa (Lumizyme), 1 mg	G	9277
C9279	Injection, ibuprofen, 100 mg	G	9279
C9280	Injection, eribulin mesylate, 1 mg	G	9280
C9281	Injection, pegloticase, 1 mg	G	9281
C9282	Injection, ceftaroline fosamil, 10 mg	G	9282
C9283**	Injection, acetaminophen, 10 mg	G	9283
C9284**	Injection, ipilimumab, 1 mg	G	9284
C9285**	Lidocaine 70 mg/tetracaine 70 mg, per patch	G	9285
C9365**	Oasis Ultra Tri-Layer Matrix, per square centimeter	G	9365

Proposed CY 2012 HCPCS Code	CY 2012 Long Descriptor	Proposed CY 2012 SI	Proposed CY 2012 APC
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	G	9367
C9406**	Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries	G	9406
J0597	Injection, C-1 Esterase inhibitor (human), Berinert, 10 units	G	9269
J0775	Injection, collagenase clostridium histolyticum, 0.01 mg	G	1340
J1290	Injection, ecallantide, 1 mg	G	9263
J1572***	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg	G	0947
J3095	Injection, telavancin, 10 mg	G	9258
J3262	Injection, tocilizumab, 1 mg	G	9624
J3357	Injection, ustekinumab, 1 mg	G	9261
J3385	Injection, velaglucerase alfa, 100 units	G	9271
J7335	Capsaicin 8% patch, per 10 square centimeters	G	9268
J8562	Fludarabine phosphate, oral, 10 mg	G	1339
J9302	Injection, ofatumumab, 10 mg	G	9260
J9307	Injection, pralatrexate, 1 mg	G	9259
J9315	Injection, romidepsin, 1 mg	G	9625
Q2040	Injection, incobotulinumtoxin A, 1 unit	G	9278
Q2041**	Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco	G	1352
Q2043*	Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion	G	9273
Q2044**	Injection, belimumab, 10 mg	G	1353

*HCPCS code C9273 was deleted June 30, 2011, and replaced with HCPCS code Q2043 effective July 1, 2011.

**These HCPCS codes are effective July 1, 2011, and are not included in the Addenda to this proposed rule.

***HCPCS code J1572 has a status indicator of "G," effective July 1, 2011.

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 2012, we are proposing to continue to package payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, as discussed in section V.B.2.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 (or the Part B drug CAP rate) and the otherwise applicable OPD fee schedule amount. There is currently one radiopharmaceutical with pass-through status under the OPPS,

HCPCS code C9406 (Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries). HCPCS code C9406 was granted pass-through status beginning July 1, 2011, and is proposed to continue receiving pass-through status in CY 2012. 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 utilize the "policy-packaged" drug offset fraction for APCs containing nuclear medicine procedures, 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 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/OutpatientCodeEdit/02_OCEQtrReleaseSpecs.asp#TopOfPage. For CY 2012 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 28 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 2011, we finalized a policy to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals, as described above. For CY 2012, we are proposing to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals. Table 28 displays the proposed APCs to which nuclear medicine procedures would be assigned in CY 2012 and for which we expect that an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

TABLE 28.—PROPOSED APCs TO WHICH NUCLEAR MEDICINE PROCEDURES WOULD BE ASSIGNED FOR CY 2012

Proposed CY 2012 APC	CY 2012 APC Title
0307	Myocardial Positron Emission Tomography (PET) imaging.
0308	Non-Myocardial 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.

Proposed CY 2012 APC	CY 2012 APC Title
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 II 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 (or the Part B drug CAP rate) and the otherwise applicable OPD fee schedule amount. There is currently one contrast agent with pass-through status under the OPPS: HCPCS code C9275 (Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose). HCPCS code C9275 was granted pass-through status beginning January 1, 2011, and is proposed to continue with pass-through status in CY 2012. As described earlier 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.

We believe that a payment offset is necessary in order to provide an appropriate transitional pass-through payment for contrast agents, because all of these items are packaged when they do not have pass-through status. In accordance with our standard offset methodology, we are proposing for CY 2012 to deduct from the payment for pass-through contrast agents 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 2012, as we did in CY 2011, 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 2012 to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 29, 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/HospitalOutpatientPPS 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, for every OPPS clinical APC, the amounts and percentages of APC payment associated with packaged implantable devices, "policy-packaged" drugs, and "threshold-packaged" drugs and biologicals.

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 28 above and these APCs are displayed in Table 29 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 2012, 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 29, 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 29.--PROPOSED APCs TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2012

Proposed CY 2012 APC	Proposed CY 2012 APC Title
0080	Diagnostic Cardiac Catheterization.
0082	Coronary or Non-Coronary Atherectomy.
0083	Coronary or Non-Coronary Angioplasty and Percutaneous Valvulopasty.
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	Transcathether Placement of Intravascular Shunts.
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.
0418	Insertion of Left Ventricular Pacing Elect.
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 2011 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.

Section 1833(t)(16)(B) of the Act set the threshold for establishing separate APCs for drugs and biologicals at $50 per administration for CYs 2005 and 2006. Therefore, for CYs 2005 and 2006, we paid separately for drugs, biologicals, and radiopharmaceuticals whose per day cost exceeded $50 and packaged the costs of drugs, biologicals, and radiopharmaceuticals whose per day cost was equal to or less than $50 into the procedures with which they were billed. For CY 2007, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that were not new and did not have pass-through status was established at $55. For CYs 2008 and 2009, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that were not new and did not have pass-through status was established at $60. For CY 2010, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that were not new and did not have pass-through status was established at $65. For CY 2011, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that were not new and did not have pass-through status was established at $70. The methodology used to establish the $55 threshold for CY 2007, the $60 threshold for CYs 2008 and 2009, the $65 threshold for CY 2010, the $70 threshold for CY 2011, and our proposed approach for CY 2012 are discussed in more detail in section V.B.2.b. of this proposed rule.

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; and for CY 2011, we set the packaging threshold at $70.

Following the CY 2007 methodology, for CY 2012, we used updated 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 2012 and again rounded the resulting dollar amount ($77.63) 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 2012; however, this change in terminology reflects a change to the BLS naming convention for this series. We refer to this series generally as the PPI for Prescription Drugs below. 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 2012 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 their proposed CY 2012 packaging status for this proposed rule, we calculated on a HCPCS code-specific basis (with the exception of those drugs and biologicals with multiple HCPCS codes that include different dosages as described in section V.B.2.c. of this proposed rule and excluding diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals that we are proposing to continue to package in CY 2012, as discussed in section V.B.2.d. of this proposed rule) the per day cost of all drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals (collectively called "threshold-packaged" drugs) that had a HCPCS code in CY 2010 and were paid

(via packaged or separate payment) under the OPPS, using CY 2010 claims data processed before January 1, 2011. In order to calculate the per day costs for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2012, 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).

To calculate the CY 2012 proposed rule per day costs, we used an estimated payment rate for each drug and nonimplantable biological HCPCS code of ASP+4 percent (which is the payment rate we are proposing for separately payable drugs and nonimplantable biologicals for CY 2012, as discussed in more detail in section V.B.3.b. of this proposed rule). We used the manufacturer submitted ASP data from the fourth quarter of CY 2010 (data that were used for payment purposes in the physician's office setting, effective April 1, 2011) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2012, we are proposing to use payment rates based on the ASP data from the fourth quarter of CY 2010 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet) because these are the most recent data available for use at the time of development of this proposed rule. These data were also the basis for drug payments in the physician's office setting, effective April 1, 2011. 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 2010 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 identified 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 2010 HCPCS codes that were reported to the CY 2011 HCPCS codes that we display in Addendum B of this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet) for payment in CY 2012.

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 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 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 2012 OPPS/ASC final rule with comment period, we are proposing to use ASP data from the first quarter of CY 2011, 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, 2011, along with updated hospital claims data from CY 2010. We note that we also are proposing to use these data for budget neutrality estimates and impact analyses for the CY 2012 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 2011, which 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, 2011. These rates would then be updated in the January 2012 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2012. 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 2010 claims data and updated cost report information available for the CY 2012 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 2012 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 median cost fluctuates relative to the proposed CY 2012 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2011. Specifically, for CY 2012, 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:

- HCPCS codes for drugs and nonimplantable biologicals that were paid separately in CY 2011 and that are proposed for separate payment in CY 2012, and that

then have per day costs equal to or less than $80, based on the ASPs and hospital claims data used for this CY 2012 proposed rule, would continue to receive separate payment in CY 2012.

- HCPCS codes for drugs and nonimplantable biologicals that were packaged in CY 2011 and that are proposed for separate payment in CY 2012, and that then have per day costs equal to or less than $80, based on the ASPs and hospital claims data used for this CY 2012 proposed rule, would remain packaged in CY 2012.

- HCPCS codes for drugs and nonimplantable biologicals for which we are proposing packaged payment in CY 2012 but then have per day costs greater than $80, based on the ASPs and hospital claims data used for this CY 2012 proposed rule, would receive separate payment in CY 2012.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60485 through 60489), we implemented a policy to treat oral and injectable forms of 5-HT3 antiemetics comparably to all other threshold packaged drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals under our standard packaging methodology of packaging drugs with a per day cost less than $65. We are proposing for CY 2012 to continue our policy of not exempting these 5-HT3 antiemetic products from our standard packaging methodology. For CY 2012, we are proposing to package payment for all of the 5-HT3 antiemetics except palonosetron hydrochloride, which for CY 2012 has a estimated per day cost, from the CY 2010 claims data, above the proposed CY 2012 drug packaging threshold. Our rationale for this policy is outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60487 through 60488).

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 would include 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 2012, 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 2012.

For CY 2012, 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 2010 claims data and our pricing information at ASP+4 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. All HCPCS codes listed in Table 30 below had ASP pricing information available for this CY 2012 OPPS/ASC proposed rule. Therefore, we multiplied the weighted average ASP+4 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 30 below.

TABLE 30.--PROPOSED HCPCS CODES TO WHICH THE CY 2012 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY

Proposed CY 2012 HCPCS Code	Proposed CY 2012 Long Descriptor	Proposed CY 2012 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1070	Injection, testosterone cypionate, up to 100 mg	N
J1080	Injection, testosterone cypionate, 1 cc, 200 mg	N
J1440	Injection, filgrastim (g-csf), 300 mcg	K
J1441	Injection, filgrastim (g-csf), 480 mcg	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J2270	Injection, morphine sulfate, up to 10 mg	N
J2271	Injection, morphine sulfate, 100mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	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

Proposed CY 2012 HCPCS Code	Proposed CY 2012 Long Descriptor	Proposed CY 2012 SI
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 doseage 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 doseage 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

Proposed CY 2012 HCPCS Code	Proposed CY 2012 Long Descriptor	Proposed CY 2012 SI
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 chemotheapy 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

d. 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 our 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 (73 FR 68633 through 68636). We refer to diagnostic radiopharmaceuticals and contrast agents collectively as "policy-packaged" drugs and implantable biologicals as devices because, in CY 2010, we began to treat implantable biologicals as devices for all OPPS payment purposes.

According to our regulations at §419.2(b), as a prospective payment system, the OPPS establishes a national payment rate 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 including, but 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 efficiencies 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 has expired; (2) we believe that diagnostic radiopharmaceuticals and contrast agents function effectively as supplies that enable the provision of an independent service; and (3) section 1833(t)(14)(A)(iii) of the Act requires that payment for specified covered outpatient drugs (SCODs) be set prospectively based on a measure of average hospital acquisition cost. For these reasons, we believe it is appropriate to continue to treat diagnostic radiopharmaceuticals and contrast agents differently from other SCODs for CY 2012. 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 2012. 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 of 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).

In CY 2009, we adopted a final policy to package payment for all nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) like our longstanding policy that packaged payment for all implantable nonbiological devices without pass-through status. We finalized a policy in CY 2010 to package payment for nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body, considering them to be devices. For CY 2012, we are proposing to continue to package payment for nonpass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body, considering them to be devices. Three of the products with expiring pass-through status for CY 2012 are biologicals that, according to their FDA-approved indications, are only surgically implanted. These products are described by HCPCS codes C9361 (Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 centimeter length), C9362 (Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc), and C9364 (Porcine implant, Permacol, per square centimeter). Like the two implantable biologicals with expiring pass-through status in CY 2011 that were discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71948 through 71950), we believe that the three biologicals specified above with expiring pass-through status for CY 2012 differ from other biologicals paid under the OPPS in that they specifically function as surgically implanted devices. As a result of our proposed packaged payment methodology for nonpass-through implantable biologicals, we are proposing to package payment for HCPCS codes C9361, C9362, and

C9364 and assign them status indicator "N" for CY 2012. In addition, any new biologicals without pass-through status that are surgically inserted or implanted (through a surgical incision or a natural orifice) would be packaged in CY 2012. Moreover, for nonpass-through biologicals that may sometimes be used as implantable devices, we continue to instruct hospitals to not bill separately for the HCPCS codes for the products when used as implantable devices. This reporting ensures that the costs of these products that may be, but are not always, used as implanted biologicals are appropriately packaged into payment for the associated implantation procedures.

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.

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:

- Handling costs for drugs, biologicals, and radiopharmaceuticals administered in the HOPD are not insignificant;
- Little information is available about the magnitude of pharmacy overhead costs;
- Hospitals set charges for drugs, biologicals, and radiopharmaceuticals at levels that reflect their respective handling costs; and
- Hospitals vary considerably in their likelihood of providing services that utilize drugs, biologicals, or radiopharmaceuticals with different handling costs.

As a result of these findings, MedPAC developed seven drug categories for pharmacy and nuclear medicine handling costs based on the estimated level of hospital resources used to prepare the products (70 FR 42729). Associated with these categories were two recommendations for accurate payment of pharmacy overhead under the OPPS.

1. CMS should establish separate, budget neutral payments to cover the costs hospitals incur for handling separately payable drugs, biologicals, and radiopharmaceuticals.

2. CMS should define a set of handling fee APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes of the products that affect handling costs; CMS should instruct hospitals to submit charges for these APCs and base payment rates for the handling fee APCs on submitted charges reduced to costs.

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.

Using our CY 2010 proposed rule data, and applying our longstanding methodology for calculating the total cost of separately payable drugs and biologicals in our claims compared to the ASP dollars for the same drugs and biologicals, without applying the proposed overhead cost redistribution, we determined that the estimated aggregate cost of separately payable drugs and biologicals (status indicators "K" and "G"), including acquisition and pharmacy overhead costs, was equivalent to ASP-2 percent. Therefore, under the standard methodology for establishing payment for separately payable drugs and biologicals, we would have paid for those drugs and biologicals at ASP-2 percent for CY 2010, their equivalent average ASP-based payment rate. We also determined that the estimated aggregate cost of coded packaged drugs and biologicals with an ASP (status indicator "N"), including acquisition and pharmacy overhead costs, was equivalent to ASP+247 percent.

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). In addition, we stated that we believed that the pharmacy stakeholders' recommendation to set packaged drug and biological dollars to ASP+6 percent was inappropriate, given our understanding that an equal allocation of indirect overhead costs among packaged and separately payable drugs and biologicals would lead to a higher

observed ASP+X percent than ASP+6 percent for packaged drugs and biologicals. Further, we indicated that indirect overhead costs that are common to all drugs and biologicals have no relationship to the cost of an individual drug or biological or to the complexity of the handling, preparation, or storage of that individual drug or biological. Therefore, we indicated that we believed that indirect overhead cost alone for an inexpensive drug or biological which would be packaged could be far in excess of the ASP for that inexpensive product. We also explained that layered on these indirect costs are direct costs of staff, supplies, and equipment that are directly attributable only to the storage, handling, preparation, and distribution of drugs and biologicals and which do vary, sometimes considerably, depending upon the drug being furnished.

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. 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 that 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 would more appropriately distribute pharmacy overhead cost among packaged and separately payable drugs and biologicals. Based on this redistribution, we

proposed a CY 2010 payment rate for separately payable drugs and biologicals of ASP+4 percent. Redistributing $150 million represented a reduction in cost of coded packaged drugs and biologicals with reported ASP data in the CY 2010 proposed rule claims data of 27 percent.

We also proposed that any redistribution of pharmacy overhead cost that may arise from 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 in our claims data (no redistribution of cost would occur from other services to drugs and biologicals or vice versa). We further proposed that the claims data for 340B hospitals be included in the calculation of payment for drugs and biologicals under the CY 2010 OPPS, and that hospitals that participate in the 340B program would be paid the same amounts for separately payable drugs and biologicals as hospitals that do not participate in the 340B program (74 FR 35332 through 35333). Finally, we proposed that, in accordance with our standard drug payment methodology, the estimated payments for separately payable drugs and biologicals would be taken into account in the calculation of the weight scaler that would apply to the relative weights for all procedural services (but would not apply to separately payable drugs and biologicals) paid under the OPPS, as required by section 1833(t)(14)(H) of the Act (74 FR 35333).

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. 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 believed that our proposal to reallocate $150 million of costs from coded packaged drugs and biologicals, or one-third of the pharmacy overhead costs of these products, based upon the claims data available for the CY 2010 final rule, to separately payable drugs and biologicals was appropriate (74 FR 60511). We also acknowledged that, to some unknown extent, there are pharmacy overhead costs being attributed to the items and services reported under the pharmacy revenue code without HCPCS codes that are likely pharmacy overhead for separately payable drugs. Therefore, we reallocated $50 million or 8 percent of the total cost of uncoded packaged drug and biological cost in order to represent the pharmacy overhead cost of uncoded packaged drugs and biologicals that should be appropriately associated with the cost of separately payable drugs and biologicals. 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 drug and biologicals captured by these uncoded packaged drug costs (74 FR 60511 through 60513).

We noted that our final CY 2010 payment policy for separately payable drugs and biologicals at ASP+4 percent fell within the range of ASP-3 percent (that would have resulted from no pharmacy overhead cost redistribution from packaged to separately payable drugs and biologicals), to ASP+7 percent (that would have resulted from redistribution of pharmacy overhead cost based on expansive assumptions about the nature of uncoded packaged drug and biological cost). We finalized a policy of redistributing pharmacy overhead cost from some drugs and biologicals to other drugs and biologicals, thereby maintaining the estimated total cost of drugs and biologicals in our claims data (no redistribution of cost would occur from other services to drugs and biologicals or vice versa). We also 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). We determined the total cost of separately payable drugs using CY 2009 claims data and compared these costs to the ASP dollars (April 2010 ASP quarterly payment rates multiplied by units for the separately payable drugs and biologicals in the claims data) for the same drugs and biologicals. We determined that the total estimated payment for separately payable drugs and biologicals (status indicators "K" and "G"), including acquisition and pharmacy overhead costs, was ASP-1 percent, which also would be the ASP-based payment rate under the standard methodology that we established in CY 2006 (75 FR 46275). Additionally, we determined that the total estimated aggregate cost for packaged drugs and biologicals with a HCPCS code for which manufacturers report ASP data (status indicator "N"),

including acquisition and pharmacy overhead costs, was equivalent to ASP+296 percent. Finally, we determined that the total estimated cost for both packaged drugs and biologicals with a HCPCS code and separately payable drugs and biologicals (status indicators "N," "K," and "G") for which we also have ASP data, including acquisition and pharmacy overhead costs, was ASP+13 percent. 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, and reiterated our commitment to continue to refine our drug pricing methodology.

b. Proposed Payment Policy

Section 1833(t)(14)(A)(iii) of the Act, as described above, continues to be applicable to determining payments for SCODs for CY 2012. This provision requires

that payment for SCODs 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 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, section 1833(t)(14)(A)(iii)(II) of the Act requires that payment be equal to payment rates established under the methodology described in section 1842(o) of the Act, section 1847A of the Act (ASP+6 percent as paid for physician Part B drugs), or section 1847B of the Act (CAP), as the case may be, as calculated and adjusted by the Secretary as necessary. In accordance with sections 1842(o) and 1847A of the Act, payments for most Medicare non-OPPS Part B drugs furnished on or after January 1, 2005, are paid based on the ASP methodology. Medicare Part B drugs generally fall into three categories: physician-administered drugs (drugs furnished incident to a physician's service), drugs delivered through DME (drugs furnished under the durable medical equipment benefit), and drugs specifically covered by a statutory provision (certain oral anti-cancer and immunosuppressive drugs). Section 1833(t)(14)(E)(ii) of the Act authorizes, but does not require, the Secretary to adjust APC weights to take into account the 2005 MedPAC report relating to overhead and related expenses, such as pharmacy services and handling costs. As discussed in V.B.3.a. of this proposed rule, since CY 2006, we have used ASP data and costs estimated from charges on hospital claims data as a proxy for the sum of the average hospital acquisition cost that the statute requires for payment of SCODs and the associated pharmacy overhead cost in order to establish a combined payment rate for acquisition cost and pharmacy overhead.

Prior to CY 2010, we applied this methodology to payment for all separately payable drugs and biologicals without pass-through status, including both SCODs and other drugs and biologicals that do not meet the statutory definition of SCODs.

For the CY 2010 OPPS, as part of our ongoing efforts to improve the validity of our payments, we revised the standard methodology to include an adjustment for pharmacy overhead. As explained previously, we have acknowledged, and continue to believe, that the established method of converting billed charges to costs had the potential to "compress" the calculated costs to some degree. 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. To some unknown extent, we believe that some pharmacy overhead costs attributed to packaged drugs and biologicals may include pharmacy overhead costs for separately payable drugs.

For this CY 2012 OPPS/ASC proposed rule, we are proposing to continue to use our standard methodology for determining the total cost of separately payable drugs and biologicals in our CY 2010 claims data and comparing these costs to the ASP dollars (April 2011 ASP quarterly payment rates multiplied by units for the separately payable drugs and biologicals in the claims data) for the same drugs and biologicals. We determined that the total estimated payment for separately payable drugs and biologicals (status indicators "K" and "G"), including acquisition and pharmacy overhead costs, is ASP-2 percent, which also would be the ASP-based payment rate under the standard

methodology that we established in CY 2006 (75 FR 46275). Additionally, we determined that the total estimated aggregate cost for packaged drugs and biologicals with a HCPCS code for which manufacturers report ASP data (status indicator "N"), including acquisition and pharmacy overhead costs, is equivalent to ASP+188 percent. Finally, we determined that the total estimated cost for both packaged drugs and biologicals with a HCPCS code and separately payable drugs and biologicals (status indicators "N," "K," and "G") for which we also have ASP data, including acquisition and pharmacy overhead costs, is ASP+11 percent. Table 31 below displays our findings with regard to the percentage of ASP in comparison to the cost for packaged coded drugs and biologicals and for separately payable coded drugs and biologicals before application of the proposed overhead adjustment methodology.

TABLE 31.—CY 2012 PROPOSED RULE DATA: ASP+X CALCULATION UNDER STANDARD METHODOLOGY

	Total ASP Dollars for Drugs and Biologicals in Claims Data (in millions)*	**Total Cost of Drugs and Biologicals in Claims Data (in millions)****	**Ratio of Cost to ASP (column 3/column 2)**	**ASP+X Percent**
Uncoded Packaged Pharmaceutical Revenue Code Costs	Unknown	$502***	Unknown	Unknown
Coded Packaged Drugs and Biologicals with a reported ASP	$244	$705	2.88	ASP+188

Separately Payable Drugs and Biologicals with a reported ASP	$3,536	$3,476	0.98	ASP-2
All Coded Drugs and Biologicals with a reported ASP	$3,780	$4,181	1.11	ASP+11

*Total April 2011 ASP dollars (ASP multiplied by drug or biologicals units in CY 2010 claims) for drugs and biologicals with a HCPCS code and ASP information.
**Total cost in the CY 2010 claims data for drugs and biologicals
***Pharmacy revenue code costs without HCPCS codes.

We acknowledge 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. Specifically, we recognize that payment at ASP-2 percent for such costs may not be sufficient. We also acknowledge that ASP +188 percent may overstate the combined acquisition and pharmacy overhead cost of packaged drugs and biologicals. Therefore, given this issue, for CY 2012, we are proposing to continue the CY 2010 and CY 2011 overhead adjustment methodology, which redistributes $200 million in cost from packaged drugs with an ASP and uncoded packaged drugs, as first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60501 through 60517).

For CY 2012, because we are proposing to continue to make an overhead adjustment for another year, we believe it is appropriate to account for inflation that has occurred since the overhead redistribution amount of $200 million was applied in CY 2011. Therefore, we are proposing to apply an inflation allowance to account for inflation and changes in the prices of pharmaceuticals in the overall economy. We are

proposing to adjust the overhead redistribution amount of $200 million using the PPI for Pharmaceuticals for Human Use. The PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics (BLS) series code WPUSI07003), provided through CMS' Office of the Actuary (OACT) is a price series that reflects price changes associated with the average mix of all pharmaceuticals in the overall economy. We refer to this series generally as the PPI for Prescription Drugs. We believe that this price series is appropriate to use to update the overhead redistribution amount because the PPI for Prescription Drugs is publicly available and regularly published and because we have successfully utilized the PPI for Prescription Drugs for the past 5 years to update the drug packaging threshold as described in section V.B.2.a. of this proposed rule.

In order to apply the inflation allowance to the overhead redistribution amount for CY 2012, we used the most recent forecast of yearly index levels provided in the PPI for Prescription Drugs to calculate an updated overhead redistribution amount. After adjusting the $200 million overhead redistribution amount for inflation using the PPI for Prescription Drugs, we determined that $161 million would need to be redistributed from coded packaged drugs and biologicals with reported ASP data and $54 million would need to be redistributed from the cost of uncoded packaged drugs and biologicals without an ASP to separately payable drugs and biologicals. The proposed redistribution amount of $161 million in overhead cost from coded packaged drugs and biologicals is within the redistribution parameters established in the CY 2010 OPPS/ASC final rule with comment period of roughly one-third to one-half of overhead cost in coded packaged drugs and biologicals. The total proposed redistribution amount from both coded and uncoded

packaged drugs and biologicals to separately paid drugs and biologicals would therefore be $215 million. Having determined to redistribute overhead, we also continue to believe that the methodology to redistribute a portion of drug overhead cost from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals while keeping the total cost of drugs and biologicals in the claims data constant continues to be appropriate for the reasons set forth in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60501 through 60517). Therefore, for CY 2012, we are proposing to redistribute a total overhead redistribution amount, adjusted for inflation, of $215 million from coded and uncoded packaged drugs and biologicals to separately payable drugs and biologicals.

In the CY 2010 OPPS/ASC final rule with comment period, we reallocated $150 million in overhead cost from coded packaged drugs and biologicals with an ASP to separately payable drugs and biologicals with an ASP, or one-third of the pharmacy overhead cost of these products based upon the claims data available for the CY 2010 final rule. In addition, we noted that some of the cost associated with uncoded packaged drugs and biologicals was appropriate to redistribute to separately payable drugs and biologicals. Therefore, we made a conservative estimate, as compared with the case of coded packaged drugs and biologicals with an ASP for which we had a specific pharmacy overhead cost estimate in relationship to their known ASPs, and reallocated $50 million, or 8 percent of the total cost of uncoded packaged drugs and biologicals with no ASP. We made the assumption that whatever pharmacy overhead cost inappropriately

associated with uncoded packaged drugs and biologicals would not be less than 8 percent of total uncoded drugs and biologicals cost.

For this CY 2012 OPPS/ASC proposed rule, we note that continuing to redistribute $200 million (or $215 million with the adjustment for inflation) falls within the parameters originally established in the CY 2010 OPPS/ASC final rule with comment period. A redistribution amount of $161 million in overhead cost from coded packaged drugs and biologicals with an ASP or approximately 35 percent falls within one-third to one-half of the estimated pharmacy overhead cost. In addition, we note that a redistribution amount of $54 million in overhead cost from uncoded packaged drugs and biologicals, or approximately 11 percent, is not less than 8 percent of the total cost of uncoded packaged drugs and biologicals. Therefore, our proposal to redistribute $215 million is consistent with the overhead adjustment methodology first implemented in CY 2010. We continue to believe that a middle ground of approximately one-third to one-half of the total pharmacy overhead cost currently associated with coded packaged drugs and biologicals in the CY 2010 claims data represents the most accurate redistribution of pharmacy overhead cost.

We estimate the overhead cost for coded packaged drugs to be $544 million ($705 million in total cost for coded packaged drugs and biologicals with a reported ASP, less $161 million in total ASP dollars for coded packaged drugs and biologicals with a reported ASP). As we did in CY 2010 and CY 2011, we are proposing for CY 2012 that any redistribution of pharmacy overhead cost would occur only among drugs and biologicals in our claims data, that no redistribution of cost would occur from other

services to drugs and biologicals or vice versa. We believe that redistributing $215 million from packaged to separately payable drugs and biologicals, which includes an adjustment for inflation, is an appropriate redistribution of pharmacy overhead costs to address any charge compression in the standard methodology. This would result in a proposed CY 2012 payment rate for separately payable drugs and biologicals of ASP+4 percent. We note that, in past years, the proposed ASP+X amount decreased by at least 1 percentage point when we updated the ASP data, claims data, and cost report data between the proposed rule and the final rule with comment period. Therefore, it is possible that the proposed methodology would result in an ASP+X amount that is different from ASP+4.

As indicated in Table 31 above, if we were to propose to establish payment for separately payable drugs and biologicals under the standard methodology established in CY 2006 without applying a pharmacy overhead adjustment, we would have to propose to pay for separately payable drugs and biologicals at ASP-2 percent. However, because we are concerned about the possibility of underpaying for separately payable drugs and biologicals, we believe that a pharmacy overhead adjustment using a redistribution methodology for determining the amount of payment for drugs and biologicals, as we did for CY 2011, is appropriate for CY 2012. We acknowledge that the observed ASP-2 percent may reflect some amount of charge compression and variability attributable to the choice of a packaging threshold.

TABLE 32.—CY 2012 PROPOSED PHARMACY OVERHEAD ADJUSTMENT PAYMENT METHODOLOGY: ASP+X CALCULATION

	Total ASP Dollars for Drugs and Biologicals in Claims Data (in millions)*	Total Cost of Drugs and Biologicals in Claims Data *after adjustment* (in millions)**	Ratio of Cost to ASP (column 3/column 2)	ASP+X Percent
Uncoded Packaged Pharmaceutical Revenue Code Costs	Unknown	$448***	Unknown	Unknown
Coded Packaged Drugs and Biologicals with a reported ASP	$244	$544	2.23	ASP+123
Separately Payable Drugs and Biologicals with a reported ASP	$3,536	$3,691	1.04	ASP+4
All Coded Drugs and Biologicals with a reported ASP	$3,780	$4,181	1.11	ASP+11

*Total April 2011 ASP dollars (ASP multiplied by drug or biological units in CY 2010 claims) for drugs and biologicals with a HCPCS code and ASP information.
**Total cost in the CY 2010 claims data for drugs and biologicals
***Pharmacy revenue code costs without HCPCS codes.

We note that although it is CMS' longstanding policy under the OPPS to refrain from instructing hospitals on the appropriate revenue code to use to charge for specific services, we continue to encourage hospitals to bill all drugs and biologicals with HCPCS codes, regardless of whether they are separately payable or packaged, and to ensure that drug costs are completely reported, using appropriate revenue codes. We note that we make packaging determinations for drugs and biologicals annually based on cost information reported under HCPCS codes, and the OPPS ratesetting is best served when hospitals report charges for all items and services with HCPCS codes when they are available, whether or not Medicare makes separate payment for the items and services.

In summary, for the reasons set forth above and considering the data limitations we have previously discussed, we are proposing to continue our prior CY 2010 and CY 2011 acquisition cost proxy methodology and pharmacy overhead redistribution methodology. In addition, we are proposing to adjust the $200 million redistribution amount finalized in CY 2011 for inflation. Therefore, we are proposing to redistribute $161 million in overhead costs from coded packaged drugs and biologicals and $54 million in overhead costs from uncoded packaged drugs and biologicals to result in $215 million in costs redistributed from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals for CY 2012. The proposed redistribution amount of $161 million in overhead cost from coded packaged drugs and biologicals is within the redistribution parameters established in the CY 2010 OPPS/ASC final rule with comment period of roughly one-third to one-half of overhead cost in coded packaged drugs and biologicals. Approximately 11 percent of drug cost in uncoded packaged drugs and biologicals would be redistributed to separately payable drugs for CY 2012, and therefore, this amount continues to be no less than 8 percent of the total uncoded drug and biological cost. The result of this proposed methodology when applied using April 2011 ASPs, data for claims for services furnished during CY 2010 and processed through the Common Working File before January 1, 2010, and the most current submitted cost reports as of January 1, 2011, is a proposed ASP+4 percent amount for CY 2012.

Further, we are proposing to continue to include the claims data for 340B hospitals in the calculation of payment for drugs and biologicals under the CY 2012

OPPS because we believe excluding data from hospitals that participate in the 340B program from our ASP+X calculation, but paying those hospitals at that derived payment amount, would effectively redistribute payment to drugs or biologicals from payment for other services under the OPPS. Furthermore, we do not believe it would be appropriate to exclude claims from this subset of hospitals in the context of a proposed CY 2012 drug and biological payment policy that pays all hospitals the same rate for separately payable drugs and biologicals (74 FR 60517). In addition, we are proposing that 340B hospitals continue to be paid the same amounts for separately payable drugs and biologicals as hospitals that do not participate in the 340B program for CY 2012 because commenters have generally opposed differential payment for hospitals based on their 340B participation status. In addition, we are proposing to include claims from 340B hospitals in our assessment of average acquisition cost under section 1833(t)(14)(A)(iii) of the Act. We are proposing that the estimated payments for separately payable drugs and biologicals be taken into account in the calculation of the weight scaler that would apply to the relative weights for all procedural services (but would not apply to separately payable drugs and biologicals) paid under the OPPS, as required by section 1833(t)(14)(H) of the Act.

We note that we continue to pursue the most appropriate methodology for establishing payment for drugs and biologicals under the OPPS. Because we are always trying to improve the integrity of our data, we have previously proposed multiple mechanisms to improve the cost data available to us, but have not implemented those proposals due to hospital concerns about the administrative burden. We continue to be

interested in developing mechanisms that improve the cost data available to us while minimizing to the extent possible the administrative burden on hospitals. For the past 3 years, we have proposed an internal adjustment to redistribute an amount from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals, because the results of our standard drug payment methodology are unlikely to accurately reflect the full cost of acquisition and pharmacy overhead for separately payable and packaged drugs and biologicals due to hospital charging practices and our use of an annual drug packaging threshold. As we continue to work to refine our payment systems, a goal to which we have been consistently committed over the past several years, we encourage public input on determining alternative cost-based methodologies to aid in our ongoing evaluation of alternative cost-based methodologies that could improve upon the current methodology.

c. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

Beginning in the CY 2005 OPPS final rule with comment period, we exempted radiopharmaceutical manufacturers from reporting ASP data for all radiopharmaceuticals for payment purposes under the OPPS. (For more information, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811) and the CY 2006 OPPS final rule with comment period (70 FR 68655).) Consequently, we did not have ASP data for radiopharmaceuticals for consideration for OPPS ratesetting until we began collecting ASP for nonpass-through separately paid therapeutic radiopharmaceuticals for CY 2010. In accordance with section 1833(t)(14)(B)(i)(I) of the Act, we have classified radiopharmaceuticals under the OPPS as SCODs. As such, we have paid for

radiopharmaceuticals at average acquisition cost as determined by the Secretary and subject to any adjustment for overhead costs. For CYs 2006 and 2007, we used mean unit cost data from hospital claims to determine each radiopharmaceutical's packaging status and implemented a temporary policy to pay for separately payable radiopharmaceuticals based on the hospital's charge for each radiopharmaceutical adjusted to cost using the hospital's overall CCR. The methodology of providing separate radiopharmaceutical payment based on charges adjusted to cost through application of an individual hospital's overall CCR for CYs 2006 and 2007 was finalized as an interim proxy for average acquisition cost.

In CY 2008, we packaged payment for all diagnostic radiopharmaceuticals and we proposed and finalized a methodology to provide prospective payment for therapeutic radiopharmaceuticals (defined as those Level II HCPCS codes that include the term "therapeutic" along with a radiopharmaceutical in their long code descriptors) using mean costs derived from the CY 2006 claims data, where the costs were determined using our standard methodology of applying hospital-specific departmental CCRs to radiopharmaceutical charges, defaulting to hospital-specific overall CCRs only if appropriate departmental CCRs were unavailable (72 FR 66772). Following issuance of the CY 2009 OPPS/ASC proposed rule, section 142 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) amended section 1833(t)(16)(C) of the Act, as amended by section 106(a) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173), to further extend the payment period for therapeutic radiopharmaceuticals based on hospitals' charges adjusted to cost through

December 31, 2009. Therefore, for CY 2009, we finalized a policy to continue to pay hospitals for therapeutic radiopharmaceuticals at charges adjusted to cost through the end of CY 2009.

For CY 2010, we proposed and finalized a policy to pay for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. We allowed 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. This resulted in payment for nonpass-through separately paid therapeutic radiopharmaceuticals at ASP+4 percent for CY 2010 for products for which the manufacturer submitted ASP. We also finalized a policy to base therapeutic radiopharmaceutical payment on CY 2008 mean unit cost data derived from hospital claims if ASP information was unavailable. For CY 2011, we continued to pay for nonpass-through separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals, resulting in a payment rate for nonpass-through separately paid therapeutic radiopharmaceuticals of ASP+5 percent. We also continued to base therapeutic radiopharmaceutical payment on CY 2009 mean unit cost data derived from hospital claims if ASP information was unavailable.

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 2012.

Therefore, we are proposing to continue to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals under the ASP+X payment level established using the proposed pharmacy overhead adjustment based on a redistribution methodology to set payment for separately payable drugs and biologicals (proposed at ASP+4 percent, as discussed in section V.B.3.b. of this proposed rule) 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 2010 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.

The proposed CY 2012 payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet).

4. Proposed Payment for Blood Clotting Factors

For CY 2011, 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 2011, we provided payment for blood clotting factors under the OPPS at ASP+5 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 2011 updated furnishing fee is $0.176 per unit.

For CY 2012, we are proposing to pay for blood clotting factors at ASP+4 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 rationale for this proposed policy was first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and then 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 would 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.hhs.gov/McrPartBDrugAvgSalesPrice/.

5. 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) does 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.

For CY 2012, we are proposing to continue our payment policies for new drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals that have HCPCS codes that do not crosswalk to CY 2011 HCPCS codes, do not have pass-through status, and are without

OPPS hospital claims data. We are proposing to provide payment for new CY 2012 drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals, at ASP+4 percent, consistent with the proposed CY 2012 payment methodology for other separately payable nonpass-through drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals. 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, unless they are granted pass-through status. Only if they are pass-through drugs, nonimplantable biologicals, or therapeutic radiopharmaceuticals would they receive a different payment for CY 2012, generally equivalent to the payment these drugs and biologicals would receive in the physician's office setting, consistent with the requirements of the statute.

We also are proposing to continue our CY 2011 policy of packaging payment for all new nonpass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals with HCPCS codes but without claims data (those new CY 2012 diagnostic radiopharmaceuticals, contrast agents, and implantable biological HCPCS codes that do not crosswalk to predecessor HCPCS codes), consistent with the proposed packaging of all existing nonpass-through diagnostic radiopharmaceuticals, contrast agents and implantable biologicals, as discussed in more detail in section V.B.2.d. and IV.A.2. of this proposed rule.

In accordance with the OPPS ASP methodology, in the absence of ASP data, for CY 2012, 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. However, we note that if the WAC is also unavailable, we would make payment at 95 percent of the product's most recent AWP. We also are proposing to assign status indicator "K" (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 2012 at ASP+4 percent) for items that have not been granted pass-through status. This proposed policy, which is consistent with prior years' policies for these items, 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. Only if they are pass-through drugs, nonimplantable biologicals, or therapeutic radiopharmaceuticals would they receive a different payment for CY 2012, generally equivalent to the payment these drugs and

biologicals would receive in the physician's office setting, consistent with the requirements of the statute.

Similarly, we are proposing to continue our CY 2011 policy 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 radiopharmaceutical 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 2012 we are proposing to announce any changes to the payment amounts for new drugs and biologicals in the CY 2012 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2012 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 2012 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 2012 OPPS/ASC final rule with comment

period where they will be assigned comment indicator "NI" (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) to reflect that their interim final OPPS treatment is open to public comment on the CY 2012 OPPS/ASC final rule with comment period.

There are several nonpass-through drugs and biologicals that were payable in CY 2010 and/or CY 2011 for which we do not have CY 2010 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 2012, 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+4 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 2012. We are proposing to pay separately for items with an estimated per day cost greater than $80 (with the exception of diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals, which we are proposing to continue to package regardless of

cost as discussed in more detail in section V.B.2.d. of this proposed rule) in CY 2012. We are proposing that the CY 2012 payment for separately payable items without CY 2010 claims data would be ASP+4 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 33 below.

TABLE 33.—DRUGS AND BIOLOGICALS WITHOUT CY 2010 CLAIMS DATA

CY 2012 HCPCS Code	CY 2012 Long Descriptor	Estimated Average Number of Units Per Day	Proposed CY 2012 SI	Proposed CY 2012 APC
J0205	Injection, alglucerase, per 10 units	420	K	0900
J0364	Injection, apomorphine hydrochloride, 1 mg	12	N	N/A
J0630	Injection, calcitonin salmon, up to 400 units	1.5	N	N/A
J1680	Injection, human fibrinogen concentrate, 100 mg	49	K	1290
J2513	Injection, pentastarch, 10% solution, 100 ml	4	K	1222
J2724	Injection, protein c concentrate, intravenous, human, 10 iu	1540	K	1139
J3355	Injection, urofollitropin, 75 IU	2	K	1741
J9216	Injection, interferon, gamma 1-b, 3 million units	1	K	0838
Q0515	Injection, sermorelin acetate, 1 microgram	70	K	3050

Finally, there were five drugs and biologicals, shown in Tab le 34 below, that were payable in CY 2010, but for which we lacked CY 2010 claims data and any other

pricing information for the ASP methodology for the CY 2012 OPPS/ASC proposed rule. In CY 2009, for similar items without CY 2007 claims data and without pricing information for the ASP methodology, we previously 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 becomes 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. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71973), for CY 2011, we continued our CY 2010 policy to assign status indicator "E" to drugs and biologicals that lacked CY 2009 claims data and pricing information for the ASP methodology. We also continued our policy to change the status indicator for these products to "K" if pricing information became available and pay for them separately for the remainder of CY 2011.

For CY 2012, we are proposing to continue our CY 2011 policy to assign status indicator "E" to drugs and biologicals that lack CY 2010 claims data and pricing information for the ASP methodology. All drugs and biologicals without CY 2010

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 2012 are displayed in Table 34 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 2012.

TABLE 34.—DRUGS AND BIOLOGICALS WITHOUT CY 2010 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

CY 2012 HCPCS Code	CY 2012 Long Descriptor	Proposed CY 2012 SI
J2940	Injection, somatrem, 1 mg	E
J3305	Injection, trimetrexate glucuronate, per 25 mg	E
J8650	Nabilone, oral, 1 mg	E
J9165	Injection, diethylstilbestrol diphosphate, 250 mg	E
J9213	Injection, interferon, alfa-2a, recombinant, 3 million units	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 2.0 percent, as stated below) of total program payments estimated to be made for all covered services under the hospital OPPS furnished for that year. For a year (or portion of a year) before CY 2004, the applicable percentage was 2.5 percent; for CY 2004 and subsequent years, the applicable percentage is a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

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 1883(t)(6)(E) of the Act.

For devices, developing an estimate of pass-through spending in CY 2012 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 2012. 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 2011 or beginning in CY 2012. 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; also referred to herein as "implantable biologicals") is the device pass-through process and payment methodology only (74 FR 60476). For CY 2012, we are proposing that the estimate of pass-through spending for implantable biologicals newly eligible for pass-through payment beginning in CY 2012 be included in the pass-through spending estimate for this second group of device categories. The sum of the CY 2012 pass-through estimates for these two groups of device categories would equal the total CY 2012 pass-through spending estimate for device categories with pass-through status.

For devices eligible for pass-through payment, section 1833(t)(6)(D)(ii) of the Act establishes the pass-through payment amount as the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable OPPS fee schedule payment that the Secretary determines is associated with the device. As discussed in section IV.A.2. of this proposed rule, we deduct from the pass-through payment for an identified device category eligible for pass-through payment 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, when we believe that the predecessor device costs for the device category newly approved for pass-through payment are already packaged into the existing APC structure. For each device category that becomes newly eligible for device pass-through payment, including implantable biologicals from CY 2010 forward, we estimate pass-through spending to be the difference between payment for the device category and the device APC offset amount, if applicable, for the procedures that would use the device. If we determine that the

predecessor device costs for the new device category are not already included in the existing APC structure, the pass-through spending estimate for the device category is the full payment at charges adjusted to cost.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Because we are proposing to pay for most nonpass-through separately payable drugs and nonimplantable biologicals under the CY 2012 OPPS at ASP+4 percent, which represents the otherwise applicable fee schedule amount associated with most pass-through drugs and biologicals, and because we are proposing to pay for CY 2012 pass-through drugs and nonimplantable biologicals at ASP+6 percent or the Part B drug CAP rate, if applicable, our estimate of drug and nonimplantable biological pass-through payment for CY 2012 would not be zero, as discussed below. Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals 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 2012 would be paid at ASP+6 percent or the Part B drug CAP rate, if applicable, like other pass-through drugs and biologicals. Therefore, our estimate of pass-through payment for all diagnostic radiopharmaceuticals and contrast agents with pass-through status approved prior to CY 2012 is also not zero. We note that there are no implantable biologicals proposed to continue on pass-through status for CY 2012 and, therefore, we are not proposing to include implantable biologicals in our estimate of pass-through payment. Payment for nonpass-through implantable biologicals will continue to be packaged into the payment for the associated procedure as described in section V.B.2.d of this proposed rule.

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 and 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 diagnostic radiopharmaceutical or contrast agent that is attributable to diagnostic 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 would reduce our estimate of pass-through payment for these drugs by this amount.

We note that the Part B drug CAP program has been postponed beginning January 1, 2009. We refer readers to the Medicare Learning Network (MLN) Matters Special Edition article SE0833 for more information, available via the CMS Web site at: http://www.cms.gov/MLNMattersArticles/downloads/SE0833.pdf. As of the publication of this proposed rule, the postponement of the Part B drug CAP program is still in effect. As in past years, for this proposed rule, we do not have an effective Part B drug CAP rate for pass-through drugs and biologicals.

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 and that will continue to be eligible for pass-through payment in CY 2012. 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 2011 or beginning in CY 2012. The sum of the CY 2012 pass-through estimates for these two groups of drugs and biologicals would equal the total CY 2012 pass-through spending estimate for drugs and biologicals with pass-through status.

B. Proposed Estimate of Pass-Through Spending

We are proposing to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2012, consistent with our OPPS policy from CY 2004 through CY 2011 (75 FR 71975).

For the first group of devices for pass-through payment estimate purposes, there currently is one device category, C1749 (Endoscope, retrograde imaging/illumination colonoscope device (implantable)) that became effective October 1, 2010, has been paid as a pass-through device for CY 2011, and will continue to be eligible for CY 2012. We estimate that CY 2012 pass-through expenditures related to C1749 will be approximately $35 million.

In estimating our proposed CY 2012 pass-through spending for device categories in the second group, which also includes any estimate for implantable biologicals that are eligible for pass-through payment, 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 2012 (of which there are none); additional device categories (including categories that describe implantable biologicals) that we estimate could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2012; and contingent projections for new device categories (including categories that describe implantable biologicals) established in the second through fourth quarters of CY 2012. 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 2012 pass-through spending for this second group of device categories is $10 million. Using our established methodology, the total estimated pass-through spending for device categories for CY 2012 (spending for the first

group of device categories ($35 million) plus spending for the second group of device categories ($10 million)) equals $45 million.

To estimate CY 2012 proposed 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 2012, 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 2012 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 2012, we estimate the proposed pass-through payment amount as the difference between ASP+6 percent or the Part B drug CAP rate, as applicable, and the proposed payment rate for nonpass-through drugs and nonimplantable biologicals that would be separately paid at ASP+4 percent, aggregated across the projected CY 2012 OPPS utilization of these products. 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 2012 pass-through estimate the difference between payment for the drug or nonimplantable 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 proposed rule, we are proposing to continue to use the methodology used in CY 2011 to calculate a proposed spending estimate for this first group of drugs and biologicals to be approximately $5.7 million.

To estimate CY 2012 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 2012, 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, 2012, 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 2012), we are proposing to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2012 proposed pass-through payment estimate. We are also considering the most recent OPPS experience in approving new pass-through drugs and nonimplantable biologicals. Using our proposed methodology for estimating CY 2012 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 $13.8 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 2012 pass-through spending estimate for drugs and biologicals. Our proposed CY 2012 estimate for total pass-through spending for drugs and biologicals (spending for the first group of drugs and nonimplantable biologicals ($5.7 million) plus spending for the second group of drugs and nonimplantable biologicals ($13.8 million)) equals $19.5 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 2012 and those device categories, drugs, and nonimplantable biologicals that first become eligible for pass-through payment during CY 2012 would be approximately $64.5 million (approximately $45 million for device categories and approximately $19.5 million for drugs and non-implantable biologicals), which represents 0.15 percent of total OPPS projected total payments for CY 2012. We estimate that pass-through spending in CY 2012 would not amount to 2.0 percent of total projected OPPS CY 2012 program spending.

VII. Proposed OPPS Payment for Hospital Outpatient Visits

A. Background

Currently, hospitals report visit HCPCS codes to describe three types of OPPS services: clinic visits; emergency department visits; and critical care services. For OPPS purposes, we recognize clinic visit codes as those codes defined in the CPT code book to report evaluation and management (E/M) services provided in the physician's office or in an outpatient or other ambulatory facility. We recognize emergency department visit codes as those codes used to report E/M services provided in the emergency department. Emergency department visit codes consist of five CPT codes that apply to Type A emergency departments and five Level II HCPCS codes that apply to Type B emergency departments. For OPPS purposes, we recognize critical care codes as those CPT codes used by hospitals to report critical care services that involve the "direct delivery by a physician(s) of medical care for a critically ill or critically injured patient," as defined by the CPT code book. In Transmittal 1139, Change Request 5438, dated December 22, 2006, we stated that, under the OPPS, the time that can be reported as critical care is the time spent by a physician and/or hospital staff engaged in active face-to-face critical care of a critically ill or critically injured patient. Under the OPPS, we also recognize HCPCS code G0390 (Trauma response team associated with hospital critical care service) for the reporting of a trauma response in association with critical care services.

We are proposing to continue to recognize these CPT and HCPCS codes describing clinic visits, Type A and Type B emergency department visits, critical care

services, and trauma team activation provided in association with critical care services for CY 2012. These codes are listed below in Table 35.

TABLE 35.—PROPOSED HCPCS CODES USED TO REPORT CLINIC AND EMERGENCY DEPARTMENT VISITS AND CRITICAL CARE SERVICES

CY 2012 HCPCS Code	CY 2012 Descriptor
Clinic Visit HCPCS Codes	
99201	Office or other outpatient visit for the evaluation and management of a new patient (Level 1)
99202	Office or other outpatient visit for the evaluation and management of a new patient (Level 2)
99203	Office or other outpatient visit for the evaluation and management of a new patient (Level 3)
99204	Office or other outpatient visit for the evaluation and management of a new patient (Level 4)
99205	Office or other outpatient visit for the evaluation and management of a new patient (Level 5)
99211	Office or other outpatient visit for the evaluation and management of an established patient (Level 1)
99212	Office or other outpatient visit for the evaluation and management of an established patient (Level 2)
99213	Office or other outpatient visit for the evaluation and management of an established patient (Level 3)
99214	Office or other outpatient visit for the evaluation and management of an established patient (Level 4)
99215	Office or other outpatient visit for the evaluation and management of an established patient (Level 5)
Emergency Department Visit HCPCS Codes	
99281	Emergency department visit for the evaluation and management of a patient (Level 1)
99282	Emergency department visit for the evaluation and management of a patient (Level 2)
99283	Emergency department visit for the evaluation and management of a patient (Level 3)
99284	Emergency department visit for the evaluation and management of a patient (Level 4)
99285	Emergency department visit for the evaluation and management of a patient (Level 5)
G0380	Type B emergency department visit (Level 1)
G0381	Type B emergency department visit (Level 2)
G0382	Type B emergency department visit (Level 3)
G0383	Type B emergency department visit (Level 4)
G0384	Type B emergency department visit (Level 5)

Critical Care Services HCPCS Codes	
99291	Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes
99292	Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes
G0390	Trauma response associated with hospital critical care service

During the February 28-March 1 2011 APC Panel meeting, the APC Panel recommended that CMS continue to report claims data for clinic and emergency department visits and observation, and, if CMS identifies changes in patterns of utilization or cost, it bring those issues before the Visits and Observation Subcommittee for future consideration. The APC Panel also recommended that the work of the Visits and Observation Subcommittee continue. We are accepting these recommendations and will present the available requested data at an upcoming meeting of the APC Panel.

B. Proposed Policies for Hospital Outpatient Visits

1. Clinic Visits: New and Established Patient Visits

As reflected in Table 35 hospitals use different CPT codes for clinic visits based on whether the patient being treated is a new patient or an established patient. Beginning in CY 2009, we refined the definitions of a new patient and an established patient to reflect whether or not the patient has been registered as an inpatient or outpatient of the hospital within the past 3 years. A patient who has been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit would be considered to be an established patient for that visit, while a patient who has not been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit would be considered to be a new patient for that visit. We refer readers to the CY 2009 OPPS/ASC

final rule with comment period (73 FR 68677 through 68680) for a full discussion of the refined definitions.

We continue to believe that defining new or established patient status based on whether the patient has been registered as an inpatient or outpatient of the hospital within the 3 years prior to a visit will reduce hospitals' administrative burden associated with reporting appropriate clinic visit CPT codes, as we stated in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68677 through 68680). For CY 2012, we are proposing to continue to recognize the refined definitions of a new patient and an established patient, and applying our policy of calculating median costs for clinic visits under the OPPS using historical hospital claims data. As discussed in section II.A.2.e.(1) of the this proposed rule and consistent with our CY 2011 policy, when calculating the median costs for the clinic visit APCs (0604 through 0608), we are proposing to continue to utilize our methodology that excludes those claims for visits that are eligible for payment through the extended assessment and management composite APC 8002 (Level I Extended Assessment and Management Composite). We continue to believe that this approach results in the most accurate cost estimates for APCs 0604 through 0608 for CY 2012.

2. Emergency Department Visits

Since CY 2007, we have recognized two different types of emergency departments for payment purposes under the OPPS—Type A emergency departments and Type B emergency departments. As described in greater detail below, by providing payment for two types of emergency departments, we recognize, for OPPS payment

purposes, both the CPT definition of an emergency department, which requires the facility to be available 24 hours, and the requirements for emergency departments specified in the provisions of the Emergency Medical Treatment and Labor Act (EMTALA) (Pub. L. 99-272), which do not stipulate 24-hour availability but do specify other obligations for hospitals that offer emergency services. For more detailed information on the EMTALA provisions, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68680).

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68132), we finalized the definition of a Type A emergency department to distinguish it from a Type B emergency department. A Type A emergency department must be available to provide services 24 hours a day, 7 days a week, and meet one or both of the following requirements related to the EMTALA definition of a dedicated emergency department specified at 42 CFR 489.24(b), specifically: (1) it is licensed by the State in which it is located under the applicable State law as an emergency room or emergency department; or (2) it is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment. For CY 2007 (71 FR 68140), we assigned the five CPT E/M emergency department visit codes for services provided in Type A emergency departments to five Emergency Visit APCs, specifically APC 0609 (Level 1 Emergency Visits), APC 0613 (Level 2 Emergency Visits), APC 0614 (Level 3 Emergency Visits), APC 0615 (Level 4 Emergency Visits), and APC 0616 (Level 5 Emergency Visits). We defined a Type B emergency department as any dedicated

emergency department that incurred EMTALA obligations but did not meet the CPT definition of an emergency department. For example, a hospital department that may be characterized as a Type B emergency department would meet the definition of a dedicated emergency department but may not be available 24 hours a day, 7 days a week. Hospitals with such dedicated emergency departments incur EMTALA obligations with respect to an individual who presents to the department and requests, or has a request made on his or her behalf, examination or treatment for a medical condition.

To determine whether visits to Type B emergency departments have different resource costs than visits to either clinics or Type A emergency departments, in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68132), we finalized a set of five HCPCS G-codes for use by hospitals to report visits to all entities that meet the definition of a dedicated emergency department under the EMTALA regulations but that are not Type A emergency departments. These codes are called "Type B emergency department visit codes." In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68132), we explained that these new HCPCS G-codes would serve as a vehicle to capture median cost and resource differences among visits provided by Type A emergency departments, Type B emergency departments, and clinics. We stated that the reporting of specific HCPCS G-codes for emergency department visits provided in Type B emergency departments would permit us to specifically collect and analyze the hospital resource costs of visits to these facilities in order to determine if, in the future, a proposal for an alternative payment policy might be warranted. We expected hospitals to

adjust their charges appropriately to reflect differences in Type A and Type B emergency department visit costs.

As we noted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68681), the CY 2007 claims data used for that rulemaking were from the first year of claims data available for analysis that included hospitals' cost data for these new Type B emergency department HCPCS visit codes. Based on our analysis of the CY 2007 claims data, we confirmed that the median costs of Type B emergency department visits were less than the median costs of Type A emergency department visits for all but the level 5 visit. In other words, the median costs from the CY 2007 hospital claims represented real differences in the hospital resource costs for the same level of visits in a Type A or Type B emergency department. Therefore, for CY 2009, we adopted the August 2008 APC Panel recommendation to assign Levels 1 through 4 Type B emergency department visits to their own APCs and to assign the Level 5 Type B emergency department visit to the same APC as the Level 5 Type A emergency department visit.

As discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60548 through 60551), analyses of CY 2008 hospitals' cost data from claims data used for CY 2010 ratesetting for the emergency department HCPCS G-codes demonstrated that the pattern of relative cost differences between Type A and Type B emergency department visits was largely consistent with the distributions we observed in the CY 2007 data, with the exception that, in the CY 2008 data, we observed a relatively lower HCPCS code-specific median cost associated with Level 5 Type B emergency

department visits compared to the HCPCS code-specific median cost of Level 5 Type A emergency department visits. As a result, for CY 2010, we finalized a policy to continue to pay Levels 1 through 4 Type B emergency department visits through four levels of APCs, and to pay for Level 5 Type B emergency department visits through new APC 0630 (Level 5 Type B Emergency Department Visit), to which the Level 5 Type B emergency department visit HCPCS code is the only service assigned.

As we noted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71987), the pattern of relative cost differences between Type A and Type B emergency department visits is consistent with the distributions we observed in the CY 2008 claims data. Therefore, we finalized our proposal to continue to pay for Type B emergency department visits in CY 2011 based on their median costs through five levels of APCs: APC 0626 (Level 1 Type B Emergency Department Visit), APC 0627 (Level 2 Type B Emergency Department Visit), APC 0628 (Level 3 Type B Emergency Department Visit), APC 0629 (Level 4 Type B Emergency Department Visit), and APC 0630.

For CY 2012, we continue to believe that this configuration pays appropriately for each level of Type B emergency department visits based on estimated resource costs from the most recent CY 2010 claims data. Therefore, we are proposing to continue to pay for Type B emergency department visits in CY 2012 based on their median costs through the five levels of Type B emergency department APCs (APCs 0626 through 0630). We also note that, as discussed in section II.A.2.e.(1) of this proposed rule and consistent with our CY 2011 policy, when calculating the proposed median costs for the emergency department visit and critical care APCs (0609 through 0617 and 0626 through

0630), we are proposing to utilize our methodology that excludes those claims for visits that are eligible for payment through the extended assessment and management composite APC 8002. We believe that this approach would result in the most accurate cost estimates for APCs 0604 through 0608 for CY 2012.

Table 36 below displays the proposed median costs for each level of Type B emergency department visit APCs under the proposed CY 2012 configuration, compared to the proposed CY 2012 median costs for each level of clinic visit APCs and each level of Type A emergency department visit APCs.

TABLE 36.—COMPARISON OF PROPOSED MEDIAN COSTS FOR CLINIC VISIT APCs, TYPE B EMERGENCY DEPARTMENT VISIT APCs, AND TYPE A EMERGENCY DEPARTMENT VISIT APCs

Visit Level	Proposed CY 2012 Clinic Visit Approximate APC Median Cost	Proposed CY 2012 Type B Emergency Department Approximate APC Median Cost	Proposed CY 2012 Type A Emergency Visit Approximate APC Median Cost
Level 1	$50	$41	$52
Level 2	$75	$59	$89
Level 3	$105	$94	$142
Level 4	$138	$141	$229
Level 5	$178	$271	$340

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 is 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 believe it is 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 our historical data, into which the cost of the ancillary services is intrinsically packaged, and 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 will 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 them 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 will be 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 proposed CY 2012 median costs for critical care services are based upon CY 2010 claims data, which reflect the CPT billing guidance that was in effect prior to CY 2011, we are proposing to continue 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 data, into which the cost of the ancillary services is intrinsically packaged. We 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.

3. Visit Reporting Guidelines

Since April 7, 2000, we have instructed 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. Because a national set of hospital-specific codes and guidelines do not currently exist, we have advised hospitals that each hospital's internal guidelines that determine the levels of clinic and emergency department visits to be reported should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes.

As noted in detail in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66802 through 66805), we observed a normal and stable distribution of clinic and emergency department visit levels in hospital claims over the past several years. The data indicated that hospitals, on average, were billing all five levels of visit codes with varying frequency, in a consistent pattern over time. Overall, both the clinic and emergency department visit distributions indicated that hospitals were billing consistently over time and in a manner that distinguished between visit levels, resulting in relatively normal distributions nationally for the OPPS, as well as for specific classes of hospitals. The results of these analyses were generally consistent with our understanding of the clinical and resource characteristics of different levels of hospital outpatient clinic and emergency department visits. In the CY 2008 OPPS/ASC proposed rule (72 FR 42764

through 42765), we specifically invited public comment as to whether a pressing need for national guidelines continued at this point in the maturation of the OPPS, or if the current system where hospitals create and apply their own internal guidelines to report visits was currently more practical and appropriately flexible for hospitals. We explained that, although we have reiterated our goal since CY 2000 of creating national guidelines, this complex undertaking for these important and common hospital services was proving more challenging than we initially anticipated as we received new and expanded information from the public on current hospital reporting practices that led to appropriate payment for the hospital resources associated with clinic and emergency department visits. We stated our belief that many hospitals had worked diligently and carefully to develop and implement their own internal guidelines that reflected the scope and types of services they provided throughout the hospital outpatient system. Based on public comments, as well as our own knowledge of how clinics operate, it seemed unlikely that one set of straightforward national guidelines could apply to the reporting of visits in all hospitals and specialty clinics. In addition, the stable distribution of clinic and emergency department visits reported under the OPPS over the past several years indicated that hospitals, both nationally in the aggregate and grouped by specific hospital classes, were generally billing in an appropriate and consistent manner as we would expect in a system that accurately distinguished among different levels of service based on the associated hospital resources.

Therefore, we did not propose to implement national visit guidelines for clinic or emergency department visits for CY 2008. As we have done since publication of the

CY 2008 OPPS/ASC final rule with comment period, we again examined the distribution of clinic and Type A emergency department visit levels based upon updated CY 2010 claims data available for the CY 2012 proposed rule. Analysis of this data confirmed that we continue to observe a normal and relatively stable distribution of clinic and emergency department visit levels in hospital claims compared to CY 2009 data. We note that we have observed a slight shift over time toward higher numbers of level 4 and level 5 visits relative to the lower level visits, when comparing the distributions of Type A emergency department visit levels from CY 2005 claims data to those from CY 2010. We also note that, in aggregate, hospitals' charges for these higher level emergency department visits seem to be trending upward year over year. We welcome comment on whether this is consistent with individual hospitals' experiences in developing, implementing, and refining their own guidelines over the last several years. We continue to believe that generally, hospitals are billing in an appropriate and consistent manner that distinguishes among different levels of visits based on their required hospital resources. We are encouraging hospitals to continue to report visits during CY 2012 according to their own internal hospital guidelines. As originally noted in detail in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66648), we continue to expect that hospitals will not purposely change their visit guidelines or otherwise upcode clinic and emergency department visits for purposes of extended assessment and management composite APC payment.

In addition, we note our continued expectation 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 more specific questions related to the creation of internal guidelines to contact their servicing fiscal intermediary or MAC.

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. Sections 1861(ff)(1) and (ff)(2) of the Act specify the items and services that are defined as partial hospitalization services and some conditions under which Medicare payment for the items and services will be made. Section 1861(ff)(3) of the Act specifies that a partial hospitalization program (PHP) is one that is furnished by a hospital or community mental health center (CMHC) that meets the requirements specified under that subsection of the Act.

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 the program 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 definition 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). 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 existing 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 those services furnished by hospitals to their outpatients. 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, CMS 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 August 1, 2000 (65 FR 18452 through 18455). Under this methodology, the median per diem costs are used to calculate the relative payment weights for PHP APCs.

From CY 2003 through CY 2006, the median per diem cost for CMHCs fluctuated significantly from year to year, while the median per diem cost 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 costs by computing a separate per diem cost for each day rather than for each bill. A complete discussion of these refinements can be found in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66671 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 pay 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.C.2. 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 for days when fewer than 3 units of therapeutic services are provided.

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). We believe 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.2. 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.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we established four separate PHP APC per diem payment rates, two for CMHC PHPs (for Level I and Level II services for CMHCs) and two for hospital-based PHPs (Level I and Level II services for hospital-based PHPs). We proposed that CMHC PHP APC rates would be based only on CMHC data and hospital-based PHP APC rates 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 final rule with comment period (75 FR 71991), for

CY 2011, using CY 2009 cost data, CMHC costs had significantly decreased again. We attributed the decrease to the lower cost structure of CMHCs compared to hospitals, and not the impact of CY 2009 policies. CMHCs had 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 would be 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 were concerned that paying hospital-based PHP programs at a lower rate than their cost structure reflects could lead to closures and possible access problems for hospital-based programs for Medicare beneficiaries. Creating the four payment rates (two for CMHC PHPs and two for hospital-based PHPs) supported continued access to the PHP benefit, including a more intensive level of care, while also providing appropriate payment based on the unique cost structures of CMHC PHPs and hospital-based PHPs. In addition, separation of cost 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 CMHC providers to CMHC rates based solely on CMHC data for the two CMHC PHP APC per diem payments. For the transition period, we calculated the CMHC PHP APC Level I and Level II rates 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 would move

us in the direction of our goal, which is to pay appropriately for PHP services based on each provider type's cost data, while at the same time allow providers time to adjust their business operations and protect access to care for beneficiaries. 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 of these four payment rates.

After publication of the CY 2011 OPPS/ASC final rule with comment period, in the case of *Paladin Community Mental Health Center v. Sebelius* (No. 1:10-CV-00949-LY (W.D. Tex.)), a CMHC and one of its outpatients challenged the OPPS 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). Specifically, the plaintiffs in the case challenged the use of cost data derived from both hospitals and CMHCs in determining the relative payment weights for the OPPS rates for PHP services furnished by CMHCs. The plaintiffs alleged that section 1833(t)(2)(C) of the Act requires that such relative payment weights be based on cost data derived solely from hospitals. The Secretary has filed a motion to dismiss in this case, which is pending before the district court.

In addition to raising various jurisdictional defenses in the *Paladin* case, the Secretary argued that the agency had permissibly interpreted the statute in determining the relative payment weights for the OPPS rates for PHP services for CMHCs in CY 2011 on the basis of cost data derived from both hospitals and CMHCs. As discussed above, 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 . . .) . . . based on . . . hospital costs." Numerous courts have held that "based on" does not mean

"based exclusively on." Thus, it was reasonable to interpret the statute to permit the use of cost data from CMHCs as well as from hospitals.

For CY 2012, as discussed in section VII.B. of this proposed rule, we are proposing to determine the relative payment weights for PHP services by CMHCs based on cost data derived solely from CMHCs and the relative payment weights for hospital-based PHP services based exclusively on hospital cost data. We believe that, for purposes of this proposed rule for CY 2012, the statute is reasonably interpreted to allow the relative payment weights for the OPPS rates for PHP services provided by CMHCs to be based solely on CMHC cost data, whereas the corresponding relative payment weights for hospital-provided PHP services would be based exclusively on hospital cost 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), CMS developed the APCs, as set forth in §419.31 of the regulations (65 FR 18446 and 18447; 63 FR 47559 and 47560). As discussed in section X.B. of this proposed rule, 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 hospital-based and CMHC-based settings, on the basis of only 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 subsequently established new APCs for PHP services based exclusively on hospital costs. 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 solely on." Thus, the relative payment weights for the two APCs for CMHC-provided PHP services in CY 2011 were "based on" hospital data, no less than the relative payment weights for the two APCs for hospital-provided PHP services.

Although we used only hospital data to establish the original relative payment weights for APC 0033 and later used hospital data to establish four new relative payment weights for PHP services, we believe that we have the authority to discontinue the use of hospital data after the original establishment of the relative payment weights for a given APC. 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 by CMHCs based on "new cost data, and other relevant information and factors."

B. Proposed PHP APC Update for CY 2012

To develop the proposed payment rates for the PHP APCs for CY 2012, we used CY 2010 claims data and computed median per diem costs in the following categories: (1) days with 3 services; and (2) days with 4 or more services. These proposed median per diem costs were computed separately for CMHC PHPs and hospital-based PHPs, as shown in Table 37 below.

TABLE 37.—PROPOSED PHP MEDIAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHPs, BY CATEGORY, BASED ON CY 2010 CLAIMS DATA

Category	CMHC PHPs	Hospital-Based PHPs
Days with 3 services	$97.78	$162.34
Days with 4 or more services	$113.62	$189.87

Using CY 2010 claims data and the refined methodology for computing PHP per diem costs adopted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66671 through 66676), we computed proposed median per diem costs for CY 2012 for each provider type using its own claims data. The data results indicate that, although both CMHCs and hospital-based PHPs have decreased costs for Level I and Level II services from CY 2011 to CY 2012, the median per diem costs for CMHC PHPs continue to be substantially lower than the median per diem costs for hospital-based PHPs, given the same units of service. The approximate median per diem costs for 3 services are $98 for CMHC PHPs compared to $162 for hospital-based PHPs. Furthermore, the approximate median per diem costs for 4 or more services are $114 for CMHC PHPs compared to $190 for hospital-based PHPs. The difference in costs between CMHC PHPs and hospital-based PHPs underscores the need to pay each provider type based on use of its own data.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991), we noted that CMHCs' costs decreased from $139 in CY 2009 (using CY 2007 data) to $118 for CY 2011 (using CY 2009 claims data) for Level I services (3 services); and from $172 for CY 2009 to $123 for CY 2011 for Level II services (4 or more services). For

this CY 2012 proposed rule, our analysis of claims data (using CY 2010 claims data) shows that CMHCs' approximate median per diem costs continue to decrease from $118 for CY 2011 (using CY 2009 claims data) to $98 for CY 2012 for Level I services (3 services), and from $123 for CY 2011 (using CY 2009 claims data) to $114 for CY 2012 for Level II services (4 or more services). We can reasonably attribute some of the decrease in costs to targeted fraud and abuse efforts implemented by the Department's Center for Program Integrity and the Office of Inspector General, and by the U.S. Department of Justice, collectively.

We note that hospital-based PHPs also show a decrease in costs for CY 2012 (using CY 2010 claims data). Although hospital-based PHPs have historically been consistent in their median costs since the inception of the OPPS, the CY 2010 claims data indicated a decrease in their median per diem costs since last year. Hospital-based PHPs' approximate median per diem costs decreased from $184 for CY 2011 (using CY 2009 claims data) to $162 for CY 2012 (using CY 2010 claims data) for Level I services (3 services), and from $236 for CY 2011 (using CY 2009 claims data) to $190 for CY 2012 (using CY 2010 claims data) for Level II services (4 or more services). We can attribute this decrease in costs to one provider whose costs inflated the CY 2011 hospital-based cost data and increased the CY 2011 hospital-based PHP median for Level II services by approximately $30. We included this provider in the CY 2011 ratesetting because this provider had paid claims in CY 2009. Subsequently, this provider did not bill for PHP services during CY 2010 and, therefore, was not included in the proposed CY 2012 ratesetting.

Based on the results of our analysis of the CY 2010 claims data, for CY 2012, we are proposing to calculate the proposed CMHC PHP APC per diem payment rates for Level I and Level II services using only CMHC data and calculating the proposed hospital-based PHPs APC per diem payment rates for Level I and Level II services using only hospital-based PHP data. Basing payment rates specific to each type of provider's own data would continue to support access to the PHP benefit, including a more intensive level of care, while also providing appropriate payment commensurate with the cost structures of CMHC PHPs and hospital-based PHPs. We invite public comments on our proposal to calculate the CMHC PHP APC per diem payment rates using only CMHC claims data and the hospital-based PHP APC per diem rates using only hospital data.

We are proposing the following APC median per diem costs for PHP services for CY 2012:

TABLE 38.--PROPOSED CY 2012 MEDIAN PER DIEM COSTS FOR CMHC PHP SERVICES

Proposed APC	Group Title	Proposed Median Per Diem Costs
0172	Level I Partial Hospitalization (3 services) for CMHCs	$97.78
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	$113.62

TABLE 39.--PROPOSED CY 2012 MEDIAN PER DIEM COSTS FOR HOSPITAL-BASED PHP SERVICES

Proposed APC	Group Title	Proposed Median Per Diem Costs
0175	Level I Partial Hospitalization (3 services) for hospital-based PHPs	$162.34
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	$189.87

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 PHP charges 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. 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 2012. We are proposing that a portion of that 1.0 percent, an amount equal to 0.14 percent of outlier payments (or 0.0014 percent of total OPPS payments), would be allocated to CMHCs for

PHP outlier payments. In section II.G. of this proposed rule, we are proposing to set a dollar threshold in addition to an APC multiplier threshold for OPPS outlier payments. However, 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 2012 at 3.40 times the APC payment amount and the CY 2012 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.

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

A. Background

Section 1833(t)(1)(B)(i) of the Act gives the Secretary broad authority to determine the services to be covered and paid for under the OPPS. Before implementation of the OPPS in August 2000, Medicare paid reasonable costs for services provided in the HOPD. The claims submitted were subject to medical review by the fiscal intermediaries to determine the appropriateness of providing certain services in the outpatient setting. We did not specify in our regulations those services that were appropriate to provide only in the inpatient setting and that, therefore, should be payable only when provided in that setting.

In the April 7, 2000 final rule with comment period (65 FR 18455), we identified procedures that are typically provided only in an inpatient setting and, therefore, would not be paid by Medicare under the OPPS. These procedures comprise what is referred to as the "inpatient list." The inpatient list specifies those services for which the hospital will be paid only when provided in the inpatient setting because of the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. As we discussed in that rule and in the November 30, 2001 final rule with comment period (66 FR 59884), we may use any of a number of criteria we have specified when reviewing procedures to determine whether or not they should be removed from the inpatient list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. Those criteria include the following:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be performed in most outpatient departments.
- The procedure is related to codes that we have already removed from the inpatient list.

In the November 1, 2002 final rule with comment period (67 FR 66741), we added the following criteria for use in reviewing procedures to determine whether they

should be removed from the inpatient list and assigned to an APC group for payment under the OPPS:

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

The list of codes that we are proposing to be paid by Medicare in CY 2012 only as inpatient procedures is included as Addendum E to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site).

B. Proposed Changes to the Inpatient List

For the CY 2012 OPPS, we are proposing to use the same methodology described in the November 15, 2004 final rule with comment period (69 FR 65835) to identify a subset of procedures currently on the inpatient list that are being performed a significant amount of the time on an outpatient basis. Using this methodology, we identified two procedures that met the criteria for potential removal from the inpatient list for CY 2012. We then clinically reviewed these two potential procedures for possible removal from the inpatient list and found them to be appropriate candidates for removal from the inpatient list. During the February 28-March 1, 2011 meeting of the APC Panel, we solicited the APC Panel's input on the appropriateness of removing these two procedures from the CY 2012 inpatient list: CPT codes 21346 (Open treatment of nasomaxillary complex fracture

(Lefort II type); with wiring and/or local fixation) and 54411 (Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue).

As we indicated in the CY 2011 final rule with comment period (75 FR 71996),we solicited the APC Panel's input on the appropriateness of removing the procedures described by CPT codes 35045 (Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery) and 54650 (Orchiopexy, abdominal approach, for intra-abdominal testis (eg, Fowler-Stephens)), from the CY 2012 inpatient list. We also solicited the APC Panel's input on the appropriateness of removing the following procedures identified in a comment letter addressed to the APC Panel: CPT codes 61154 (Burr hole(s) with evacuation and/or drainage of hematoma, extradural or subdural); 61156 (Burr hole(s); with aspiration of hematoma or cyst, intracerebral); and 61210 (Burr hole(s); for implanting ventricular catheter, reservoir, eeg electrode(s), pressure recording device, or other cerebral monitoring device (separate procedure)). Following the discussion at its February 28-March 1, 2011 meeting, the APC Panel recommended that CMS remove from the CY 2012 inpatient list CPT codes 21346, 54411, 35045, 54650, and 61210. The APC Panel made no recommendation regarding CPT codes 61154 and 61156.

Additionally, during the February 28-March 1, 2011 meeting of the APC Panel, an APC Panel member requested removal of the following CPT codes from the CY 2012

inpatient list: 22551 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2); 22552 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure)); 22554 (Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2); 22585 (Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2, each additional interspace (List separately in addition to code for primary procedure)); 61107 (Twist drill hole(s) for subdural, intracerebral, or ventricular puncture; for implanting ventricular catheter, pressure recording device, or other intracerebral monitoring device); and 63267 (Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar). Following the discussion at its February 28-March 1, 2011 meeting, the APC Panel recommended that CMS remove from the CY 2012 inpatient list CPT codes 22551, 22552, 22554, 22585, 61107, and 63267.

For CY 2012, we are proposing to accept the APC Panel's recommendations to remove the procedures described by CPT codes 21346, 35045, and 54650 from the inpatient list because we agree with the APC Panel that the procedures may be appropriately provided as hospital outpatient procedures for some Medicare beneficiaries, based upon the evaluation criteria mentioned above. We also are proposing to not accept the APC Panel's recommendations to remove the procedures described by CPT codes

22551, 22552, 22554, 22585, 54411, 61107, 61210, and 63267, because upon further clinical review subsequent to the February 28-March 1, 2011 APC Panel meeting, we do not believe that these procedures may be appropriately provided as hospital outpatient procedures for some Medicare beneficiaries, based upon the evaluation criteria mentioned above, due to the clinical intensity of services provided. Furthermore, according to our utilization data, the procedures described by CPT codes 22551, 22552, 22554, 22585, 54411, 61107, 61210, and 63267 have very low volume in the outpatient hospital setting. We note that despite its low overall volume, CPT code 54411 is performed a significant percentage of the time in the outpatient hospital setting; however, we do not believe that the outpatient procedures being performed are truly reflective of the intensity of services requisite when performing the procedure as described by the CPT code's long descriptor. We invite public comment on the inclusion of CPT code 54411 on the CY 2012 inpatient list. The three procedures we are proposing to remove from the inpatient list for CY 2012 and their CPT codes, long descriptors, proposed APC assignments, and proposed status indictors are displayed in Table 40 below.

TABLE 40.—PROCEDURES PROPOSED FOR REMOVAL FROM THE INPATIENT LIST AND THEIR PROPOSED APC ASSIGNMENTS FOR CY 2012

HCPCS Code	Long Descriptor	Proposed CY 2012 APC Assignment	Proposed CY 2012 Status Indicator
21346	Open treatment of nasomaxillary complex fracture (Lefort II type); with wiring and/or local fixation	0254	T

HCPCS Code	Long Descriptor	Proposed CY 2012 APC Assignment	Proposed CY 2012 Status Indicator
35045	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery	0093	T
54650	Orchiopexy, abdominal approach, for intra-abdominal testis (eg, Fowler-Stephens)	0154	T

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

A. Background

In the CY 2000 OPPS final rule with comment period, CMS established the hospital OPPS and indicated that direct supervision is the standard for all hospital outpatient therapeutic services covered and paid by Medicare in hospitals and in provider-based departments (PBDs) of hospitals (65 FR 18524 through 18526). Currently, as discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72008), this standard requires the supervisory practitioner to be immediately available to furnish assistance and direction throughout the performance of a hospital outpatient therapeutic service or procedure. In the CY 2000 OPPS final rule with comment period, we established in regulation at §410.28(e) that outpatient diagnostic services furnished in PBDs of hospitals must be supervised at the level indicated in the Medicare Physician Fee Schedule (MPFS) for each service, that is, general, direct or personal supervision. Since that time, we have clarified and refined these rules in several

ways. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71998 through 72001), we provided a comprehensive review of the history of the supervision policies for both outpatient therapeutic and diagnostic services from the inception of the OPPS through CY 2010. In this section, we provide a more condensed overview of our supervision policy during that time period, and present background on issues that have arisen during the CY 2011 payment year.

By way of overview, we have defined supervision in the hospital outpatient setting by drawing on the three levels of supervision that CMS defined for the physician office setting at §410.32(b) prior to establishment of the OPPS: general, direct, and personal supervision. Over time, we have tailored these definitions as needed to apply them in the hospital outpatient setting, so the definitions or applications in the OPPS may differ slightly from those in the physician office setting. This is the case in defining direct supervision, where the MPFS requires presence "in the office suite," and the OPPS currently does not require presence within any specific physical boundary (in the past, the OPPS rules for direct supervision required presence on the hospital campus or in the PBD) (75 FR 72008, 72012).

To date, for purposes of the hospital outpatient setting, we have only defined direct and general supervision, and we have only defined general supervision insofar as it applies to the provision of nonsurgical extended duration therapeutic services (extended duration services) for which we require direct supervision during an initiation period, followed by a minimum standard of general supervision for the duration of the service (75 FR 72012). Under the OPPS, general supervision means that the service is furnished

under the overall direction and control of the physician or appropriate nonphysician practitioner, but his or her physical presence is not required during the performance of the service. Direct supervision means that the physician or appropriate nonphysician practitioner is immediately available to furnish assistance and direction throughout the performance of a therapeutic service or procedure; however, he or she does not have to be present in the room where the service or procedure is being performed.

In the CY 2000 OPPS final rule with comment period (65 FR 18524 through 18526), we adopted physician supervision policies as a condition of payment under the OPPS to ensure that Medicare pays for high quality hospital outpatient services that are furnished in a safe and effective manner and consistent with Medicare requirements. The agency has long divided hospital outpatient services into the two categories of "diagnostic" services and other "therapeutic" services that aid the physician in the treatment of patients (Section 3112 of the Medicare Part A Intermediary Manual (July 1987)). Thus, we considered all nondiagnostic services to be "therapeutic services" which would include, but not be limited to, the services listed under section 1861(s)(2)(B) of the Act as incident to the services of physicians. As early as 1985, the agency defined therapeutic services as those services and supplies (including the use of hospital facilities) which are incident to the services of physicians in the treatment of patients (Section 3112.4 of the Medicare Part A Intermediary Manual (May 1985)). In recognition of this historic classification of services, we established a direct supervision standard for outpatient therapeutic services under our regulation at §410.27, which establishes the conditions for payment for outpatient hospital services provided "incident

to" physicians' services. In the text of §410.27, we also established standards requiring that these services be furnished either by or under arrangements made by the participating hospital (§410.27(a)(1)(i)), either in the hospital or in a location that the agency designates as a department of a provider under §413.65 of the regulations (§410.27(a)(1)(iii)). Since 2000, we have maintained the classification of services as either diagnostic or therapeutic in our manual guidance that establishes the conditions of payment for hospital outpatient services under the OPPS (Sections 20.4 and 20.5, Chapter 6 of the Medicare Benefit Policy Manual (Pub. 100-02)). In the requirements for therapeutic services, in addition to the direct supervision standard, we applied the requirements of §§410.27(a)(1)(i) and (a)(1)(iii) regarding under arrangement and provider-based site of service to all outpatient therapeutic services that are paid under the OPPS (Section 20.5, Chapter 6 of the Medicare Benefit Policy Manual (Pub. 100-02)).

In the CY 2000 OPPS final rule with comment period, we amended our regulation at §410.27 to specify that direct supervision is required for outpatient hospital services and supplies furnished incident to a physician's service in a location we designate as a department of a provider under §413.65 of our regulations. We specified further in the regulation that direct supervision means the physician must be present on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the service or procedure. The requirement to be "immediately available" was included in the regulation, although at that time we did not define the term. Although the regulation required the physician to be present on the premises of the location where services were being furnished, it specified that the physician did not have

to be present in the room when the procedure was performed. In the CY 2000 OPPS final rule with comment period (65 FR 18525), we emphasized the importance of establishing a supervision standard for services furnished in departments of the hospital that are not located on campus, indicating that our amendment applies to services furnished at an entity that is located off the campus of a hospital that we designate as having provider-based status in accordance with the provisions of §413.65. In response to a commenter, we stated that, in accordance with Section 3112.4(A) of the Intermediary Manual, we assume the direct supervision standard is met when outpatient therapeutic services are provided incident to a physician's service in an on-campus department of a hospital.

In the CY 2000 OPPS final rule with comment period, we also defined the supervision standards for outpatient hospital diagnostic services furnished in PBDs of hospitals in §410.28(e) of our regulations. The regulation at §410.28(e) provided that diagnostic services furnished at facilities having provider-based status must be performed under the level of supervision indicated for the diagnostic test under the MPFS in accordance with the definitions in §§410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii). In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60588 through 60591, and 60680), we revised §410.28(e) to extend the supervision standards we had established for outpatient diagnostic tests furnished in PBDs to also apply to services furnished in the hospital setting or any other location where diagnostic services may be provided under arrangement. The supervision rules for diagnostic services under the regulation at §410.28(e) explicitly apply to hospitals that are paid in accordance with section 1833(t)

of the Act, which is the statutory authority for the OPPS. As noted in the CY 2010 OPPS/ASC final rule with comment period, Medicare makes payments to CAHs in accordance with section 1834(g) of the Act. Accordingly, CAHs are not subject to the supervision requirements for outpatient diagnostic services at this time. The supervision requirements for outpatient diagnostic services were also set forth in Section 20.4, Chapter 6, of the Medicare Benefit Policy Manual.

In the years following establishment of the initial OPPS regulations, we began to receive inquiries from providers about the supervision requirements. Many of these inquiries led us to believe that some hospitals may have misunderstood our statement to the effect that we assume physician supervision requirements are met for services furnished on the hospital premises, and were providing either general supervision or no supervision for therapeutic services furnished incident to physicians' services in the outpatient setting and for which we had established a requirement of direct supervision. Therefore, in the CY 2009 OPPS/ASC proposed rule and final rule with comment period (73 FR 41518 through 41519 and 73 FR 68702 through 68704, respectively), we clarified and restated the various supervision requirements for outpatient hospital therapeutic and diagnostic services. We clarified that therapeutic services furnished in the hospital and in all PBDs of the hospital, specifically both on-campus and off-campus PBDs, must be provided under the direct supervision of physicians. We also reiterated that all diagnostic services furnished in PBDs, whether on or off the hospital's main campus, should be supervised according to the levels assigned for the individual tests under the MPFS. We

received very few public comments regarding this clarification and restatement during the comment period.

In response to concerns about our policy restatement articulated by stakeholders after publication of the CY 2009 OPPS/ASC final rule with comment period, we further refined our supervision policies in the CY 2010 OPPS/ASC proposed rule and final rule with comment period (74 FR 35365 and 74 FR 60679 through 60680, respectively). We established rules for diagnostic services furnished in locations other than PBDs (that is, in the hospital and under arrangement in nonhospital facilities). Accordingly, we expanded and refined the regulatory language regarding direct supervision of diagnostic services in those locations to refer to presence of the supervisory practitioner in the hospital or PBD (for services furnished in those locations) or in the office suite (for services furnished under arrangement in nonhospital space). For therapeutic services, we increased hospitals' flexibility regarding the direct supervision requirement by allowing all nonphysician practitioners whose services are those the practitioner is legally authorized to perform under State law that "would otherwise be covered if furnished by a physician or as an incident to a physician's service" ("would be physicians' services") to supervise outpatient therapeutic services that are within their scope of practice under State law and their hospital-granted or CAH-granted privileges (sections 1861(s)(2)(K) through (N) of the Act; §§410.71 through 410.77 of the regulations). However, in implementing the new benefits for pulmonary rehabilitation (PR), cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) services, we required that direct supervision of those services furnished in the hospital outpatient setting must be provided by a doctor of medicine or a

doctor of osteopathy because, as we discussed in the CY 2010 and CY 2011 OPPS/ASC final rules with comment period (74 FR 60573 and 60582 and 75 FR 72009, respectively), the statute specifies that these services are physician-supervised (section 144(a)of the Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110-275). In addition, in the CY 2011 OPPS/ASC final rule with comment period, we revised our regulations at §410.27 to remove the physical boundary requirements for direct supervision, and instead to allow the supervisory practitioner simply to be "immediately available," meaning physically present, interruptible, and able to furnish assistance and direction throughout the performance of the procedure, but without reference to any particular physical boundary.

In the CY 2010 OPPS/ASC final rule with comment period, we finalized a technical correction to the regulation at §410.27 to clarify that the direct supervision requirement under that section applies to services furnished in CAHs as well as hospitals. Specifically, we added the phrase "or CAH" in the title and throughout the regulation text wherever the text referred only to "hospital," to clarify that the requirements for payment of hospital outpatient therapeutic services in that section apply to CAHs as well as other types of hospitals. As we discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72000), we viewed this as a technical correction because the Act applies the same regulations to hospitals and CAHs when appropriate (CAHs are included if "the context otherwise requires" under section 1861(e) of the Act).

In response to our clarification that CAHs are subject to the direct supervision standard for payment of outpatient therapeutic services, CAHs and the hospital

community at large suggested that CAHs should be exempt from this requirement because the requirement is at odds with longstanding and prevailing practices of many CAHs. For example, commenters noted that, due to low volume of services, a practitioner retained on the campus of a small rural hospital or CAH to meet supervision requirements may not have other concurrent responsibilities or patient care, which could lead to inefficiencies. In their correspondence and discussion in public forums, CAHs and small rural hospitals explicitly raised concerns about services that extend after regular operating hours, especially observation services. They asserted that direct supervision is not clinically necessary for some services that have a significant monitoring component that is typically performed by nursing or other auxiliary staff, including IV hydration, blood transfusions, and chemotherapy. They stated that their facilities have protocols to safely deliver all of these services, relying on nursing or other hospital staff to provide the service and having a physician or nonphysician practitioner available by phone to furnish assistance and direction throughout the duration of the therapeutic service.

We provided guidance regarding the flexibility that we believe exists within our requirement for direct supervision for an emergency physician or nonphysician practitioner, who would be the most likely practitioners staffing a small rural hospital or CAH, to provide the supervision, on the CMS Web site at: http://www.cms.gov/HospitalOutpatientPPS/05_OPPSGuidance.asp#TopOfPage. However, these hospitals continued to express difficulty in meeting the standard. Small rural hospitals and CAHs indicated that, regulations notwithstanding, many of them did

not have appropriate staff arrangements to provide the required supervision of some services, particularly services being provided after hours or consisting of a significant monitoring component that last for an extended period of time. In addition, the broader hospital community began requesting that we modify our policy to permit a lower level of supervision for therapeutic services for all hospitals.

After consideration of these requests, on March 15, 2010, we issued a **Federal Register** notice of nonenforcement of the requirement for direct supervision of outpatient therapeutic services in CAHs (which is available on the CMS Web site at: http://www.cms.gov/HospitalOutpatientPPS/Downloads/CMS_1504FC_OPPS_2011_FR_Physician_Supervision_Nonenf_Notice.pdf). While CAHs remained subject to the direct supervision standard, we instructed our contractors not to evaluate or enforce the standard in CY 2010 until the agency could revisit the supervision policy during the CY 2011 rulemaking cycle.

As indicated above, in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71998 through 72013), we further adjusted the direct supervision standard to increase flexibility for hospitals while maintaining an appropriate level of quality and safety and consistent with the incident to statutory provision. Specifically, we redefined direct supervision to remove all requirements that the supervisory practitioner remain present within a particular physical boundary, although we continued to require immediate availability. We also established a new category of services, "nonsurgical extended duration therapeutic services" (extended duration services), which have a substantial monitoring component. We specified that direct supervision is required for

these services during an initiation period, but once the supervising physician or nonphysician practitioner has determined the patient is stable, the service can continue under general supervision.

In addition, in response to concerns expressed by the industry about appropriate levels of supervision for certain services furnished in various settings (for example, chemotherapy administration, and post-operative recovery services), we stated our intent to create through the CY 2012 rulemaking cycle an independent advisory review process for consideration of stakeholder requests for assignment of supervision levels other than direct supervision for specific outpatient hospital therapeutic services. We stated that the review entity would evaluate services for assignment of both higher (personal) and lower (general) levels of supervision because, in the course of evaluating a given service, the review entity may find that personal supervision is the most appropriate level (75 FR 72006). We also indicated that, as an interim measure while we are in the process of establishing an advisory review body, we would extend the nonenforcement policy for direct supervision of outpatient therapeutic services provided in CAHs for a second year through CY 2011 (which is available at the CMS Website at: http://www.cms.gov/HospitalOutpatientPPS/Downloads/CMS_1504FC_OPPS_2011_FR_Physician_Supervision_Nonenf_Notice.pdf). In addition, we expanded the nonenforcement notice to include small and rural hospitals that have 100 or fewer beds, as defined by TOPs criteria, because we believe that these hospitals experience resource constraints that are similar to CAHs.

We indicated that we would consider the Federal Advisory Ambulatory Payment Classification (APC) Panel as a potential candidate to serve as the independent review entity to consider requests for alternative service-specific supervision standards, and we requested public comment both on that idea and on other aspects of the review process, such as evaluation criteria and the potential structure of the process. We suggested the APC Panel could serve as the review entity because it is already funded and established by law under the Federal Advisory Committee Act (FACA, Pub. L. 92-463) to make independent recommendations to CMS. The APC Panel membership is geographically diverse, and it includes members with clinical as well as administrative, hospital billing, and coding expertise. In response to our discussion in the CY 2011 OPPS/ASC final rule with comment period, we received public comments and other considerable input on these topics from the hospital and CAH community and from rural stakeholders. In this proposed rule, we discuss these comments and our proposals for the independent review process in CY 2012, taking into account the comments received in response to the CY 2011 OPPS/ASC final rule with comment period.

With respect to outpatient hospital diagnostic services, following our revisions to the regulation at §410.28(e) in the CY 2010 OPPS/ASC final rule with comment period described above, we have received very few comments from stakeholders regarding our revised policy. Therefore, we are not proposing any changes to those requirements in this proposed rule.

B. Issues Regarding the Supervision of Hospital Outpatient Therapeutic Services Raised by Hospitals and Other Stakeholders

1. Independent Review Process

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72012), we stated our intent to develop an independent technical review process through our CY 2012 rulemaking. Public comments that we received on this statement of intent focused on three primary topics: the potential nature of the review entity; the potential nature and structure of the review process; and potential means of evaluating services.

Commenters were generally favorable towards the establishment of an independent review entity, including use of the APC Panel as that entity, provided that CMS expand the APC Panel charter and its membership to include representatives of CAHs. They also were concerned that CMS ensure an adequate representation of clinicians on the Panel to provide the appropriate clinical review of supervision levels. Some commenters supported creation by law of a new committee comprised solely of clinicians (at least 15 multi-specialty physicians and mid-levels). Citing the potentially significant impact of the supervision rules on rural and CAH providers, these commenters also recommended that at least 50 percent of committee members be comprised of representatives of CAHs and other providers from rural States, with recommendations for supervision levels decided by majority vote. Other commenters preferred use of an existing body (for example, the APC Panel or the Relative Value Scale Update Committee (RUC)) and emphasized inclusion of nonclinical professionals with expertise in hospital/facility resource consumption in order to balance the panel's expertise. Some

commenters sought to assure that if the APC Panel were selected, it would remain appropriately balanced and qualified to carry out its current role in APC deliberations under section 1833(t)(9)(A) of the Act. Commenters also were supportive of CMS using its authority to convene a Technical Expert Panel (TEP) as the review entity, but noted potential lack of available funding.

In considering these issues, we believe that the best course of action is to obtain independent advice with the transparency, formality and process associated with a Federal advisory committee. Stakeholders may view the recommendations of a FACA Committee as having greater legitimacy and, thus, its recommendations could be more useful to CMS than the recommendations that would be offered by other types of groups such as the American Medical Association's Relative Value Update Committee or a TEP. A TEP might be more conducive to in-depth research and data analysis, but unless the TEP complies with the Federal Advisory Committee Act, the TEP as a group cannot provide advice to CMS.

At this time, funding is not available to CMS to convene a new entity; therefore, we believe the most realistic and appropriate option is to use an existing body for reviewing supervision levels. We agree with commenters that the review body should be representative of all types of facilities that are subject to the supervision rules for payment, but we disagree that it should be 50 percent representative of a specific class of hospitals, particularly if those hospitals represent a minority of hospital outpatient service volume and payments. In addition, while we agree with commenters that clinical expertise is critical to this review process, we believe that additional perspectives should

be represented, including those of hospital administrators and coding representatives. Under the FACA, committees and their subcommittees must have balanced membership with respect to points of view represented and the topics that are under their consideration; therefore, a Federal advisory review entity would be required to have a balanced representation of geographic interests, including those of CAHs and rural hospitals. It also would be required to have a balanced representation of clinical as well as any other relevant expertise.

With respect to structure of the actual review process, most commenters requested that we subject the recommendations of the review entity and CMS' decisions to notice and comment rulemaking. However, most commenters also requested a "real-time" process that would be more flexible than annual rulemaking and allow for continuous evaluation of services. Commenters further requested that there be a mechanism for reconsideration of CMS' decisions. In addition, they requested that CMS not allow any information presented to the review entity in the course of the review process to be used for enforcement purposes.

We believe that employing a subregulatory process to establish CMS' final decisions may best serve the interests of beneficiaries and also meet the needs of other stakeholders. While rulemaking would arguably provide some additional procedural protections to stakeholders in terms of an opportunity for notice and comment, due to the time involved in rulemaking, stakeholders would only be able to request changes in supervision levels once a year. Similarly, if confined to annual rulemaking, CMS would not be able to make swift changes to address any problems associated with supervision

levels, for example access to care. Historically, CMS has used subregulatory processes rather than rulemaking to issue changes in certain administrative specifications at the level of individual CPT codes due to a need for agility in making such changes. For example, CMS has used a subregulatory process to set supervision levels for individual diagnostic services under the MPFS, which are adopted for provision of those services in the hospital outpatient setting. Given the strong stakeholder interest in policy changes in supervision levels for outpatient hospital therapeutic services, we believe we should provide an opportunity for public comment on our proposed decisions (which would be based upon the review entity's recommendations) prior to finalizing them.

We agree with commenters that there should be a means of requesting reevaluation of CMS' decisions. However, because there is a potential for significant administrative burden in reconsidering requests for reevaluation, we believe that stakeholders should be required to provide significant justification to support consideration of a request for a change in supervision levels that has previously been considered, such as new clinical evidence, new technology, or new techniques in how patient care is furnished. In addition, we believe that new consideration of previously considered requests should receive the same independent evaluation as the initial request. Therefore, once we decide to consider a decision, we would request a new review by the independent review entity and follow the same process as a new request. The review entity would then deliberate and make a new recommendation to CMS, and CMS would then make another determination based on the new recommendation.

We received substantial comment on how we might structure the evaluation process. First, stakeholders continued to request that we establish a default supervision standard of general supervision for all therapeutic services, and assign direct supervision only as indicated through the review process. Commenters believed it was important that the review entity and CMS not consider services for assignment of personal supervision because many services that might qualify for personal supervision are already personally performed by a physician or nonphysician practitioner. Commenters also noted that certain services are not furnished personally by these practitioners and instead are furnished personally by auxiliary personnel such as technicians or registered nurses (RNs). However, commenters maintained that hospitals currently furnish adequate supervision of those services by higher-level practitioners. Further, they requested that any evaluation for personal supervision be based on clinical evidence and evidence of a current deficiency in the quality of care.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72006), we expressed our belief that direct supervision is the most appropriate level of supervision for most hospital outpatient therapeutic services due to the "incident to" nature of most hospital outpatient therapeutic services. We discussed how our historic requirements for physician (or nonphysician practitioner) orders and direct physician involvement in patient care stem from our interpretation of the nature of incident to services under the law. We reviewed our regulations and other guidance over the years which reflect these beliefs and interpretations (75 FR 71999 and 72005).

We continue to believe that, while the statute does not explicitly mandate direct supervision, direct supervision is the most appropriate level of supervision for most hospital outpatient services that are authorized for payment as "incident to" physicians' services unless personal supervision is appropriate. We also believe that the "incident to" nature of hospital outpatient therapeutic services under the law permits us to recognize specific circumstances in which general supervision is appropriate, as we have for extended duration services, and that CMS has authority to accept a recommendation by the review entity of general supervision for a given service. However, we continue to believe that direct supervision is the most appropriate level of supervision for the great majority of hospital outpatient therapeutic services and, as such, it is the proper choice for a default supervision standard.

In the course of evaluating a stakeholder request for review of the supervision level required for a given service, the independent review entity may recommend that personal supervision is the most appropriate level of supervision for the service. It may also be appropriate to assign personal supervision to certain services to ensure that auxiliary personnel or personnel in training (such as medical students) are adequately supervised. As we indicated in last year's final rule with comment period, our supervision policy is designed to preserve both the quality and safety of purchased hospital outpatient services for Medicare beneficiaries. Accordingly, we believe that the review entity should have authority to recommend personal supervision for a service if, in the course of its evaluation, it believes that personal supervision is most appropriate and safe.

We believe that the review entity should base its recommendations on any clinical evidence that is available. It should also take into consideration any known impacts of supervision on the quality of care. As we have previously noted (75 FR 72005), while literature or clinical opinions may exist on the risk of adverse outcomes and susceptibility to medical error associated with the provision of specific hospital outpatient procedures when a physician is not present, we do not know of any analyses that have directly examined levels of supervision and patient outcomes in the hospital outpatient setting. This may be an area for future study.

With respect to an initial agenda of services for the review entity, commenters recommended that CMS begin evaluating services with work Relative Value Units (RVUs) < 1.0 (approximately 160 services), which they believe would include many extended duration services. They also requested that CMS evaluate surgical procedures (especially minor surgical procedures) and portions of the surgical recovery period for general supervision. We continue to support direct supervision as the default supervision level for all hospital outpatient therapeutic services. We believe it would be appropriate to solicit services for evaluation from stakeholders, in a process similar to that currently used to solicit agenda items for the APC Panel meetings. Also, it will be important for CMS to be able to place services on the Panel agenda as issues arise, similar to the way the agency brings inpatient only procedures before the APC Panel for consideration of removal from the inpatient only list. If we received an unmanageable number of requests during a particular period, we propose to prioritize requests according to service volume, total expenditures for the service, frequency of requests, and the repetition of requests

from prior public comments. In addition, we propose to require the submitter of a request to furnish a justification for the request, supported to the extent possible with clinical evidence. We would use the justifications to assist in prioritizing agenda items.

Commenters suggested that evaluation criteria include the general categories of risk, complexity, the type of professional and scope of practice of the professional furnishing the service, and whether the service is furnished in a CAH or rural facility, taking into consideration the workforce typically available to those hospitals. We agree with the suggested general parameters of risk and complexity, and we offer several similar potential measures below for the public's consideration. In recommending a level of supervision that would apply for a particular service described by a CPT code, we also believe that the review entity could take into consideration the varied environments in which the service described by that code may be delivered. We anticipate that representatives of different types of facilities on the Panel will facilitate an understanding of any potential variation in conditions at different types of facilities.

Under the conditions of participation for hospitals at §482.11(a), hospitals must comply with applicable Federal law related to the health and safety of patients. Under §482.11(c), hospitals must also assure that personnel are licensed or meet other applicable standards of State or local law. Registered nurses (RNs) are not authorized to independently furnish services that would be physicians' services if furnished by a physician as described in section 1861(s)(2)(K) of the Act. In addition, under their State scope of practice, RNs are not licensed to independently furnish these services. Under the condition of participation regulation at §482.11, hospitals must comply with these

Federal and State rules. Because under the law RNs are not permitted to furnish "would be" physicians' services, we do not believe RNs should be permitted to supervise those services. Therefore, under the regulations at §§410.27 and 482.11, RNs cannot supervise "would be" physicians' services that they may not independently furnish (though they may furnish some of them under the supervision of an appropriately higher level practitioner), even in a CAH or rural facility that may be experiencing difficulty obtaining a higher level practitioner to supervise or furnish those services. In this case, the statute and the regulations determine at the service level which nonphysician professionals can and cannot supervise therapeutic services.

Furthermore, we note that we anticipate extending the notice of nonenforcement for direct supervision of outpatient therapeutic services in both CAHs and small rural hospitals another year through CY 2012, which we discuss in section X.C.2. of this proposed rule.

2. Conditions of Payment and Hospital Outpatient Therapeutic Services Described by Different Benefit Categories

Another issue that has been raised to us is the applicability of the payment conditions for hospital outpatient therapeutic services in §410.27 to services described in paragraphs or subparagraphs of section 1861(s) of the Act other than section 1861(s)(2)(B) of the Act, which describes outpatient hospital services incident to physicians' services. Over the years, and particularly in recent months, we have received inquiries asking that we explain or clarify our application of the payment conditions under our regulation at §410.27, which explicitly applies to "hospital services and

supplies furnished incident to a physician service to outpatients," to outpatient therapeutic services other than those specified under section 1861(s)(2)(B) of the Act. For example, we have received inquiries as to whether it is permissible for hospitals to furnish radiation therapy (described under section 1861(s)(4) of the Act) or ambulatory surgical center services (described under section 1832(a)(2)(F)(i) of the Act) under arrangement in locations that are not provider-based. Some have suggested that the language in §410.27 is not applicable to services described by benefit categories in section 1861(s) of the Act other than section 1861(s)(2)(B) of the Act because §410.27 only refers to "incident to" services.

Although we acknowledge the language of §410.27 could be read as limited to services and supplies described under section 1861(s)(2)(B) of the Act, hospital services incident to physicians' services furnished to outpatients, we have not interpreted the regulation so narrowly. For instance, in the CY 2010 OPPS/ASC final rule with comment period, we noted that, long before the OPPS, we required that hospital services and supplies furnished to outpatients incident to a physician's service must be furnished "on a physician's order by hospital personnel and under a physician's supervision" (section 3112.4 of the Medicare Intermediary Manual). We also clearly treated all nondiagnostic services that are furnished to hospital outpatients as "incident to services" (sections 3112 and 3112.4 of the Medicare Intermediary Manual; Section 20.5, Chapter 6, of the Medicare Benefit Policy Manual (Pub. 100-02)). While we have not delineated this position as clearly in the regulations, and while the regulation text of §410.27 only explicitly refers to "incident to" services, we note that our policy is longstanding and, in

fact, predates the OPPS. In longstanding manual guidance, we have expressed our view that direct supervision is required for hospital outpatient therapeutic services, and suggested that this requirement stems from the "incident to" nature of those services. In the CY 2010 OPPS/ASC final rule with comment period, we stated, "Therapeutic services and supplies which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physicians and practitioners in the treatment of patients" (74 FR 60584 through 60585). We indicated that outpatient therapeutic services and supplies must be furnished under the order of a physician or other appropriate nonphysician practitioner, and by hospital personnel under the direct supervision of a physician or appropriate nonphysician practitioner.

Thus, we have long maintained that all hospital outpatient therapeutic services are, in some sense, furnished "incident to" a physician's service even when described by benefit categories other than the specific "incident to" provision in section 1861(s)(2)(B) of the Act. Because hospital outpatient therapeutic services are furnished "incident to" a physician's professional service, we believe the conditions for payment, including the direct supervision standard, should apply to all of these services. As discussed above, because the statute includes specific requirements for physician supervision of PR, CR, and ICR, we believe that those statutory specifications take precedence over the agency's general requirements.

C. Proposed Policies on Supervision Standards for Outpatient Therapeutic Services in Hospitals and CAHs

In this proposed rule, we are proposing policies for the independent review process, grouped under three key topics: selection of a review body; structure of the review process; and evaluation criteria.

1. Selection of Review Entity

We are proposing that the existing APC Panel serve as the independent review entity. However, we would make some modifications to the APC Panel scope and composition in order to create a body that is prepared to address supervision standards and reflects the full range of parties subject to the standards. Specifically, we would use the discretionary authority in the Panel charter to expand its scope to include the topic of supervision standards. We are proposing to add several (2 to 4) representatives of CAHs as Panel members so that all hospitals subject to the supervision rules for payment would be represented. However, CAHs would not participate in deliberations about APC assignments under the OPPS, as these assignments do not affect CAHs. According to customary practice for the APC Panel, we are proposing to create a supervision subcommittee on the Panel, with balanced representation, that is charged to evaluate appropriate supervision standards for individual services and present its deliberations to the full Panel. Each member of the full Panel would then vote to decide on the Panel's recommendation to CMS.

We are proposing to use the APC Panel for many reasons. As we discussed above, funding is not available to CMS at this time to convene a new entity. Also, it is

not clear that the entire resources of a new body are necessary to accomplish the consideration of service-specific supervision standards, especially once initial determinations are made regarding key services. We are also proposing to use the APC Panel because we believe it is important to obtain advice that carries the weight of a Federal advisory recommendation, which may have greater legitimacy both with stakeholders and with CMS compared to the opinions of other types of groups.

In addition to being already established and funded, the APC Panel would necessarily be inclusive and well-balanced because it is subject to the FACA rules. Consistent with stakeholders' requests that the review entity have balanced representation from all hospitals that are subject to the supervision rules, the Federal Advisory APC Panel would be required by the FACA to have balanced membership on committees and their subcommittees with respect to the topics – in this case, supervision – that are under their consideration. In addition, the Panel incorporates clinical as well as facility, administrative, and coding perspectives. Commenters have been generally favorable towards selection of the APC Panel, provided we make the changes to the APC Panel that we are proposing in this proposed rule.

2. Review Process

We are proposing to issue agency decisions based on APC Panel recommendations through sub-regulatory guidance. We would use a process similar to the one currently used to set supervision levels for diagnostic services under the MPFS, which are adopted for provision of those services in the hospital outpatient setting. CMS' decisions (which would be based upon the Panel's recommendations) would be posted on

the OPPS Web site for public review and comment, and would be effective either in July or January following the most recent APC Panel meeting, or only in January of the upcoming payment year. In setting the diagnostic supervision levels under the MPFS, there is no provision for public comment. However, given the strong stakeholder interest in this topic and the extent of prior dialogue with the various stakeholders, we believe it is important to provide some means of notice and comment on our proposed decisions prior to finalizing them.

The flexibility of a subregulatory process in comparison to rulemaking would allow stakeholders to submit requests for evaluations of services on a more frequent basis (at least twice a year at APC Panel meetings) rather than only annually, which most commenters requested. It also would give CMS the ability to respond more rapidly to any issues that may arise in access to care or patterns of care. Subjecting CMS' decisions to notice and comment rulemaking would provide a more structured, formal review of decisions, but changes could only be requested or made once a year due to the annual OPPS/ASC rulemaking cycle.

3. Evaluation Criteria

To begin evaluating services in CY 2012, we are proposing to use the same APC Panel process that is used to solicit services or categories of services from stakeholders to construct the agenda to solicit potential services for consideration of a change in supervision level. In addition, as discussed in section X.C.2. of this proposed rule, we are proposing that CMS would have the ability independently to ask the Panel to review the supervision level for one or more services as necessary. If we receive an unmanageable

number of requests, we are proposing to prioritize requests by service volume, total expenditures and/or frequency of requests. We also are proposing to prioritize services requested for review through public comment on the CY 2010 and CY 2011 OPPS/ASC proposed rules. We are proposing to require requests to include justification for the change in supervision level that is sought, supported to the extent possible with clinical evidence. We also would consider these justifications in deciding which services to forward to the APC Panel for evaluation.

We are proposing to charge the Panel with recommending a supervision level (general, direct, or personal) to ensure an appropriate level of quality and safety for delivery of a given service, as defined by a CPT code. The Panel should take into consideration the context in which the service is delivered, that is, the clinical, payment, and quality context of a patient encounter. In recommending a supervision level to CMS, we are proposing that the Panel assess whether there is a significant likelihood that the supervisory practitioner would need to reassess the patient and modify treatment during or immediately following the therapeutic intervention, or provide guidance or advice to the individual who provides the service. In answering that question, the Panel would consider--

- Complexity of the service;
- Acuity of the patients receiving the service;
- Probability of unexpected or adverse patient event; and
- Expectation of rapid clinical changes during the therapeutic service or procedure.

These criteria include, but extend well beyond, the likelihood of the need to manage medical emergencies during or after the provision of the service. As we have stated in previous rules (74 FR 60580 and 75 FR 72007 and 72010), the supervisory responsibility is more than the mere capacity to respond to an emergency. It also includes being available to reassess the patient and potentially modify treatment as needed on a nonemergency basis. It includes the ability to redirect or take over performance of the service and to issue any additional necessary orders.

We are proposing that, in the event there has been a previous consideration and decision on the supervision standard for a service, we would consider the request and, as warranted, forward the request to the APC Panel for its review. For requests for review of a service that has already been considered, we are proposing to require the requestor to submit new evidence to support a change in policy, for example, evidence of a change in clinical practice patterns due to new techniques or new technology. If sufficient new information was provided with the request, CMS would send the request to the APC Panel, and the Panel would reconsider the service and make another recommendation to CMS, which could be the same or a different level of supervision than the current level for the service.

Finally, in the interim period while we work toward establishing the independent review process, we anticipate that we will extend the notice of nonenforcement of the requirement for direct supervision in CAHs and small rural hospitals as defined by the notice (available on the CMS Web site at: http://www.cms.gov/HospitalOutpatientPPS/01_overview.asp) another year, through

CY 2012. The purpose of this proposed policy would continue to be to allow these facilities time to meet the direct supervision standard while we continue to deliberate on any policy alternatives. Under our current timeline, we would not complete policy decisions on many key services until sometime in 2012.

We note that we have not yet defined the terms "personal supervision" or "general supervision" for the hospital outpatient setting, except, as explained above, for general supervision in relation to extended duration services in §410.27(a)(1)(v)(A). Because we are proposing to allow the independent review entity to recommend that CMS assign either personal or general supervision to other hospital outpatient therapeutic services, we are proposing to define these terms in the regulations at proposed new §410.27(b)(1)(vi). We are proposing to use the definitions established for purposes of the MPFS as specified at §410.32(b)(3). Specifically, "personal supervision" would have the same meaning as the definition specified at §410.32(b)(3)(iii) and "general supervision" would have the same meaning as the definition specified in §410.32(b)(3)(i), which is the same definition that we established for the general supervision portion of an extended duration service.

4. Conditions of Payment and Hospital Outpatient Therapeutic Services Described by Different Benefit Categories

With respect to the issue of application of the payment conditions in §410.27 to services described by benefit categories other than section 1861(s)(2)(B) of the Act, we are proposing to amend our regulations to clarify our policy. Therapeutic services and supplies described by benefit categories other than the hospital outpatient "incident to" services under section 1861(s)(2)(B) of the Act are nevertheless subject to the conditions

of payment in §410.27 when they are furnished to hospital outpatients and paid under the OPPS or to CAHs under section 1834(g) of the Act.

We believe that this clarification could most readily be accomplished by more specifically defining the services and supplies described in the regulation text to which the requirements at §410.27 apply. Accordingly, we are proposing to revise the description of the services and supplies addressed in §410.27(a) by adding the term "therapeutic" so that paragraph (a) would read, "Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service" to outpatients. We are proposing to define these services, similar to the way they are currently defined in Section 20.5, Chapter 6, of the Medicare Benefit Policy Manual, to mean "all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or practitioner in the treatment of the patient." We would also add the term "therapeutic" to the title of §410.27 so that it would read, "Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions."

We believe it is important that we continue to apply the requirements in §410.27 to all hospital outpatient therapeutic services and supplies that are paid under the OPPS and to services furnished in CAHs that are paid under section 1834(g) of the Act. In addition to the supervision rules, the payment conditions in §410.27 include rules regarding services furnished under arrangements and in PBDs. The goals of the "under arrangements" and PBD rules are different from the safety and quality goals of the supervision rules. They ensure clinical and financial integration between the main

hospital and any on-campus or off-campus departments of hospitals. In particular, §410.27(a)(1)(iii) subjects hospital outpatient services to the requirements in §413.65 for PBDs of hospitals. The provider-based regulations in §413.65 govern numerous aspects of PBD operations including quality assurance, accountability to hospital medical director staff, licensure, personnel management, how far the departments can be located from the main hospital, and assurance that the departments are serving the same population as the main provider. Section 410.27(e) subjects services to the "under arrangement" regulations at §410.42(a) which govern the liabilities of the beneficiary and other parties when hospitals contract services out. It is important to reiterate that §410.27 is applicable to all hospital outpatient therapeutic services. We note, for example, that ASCs are not permitted to enter into arrangements with hospitals to furnish hospital outpatient services. We believe we should clarify and reinforce our longstanding policy that hospitals are not permitted to furnish therapeutic services or surgery under arrangement with ASCs because under §413.65(a)(1)(ii)(A), CMS does not make provider-based determinations regarding ASCs and under §410.27(a)(1)(iii) therapeutic services must be furnished in provider-based space. Moreover, a hospital is not permitted to furnish services to hospital outpatients under arrangements with an ASC because ASCs are paid under section 1833(i)(2)(D) of the Act (the ASC payment system), not under section 1833(t) of the Act (the OPPS payment system). As a result, an ASC could not be a provider-based department of a hospital for purposes of §410.27. If §410.27 did not apply, an ASC could furnish hospital outpatient therapeutic services under arrangements and obtain payment at the OPPS rate rather than the ASC rate. This practice would

distort the financial incentives within those payment systems, and would be contrary to the advice and determinations that have historically been made by CMS and other enforcement bodies such as the Office of the Inspector General.

In addition, §410.27(a)(1)(ii) subjects hospital outpatient services to the incident to rules that CMS has historically applied to all therapeutic services. As we discussed above, these rules ensure that services are ordered by a physician (or appropriate nonphysician practitioner) and that he or she is directly involved in the delivery of care. Sections 410.27(b) and (c) subject services to other significant rules governing drugs and biologicals and emergency services.

Additionally, we believe that there is a similar level of clinical risk in the therapeutic hospital outpatient services covered under other benefit categories that are not explicitly defined as "incident to" services. For example, stereotactic radiosurgery (a radiation therapy service under section 1861(s)(4) of the Act) is a high risk and technically demanding surgical procedure. We do not believe that the current requirements under §410.27 regarding supervision, under arrangement, provider-based, and other aspects of service, were intended to apply only to a subset of hospital outpatient therapeutic services and supplies, or that the agency ever intended to omit large classes of services that are routinely furnished to hospital outpatients from being governed by this regulation.

5. Technical Corrections to the Supervision Standards for Hospital Outpatient Therapeutic Services Furnished in Hospitals or CAHs

We recently noted that the text of §§410.27(b) and (c) includes cross-references to section §410.168 of the regulations, which is obsolete. We believe that §410.27(b) refers to §410.168 in error and should instead reference §410.29 (Limitations on drugs and biologicals). We are proposing to correct §410.27(b) so that it cross-references §410.29. It would then read, "Drugs and biological are also subject to the limitations specified in §410.29." In addition, we are proposing to update §410.27(c) to cross-reference the sections of the regulation that have replaced §410.168, that is, Part 424, Subparts G and H. For this update, we are proposing to revise paragraph (c) to read, "Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in subpart G of Part 424 of this chapter" and to add a new paragraph (d) to read, "Rules on emergency services furnished to outpatients in a foreign country are specified in subpart H of Part 424 of this chapter". Accordingly, we are proposing to redesignate the existing paragraphs (d) through (f) of §410.27 as paragraphs (e) through (g), respectively.

In addition, we noted that CAHs are not specifically named in the definition of nonsurgical extended duration therapeutic services at §410.27(a)(1)(iv)(E). We are making a technical correction to insert the words "or CAH" after "hospital" in this paragraph. This is the same technical correction that we made throughout §410.27 in the CY 2010 OPPS/ASC final rule with comment period, discussed above. This technical correction clarifies that CAHs are subject to all of the requirements of §410.27 in the same manner as all other types of hospitals.

6. Summary

In summary, we are proposing to establish the Federal Advisory APC Panel as an independent review body that would evaluate individual outpatient therapeutic services for potential assignment by CMS of general (lower) or personal (higher) supervision. We are proposing to amend the APC Panel charter to render the Panel more appropriate for this task by expanding its scope to include the topic of supervision. We also are proposing to add two to four members to the Panel who would be representative of CAHs, so that there is broad representation of the types of hospitals that are subject to the supervision rules for payment. We are proposing to use the standard APC Panel protocols with respect to frequency of meetings and receiving requests for evaluation and reconsideration of services. However, CMS' decisions based on the Panel's recommendations would not be subject to notice and comment rulemaking, in contrast to recommendations by the Panel on issues other than supervision. We are proposing several means of prioritizing requests for evaluations, particularly if the Panel agenda could not accommodate all timely requests at a particular meeting. We also are proposing clinical and other evaluation criteria that the Panel would use in recommending a supervision level that would apply at the individual CPT code level. As we have not yet defined personal supervision or general supervision for all hospital outpatient therapeutic services, we are proposing definitions for these terms in this proposed rule.

We anticipate extending the notice of nonenforcement for direct supervision in CAHs and small rural hospitals as defined by the notice through CY 2012, because, even if the new APC Panel review process is adopted, we likely will not have finalized our

policy decisions on many key services that are reviewed during that year. In addition, we are proposing to clarify our policy that the requirements under §410.27 apply to outpatient therapeutic services and supplies furnished in hospitals and in CAHs, which includes services and supplies described by Medicare benefit categories other than section 1861(s)(2)(B) of the Act. To that end, we are proposing to redefine the services described in that section to clarify the nature and scope of the included services.

XI. Proposed OPPS Payment Status and Comment Indicators

A. Proposed 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 2012 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.hhs.gov/HospitalOutpatientPPS . 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 this 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.hhs.gov/HospitalOutpatientPPS.

For CY 2012, we are not proposing to make any changes to the definitions of status indicators that were listed in Addendum D1 of the CY 2011 OPPS/ASC final rule with comment period. The proposed CY 2012 status indicators and their definitions are listed in the tables under sections XI.A.1., 2., 3., and 4. of this proposed rule.

1. Proposed Payment Status Indicators to Designate Services That Are Paid under the OPPS

Indicator	Item/Code/Service	OPPS Payment Status
G	Pass-Through Drugs and Biologicals	Paid under OPPS; separate APC payment.
H	Pass-Through Device Categories	Separate cost-based pass-through payment; not subject to copayment.
K	Nonpass-Through Drugs and Nonimplantable Biologicals, including Therapeutic Radiopharmaceuticals	Paid under OPPS; separate APC payment.
N	Items and Services Packaged into APC Rates	Paid under OPPS; payment is packaged into payment for other services. Therefore, there is no separate APC payment.
P	Partial Hospitalization	Paid under OPPS; per diem APC payment.
Q1	STVX-Packaged Codes	Paid under OPPS; Addendum B displays APC assignments when services are separately payable. (1) Packaged APC payment if billed on the same date of service as a HCPCS code assigned status indicator “S,” “T,” “V,” or “X.” (2) In all other circumstances, payment is made through a separate APC payment.

Indicator	Item/Code/Service	OPPS Payment Status
Q2	T-Packaged Codes	Paid under OPPS; Addendum B displays APC assignments when services are separately payable. (1) Packaged APC payment if billed on the same date of service as a HCPCS code assigned status indicator "T." (2) In all other circumstances, payment is made through a separate APC payment.
Q3	Codes that may be paid through a composite APC	Paid under OPPS; Addendum B displays APC assignments when services are separately payable. Addendum M displays composite APC assignments when codes are paid through a composite APC. (1) Composite APC payment based on OPPS composite-specific payment criteria. Payment is packaged into a single payment for specific combinations of services. (2) In all other circumstances, payment is made through a separate APC payment or packaged into payment for other services.
R	Blood and Blood Products	Paid under OPPS; separate APC payment.
S	Significant Procedure, Not Discounted When Multiple	Paid under OPPS; separate APC payment.
T	Significant Procedure, Multiple Reduction Applies	Paid under OPPS; separate APC payment.
U	Brachytherapy Sources	Paid under OPPS; separate APC payment.
V	Clinic or Emergency Department Visit	Paid under OPPS; separate APC payment.
X	Ancillary Services	Paid under OPPS; separate APC payment.

We are not proposing any changes to the definitions of status indicators listed above for the CY 2012 OPPS. The proposed CY 2012 status indicators and their

definitions are displayed in both the table above and in Addendum D1 on the CMS Web site at: http://www.cms.hhs.gov/HospitalOutpatientPPS.

2. Proposed Payment Status Indicators to Designate Services That Are Paid under a Payment System Other Than the OPPS

We are not proposing to make any changes to the definitions of status indicators listed below for the CY 2012 OPPS.

Indicator	Item/Code/Service	OPPS Payment Status
A	Services furnished to a hospital outpatient that are paid under a fee schedule or payment system other than OPPS, for example:	Not paid under OPPS. Paid by fiscal intermediaries/MACs under a fee schedule or payment system other than OPPS. Services are subject to the deductible and coinsurance unless indicated otherwise.
	● Ambulance Services	
	● Clinical Diagnostic Laboratory Services	Not subject to deductible or coinsurance.
	● Non-Implantable Prosthetic and Orthotic Devices	
	● EPO for ESRD Patients	
	● Physical, Occupational, and Speech Therapy	
	● Routine Dialysis Services for ESRD Patients Provided in a Certified Dialysis Unit of a Hospital	
	● Diagnostic Mammography	
	● Screening Mammography	Not subject to deductible or coinsurance.
C	Inpatient Procedures	Not paid under OPPS. Admit patient. Bill as inpatient.
F	Corneal Tissue Acquisition; Certain CRNA Services; and Hepatitis B Vaccines	Not paid under OPPS. Paid at reasonable cost.
L	Influenza Vaccine; Pneumococcal Pneumonia Vaccine	Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance.

Indicator	Item/Code/Service	OPPS Payment Status
M	Items and Services Not Billable to the Fiscal Intermediary/MAC	Not paid under OPPS.
Y	Non-Implantable Durable Medical Equipment	Not paid under OPPS. All institutional providers other than home health agencies bill to DMERC.

The proposed CY 2012 status indicators and their definitions displayed in the table above are also displayed in Addendum D1 on the CMS Web site at: http://www.cms.hhs.gov/HospitalOutpatientPPS.

3. Proposed Payment Status Indicators to Designate Services That Are Not Recognized under the OPPS But That May Be Recognized by Other Institutional Providers

We are not proposing changes to the definitions of status indicators listed below for the CY 2012 OPPS.

Indicator	Item/Code/Service	OPPS Payment Status
B	Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and13x)	Not paid under OPPS.
		● May be paid by fiscal intermediaries/MACs when submitted on a different bill type, for example, 75x (CORF), but not paid under OPPS.
		● An alternate code that is recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x) may be available.

The proposed status indicators and their definitions listed in the table above are also displayed in Addendum D1 on the CMS Web site at: http://www.cms.hhs.gov/HospitalOutpatientPPS.

4. Proposed Payment Status Indicators to Designate Services That Are Not Payable by Medicare on Outpatient Claims

We are not proposing changes to the definitions of payment status indicators listed below for the CY 2012 OPPS.

Indicator	Item/Code/Service	OPPS Payment Status
D	Discontinued Codes	Not paid under OPPS or any other Medicare payment system.
E	Items, Codes, and Services:	Not paid by Medicare when submitted on outpatient claims (any outpatient bill type).
	● That are not covered by any Medicare outpatient benefit based on statutory exclusion	
	● That are not covered by any Medicare outpatient benefit for reasons other than statutory exclusion.	
	● That are not recognized by Medicare for outpatient claims; alternate code for the same item or service may be available	
	● For which separate payment is not provided on outpatient claims	

The proposed CY 2012 payment status indicators and their definitions listed in the table above are also displayed in AddendumD1 on the CMS Web site at: http://www.cms.hhs.gov/HospitalOutpatientPPS.

B. Proposed Comment Indicator Definitions

For the CY 2012 OPPS, we are proposing to use the same two comment indicators that are in effect for the CY 2011 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 using the "CH" indicator in this proposed rule to call attention to proposed changes in the payment status indicator and/or APC assignment for HCPCS codes for CY 2012 compared to their assignment as of June 30, 2011. We believe that using the "CH" indicator in this proposed rule will help facilitate the public's review of the changes that we are proposing for CY 2012.

We are proposing to use the "CH" comment indicator in the CY 2012 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 2012 compared to their assignment as of December 31, 2011. We believe that using the "CH" indicator in the CY 2012 OPPS/ASC final rule with comment period will facilitate the public's review of the changes that we will make for CY 2012. The use of the comment indicator "CH" in association with a composite APC indicates that the configuration of the composite APC has changed from the CY 2012 OPPS/ASC final rule with comment period.

We are proposing to continue our current policy regarding the use of comment indicator "NI."

Any existing HCPCS code numbers with substantial revisions to the code descriptors for CY 2012 compared to the CY 2011 descriptors will be labeled with comment indicator "NI" in Addendum B to the CY 2012 OPPS/ASC final rule with comment period. However, in order to receive the comment indicator "NI," the CY 2012 revision to the code descriptor (compared to the CY 2011 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 on the CY 2012 OPPS/ASC final rule with comment period. Like all codes labeled with comment indicator "NI," we will respond to public comments and finalize their OPPS treatment in the CY 2013 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 2012 will also be labeled with comment indicator "NI" in Addendum B to the CY 2012 OPPS/ASC final rule with comment period.

Only HCPCS codes with comment indicator "NI" in the CY 2012 OPPS/ASC final rule with comment period will be subject to comment. HCPCS codes that do not appear with comment indicator "NI" in the CY 2012 OPPS/ASC final rule with comment period will not be open to public comment, unless we specifically request additional comments elsewhere in the final rule with comment period. The CY 2012 treatment of HCPCS codes that appear in the CY 2012 OPPS/ASC final rule with comment period to

which comment indicator "NI" is not appended will be open to public comment during the comment period for this proposed rule, and we will respond to those comments in the CY 2012 OPPS/ASC final rule with comment period.

For the CY 2012 OPPS, we are not proposing any changes to the definitions of the OPPS comment indicators for CY 2012. Their proposed definitions are listed in Addendum D2 on the CMS Web site at: http://www.cms.hhs.gov/HospitalOutpatientPPS.

XII. OPPS Policy and Payment Recommendations

A. MedPAC Recommendations

MedPAC was established under section 1805 of the Act to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to Congress not later than March and June of each year that contain its Medicare payment policy recommendations. This section describes recent recommendations relevant to the OPPS that have been made by MedPAC.

The March 1, 2011 MedPAC "Report to Congress: Medicare Payment Policy" included the following recommendation relating to the Medicare hospital IPPS and, in part, to the Medicare hospital OPPS:

Recommendation 3: "The Congress should increase payment rates for the acute care hospital inpatient and outpatient prospective payment systems in 2012 by 1 percent. The Congress should also require the Secretary of Health and Human Services to make adjustments to inpatient payment rates in future years to fully recover all overpayments due to documentation and coding improvements." (page 60)

MedPAC further stated that: "For outpatient hospital services, the Commission is concerned that significant payment disparities among Medicare's ambulatory care settings (hospital outpatient departments, ambulatory surgical centers, and physician offices) for similar services are fostering undesirable financial incentives. Physician practices and ambulatory surgical centers are being reorganized as hospital outpatient entities in part to receive higher reimbursements. The Commission believes that Medicare should seek to pay similar amounts for similar services, taking into account differences in quality of care and in the relative risks of the patient populations. The Commission is concerned by the trend to reorganize for higher reimbursement and will examine this issue. However, in the interim, the modest update of 1 percent is warranted in the hospital outpatient setting to slow the growing payment rate disparities among ambulatory care settings." (page 61)

CMS Response: We note that MedPAC's recommendation is for the Congress to increase IPPS and OPPS payment rates by 1 percent in 2010. Absent action by Congress, we are proposing to follow the statutory requirements that govern the amount of the annual OPD fee schedule increase factor to the OPPS for CY 2012. We discuss the proposed CY 2012 OPD fee schedule increase factor in section II.B. of this proposed rule.

We look forward to reviewing the results of MedPAC's examination of what it perceives as a trend towards reorganization of ambulatory surgical centers and physician offices as hospital outpatient departments to maximize program payment.

The full March 2011 MedPAC report can be downloaded from MedPAC's Web site at: http://www.medpac.gov/documents/Mar11_EntireReport.pdf.

B. APC Panel Recommendations

Recommendations made by the APC Panel meeting held on February 28 and March 1, 2011 are discussed in the sections of this proposed rule that correspond to topics addressed by the APC Panel. The reports and recommendations from the APC Panel's February 28 and March 1, 2011 meeting regarding payment under the OPPS for CY 2012 are available on the CMS Web site at: http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

C. OIG Recommendations

The mission of the Office of the Inspector General (OIG), as mandated by Pub. L. 95–452, as amended, is to protect the integrity of the U.S. Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections.

On October 22, 2010, the OIG published a memorandum report entitled "Payment for Drugs under the Hospital Outpatient Prospective Payment System" (OIG-03-09-00420). The report may be viewed on the Web site at: http://oig.hhs.gov/oei/reports/oei-03-09-00420.pdf. The OIG did not make any recommendations to CMS regarding Medicare payment for drugs and biologicals under the OPPS.

CMS Response: We appreciate the work of the OIG regarding the payment for drugs under the OPPS, and we will take the findings in its report into consideration in the development of our proposed payment policy for CY 2012.

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

A. Background

1. Legislative Authority for the ASC Payment System

Section 1832(a)(2)(F)(i) of the Act provides that benefits under Medicare Part B include payment for facility services furnished in connection with surgical procedures specified by the Secretary that are performed in an Ambulatory Surgical Center (ASC). To participate in the Medicare program as an ASC, a facility must meet the standards specified in section 1832(a)(2)(F)(i) of the Act, which are set forth in 42 CFR Part 416, Subpart B and Subpart C of our regulations. The regulations at 42 CFR Part 416, Subpart B describe the general conditions and requirements for ASCs, and the regulations at Subpart C explain the specific conditions for coverage for ASCs.

Section 141(b) of the Social Security Act Amendments of 1994, Pub. L. 103-432, required establishment of a process for reviewing the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act for intraocular lenses (IOLs) that belong to a class of new technology intraocular lenses (NTIOLs). That process was the subject of a final rule entitled "Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers," published on June 16, 1999, in the **Federal Register** (64 FR 32198).

Section 626(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108-173, added subparagraph (D) to section 1833(i)(2) of the Act, which required the Secretary to implement a revised ASC payment system to be effective not later than January 1, 2008. Section 626(c) of the MMA amended section 1833(a)(1) of the Act by adding new subparagraph (G), which requires that, beginning with implementation of the revised ASC payment system, payment for surgical procedures furnished in ASCs shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under the revised payment system.

Section 109(b) of the Medicare Improvements and Extension Act of 2006 of the Tax Relief and Health Care Act of 2006 (MIEA-TRHCA), Pub. L. 109-432, amended section 1833(i) of the Act by redesignating clause (iv) as clause (v) and adding a new clause (iv) to paragraph (2)(D) and by adding new paragraph (7).

Section 1833(i)(2)(D)(iv) of the Act authorizes, but does not require, the Secretary to 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)." Section 1833(i)(7)(A) of the Act states that the Secretary may provide that any ASC that does not submit quality measures to the Secretary in accordance with paragraph (7) will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year.

Section 1833(i)(7)(B) of the Act provides that, "[e]xcept as the Secretary may otherwise provide," the hospital outpatient quality data provisions of subparagraphs (B) through (E)

of section 1833(t)(17) of the Act, added by section 109(a) of the MIEA-TRHCA, shall apply to ASCs in a similar manner to the manner in which they apply under these paragraphs to hospitals under the Hospital OQR Program.

Sections 4104 and 10406 of the Affordable Care Act, Pub. L. 111-148, amended section 1833(a)(1) and (b)(1) of the Act to 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 4104(c) of the Affordable Care Act amended section 1833(b)(1) of the Act to waive the Part B deductible for colorectal cancer screening tests that become diagnostic. These provisions apply to these items and services furnished in an ASC on or after January 1, 2011.

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act to require that, effective for CY 2011 and subsequent years, any annual update under the ASC payment system be reduced by a productivity adjustment, which is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). Application of this productivity 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.

For a detailed discussion of the legislative history related to ASCs, we refer readers to the June 12, 1998 proposed rule (63 FR 32291 through 32292).

2. Prior Rulemaking

On August 2, 2007, we published in the **Federal Register** (72 FR 42470) the final rule for the revised ASC payment system, effective January 1, 2008 (the "August 2, 2007 final rule"). In that final rule, we revised our criteria for identifying surgical procedures that are eligible for Medicare payment when furnished in ASCs and adopted the method we would use to set payment rates for ASC covered surgical procedures and covered ancillary services furnished in association with those covered surgical procedures beginning in CY 2008. We also established a policy for treating new and revised Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes under the ASC payment system. This policy is consistent with the OPPS to the extent possible (72 FR 42533).

In addition, we established a standard ASC ratesetting methodology that bases payment for most services on the list of ASC covered surgical procedures on the OPPS relative payment weight multiplied by the ASC conversion factor. We also established modifications to this methodology for subsets of services, such as device-intensive services (where the estimated device portion of the ASC payment is the same as that paid under the OPPS) and services that are predominantly performed in the office setting and covered ancillary radiology services (where ASC payment may be based on the MPFS

non-facility practice expense (PE) Relative Value Units (RVUs)). Additionally, we established a policy for updating the conversion factor, the relative payment weights, and the ASC payment rates on an annual basis. We also annually update the list of procedures for which Medicare does not make an ASC payment.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66827), we updated and finalized the CY 2008 ASC rates and lists of covered surgical procedures and covered ancillary services. We also made regulatory changes to 42 CFR Parts 411, 414, and 416 related to our final policies to provide payments to physicians who perform non-covered ASC procedures in ASCs based on the facility PE RVUs, to exclude covered ancillary radiology services and covered ancillary drugs and biologicals from the categories of designated health services (DHS) that are subject to the physician self-referral prohibition, and to reduce ASC payments for surgical procedures when the ASC receives full or partial credit toward the cost of the implantable device.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68722), we updated and finalized the CY 2009 ASC rates and lists of covered surgical procedures and covered ancillary services.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60596), we updated and finalized the CY 2010 ASC rates and lists of covered surgical procedures and covered ancillary services. We also corrected some of those ASC rates in a correction notice published in the **Federal Register** on December 31, 2009 (74 FR 69502). In that correction notice, we revised the ASC rates to reflect changes in the MPFS conversion factor and PE RVUs listed for some CPT codes in Addendum B to

the CY 2010 MPFS final rule with comment period (74 FR 62017), which were incorrect due to methodological errors and were subsequently corrected in a correction notice to that final rule with comment period (74 FR 65449). We also published a second correction notice in the **Federal Register**, to address changes to the ASC rates resulting from corrections to the PE RVUs identified subsequent to publication of the December 31, 2009 correction notice (75 FR 45700). Finally, we published a notice in the **Federal Register**, to reflect changes to CY 2010 ASC payment rates for certain ASC services due to changes to the OPPS and MPFS under the Affordable Care Act and to reflect technical changes to the ASC payment rates announced in prior correction notices (75 FR 45769).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71800), we updated and finalized the CY 2011 ASC rates and lists of covered surgical procedures and covered ancillary services. We corrected some of the ASC rates that were published in Addenda AA and BB, as well as errors in the preamble text, in a correction notice published in the **Federal Register** on March 11, 2011 (76 FR 13292). The corrections to the ASC Addenda were primarily due to changes to the MPFS conversion factor and PE RVUs listed for some CPT codes in Addendum B and Addendum C to the MPFS for CY 2011 which, in turn, affected office-based and ancillary radiology payment under the ASC payment system. Following legislative changes to the MPFS for CY 2011 associated with passage of section 101 of the Medicare and Medicaid Extenders Act of 2010 that occurred after publication of the CY 2011 OPPS/ASC and MPFS final rules with comment periods, we posted revised ASC Addenda on our Web site to reflect

associated changes to office-based and ancillary radiology payment under the ASC payment system.

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

The August 2, 2007 final rule established our policies for determining which procedures are 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 surgical procedures 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 crosswalk or are clinically similar to ASC covered surgical procedures (72 FR 42478). We note that we added over 800 surgical procedures to the list of covered surgical procedures for ASC payment in CY 2008, the first year of the revised ASC payment system, based on the criteria for payment that we adopted in the August 2, 2007 final rule as described above in this section.

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: brachytherapy sources; certain implantable items that have pass-through status under the OPPS; certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; certain drugs and biologicals for which separate payment is allowed under the OPPS; and 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 XIII.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 updates for ASC services throughout the year (January, April, July, and October). 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 through the

January quarterly update. New Category I CPT vaccine codes are released twice a year and thus are implemented through the January and July quarterly updates.

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 medical services and 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. 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 ASCs are addressed both through the ASC quarterly update Change Requests (CRs) and through the annual rulemaking cycle. 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 are recognized on Medicare claims) outside of the formal rulemaking process via ASC quarterly update CRs. This quarterly process offers ASCs 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 more timely manner than if we waited for the annual rulemaking process. We solicit comments on the new codes recognized for ASC payment and finalize our proposals related to these codes through our annual rulemaking process.

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 in the annual OPPS/ASC final rule with comment period 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.

In Table 41 below, we summarize our proposed process for updating the HCPCS codes recognized under the ASC payment system.

TABLE 41.—PROPOSED COMMENT TIMEFRAME FOR NEW HCPCS CODES

OPPS/ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April l, 2011	Level II HCPCS Codes	April 1, 2011	CY 2012 OPPS/ASC proposed rule	CY 2012 OPPS/ASC final rule with comment period
July 1, 2011	Level II HCPCS Codes	July 1, 2011	CY 2012 OPPS/ASC proposed rule	CY 2012 OPPS/ASC final rule with comment period
	Category I (certain vaccine codes) and III CPT codes	July 1, 2011	CY 2012 OPPS/ASC proposed rule	CY 2012 OPPS/ASC final rule with comment period
October 1, 2011	Level II HCPCS Codes	October 1, 2011	CY 2012 OPPS/ASC final rule with comment period	CY 2013 OPPS/ASC final rule with comment period
January 1, 2012	Level II HCPCS Codes	January 1, 2012	CY 2012 OPPS/ASC final rule with comment period	CY 2013 OPPS/ASC final rule with comment period
	Category I and III CPT Codes	January 1, 2012	CY 2012 OPPS/ASC final rule with comment period	CY 2013 OPPS/ASC final rule with comment period

This process is discussed in detail below. We have separated our discussion into two sections based on whether we are proposing to solicit public comments in this CY 2012 OPPS/ASC proposed rule (and responding to those comments in the CY 2012 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2012 OPPS/ASC final rule with comment period (and responding to

those comments in the CY 2013 OPPS/ASC final rule with comment period). We note that we sought public comment in the CY 2011 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2011. We also sought public comments in the CY 2011 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2010. These new codes, with an effective date of October 1, 2010, or January 1, 2011, were flagged with comment indicator "N1" in Addendum AA and BB to the CY 2011 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 2011 OPPS/ASC final rule with comment period. We will respond to public comments and finalize our proposed ASC treatment of these codes in the CY 2012 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 2011 for Which We Are Soliciting Public Comments in this CY 2012 OPPS/ASC Proposed Rule

In the April and July CRs, we made effective for April 1 or July 1, 2011, a total of 13 new Level II HCPCS codes and 6 new Category III CPT codes that were not addressed in the CY 2011 OPPS/ASC final rule with comment period. The 13 new Level II HCPCS codes describe covered ancillary services.

In the April 2011 ASC quarterly update (Transmittal 2185, CR 7343, dated March 25, 2011), we added four new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 42 below, these

included HCPCS codes C9280 (Injection, eribulin mesylate, 1 mg), C9281 (Injection, pegloticase, 1 mg), C9282 (Injection, ceftaroline fosamil, 10 mg), and Q2040 (Injection, incobotulinumtoxin A, 1 unit). We note that HCPCS code Q2040 replaced HCPCS code C9278 (Injection, incobotulinumtoxin A, 1 unit) beginning April 1, 2011. HCPCS code C9278 was effective January 1, 2011, and deleted for dates of service April 1, 2011 and forward, because it was replaced with HCPCS code Q2040.

In the July 2011 quarterly update (Transmittal 2235, Change Request 7445, dated June 03, 2011), we added nine new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 43, we provided separate payment for HCPCS codes C9283 (Injection, acetaminophen, 10 mg), C9284 (Injection, ipilimumab, 1 mg), C9285 (Lidocaine 70 mg/tetracaine 70mg, per patch), C9365 (Oasis Ultra Tri-Layer matrix, per square centimeter), C9406 (Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries), Q2041 (Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco), Q2042 (Injection, hydroxyprogesterone caproate, 1 mg), Q2043 (Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion), and Q2044 (Injection, belimumab, 10 mg). We note that HCPCS code Q2041 is replacing HCPCS code J7184 and HCPCS code Q2043 is replacing HCPCS code C9273 beginning July 1, 2011.

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 these 13 new Level II HCPCS codes to indicate that they are separately paid when

provided in ASCs. We are soliciting public comment on the proposed CY 2012 ASC payment indicators and payment rates for the drugs and biologicals, as listed in Tables42 and 43 below. Those HCPCS codes became payable in ASCs, beginning in April or July 2011, respectively, and are paid at the ASC rates posted for the appropriate calendar quarter on the CMS Web site at http://www.cms.gov/ASCPayment/.

The HCPCS codes listed in Table 42 are included in Addendum BB to this proposed rule. We note that all ASC addenda are referenced in section XVII. of this proposed rule and are only available via the Internet on the CMS Web site. Because HCPCS codes that became effective for July (listed in Table 43) 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 2012 OPPS/ASC final rule with comment period. Thus, the codes implemented by the July 2011 ASC quarterly update CR and their proposed CY 2012 payment rates (based on July 2011 ASP data) that are displayed in Table43 are not included in Addendum BB to this proposed rule. The final list of covered ancillary services and the associated payment weights and payment indicators will be included in Addendum BB to the CY 2012 OPPS/ASC final rule with comment period, consistent with our annual update policy.

TABLE 42.—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2011

CY 2011 HCPCS Code	CY 2011 Long Descriptor	Proposed CY 2012 Payment Indicator
C9280	Injection, eribulin mesylate, 1 mg	K2
C9281	Injection, pegloticase, 1 mg	K2
C9282	Injection, ceftaroline fosamil, 10 mg	K2
Q2040	Injection, incobotulinumtoxin A, 1 unit	K2

TABLE 43.—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2011

CY 2011 HCPCS Code	CY 2011 Descriptor	Proposed CY 2012 Payment Indicator	Proposed CY 2012 ASC Payment Rate
C9283	Injection, acetaminophen, 10 mg	K2	$0.11
C9284	Injection, ipilimumab, 1 mg	K2	$127.20
C9285	Lidocaine 70 mg/tetracaine 70mg, per patch	K2	$13.57
C9365	Oasis Ultra Tri-Layer matrix, per square centimeter	K2	$10.60
C9406	Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries	K2	$1,908.00
Q2041	Injection, von willebrand factor complex (human), Wilate, 1 i.u. vwf:rco	K2	$0.88
Q2042	Injection, hydroxyprogesterone caproate, 1 mg	K2	$2.90
Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion	K2	$32,860.00
Q2044	Injection, belimumab, 10 mg	K2	$39.15

Through the July 2011 quarterly update CR, we also implemented ASC payment for six new Category III CPT codes as ASC covered surgical procedures, effective

July 1, 2011. These codes are listed in Table 44 below, along with their proposed payment indicators and proposed payment rates for CY 2011. Because new Category III CPT and Level II HCPCS codes that become effective for July are not available to us in time for incorporation into the Addenda to the OPPS/ASC proposed rule, our policy is to include the codes, their proposed payment indicators, and proposed 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 Addendum AA to the CY 2012 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 all six of the new Category III CPT codes to be implemented in July 2011. We believe that these procedures would not pose a significant safety risk to Medicare beneficiaries or would not 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 2011 through the quarterly update CR, as listed in Table 44 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2012 OPPS/ASC final rule with comment period.

TABLE 44.—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2011 AS ASC COVERED SURGICAL PROCEDURES

CY 2011 HCPCS Code	CY 2011 Long Descriptor	Proposed CY 2012 Payment Indicator	Proposed CY 2012 ASC Payment Rate
0263T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest	G2	$1,218.58
0264T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest	G2	$1,218.58
0265T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy	G2	$1,218.58
0269T	Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	G2	$1,444.14
0270T	Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	G2	$841.60
0271T	Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	G2	$1,126.88

In summary, for CY 2011, we are soliciting public comments on the proposed payment indicators and the payment rates, if applicable, for the new Level II HCPCS codes and Category III CPT codes that were newly recognized in April or July 2011 through the respective quarterly update CRs. These codes are listed in Tables 42, 43 and 44 of this proposed rule. We are proposing to finalize their payment indicators and their payment rates, if applicable, in the CY 2012 OPPS/ASC final rule with comment period.

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 2012 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 2012. Specifically, for CY 2012, we are proposing to include in Addenda AA and BB to the CY 2012 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2012 that would be incorporated in the January 2012 ASC quarterly update CR and the new Level II HCPCS codes, effective October 1, 2011 or January 1, 2012, that would be released by CMS in its October 2011 and January 2012 ASC quarterly update CRs. These codes would be 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 have assigned them an interim payment status. Their payment indicators and payment rates, if applicable, would be open to public comment in the CY 2012 OPPS/ASC final rule with comment period and would be finalized in the CY 2013 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. Upon review, we did not identify any procedures that are currently excluded from the ASC list of procedures that met the definition of a covered surgical procedure based on our expectation that they would not pose a significant safety risk to Medicare beneficiaries or would require an overnight stay if performed in ASCs. Therefore, we are not proposing additions to the list of ASC covered surgical procedures for CY 2012.

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 non-facility 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 non-facility PE RVUs; payment based on MPFS non-facility PE RVUs); or

"R2" (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS non-facility 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 non-facility 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 2012 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 2010 volume and utilization data and the clinical characteristics for all surgical procedures that are assigned payment indicator "G2" in CY 2011, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically "P2*," "P3*," or "R2*" in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72033 through 72038).

Based on our review of the CY 2010 volume and utilization data, we identified ten 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. Our medical advisors believe the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The 10 CPT codes we are proposing to permanently designate as office-based are listed in Table 45 below.

TABLE 45.—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR PERMANENT OFFICE-BASED DESIGNATION FOR 2012

CY 2011 CPT Code	CY 2011 Long Descriptor	CY 2011 ASC Payment Indicator	Proposed CY 2012 ASC Payment Indicator
0213T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level	G2	R2
0214T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; second level (list separately in addition to code for primary procedure)	G2	R2
0215T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; third and any additional level(s) (list separately in addition to code for primary procedure)	G2	R2
0216T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level	G2	R2

CY 2011 CPT Code	CY 2011 Long Descriptor	CY 2011 ASC Payment Indicator	Proposed CY 2012 ASC Payment Indicator
0217T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; second level (list separately in addition to code for primary procedure)	G2	R2
0218T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; third and any additional level(s) (list separately in addition to code for primary procedure)	G2	R2
35475	Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel	G2	P3
35476	Transluminal balloon angioplasty, percutaneous; venous	G2	P3
41530	Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session	G2	P2
69801	Labyrinthotomy, with or without cryosurgery including other nonexcisional destructive procedures or perfusion of vestibuloactive drugs (single or multiple perfusions); transcanal	G2	P3

We also reviewed CY 2010 volume and utilization data and other information for the 23 procedures finalized for temporary office-based status in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72036 through 72038). Among these 23 procedures, there were very few claims data for eight 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 0232T (Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed); CPT code C9800 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies); CPT code 37761 (Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg); 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 2012.

As a result of our review of the remaining fifteen procedures that have temporary office-based designations for CY 2011 for which we do have claims data, we are proposing that none of the procedures be designated as office-based in CY 2012. The 15 surgical procedure codes are:

- CPT code 21015 (Radical resection of tumor (eg, malignant neoplasm), soft tissue of face or scalp; less than 2 cm);

- CPT code 21555 (Excision, tumor, soft tissue of neck or anterior thorax, subcutaneous; less than 3 cm);
- CPT code 21930 (Excision, tumor, soft tissue of back or flank, subcutaneous; less than 3 cm);
- CPT code 23075 (Excision, tumor, soft tissue of shoulder area, subcutaneous; less than 3 cm);
- CPT code 24075 (Excision, tumor, soft tissue of upper arm or elbow area, subcutaneous; less than 3 cm);
- CPT code 25075 (Excision, tumor, soft tissue of forearm and/or wrist area, subcutaneous; less than 3 cm);
- CPT code 26115 (Excision, tumor or vascular malformation, soft tissue of hand or finger, subcutaneous; less than 1.5 cm);
- CPT code 27047 (Excision, tumor, soft tissue of pelvis and hip area, subcutaneous; less than 3 cm);
- CPT code 27327 (Excision, tumor, soft tissue of thigh or knee area, subcutaneous; less than 3 cm);
- CPT code 27618 (Excision, tumor, soft tissue of leg or ankle area, subcutaneous; less than 3 cm);
- CPT code 28039 (Excision, tumor, soft tissue of foot or toe, subcutaneous; 1.5 cm or greater);
- CPT code 28041 (Excision, tumor, soft tissue of foot or toe, subfascial (eg, intramuscular); 1.5 cm or greater);

- CPT code 28043 (Excision, tumor, soft tissue of foot or toe, subcutaneous; less than 1.5 cm);
- CPT code 28045 (Excision, tumor, soft tissue of foot or toe, subfascial (eg, intramuscular); less than 1.5 cm); and
- CPT code 28046 (Radical resection of tumor (eg, malignant neoplasm), soft tissue of foot or toe; less than 3 cm).

The volume and utilization data for these CPT codes 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 2012.

The proposed CY 2012 payment indicator designations for the 23 procedures that were temporarily designated as office-based in CY 2011 are displayed in Table 46 below. The procedures for which the proposed office-based designations for CY 2012 are temporary also are indicated by asterisks in Addendum AA to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site).

TABLE 46.—PROPOSED CY 2012 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2011 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2011 CPT Code	CY 2011 Long Descriptor	CY 2011 ASC Payment Indicator	Proposed CY 2012 ASC Payment Indicator**
21015	Radical resection of tumor (eg, malignant neoplasm), soft tissue of face or scalp; less than 2 cm)	R2*	G2
21555	Excision, tumor, soft tissue of neck or anterior thorax, subcutaneous; less than 3 cm	P3*	G2
21930	Excision, tumor, soft tissue of back or flank, subcutaneous; less than 3 cm	P3*	G2
23075	Excision, tumor, soft tissue of shoulder area, subcutaneous; less than 3 cm	P3*	G2
24075	Excision, tumor, soft tissue of upper arm or elbow area, subcutaneous; less than 3 cm	P3*	G2
25075	Excision, tumor, soft tissue of forearm and/or wrist area, subcutaneous; less than 3 cm	P3*	G2
26115	Excision, tumor or vascular malformation, soft tissue of hand or finger, subcutaneous; less than 1.5 cm	P3*	G2
27047	Excision, tumor, soft tissue of pelvis and hip area, subcutaneous; less than 3 cm	P3*	G2
27327	Excision, tumor, soft tissue of thigh or knee area, subcutaneous; less than 3 cm	P3*	G2
27618	Excision, tumor, soft tissue of leg or ankle area, subcutaneous; less than 3 cm	P3*	G2
28039	Excision, tumor, soft tissue of foot or toe, subcutaneous; 1.5 cm or greater	P3*	G2
28041	Excision, tumor, soft tissue of foot or toe, subfascial (eg, intramuscular); 1.5 cm or greater	R2*	G2
28043	Excision, tumor, soft tissue of foot or toe, subcutaneous; less than 1.5 cm	P3*	G2
28045	Excision, tumor, soft tissue of foot or toe, subfascial (eg, intramuscular); less than 1.5 cm	P3*	G2

CY 2011 CPT Code	CY 2011 Long Descriptor	CY 2011 ASC Payment Indicator	Proposed CY 2012 ASC Payment Indicator**
28046	Radical resection of tumor (eg, malignant neoplasm), soft tissue of foot or toe; less than 3 cm	R2*	G2
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg	R2*	R2*
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy	R2*	R2*
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*	R2*
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies	R2*	R2*

* If designation is temporary.
**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 finalized for publication, current law authorizes a negative update to the MPFS payment rates for CY 2012. For a discussion of those rates, we refer readers to the CY 2012 MPFS proposed rule.

We invite public comment on these proposals.

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. We assigned payment indicators "H8" (Device-intensive procedure on ASC list in CY 2007; paid at adjusted rate) and "J8" (Device-intensive procedure added to ASC list in CY 2008 or later; paid at adjusted rate) to identify the procedures that were eligible for ASC payment calculated according to the modified methodology, depending on whether the procedure was included on the ASC list of covered surgical procedures prior to CY 2008 and, therefore, subject to transitional payment as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68739 through 68742).

As discussed in section XIII.F.2. of this proposed rule, because the 4-year transition to the ASC payment rates under the standard methodology is complete and, therefore, identification of device-intensive procedures that are subject to transitional payment methodology is no longer necessary, we are proposing to delete payment indicator "H8" (Device-intensive procedure on ASC list in CY 2007; paid at adjusted rate). The device-intensive procedures for which the device-intensive payment

methodology will apply in CY 2012 or later will be assigned payment indicator "J8" (Device-intensive procedure; paid at adjusted rate).

(2) Proposed Changes to List of Covered Surgical Procedures Designated as Device-Intensive for CY 2012

We are proposing to update the ASC list of covered surgical procedures that are eligible for payment according to the device-intensive procedure payment methodology for CY 2012, 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 2010 OPPS claims and cost report data available for this 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 2012 are listed in Table 47 below. The CPT code, the CPT code short descriptor, the proposed CY 2012 ASC payment indicator, the proposed CY 2012 OPPS APC assignment and title, and the proposed CY 2012 OPPS APC device offset percentage are also listed in Table 47 below. All of these procedures are included in Addendum AA to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site).

TABLE 47.—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE-INTENSIVE DESIGNATION FOR CY 2012

CPT Code	Short Descriptor	Proposed CY 2012 ASC Payment Indicator	Proposed CY 2012 OPPS APC	Proposed CY 2012 OPPS APC Title	Proposed CY 2012 Device-Dependent APC Offset Percentage
24361	Reconstruct elbow joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%
24363	Replace elbow joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%
24366	Reconstruct head of radius	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%
25441	Reconstruct wrist joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%
25442	Reconstruct wrist joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%
25446	Wrist replacement	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%
27446	Revision of knee joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%
33206	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	71%
33207	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	71%
33208	Insertion of heart pacemaker	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	73%
33212	Insertion of pulse generator	J8	0090	Insertion/Replacement of Pacemaker Pulse Generator	73%

CPT Code	Short Descriptor	Proposed CY 2012 ASC Payment Indicator	Proposed CY 2012 OPPS APC	Proposed CY 2012 OPPS APC Title	Proposed CY 2012 Device-Dependent APC Offset Percentage
33213	Insertion of pulse generator	J8	0654	Insertion/Replacement of a permanent dual chamber pacemaker	74%
33214	Upgrade of pacemaker system	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	73%
33224	Insert pacing lead & connect	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	73%
33225	Lventric pacing lead add-on	J8	0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	87%
33240	Insert pulse generator	J8	0107	Insertion of Cardioverter-Defibrillator	88%
33249	Eltrd/insert pace-defib	J8	0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	87%
33282	Implant pat-active ht record	J8	0680	Insertion of Patient Activated Event Recorders	72%
53440	Male sling procedure	J8	0385	Level I Prosthetic Urological Procedures	61%
53444	Insert tandem cuff	J8	0385	Level I Prosthetic Urological Procedures	61%
53445	Insert uro/ves nck sphincter	J8	0386	Level II Prosthetic Urological Procedures	70%
53447	Remove/replace ur sphincter	J8	0386	Level II Prosthetic Urological Procedures	70%
54400	Insert semi-rigid prosthesis	J8	0385	Level I Prosthetic Urological Procedures	61%
54401	Insert self-contd prosthesis	J8	0386	Level II Prosthetic Urological Procedures	70%

CPT Code	Short Descriptor	Proposed CY 2012 ASC Payment Indicator	Proposed CY 2012 OPPS APC	Proposed CY 2012 OPPS APC Title	Proposed CY 2012 Device-Dependent APC Offset Percentage
54405	Insert multi-comp penis pros	J8	0386	Level II Prosthetic Urological Procedures	70%
54410	Remove/replace penis prosth	J8	0386	Level II Prosthetic Urological Procedures	70%
54416	Remv/repl penis contain pros	J8	0386	Level II Prosthetic Urological Procedures	70%
55873	Cryoablate prostate	J8	0674	Prostate Cryoablation	57%
61885	Insrt/redo neurostim 1 array	J8	0039	Level I Implantation of Neurostimulator Generator	85%
61886	Implant neurostim arrays	J8	0315	Level II Implantation of Neurostimulator Generator	88%
62361	Implant spine infusion pump	J8	0227	Implantation of Drug Infusion Device	81%
62362	Implant spine infusion pump	J8	0227	Implantation of Drug Infusion Device	81%
63650	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%
63655	Implant neuro-electrodes	J8	0061	Level II Implantation/Revision/Replacement of Neurostimulator Electrodes	64%
63663	Revise spine eltrd	J8	0040	Level I Implantation/Revision/Re	55%

CPT Code	Short Descriptor	Proposed CY 2012 ASC Payment Indicator	Proposed CY 2012 OPPS APC	Proposed CY 2012 OPPS APC Title	Proposed CY 2012 Device-Dependent APC Offset Percentage
	perq aray			placement of Neurostimulator Electrodes	
63664	Revise spine eltrd plate	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%
63685	Insrt/redo spine n generator	J8	0039	Level I Implantation of Neurostimulator Generator	85%
64553	Implant neuro-electrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%
64555	Implant neuro-electrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%
64560	Implant neuro-electrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%
64561	Implant neuro-electrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%
64565	Implant neuro-electrodes	J8	0040	Level I Implantation/Revision/Replacement of Neurostimulator Electrodes	55%

CPT Code	Short Descriptor	Proposed CY 2012 ASC Payment Indicator	Proposed CY 2012 OPPS APC	Proposed CY 2012 OPPS APC Title	Proposed CY 2012 Device-Dependent APC Offset Percentage
64568	Implant neuro-electrodes	J8	0318	Implantation of Neurostimulator Electrodes, Cranial Nerve	86%
64575	Implant neuro-electrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	64%
64577	Implant neuro-electrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	64%
64580	Implant neuro-electrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	64%
64581	Implant neuro-electrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	64%
64590	Insrt/redo pn/gastr stimul	J8	0039	Level I Implantation of Neurostimulator Generator	85%
65770	Revise cornea with implant	J8	0293	Level VI Anterior Segment Eye Procedures	67%
69714	Implant temple bone w/stimul	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%
69715	Temple bne implnt w/stimulat	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%
69717	Temple bone implant revision	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%
69718	Revise temple bone	J8	0425	Level II Arthroplasty or Implantation with	60%

CPT Code	Short Descriptor	Proposed CY 2012 ASC Payment Indicator	Proposed CY 2012 OPPS APC	Proposed CY 2012 OPPS APC Title	Proposed CY 2012 Device-Dependent APC Offset Percentage
	implant			Prosthesis	
69930	Implant cochlear device	J8	0259	Level VII ENT Procedures	83%

We invite public comment on these proposals.

d. ASC Treatment of Surgical Procedures Proposed for Removal from the OPPS Inpatient List for CY 2012

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 three procedures we are proposing to remove from the OPPS inpatient list for CY 2012 according to the criteria for exclusion from the list of covered ASC surgical procedures. We believe that these three procedures should continue to be excluded from the ASC list of covered surgical procedures for CY 2012 because they would be expected to pose a significant risk to beneficiary safety or to require an overnight stay in ASCs. A full discussion about the APC Panel's recommendations regarding the procedures we are proposing to remove from the OPPS inpatient list for CY 2012 may be found in section IX.B. of this proposed rule. The

HCPCS codes for these three procedures and their long descriptors are listed in Table 48 below.

TABLE 48.—PROCEDURES PROPOSED FOR EXCLUSION FROM THE ASC LIST OF COVERED PROCEDURES FOR CY 2012 THAT ARE PROPOSED FOR REMOVAL FROM THE CY 2012 OPPS INPATIENT LIST

CPT Code	Long Descriptor
21346	Open treatment of nasomaxillary complex fracture (Lefort II type); with wiring and/or local fixation
35045	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery
54650	Orchiopexy, abdominal approach, for intra-abdominal testis (eg, Fowler-Stephens)

We invite public comment 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 2012 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 2012. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2011 may be proposed for packaged status under the CY 2012 OPPS and, therefore, also under the ASC payment system for CY 2012. Comment indicator "CH," discussed in section XIII.F. of this proposed rule, is used in Addendum BB to this proposed rule (which is referenced in section XVII. of this proposed rule and available on 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 2012.

Except for the Level II HCPCS codes listed in Table 43 of this proposed rule, all ASC covered ancillary services and their proposed payment indicators for CY 2012 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 indicator "G2." For procedures assigned payment indicator "A2," our final policy established blended rates to be used during the transitional period and, beginning in CY 2011, ASC rates calculated according to the ASC standard ratesetting methodology. 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 2011 OPPS/ASC final rule with comment period

(75 FR 72024 through 72064), we updated the CY 2010 ASC payment rates for ASC covered surgical procedures with payment indicators of "A2," "G2," "H8," and "J8" using CY 2009 data, consistent with the CY 2011 OPPS update. Payment rates for device-intensive procedures also were updated to incorporate the CY 2011 OPPS device offset percentages. Because transitional payments were no longer required in CY 2011, we calculated CY 2011 payments for procedures formerly subject to the transitional payment methodology (payment indicators "A2" and "H8") using the standard rate setting methodology, incorporating the device-intensive methodology, as appropriate.

Payment rates for office-based procedures (payment indicators "P2," "P3," and "R2") are the lower of the MPFS non-facility PE RVU-based amount (we refer readers to the CY 2012 MPFS proposed rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72024 through 72064), 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 2011 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 2011 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 2012

We are proposing to update ASC payment rates for CY 2012 using the established rate calculation methodologies under §416.171. Under §416.171(c)(4), the transitional

payment rates are no longer used for CY 2011 and subsequent calendar years for a covered surgical procedure designated in accordance with §416.166. Thus, we are proposing to calculate CY 2012 payments for procedures formerly subject to the transitional payment methodology (payment indicators "A2" and "H8") using the proposed CY 2012 ASC rate calculated according to the ASC standard ratesetting methodology, incorporating the device-intensive procedure methodology, as appropriate. We are proposing to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicator "G2." We are proposing to modify or delete the payment indicators for procedures that were subject to transitional payment prior to CY 2011 (we refer readers to our discussion in section XIII.F.2. of this proposed rule).

We are proposing that payment rates for office-based procedures (payment indicators "P2," "P3," and "R2") and device-intensive procedures that were not subject to transitional payment (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 2012 OPPS proposal that reflects updated OPPS device offset percentages, and to make payment for office-based procedures at the lesser of the CY 2012 proposed MPFS non-facility PE RVU-based amount or the proposed CY 2012 ASC payment amount calculated according to the standard ratesetting methodology.

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

Our ASC policy with regard to payment for costly devices implanted in ASCs at no cost or with full or partial credit as set forth in §416.179 is consistent with the OPPS policy. The proposed CY 2012 OPPS APCs and devices subject to the adjustment policy are discussed in section IV.B.2. of this proposed rule. The established ASC policy includes adoption of the OPPS policy for reduced payment to providers when a specified device is furnished without cost or with full 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 2012. Table 49 below displays the ASC covered device-intensive procedures that we are proposing would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2012. Specifically, when a procedure that is listed in Table 49 is performed to implant a device that is listed in Table 50 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.

We also are proposing to reduce the payment for implantation procedures listed in Table 49 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 49 when the facility receives a partial credit of 50 percent or more of the cost of a device listed in Table 50 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.

TABLE 49.—PROPOSED CY 2012 PROCEDURES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY

CPT Code	Short Descriptor	Proposed CY 2012 ASC Payment Indicator	Proposed CY 2012 OPPS APC	OPPS APC Title	Proposed CY 2012 OPPS Full APC Offset Percentage	Proposed CY 2012 OPPS Partial APC Offset Percentage
24361	Reconstruct elbow joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%	30%
24363	Replace elbow joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%	30%
24366	Reconstruct head of radius	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%	30%
25441	Reconstruct wrist joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%	30%
25442	Reconstruct wrist joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%	30%
25446	Wrist replacement	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%	30%
27446	Revision of knee joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%	30%
33206	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	71%	35%
33207	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	71%	35%
33208	Insertion of heart pacemaker	J8	0655	Insertion/Replacement /Conversion of a permanent dual chamber pacemaker	74%	37%

CPT Code	Short Descriptor	Proposed CY 2012 ASC Payment Indicator	Proposed CY 2012 OPPS APC	OPPS APC Title	Proposed CY 2012 OPPS Full APC Offset Percentage	Proposed CY 2012 OPPS Partial APC Offset Percentage
33212	Insertion of pulse generator	J8	0090	Insertion/Replacement of Pacemaker Pulse Generator	73%	37%
33213	Insertion of pulse generator	J8	0654	Insertion/Replacement of a permanent dual chamber pacemaker	74%	37%
33214	Upgrade of pacemaker system	J8	0655	Insertion/Replacement /Conversion of a permanent dual chamber pacemaker	73%	37%
33224	Insert pacing lead & connect	J8	0655	Insertion/Replacement /Conversion of a permanent dual chamber pacemaker	73%	37%
33225	Lventric pacing lead add-on	J8	0108	Insertion/Replacement /Repair of Cardioverter-Defibrillator Leads	87%	43%
33240	Insert pulse generator	J8	0107	Insertion of Cardioverter-Defibrillator	88%	44%
33249	Eltrd/insert pace-defib	J8	0108	Insertion/Replacement /Repair of Cardioverter-Defibrillator Leads	87%	43%
33282	Implant pat-active ht record	J8	0680	Insertion of Patient Activated Event Recorders	72%	36%
53440	Male sling procedure	J8	0385	Level I Prosthetic Urological Procedures	61%	30%
53444	Insert tandem cuff	J8	0385	Level I Prosthetic Urological Procedures	61%	30%
53445	Insert uro/ves nck sphincter	J8	0386	Level II Prosthetic Urological Procedures	70%	35%
53447	Remove/replac e ur sphincter	J8	0386	Level II Prosthetic Urological Procedures	70%	35%
54400	Insert semi-rigid prosthesis	J8	0385	Level I Prosthetic Urological Procedures	61%	30%

CPT Code	Short Descriptor	Proposed CY 2012 ASC Payment Indicator	Proposed CY 2012 OPPS APC	OPPS APC Title	Proposed CY 2012 OPPS Full APC Offset Percentage	Proposed CY 2012 OPPS Partial APC Offset Percentage
54401	Insert self-contd prosthesis	J8	0386	Level II Prosthetic Urological Procedures	70%	35%
54405	Insert multi-comp penis pros	J8	0386	Level II Prosthetic Urological Procedures	70%	35%
54410	Remove/replace penis prosth	J8	0386	Level II Prosthetic Urological Procedures	70%	35%
54416	Remv/repl penis contain pros	J8	0386	Level II Prosthetic Urological Procedures	70%	35%
61885	Insrt/redo neurostim 1 array	J8	0039	Level I Implantation of Neurostimulator Generator	85%	43%
61886	Implant neurostim arrays	J8	0315	Level II Implantation of Neurostimulator Generator	88%	44%
62361	Implant spine infusion pump	J8	0227	Implantation of Drug Infusion Device	81%	40%
62362	Implant spine infusion pump	J8	0227	Implantation of Drug Infusion Device	81%	40%
63650	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/ Replacement of Neurostimulator Electrodes	55%	27%
63655	Implant neuroelectrodes	J8	0061	Level II Implantation/Revision/ Replacement of Neurostimulator Electrodes	64%	32%
63663	Revise spine eltrd perq aray	J8	0040	Level I Implantation/Revision/ Replacement of Neurostimulator Electrodes	55%	27%

CPT Code	Short Descriptor	Proposed CY 2012 ASC Payment Indicator	Proposed CY 2012 OPPS APC	OPPS APC Title	Proposed CY 2012 OPPS Full APC Offset Percentage	Proposed CY 2012 OPPS Partial APC Offset Percentage
63664	Revise spine eltrd plate	J8	0040	Level I Implantation/Revision/ Replacement of Neurostimulator Electrodes	55%	27%
63685	Insrt/redo spine n generator	J8	0039	Level I Implantation of Neurostimulator Generator	85%	43%
64553	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/ Replacement of Neurostimulator Electrodes	55%	27%
64555	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/ Replacement of Neurostimulator Electrodes	55%	27%
64560	Implant neuroelectrodes	J8	0040	Level I Implantation/Revision/ Replacement of Neurostimulator Electrodes	55%	27%
64561	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes	55%	27%
64565	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes	55%	27%
64568	Implant neuroelectrodes	J8	0318	Implantation of Neurostimulator Electrodes, Cranial Nerve	86%	43%

CPT Code	Short Descriptor	Proposed CY 2012 ASC Payment Indicator	Proposed CY 2012 OPPS APC	OPPS APC Title	Proposed CY 2012 OPPS Full APC Offset Percentage	Proposed CY 2012 OPPS Partial APC Offset Percentage
64575	Implant neuroelectrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	64%	32%
64577	Implant neuroelectrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	64%	32%
64580	Implant neuroelectrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	64%	32%
64581	Implant neuroelectrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	64%	32%
64590	Insrt/redo pn/gastr stimul	J8	0039	Level I Implantation of Neurostimulator Generator	85%	43%
69714	Implant temple bone w/stimul	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%	30%
69715	Temple bne implnt w/stimulat	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%	30%
69717	Temple bone implant revision	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%	30%
69718	Revise temple bone implant	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	60%	30%
69930	Implant cochlear device	J8	0259	Level VII ENT Procedures	83%	41%

TABLE 50.—PROPOSED DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2012 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT

CY 2011 Device HCPCS Code	CY 2011 Short Descriptor
C1721	AICD, dual chamber
C1722	AICD, single chamber
C1762	Conn tiss, human(inc fascia)
C1763	Conn tiss, non-human
C1764	Event recorder, cardiac
C1767	Generator, neurostim, imp
C1771	Rep dev, urinary, w/sling
C1772	Infusion pump, programmable
C1776	Joint device (implantable)
C1778	Lead, neurostimulator
C1779	Lead, pmkr, transvenous VDD
C1781	Mesh (implantable)
C1785	Pmkr, dual, rate-resp
C1786	Pmkr, single, rate-resp
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
C1897	Lead, neurostim, test kit
C1898	Lead, pmkr, other than trans
C1900	Lead coronary venous
C2618	Probe, cryoablation
C2619	Pmkr, dual, non rate-resp
C2620	Pmkr, single, non rate-resp
C2621	Pmkr, other than sing/dual
C2622	Prosthesis, penile, non-inf
C2626	Infusion pump, non-prog, temp
C2631	Rep dev, urinary, w/o sling
L8614	Cochlear device/system
L8680	Implt neurostim elctr each
L8685	Implt nrostm pls gen sng rec

CY 2011 Device HCPCS Code	CY 2011 Short Descriptor
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

We invite public comment on these proposals.

d. Waiver of Coinsurance and Deductible for Certain Preventive Services

Section 1833(a)(1) and (b)(1) of the Act waives 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 and 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, please see the CY 2011 OPPS/ASC final rule with comment period (75 FR 72047 through 72049). We are proposing no changes to our policies or the list of services. We have identified these services with a double asterisk in Addenda AA and BB to this proposed rule.

e. Proposed 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." As detailed in section II.A.2.e.(6) of this proposed rule, we are proposing to create an OPPS composite APC (Composite APC 8009 (Cardiac Resynchronization Therapy - ICD Pulse Generator and Leads)) which would be used when CPT code 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (including upgrade to dual chamber system)) and CPT code 33249 (Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator) are performed on the same date of service. We also are proposing to cap the OPPS payment rate for composite APC 8009 at the most comparable Medicare severity diagnosis-related group (MS-DRG) payment rate established under the IPPS that would be provided to acute care hospitals for providing CRT-D services to hospital inpatients. In other words, we are proposing to pay APC 8009 at the lesser of the APC 8009 median cost or the IPPS standardized payment rate for MS-DRG 227 (Cardiac Defibrillator Implant without Cardiac Catheterization without Major Complication or Comorbidity). This would ensure appropriate and equitable payment to hospitals and that we do not create an inappropriate payment incentive to provide CRT-D services in one setting of care over another by

paying more for CRT-D in the outpatient setting compared to the inpatient setting. Specifically, for the CY 2012 OPPS, we are proposing that if the APC 8009 median cost that we will calculate for the CY 2012 OPPS/ASC final rule with comment period exceeds the FY 2012 IPPS standardized payment rate for MS-DRG 227, we would establish the OPPS payment amount at the FY 2012 IPPS standardized payment amount for MS-DRG 227 (currently estimated at $26,365).

Because CPT code 33225 and CPT code 33249 are on the list of ASC covered surgical procedures, we are proposing to establish an ASC payment rate that is based on the OPPS payment rate applicable to APC 8009 when these procedures are performed on the same date of service in an ASC. Again, we do not want to create an inappropriate payment incentive to provide CRT-D services in one setting of care over another by paying more for CRT-D in ASCs compared to the hospital outpatient setting. Because CPT codes 33225 and 33249 are on the proposed list of device-intensive procedures for CY 2012, we are proposing to apply the usual device-intensive methodology based on the OPPS payment rate applicable to APC 8009 (which is the lesser of the APC 8009 median cost that we will calculate for the CY 2012 OPPS/ASC final rule with comment period or the FY 2012 IPPS standardized payment rate for MS-DRG 227). 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 33225 and 33249 are performed on the same date of service to receive the appropriate CRT-D composite payment.

In a related issue, as detailed in section III.D.6 of this proposed rule, CPT codes 33225 and 33249 are the only procedures proposed for inclusion in APC 0108. We are

proposing that these codes would be paid under APC 0108 only if they are not reported on the same date of service. Further, we are proposing to pay the OPPS payment rate for services that are assigned to APC 0108 at the lesser of the APC 0108 median cost or the IPPS standardized payment rate for MS-DRG 227. For ASC payment in CY 2012, we are proposing to apply the device-intensive methodology to calculate payment for CPT codes 33225 and 33249 based on the OPPS payment rate applicable to APC 0108 (which is the lesser of the APC 0108 median cost that we will calculate for the CY 2012 OPPS/ASC final rule with comment period or the FY 2012 IPPS standardized payment rate for MS-DRG 227).

We invite public comment on these proposals.

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 under the OPPS. 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 non-facility 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 OPPS relative payment weights rather than the MPFS non-facility RE RVU amount, regardless of which is lower. This modification to the ASC payment methodology for ancillary services was finalized in response to a CY 2011 OPPS/ASC proposed rule comment that suggested it is inappropriate to use the MPFS-based payment methodology for nuclear medicine procedures because the associated diagnostic radiopharmaceutical, though packaged under the ASC payment system, is separately paid under the MFPS. We set the payment indicator to "Z2" for 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 non-facility PE RVU-based amount to ensure that the ASC will be compensated for the cost associated with the diagnostic radiopharmaceuticals.

ASC payment policy for brachytherapy sources generally mirrors the payment policy under the OPPS. We finalized our policy in the CY 2008 OPPS/ASC final rule

with comment period (72 FR 42499) to pay for brachytherapy sources applied in ASCs at the same prospective rates that were adopted under the OPPS or, if OPPS rates were unavailable, at contractor-priced rates. After publication of that rule, section 106 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110-173) mandated that, for the period January 1, 2008 through June 30, 2008, brachytherapy sources be paid under the OPPS at charges adjusted to cost. Therefore, consistent with our final overall ASC payment policy, we paid ASCs at contractor-priced rates for brachytherapy sources provided in ASCs during that period of time. Beginning July 1, 2008, brachytherapy sources applied in ASCs were to be paid at the same prospectively set rates that were finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 67165 through 67188). Immediately prior to the publication of the CY 2009 OPPS/ASC proposed rule, section 142 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275) amended section 1833(t)(16)(C) of the Act (as amended by section 106 of the Medicare, Medicaid, and SCHIP Extension Act of 2007, Pub. L. 110-173) to extend the requirement that brachytherapy sources be paid under the OPPS at charges adjusted to cost through December 31, 2009. Therefore, consistent with final ASC payment policy, ASCs continued to be paid at contractor-priced rates for brachytherapy sources provided integral to ASC covered surgical procedures during that period of time.

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 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 only device that is eligible for pass-through payment in the OPPS is described by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (Implantable). Payment for HCPCS code C1749 under the ASC payment system is contractor priced.

b. Proposed Payment for Covered Ancillary Services for CY 2012

For CY 2012, 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 2012 OPPS and ASC payment rates. The proposed CY 2012 OPPS payment methodologies for separately payable drugs and biologicals and brachytherapy sources are discussed in section II.A. and section V.B. of this proposed rule, respectively, and we are proposing to set the CY 2012 ASC payment rates for those services equal to the proposed CY 2012 OPPS rates.

Consistent with established ASC payment policy (72 FR 42497), the proposed CY 2012 payment for separately payable covered radiology services is based on a comparison of the CY 2012 proposed MPFS non-facility PE RVU-based amounts (we refer readers to the CY 2012 MPFS proposed rule) and the proposed CY 2012 ASC payment rates calculated according to the ASC standard ratesetting methodology and

then set at the lower of the two amounts. Alternatively, payment for a radiology service may be packaged into the payment for the ASC covered surgical procedure if the radiology service is 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 non-facility 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 non-facility 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 non-facility 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 2012. 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 MFPS), we are proposing 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. We have made proposed changes to the regulation text at §416.171(d) to reflect this proposal.

Most covered ancillary services and their proposed payment indicators are listed in Addendum BB to this proposed rule (which is referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site).

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 and the deadline for submission of public comments regarding those requests.

In accordance with section 141(b)(3) of Pub. L. 103-432 and our regulations at §416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests.

- In the 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 three major criteria set out at 42 CFR 416.195:

- Criterion 1 (42 CFR 416.195(a)(1),(2)): The IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs must have been approved by the FDA for use in labeling and advertising;
- Criterion 2 (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
- Criterion 3 (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 superior 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 entitled *CMS Approved NTIOLs*, with the associated qualifying IOL models, posted on the CMS Web site at: http://www.cms.gov/ASCPayment/08_NTIOLs.asp#TopOfPage.

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/ASCPayment/08_NTIOLs.asp#TopOfPage. 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 with comment period 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 2012 and Deadline for Public Comments

We received four requests for review to establish a new NTIOL class for CY 2012 by the March 5, 2011 due date. Summaries of these requests follow.

a. *Requestor/Manufacturer:* Alcon Laboratories, Inc. (Alcon)

Lens Model Numbers: Acrysof Natural IQ and Acrysof Natural IOLs, Models SN60WF (aspheric optic, single piece), SN60AT (spherical optic, single piece), MN60MA (spherical optic, multi-piece), MN60AC (spherical optic, multi-piece).

Summary of the Request: Alcon submitted a request for CMS to determine that its Acrysof Natural IOLs meet the criteria for recognition as NTIOLs and to concurrently establish a new class of NTIOLs for "blue-light-filtering IOLs that improve driving safety under glare conditions," with these IOLs as members of the class. We reviewed a similar

request by Alcon during the CY 2011 NTIOL application cycle (75 FR 72052). As part of its CY 2012 request, Alcon submitted descriptive information about the candidate IOLs as outlined in the guidance document that is available on the CMS Web site for the establishment of a new class of NTIOLs, as well as information regarding approval of the candidate IOLs by the FDA. This information included the approved labeling for the candidate IOLs, a summary of the IOLs' safety and effectiveness, a copy of the FDA's approval notifications, and instructions for their use.

In its CY 2012 request, Alcon asserts that its request is based on studies demonstrating that the Acrysof Natural IOLs with a blue-light-filtering chromophore filter light in a manner that approximates the human crystalline lens in the 400-475 nm blue light wavelength range to reduce glare that impairs the ability of the eye to differentiate objects from the background. Alcon further states that glare reduction can help beneficiaries avoid hazards that can be caused by glare. Alcon also states that at present there are no active or expired NTIOL classes that describe IOLs similar to the Acrysof Natural IOLs.

We established in the CY 2007 OPPS/ASC final rule with comment period that when reviewing a request for recognition of an IOL as an NTIOL and a concurrent request to establish a new class of NTIOLs, we would base our determination on consideration of the three major criteria at 42 CFR 416.195(a) and listed above. We have begun our review of Alcon's request to recognize its Acrysof Natural IOLs as NTIOLs and concurrently establish a new class of NTIOLs. We are soliciting public comment on these candidate IOLs with respect to the established three major NTIOL criteria.

First, for an IOL to be recognized as an NTIOL we require that the IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs must have been approved by the FDA for use in labeling and advertising. The approved labels for the Alcon IOLs all state the following: "Alcon's proprietary blue light filtering chromophore filters light in a manner that approximates the human crystalline lens in the 400-475 nm blue light wavelength range." The FDA labels for these IOLs do not otherwise reference specific clinical benefits of blue light filtering. We are interested in public comments on the clinical relevance of blue light filtering in an IOL. Specifically, we are interested in public comments regarding the assertion that the specific blue light filtering properties associated with the candidate IOLs improve driving safety via the reduction of glare disability.

Second, according to 42 CFR 416.195(a)(3), we also require that the candidate IOL not be described by an active or expired NTIOL class; that is, it does not share the predominant, class-defining characteristic associated with improved clinical outcomes with designated members of an active or expired NTIOL class. In the CY 2007 OPPS final rule, in response to a comment we explained our interpretation of 42 CFR 416.195(a)(3) as follows:

"[R]evised §416.195(a)(3) does not preclude from consideration as a member of a new class of NTIOL a lens that includes as one of its characteristics a class-defining characteristic associated with members of an active or expired class. Only if that shared characteristic were the predominant characteristic of the lens would it be precluded from

approval as a new class of NTIOL. However, if the lens featured other characteristics, one or more of which predominated, that were clearly tied with improved clinical outcomes, the lens would not be disqualified from consideration as an NTIOL just because it also shared a characteristic with members of an active or expired class." (71 FR 68178).

As noted above, 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: Multifocal and Reduction in Preexisting Astigmatism classes, both of which were created in 2000 and expired in 2005, and the Reduced Spherical Aberration class, which was created in 2006 and expired on February 26, 2011. As mentioned above, a table entitled *CMS Approved NTIOLs*, with the associated qualifying IOL models, is posted on the CMS Web site at: http://www.cms.gov/ASCPayment/08_NTIOLs.asp#TopOfPage. The class-defining characteristic specific to IOLs that are members of these three expired classes is evident in the name assigned to the class. For example, IOLs recognized as members of the reduced spherical aberration class are characterized by their aspheric design that results in reduced spherical aberration. Based on the information in the table entitled *CMS Approved NTIOLs*, a candidate IOL's predominant characteristic may not be described by any of the three expired NTIOL classes.

In the case of one of four of Alcon's candidate IOLs, the Acrysof Natural IQ Aspheric IOL model SN60WF, it is a member of the expired reduced spherical aberration NTIOL class (75 FR 72052). For the purposes of satisfying §416.195(a)(3), CMS must

be able to determine which lens characteristic is predominant for Alcon's model SN60WF, asphericity (resulting in reduced spherical aberration) or blue-light filtering. If the predominant characteristic is asphericity, then the model SN60WF IOL would be disqualified under §416.195(a)(3). This determination is particularly relevant given that the clinical benefit attributed to both of these lens characteristics is improved night driving. To our knowledge, Alcon has not compared the IOL model SN60WF (a blue-light filtering aspheric IOL) to a non-blue-light filtering aspheric IOL to determine if there are any night driving benefits attributable to the blue-light filtering characteristic in addition to the improved night driving attributable to the aspheric optic. Such information would assist us in evaluating whether blue-light filtering predominates or is subordinate to the IOL's asphericity. We are soliciting public comments on whether blue-light filtering can be considered the predominant IOL characteristic for the model SN60WF IOL. We also welcome public comments that address whether blue light-filtering and the associated clinical benefits of the other three of Alcon's candidate IOLs (that is, SN60AT, MN60MA, MN60AC) are described by any of the expired NTIOL classes.

Third, our NTIOL evaluation criteria also require that an applicant submit evidence demonstrating that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison to currently available IOLs. We note that in the CY 2007 OPPS/ASC final rule with comment period, we sought comments as to what constitutes currently available IOLs for purposes of such comparisons, and we received several comments in response to our solicitation (71 FR 68178). We agreed with

commenters that we should remain flexible with respect to our view of "currently available lenses" for purposes of reviewing NTIOL requests, in order to allow for consideration of technological advances in lenses over time. This means that we do not expect that "currently available lenses" would remain static over time and always necessarily default to the classic spherical monofocal IOL for every candidate NTIOL class. Therefore, we believe that "currently available lenses" for purposes of reviewing NTIOL requests should depend upon the class-defining characteristic and the associated purported improved clinical outcome of the candidate NTIOL. For example, for some candidate NTIOLs the most appropriate comparison IOL would be a spherical monofocal IOL, while other candidate NTIOLs may be more appropriately compared to aspheric IOLs.

For purposes of reviewing Alcon's request to establish a new NTIOL class for CY 2012, we are proposing that aspheric monofocal IOLs represent the currently available IOLs against which the candidate NTIOLs should be compared in order to establish a new class. According to publicly available data from Market Scope, LLC, IOLs with aspheric optics accounted for over 86 percent of the IOLs implanted in the United States during 2010. In addition, data submitted by Alcon shows that the overwhelming majority of IOLs sold by Alcon have aspheric optics. Furthermore, the aspheric design that results in reduced spherical aberration was the class defining characteristic for IOLs recognized as members of the expired reduced spherical aberration NTIOL class. The primary clinical outcome associated with reduced spherical aberration (for purposes of establishing it as an NTIOL class) was safer night driving

(71 FR 4588). Alcon asserts that what makes its candidate IOLs superior to other currently available IOLs is improved driving safety under glare conditions. Glare conditions during driving primarily occur at night due to headlights from oncoming cars. The primary improved clinical outcome from reduced spherical aberration IOLs (an expired NTIOL class) was safer night driving and the purported primary improved clinical outcome from Alcon's blue light-filtering IOLs is also safer night driving. Therefore, the most relevant type of currently available IOLs against which the Alcon blue filtering IOLs should be compared is aspheric IOLs. In particular, the relevant comparison would be the performance of an aspheric blue-light filtering IOL versus an aspheric non-blue light filtering IOL. This comparison would test the hypothesis of whether blue-light filtering improved night driving in comparison to aspheric optics, which has been shown to improve night driving. We seek public comment on our view of "currently available lenses" for the purposes of evaluating Alcon's candidate IOLs against currently available IOLs.

We are reviewing the evidence submitted with Alcon's CY 2012 request. Although Alcon submitted various types of literature in support of its application, it relies primarily on two studies in support of its hypothesis that blue light filtering IOLs improve driving safety under glare conditions as compared to currently available IOLs. The first of these two submitted articles is: Hammond B, et al. Contralateral comparison of blue-filtering intraocular lenses: glare disability, heterochromic contrast, and photostress recovery, *Clinical Ophthalmology*. 2010;4:1465-1473 (Hammond 2010). This article compared visual performance (as measured by glare disability, heterochromic contrast

threshold, and photostress recovery time) in eyes with blue-light-filtering IOLs versus contralateral eyes with IOLs that do not filter blue light. The second article, which Alcon describes as its "pivotal study," is: Gray R, et al. Reduced effect of glare disability on driving performance in patients with blue light-filtering intraocular lenses, *J Cataract Refract Surg.* 2011;37:38-44. This study compared the effects of glare on driving performance using a driving simulator in patients who had implantation of a blue light-filtering acrylic IOL and those who had implantation of an acrylic IOL with no blue-light filter. Overall, the evidence submitted provides us with important information that is critical to our review of this request. However, in making our decision as to whether to establish a new class of NTIOL based on the primary characteristic of the candidate lenses, we are also interested in what other information the public can contribute related to the asserted benefits of the blue light filtering IOL. Specifically, we are seeking public comment and relevant data on the following:

- Are there other peer-reviewed studies or other information that would support or disprove the claims of clinical benefit made by Alcon?
- How do you interpret the results of the Hammond 2010 study, given that the blue light-filtering group included patients with spherical blue light filtering IOLs and patients with aspheric blue light filtering IOLs?
- Does the Maxwellian optical system that was employed in the Hammond 2010 study mitigate the impact of the aspheric optics of some of the study subjects in the blue light-filtering group?

- Is the sample size used in both studies sufficient to conclude that a blue light filtering IOL would reduce glare disability and improve driving safety in the Medicare population?

- What kind of study design would be appropriate to prove the claim of significant clinical benefit due to glare reduction on which the new class would be based?

- Are the submitted data enough to prove that the blue filtering optic is responsible for reduction in glare disability as asserted by applicant?

- Did these studies use an appropriate comparator IOL?

Furthermore, in accordance with our established NTIOL review process, we are also seeking public comments on all of the review criteria for establishing a new NTIOL class that would be based on the ability of the Acrysof Natural IOLs to filter blue light and subsequently help beneficiaries avoid hazards that can be caused by glare while driving. We will give all comments full consideration regarding Alcon's candidate IOLs.

b. *Requestor/Manufacturer:* Bausch & Lomb, Inc. (B&L)

Lens Model Numbers: Xact Foldable Hydrophobic Acrylic Ultraviolet Light-Absorbing Posterior Chamber Intraocular Lenses, Models X-60 and X-70 (Xact IOLs).

Summary of the Request: B&L submitted a request for CMS to determine that its Xact IOLs meet the criteria for recognition as NTIOLs and to concurrently establish a new class of NTIOLs for "glistening-free" IOLs. Glistenings are fluid-filled microvacuoles that can form within an IOL optic when the IOL is in an aqueous environment. According to B&L, "glistenings have been associated with decreased

contrast sensitivity, increased glare, decreased visual acuity, and impaired fundus visualization." B&L further states that "in some cases, this has lead to IOL explantation and exchange, which carries significant risks that increase the longer the IOL is implanted." As part of its request, B&L submitted descriptive information about the candidate IOLs as outlined in the guidance document that is available on the CMS Web site for the establishment of a new class of NTIOLs, as well as information regarding approval of the candidate IOL by the FDA. This information included draft FDA labeling for the Xact IOLs. Final FDA labeling is currently pending.

In its CY 2012 request, B&L asserts that because the Xact IOLs are glistening-free, they eliminate the decreased contrast sensitivity, increased glare, decreased visual acuity, and impaired fundus visualization associated with glistenings, and may likewise decrease the need for explantations associated with those conditions. B&L also concludes that use of a glistening-free IOL results in measurable, clinically meaningful, improved outcomes in comparison with currently available IOLs. B&L also states that the glistening-free characteristic is not described by a previously-approved NTIOL class.

As with the other CY 2012 NTIOL applications discussed in this proposed rule, we will base our determination of the B&L application on consideration of the three major evaluation criteria that are discussed above. We have begun our review of B&L's request to recognize its Xact IOLs as NTIOLs and concurrently establish a new class of NTIOLs. We are soliciting public comment on these candidate IOLs with respect to the established NTIOL criteria as discussed above.

First, for an IOL to be recognized as an NTIOL we require that the IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs must have been approved by the FDA for use in labeling and advertising. The submitted FDA label for the Xact IOLs states the following:

"In the IDE [investigational device exemption] clinical trial, 'glistenings' were observed in some cases. Glistenings, known to sometimes occur in some other hydrophobic acrylic IOLs, are microscopic vacuoles within the optic of the IOL that are visible through the slit lamp as multiple small refractile specks. *Analysis of the clinical data confirmed no effect of glistenings on visual outcomes*." [Emphasis added.]

"Testing established that glistenings were eliminated by a change in the IOL hydration solution from 10.0% saline to 0.9% saline. This was confirmed in an additional clinical trial conducted outside of the United States. In this study, 172 eyes of 142 patients were examined at least once between 1 and 6 months, and 123 eyes of 101 patients were examined at least once between 6 months and 2 years. No glistenings were observed at any time."

The FDA label for the XACT IOLs does not otherwise reference specific clinical benefits of the glistening-free property. In fact, the italicized sentence in the above-quoted language on the IDE study from the FDA label states that an "[a]nalysis of the clinical data confirmed no effect of glistenings on visual outcomes." We are interested in public comments on the clinical relevance of glistenings in IOLs, and the incidence of glistenings severe enough to cause measurable visual symptoms in recently

pseudophakic Medicare beneficiaries. In addition, we are interested in public comments regarding the assertion by B&L that the glistening-free property associated with the Xact IOLs would eliminate the decreased contrast sensitivity, increased glare, decreased visual acuity, and impaired fundus visualization associated with glistenings, and may likewise decrease the need for explantations associated with those conditions.

Second, we also require that the candidate IOL not be described by an active or expired NTIOL class; that is, it does not share the predominant, class-defining characteristic associated with improved clinical outcomes with designated members of an active or expired NTIOL class. We refer readers to the discussion above for more information on the three expired NTIOL classes. The proposed class-defining characteristic and associated clinical benefits of the Xact IOLs, specifically the glistening-free property, cannot be similar to the class-defining characteristics and associated benefits of the three expired NTIOL classes. We welcome public comments that address whether the proposed class-defining characteristic and associated clinical benefits of the candidate B&L IOLs are described by the expired NTIOL classes.

Third, our NTIOL evaluation criteria also require that an applicant submit evidence demonstrating that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison to currently available IOLs. As discussed above, we remain flexible with respect to our view of "currently available lenses" for purposes of reviewing NTIOL requests, in order to allow for consideration of technological advances in lenses over time. We also believe that "currently available lenses" for purposes of reviewing NTIOL requests should depend upon the class-defining characteristic and the

associated purported improved clinical outcome of the candidate NTIOL class. For purposes of reviewing B&L's request to establish a new NTIOL class for CY 2012, we believe that the full spectrum of currently available IOL materials should be represented in the comparator IOLs, but that the particular design of the optic (for example, aspheric versus spherical) is less critical to evaluating the benefits of glistening-free IOLs as glistenings are related more to the IOL optic material than to the optical surface characteristics of the IOL. We are seeking public comment on our view of "currently available lenses" for the purposes of evaluating B&L's candidate IOLs against currently available IOLs.

We are reviewing the evidence submitted with B&L's CY 2012 request. B&L submitted a variety of articles including studies and case reports focused on IOLs with glistenings. It is apparent from these articles that glistenings are a real phenomenon and that glistenings are primarily associated with acrylic hydrophobic IOLs, but they can also occur to some degree in IOLs of other material types. However, there are several significant questions with respect to glistenings, and we solicit public comment on these questions as follows:

- Is there a particular IOL material type that is more likely to result in symptomatic glistenings relative to other material types?
- What is the clinical significance (from the patient's perspective) of glistenings? More specifically, what evidence is available to demonstrate that glistenings cause any of the following:
  - Decreased contrast sensitivity;

- Increased glare disability;
- Decreased visual acuity;
- Impaired fundus visualization;
- Symptoms resulting in IOL explantations.

● What is the incidence of glistenings in IOLs currently available in the United States?

● If a certain level of severity of glistenings is required before they cause symptoms, what is the incidence of glistenings of this severity level in IOLs currently available in the United States?

c. *Requestor/Manufacturer*: Hoya Surgical Optics, Inc. (Hoya)

Lens Model Numbers: iSert IOL System, Model PY-60R

Summary of the Request: Hoya submitted a request for CMS to determine that its iSert IOL System satisfies the criteria for recognition as an NTIOL and to concurrently establish a new class of NTIOLs for "aseptically integrated IOL and injector systems." The iSert IOL System is an IOL preloaded in a plastic, sterile, disposable injection system. According to Hoya, the iSert System provides a lens injector with an integrated IOL inside it within a single, sterile package for delivery to the operating field. According to Hoya, the iSert System has the following benefits, in that compared to other IOLs it:

● Eliminates the risk of complications associated with improper processing of reusable forceps or injectors used for all other foldable IOLs;

- Accelerates postoperative recovery through decreased risk of ocular damage due to complications associated with improper processing of reusable forceps or injectors used for other foldable IOLs;

- Provides a clinical advantage compared to existing IOLs by allowing the IOL to be placed in the eye without contacting external ocular tissues or reusable injection instruments; and

- Improves overall safety of cataract/IOL surgery by reducing the number of reusable instruments that must be properly cleaned and sterilized between cases.

As part of its request, Hoya submitted descriptive information about the iSert System as outlined in the guidance document described above that is available on the CMS Web site for the establishment of a new class of NTIOLs, as well as information regarding approval of the candidate IOL by the FDA. This information included the FDA labeling, the FDA letter of approval, and the summary of safety and effectiveness for the iSert System.

As with the other CY 2012 NTIOL requests, we will base our determination of the Hoya request on consideration of the three major criteria that are discussed above. We have begun our review of Hoya's request to recognize its iSert System as an NTIOL and concurrently establish a new class of NTIOLs. We are soliciting public comment on this candidate IOL with respect to the established NTIOL criteria.

First, for an IOL to be recognized as an NTIOL we require that the IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available

IOLs must have been approved by the FDA for use in labeling and advertising. The FDA label for the iSert System states the following under the heading DEVICE DESCRIPTION:

"The Hoya iSert™ Model PY-60R Intraocular Lens (IOL) is an ultraviolet absorbing posterior chamber intraocular lens designed to be implanted posterior to the iris where the lens will replace the optical function of the natural crystalline lens. However, accommodation will not be replaced. PY-60R is loaded in a disposable injector consists [sic] of Case, Tip, Body, Slider, Rod, Plunger, and Screw."

The FDA label for the iSert System states the following under the heading INDICATIONS:

"The Hoya iSert™ Model PY-60R Intraocular Lens is indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed."

The FDA label for the iSert System does not otherwise reference claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs. Section 416.195(a)(2) requires that "[c]laims 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." The FDA label for the iSert System lacks any such claims. The only statement in the above-quoted language from the FDA label that is any different from the typical device description and indications for a standard spherical monofocal IOL is the statement that the "PY-60R is loaded in a disposable injector consists [sic] of Case, Tip,

Body, Slider, Rod, Plunger, and Screw." However, this statement merely describes the IOL as loaded in a disposable injector. It does not appear to describe a benefit or characteristic of the IOL itself. Therefore, it would appear that the Hoya iSert System PY-60R IOL would not satisfy the requirements of 42 CFR 416.195(a)(2). However, we are soliciting public comments on this matter and will give all comments full consideration regarding Hoya's candidate IOL.

d. *Requestor/Manufacturer*: Lenstec, Inc. (Lenstec)

Lens Model Numbers: Softec HD PS

Summary of the Request: Lenstec submitted a request for CMS to determine that its Softec HD PS meets the criteria for recognition as an NTIOL and to concurrently establish a new class of NTIOLs that result in a "reduction of postoperative residual refractive error." According to Lenstec, the Softec HD PS IOL achieves a "reduction of postoperative residual refractive error" by its availability in 0.25 diopter (D) increments with a tolerance of ±0.11 D, while all other current monofocal IOLs are available in only 0.50 D increments with tolerances allowed up to ±0.40 D. According to Lenstec, patients implanted with the Softec HD PS are much more likely to be closer to the intended refractive outcome than those implanted with IOLs available only in 0.50 D increments. This greater refractive accuracy of the Softec HD PS is due to the chosen IOL power likely being closer to the calculated (desired) IOL power and because the tighter tolerance of the 0.25 D increment IOL results in the actual power of the implanted IOL to be closer to the power that the surgeon expects to implant into the patient. Lenstec also asserts that because the 0.25 D increment IOL provides greater IOL power accuracy,

patients have less postoperative residual refractive error and hence reduced postoperative blur. As part of its request, Lenstec submitted descriptive information about the candidate IOLs as outlined in the guidance document that is available on the CMS Web site for the establishment of a new class of NTIOLs, as well as information regarding approval of the candidate IOL by the FDA. This information included the FDA labeling, FDA approval letter, and summary of safety and effectiveness for the Softec HD PS IOL.

As with the other three CY 2012 NTIOL applications discussed above, we will base our determination of the Lenstec application on consideration of the three major evaluation criteria that are discussed above. We have begun our review of Lenstec's request to recognize its Softec HD PS IOL as an NTIOL and concurrently establish a new class of NTIOLs. We are soliciting public comment on this candidate IOL with respect to the established NTIOL criteria as discussed above.

First, for an IOL to be recognized as an NTIOL we require that the IOL must have been approved by the FDA and claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs must have been approved by the FDA for use in labeling and advertising. The submitted FDA label for the Softec HD PS IOL states under the heading DEVICE DESCRIPTION that "[t]he [LENSTEC Softec HD PS] IOL is offered in quarter diopter increments from 15.0 to 25.0." The FDA label for the Softec HD PS IOL does not otherwise reference claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs. We are interested in public comments on whether an IOL being offered in quarter diopter

increments can be considered a "lens characteristic with established clinical relevance in comparison with currently available IOLs," as required by 42 CFR 416.195(a)(2), or whether IOL availability quarter diopter increments is more appropriately considered not a lens characteristic per se, but instead just a manufacturer specification. We are also interested in public comments on the clinical relevance of an IOL being available in quarter diopter increments.

Second, as required by 42 CFR 416.195(a)(3), the candidate IOL must not be described by an active or expired NTIOL class; that is, it does not share the predominant, class-defining characteristic associated with improved clinical outcomes with designated members of an active or expired NTIOL class. Refer to the discussion above for more information on the three expired NTIOL classes. Lenstec states the following in its application:

"The Softec HD IOL, the parent to the Softec HD PS, was first approved for marketing in the United States on April 17, 2010 and on March 15, 2006 in the "Outside the US" (OUS) environment. This IOL is included in the just-closed "Reduced Spherical Aberration" NTIOL category. The Softec HD PS was approved for marketing by the FDA on February 2, 2011. It is currently pending approval for OUS marketing. Both IOLs are single piece, hydrophilic acrylic, aspheric, monofocal IOLs. The difference between the two is that the Softec HD has previously been available in whole, 0.50 and 0.25 diopter increments, based on dioptric power. The Softec HD PS is offered only in the dioptric range of 15.0 D to 25.0 D, in 0.25 diopter increments (each of which is manufactured to a tolerance of ±0.11D)."

Based on this statement by Lenstec, the Softec HD PS is the same lens as the Softec HD, but the Softec HD PS is available only in 0.25 D increments for a specific power range instead of being available (as is the Softec HD) in 1.0, 0.5, and 0.25 D increments. The Softec HD was included in the expired Reduced Spherical Aberration NTIOL class, and both of these IOLs share the asphericity characteristic that defines the expired Reduced Spherical Aberration NTIOL class. It appears to us that the predominant characteristic of the Softec HD PS is asphericity, as it affects the optical characteristics of the lens. Although the availability of the Softec HD PS in 0.25 D increments allows more IOL power choices for the surgeon, it does not appear to affect the functionality of the IOL. We request comments regarding what characteristic of the Softec HD PS is predominant, asphericity or availability of the IOL in 0.25 D increments.

Third, our NTIOL evaluation criteria also require that an applicant submit evidence demonstrating that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison to currently available IOLs. As discussed above, we remain flexible with respect to our view of "currently available lenses" for purposes of reviewing NTIOL requests, in order to allow for consideration of technological advances in lenses over time. We also believe that "currently available lenses" for purposes of reviewing NTIOL requests should depend upon the class-defining characteristic and the associated purported improved clinical outcome of the candidate NTIOL class. For purposes of reviewing Lenstec's request to establish a new NTIOL class for CY 2012, we believe that the full spectrum of currently available monofocal IOLs should be represented in the comparator IOLs. Lenstec asserts that what makes its candidate IOL

superior to other currently available IOLs is improved IOL power accuracy as compared to IOLs available in 0.50 D increments, and because the Softec HD PS provides greater IOL power accuracy patients implanted with it have less postoperative residual refractive error and hence reduced post-operative blur.

We are reviewing the evidence submitted with Lenstec's CY 2012 request. Lenstec submitted information and reviewed the literature on IOL optics related to the Softec HD PS. Lenstec relies primarily on one study that is the subject of an article that is currently in press and another unpublished study to support its hypothesis that the Softec HD PS IOL results in less postoperative refractive error than other IOLs. The first study submitted by Lenstec was the study that it conducted under an IDE for FDA approval of the Softec HD PS IOL. This study is being published in the journal, Contact Lens and Anterior Eye (Brown DC, Gills JP 3rd, et al. Prospective multicenter trial assessing effectiveness, refractive predictability and safety of a new aberration free, bi-aspheric intraocular lens**.** Cont Lens Anterior Eye. 2011 May 24. [Epub ahead of print]), and is available on the Internet at http://www.sciencedirect.com/science/article/pii/S1367048411000634. Refractive accuracy was not a planned outcome variable in this study. There was no control group in this study that would have allowed the investigators to control for all of the variables that impact post-cataract surgery refractive outcome and/or isolate the effect of the availability of the Softec HD PS IOL in quarter diopter increments. Lenstec compared the postoperative refractive errors of these study subjects to the results from an unrelated study performed outside of the United States (using IOLs that were available only in 0.50

D increments) and concluded based on this comparison that implantation of the Softec HD PS IOL, which is available in quarter diopter increments, results in superior refractive outcomes as compared to other IOLs.

The second study is a retrospective study of cataract cases with aspheric monofocal IOL implantation between 2009 and 2011. Of the 118 eligible eyes, 67 were implanted with IOLs available in 0.25 D increments and labeled with a manufacturing tolerance of ±0.11D (the labeled group) and 51 were implanted with IOLs available in 0.50 D increments without a labeled manufacturing tolerance (the unlabeled group). Postoperative outcomes were assessed, and prediction error was calculated and compared between groups. Mean error of prediction was -0.03 (±0.35) D for the labeled group and -0.05 (±0.46) D for the unlabeled group (p=0.64) post optimization. Mean absolute error of prediction was statistically significantly smaller in the labeled group (0.26±0.23 D) than the unlabeled group (0.37±0.28 D, p=0.04). It was observed that within ±0.25 D prediction error was achieved in 63 percent of the patients in the labeled group compared to 43 percent in the unlabeled group (p=0.03), and for within ±0.50 D, 84 percent and 69 percent (p=0.06), respectively. We request comments from the public regarding the Lenstec NTIOL request and the evidence submitted by Lenstec, and in particular would like the public to comment on the following:

- What is the clinical significance (from the patient's perspective) of a small amount of residual spherical refractive error after cataract surgery?

- What is the likelihood that a Medicare beneficiary receiving a monofocal IOL will require some form of postoperative refractive correction (that is, post-cataract surgery glasses), which is a Medicare benefit?

- If the overwhelming majority of Medicare beneficiaries receiving a monofocal IOL will require some form of postoperative refractive correction (that is, post-cataract surgery glasses), does that lessen the clinical significance of reduced postoperative residual refractive error?

- Are the studies described above properly designed to test Lenstec's hypothesis?

- Do the studies described above adequately prove Lenstec's hypothesis?

All comments on these requests must be received by [Insert 30 days from date of display at the **Federal Register**]. The announcement of CMS's determinations regarding these requests will appear in the CY 2012 OPPS/ASC final rule with comment period. If a determination of membership of the candidate IOLs in a new NTIOL class is made, this determination will be effective 30 days following the date that the final rule with comment period is published in the **Federal Register**.

4. Proposed Payment Adjustment

The current payment adjustment for a five 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 2012.

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 HCPCS 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 2012 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 ASC Addendum AA and BB for CY 2011. These addenda can be found in a file labeled ”January 2011 ASC Approved HCPCS Code and Payment Rates to Reflect the Medicare and Medicaid Extenders Act of 2010” 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 2012 proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) to indicate that a new payment indicator is proposed for assignment to an active HCPCS code for the next calendar year; an active HCPCS code is proposed for addition to the list of procedures or services payable in ASCs; or an active HCPCS code is proposed for deletion 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. The full definitions of the proposed payment indicators and comment indicators are provided in Addenda DD1 and DD2 to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site).

2. Proposed ASC Payment and Comment Indicators

The revised ASC payment system included a four-year transition to payment rates under the standard methodology for the procedures on the ASC list in CY 2007. CY 2011 was the first year of full payment under the standard methodology for the revised ASC payment system. Payment indicators "A2" (Surgical procedure on ASC list in CY 2007, payment based on OPPS relative payment weight) and "H8" (Device-intensive procedure on ASC list in CY 2007; paid at adjusted rate) were 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.

Because the four-year transitional payment period has ended and it is no longer necessary to identify device-intensive procedures that are subject to transitional payments, we are proposing to delete the ASC payment indicator "H8." We are proposing that all device-intensive procedures, for which the modified rate calculation methodology will apply, be assigned payment indicator "J8" in CY 2012 and later. In addition, we are proposing to modify the definition for payment indicator "J8" by removing "added to ASC list in CY 2008 or later" as this distinction is no longer necessary.

Although payment indicator "A2" is no longer required to identify surgical procedures subject to transitional payment, we are proposing to retain payment indicator "A2" because it is used to identify procedures that are exempted from application of the office-based designation.

As detailed in section XIV.K. of this proposed rule, we are proposing to establish an ASC Quality Reporting Program with the collection of seven claims-based quality measures beginning in CY 2012. We are proposing to require ASCs to report on ASC claims a quality data code (QDC) to be used for reporting quality data. We are proposing that an ASC would need to add a QDC to any claim involving a proposed claims-based quality measure. CMS is in the process of developing QDCs for each proposed claims-based quality measure. The QDC will be a CPT Category II code or a HCPCS Level II G-code if an appropriate CPT code is not available. More information on the QDCs that will be associated with the proposed quality measures will be provided in the CY 2012 OPPS/ASC final rule with comment period. Additionally, CMS is proposing to create a new ASC payment indicator "M5" (Quality measurement code used for reporting purposes only; no payment made) for assignment to the QDC to clarify that no payment is associated with the QDC for that claim. We are proposing that this proposed payment indicator be effective January 1, 2012.

We are not proposing any changes to the definitions of the ASC comment indicators for CY 2012. We refer readers to Addenda DD1 and DD2 to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet at the CMS Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2012 update.

We invite public comment on these proposals.

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 (B) and (D) of section 1805(b)(1) of the Act require MedPAC to submit reports to Congress not later than March 1 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 2011 MedPAC "Report to the Congress: Medicare Payment Policy" included the following recommendation relating specifically to the ASC payment system for CY 2012:

Recommendation 5: The Congress should implement a 0.5 percent increase in payment rates for ambulatory surgical center services in calendar year 2012 concurrent with requiring ambulatory surgical centers to submit cost and quality data.

CMS Response: In the August 2, 2007 final rule (72 FR 42518 through 42519), we adopted a policy to update the ASC conversion factor for consistency with section 1833(i)(2)(C) of the Act, which requires that, if the Secretary has not updated the ASC payment amounts in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for All Urban Consumers (CPI-U) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute set the update at zero for CY 2008 and CY 2009. We indicated that we planned to implement the annual updates through an adjustment to the conversion factor under the ASC payment system beginning in CY 2010 when the statutory requirement for a zero update no longer applies. Further, we noted that that we would

update the conversion factor for the CY 2010 ASC payment system by the percentage increase in the CPI-U, consistent with our policy as codified under §416.171(a)(2).

As we indicated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622), we did not require ASCs to submit cost data to the Secretary for CY 2010. We explained that the 2006 GAO report, "Medicare: Payment for Ambulatory Surgical Centers Should Be Based on the Hospital Outpatient Payment System" (GAO-07-86), concluded that the APC groups in the OPPS reflect the relative costs of surgical procedures performed in ASCs in the same way they reflect the relative costs of the same procedures when they are performed in HOPDs. Consistent with the GAO findings, CMS is using the OPPS as the basis for the ASC payment system, which provides for an annual revision of the ASC payment rates under the budget neutral ASC payment system.

In addition, we noted that, under the methodology of the revised ASC payment system, we do not utilize ASC cost information to set and revise the payment rates for ASCs, but instead rely on the relativity of hospital outpatient costs developed for the OPPS, consistent with the recommendation of the GAO. Furthermore, we explained that we have never required ASCs to routinely submit cost data and expressed our concern that a new Medicare requirement for ASCs to do so could be administratively burdensome for ASCs.

In 2009, MedPAC made a similar recommendation to that made in Recommendation 5 above. In light of that MedPAC recommendation, in the CY 2010 OPPS/ASC proposed rule (74 FR 35391), we solicited public comment on the feasibility

of ASCs submitting cost information to CMS, including whether costs should be collected from a sample or the universe of ASCs, the administrative burden associated with such an activity, the form that such a submission could take considering existing Medicare requirements for other types of facilities and the scope of ASC services, the expected accuracy of such cost information, and any other issues or concerns of interest to the public on this topic.

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60623), we summarized and responded to these comments. As noted in that final rule with comment period, commenters expressed varied opinions regarding the feasibility of requiring ASCs to submit cost data to the Secretary. Some commenters believed that requiring ASC to submit such data would not be an insurmountable obstacle and pointed out that other small facilities submit cost reports to CMS. They argued that ASC cost reports are necessary to assess the adequacy of Medicare payments and evaluate the ASC update. Other commenters, however, opposed the requirement that ASCs submit cost data to CMS because they believed such a requirement would be unnecessary and administratively burdensome. Commenters generally supported a requirement that ASCs report quality data. We refer readers to the CY 2010 OPPS/ASC final rule with comment period for a full discussion of the comments we received on the feasibility of requiring ASCs to report cost and quality data (74 FR 60623). Consistent with our CY 2010 policy, we proposed not to require ASCs to submit cost data to the Secretary for CY 2011 (75 FR 46356 through 463557). We stated that we continue to believe that our established methodology results in appropriate payment rates for ASCs. For CY 2012,

consistent with this policy and for the same reasons, we are not proposing to require ASCs to submit cost data.

Section 109(b) of the MIEA-TRHCA (Pub. L. 109-432) gives the Secretary the authority to implement ASC quality measure reporting and to reduce the payment update for ASCs that fail to report those required measures. We are proposing to require ASCs to report seven quality measures in CY 2012. Details associated with ASC quality reporting proposed for CY 2012 are discussed in section XIV.K. of this proposed rule.

Finally, we are not proposing to implement MedPAC's recommended CY 2012 ASC update of 0.5 percent. The annual update to the ASC payment system is the CPI-U. Section 3401(k) of the Affordable Care Act required that the annual ASC payment update be reduced by a productivity adjustment. As discussed in section XIII.H.2.b. of this proposed rule, the Secretary estimates that the CPI-U is 2.3 percent and the MFP adjustment is 1.4 percent. Therefore, we are proposing a 0.9 percent update for CY 2012.

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 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 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 hospital outpatient, 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 nuclear medicine procedures, the established policy is to set the relative payment weights so that the national unadjusted ASC payment rate does not exceed the MPFS unadjusted non-facility PE RVU-based amount. 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 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 (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 2012 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS non-facility 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 42531 through 42532). Consistent with our established policy, we are proposing to scale the CY 2012 relative payment weights for ASCs according to the following method. Holding ASC utilization and the mix of services constant from CY 2010, we are proposing to compare the total payment weight using the CY 2011 ASC relative payment weights (calculated under the ASC standard ratesetting methodology) with the total payment weight using the CY 2012 ASC relative payment weights (calculated under the ASC standard ratesetting methodology) to take into account the changes in the OPPS relative payment weights between CY 2011 and CY 2012. We would use the ratio of CY 2011 to CY 2012 total payment weight (the weight scaler) to scale the ASC relative payment weights for CY 2012. The proposed CY 2012 ASC scalar is 0.9373 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 weight 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 2010 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 2010 ASC claims by provider and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2010 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/ASCPayment/01_Overview.asp#TopOfPage.

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 2012 ASC payment system, we are proposing to calculate and apply the pre-floor and pre-reclassified hospital wage indices that are used for ASC payment adjustment to the ASC conversion factor, just as the OPPS wage index adjustment is calculated and applied to the OPPS conversion factor. For CY 2012, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2010 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2012 pre-floor and pre-reclassified hospital wage indices. Specifically, holding CY 2010 ASC utilization and service-mix and the proposed CY 2012 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2011 pre-floor and pre-reclassified hospital wage indices and the total adjusted payment using the proposed CY 2012 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 2011 pre-floor and pre-reclassified hospital wage indices to the total adjusted payment calculated with the proposed CY 2012 pre-floor and pre-reclassified hospital wage indices and applied the resulting ratio of 1.0003 (the proposed CY 2012 ASC wage index budget neutrality adjustment) to the CY 2011 ASC conversion factor to calculate the proposed CY 2012 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated the ASC payment amounts 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." Because the Secretary does update the ASC payment amounts annually, 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. Therefore, the annual update to the ASC payment system is the CPI-U (referred to as the CPI-U update factor).

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new clause (v) which requires that "any annual update under [the ASC payment] system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II)" (which we refer to as the MFP adjustment) effective with the calendar year beginning January 1, 2011. 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 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064), we revised §416.160 and §416.171 to reflect this provision of the Affordable Care Act (we note that these regulations do not reflect any reduction in the annual update for

failure to report on quality measures because CMS had not implemented an ASC quality reporting program).

As discussed in section XIV.K. of this proposed rule, we are proposing that ASCs begin submitting data on quality measures in CY 2012 for the CY 2014 payment determination. Because any reduction to the annual update under the ASC Quality Reporting Program will not occur until CY 2014, we are not proposing any changes to the payment methodology. We intend to address payment changes based on failure to submit quality data under the ASC Quality Reporting Program in a future rulemaking.

Without regard to the ASC Quality Reporting Program and 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 are proposing to hold the CPI-U update factor for the ASC payment system to zero. Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, then requires that the Secretary reduce the CPI-U update factor (which would be held to zero if the CPI-U percentage change is negative) 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 CPI-U percentage increase would result in a MFP-adjusted CPI-U update factor that is less than zero, then the annual 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 2012, the Secretary estimates that the CPI-U is 2.3 percent. The Secretary estimates that the MFP adjustment is 1.4 percentage points based on the methodology for calculating the MFP adjustment finalized in the CY 2011 MPFS final rule with comment period (75 FR 73391 through 73399) as revised by the proposal discussed in the CY 2012 MPFS proposed rule. Therefore, we are proposing to reduce the CPI-U of 2.3 percent by the MFP adjustment specific to this CPI-U of 1.4 percentage points, resulting in an MFP-adjusted CPI-U update factor of 0.9 percent. Therefore, we are proposing to apply a 0.9 percent MFP-adjusted update to the CY 2011 ASC conversion factor.

For CY 2012, we also are proposing to adjust the CY 2011 ASC conversion factor ($41.939) by the wage adjustment for budget neutrality of 1.0003 in addition to the MFP-adjusted update factor of 0.9 percent discussed above, which results in a proposed CY 2012 ASC conversion factor of $42.329.

3. Display of Proposed CY 2012 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are referenced in section XVII. of this proposed rule and available via the Internet on the CMS Web site) display the proposed updated ASC payment rates for CY 2012 for covered surgical procedures and covered ancillary services, respectively. These addenda contain several types of information related to the proposed CY 2012 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 2012 Payment Weight" are the proposed relative payment weights for each of the listed services for CY 2012. The payment weights for all covered surgical procedures and covered ancillary services whose ASC payment rates are based on OPPS relative payment weights are 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 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 2012 payment rate displayed in the "CY 2012 Payment" column, each ASC payment weight in the "CY 2012 Payment Weight" column is multiplied by the proposed CY 2012 conversion factor of $42.329. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the CPI-U 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 2012 Payment Weight" column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The "CY 2012 Payment" column displays the proposed CY 2012 national unadjusted ASC payment rates for all items and services. The proposed CY 2012 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 2011.

XIV. Hospital Outpatient Quality Reporting Program Updates and ASC Quality Reporting Program

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, as well as the program for physicians and other eligible professionals, known as the Physician Quality Reporting System (formerly known as the Physician Quality Reporting Initiative (PQRI)), have financial incentives for the reporting of quality data to CMS. CMS also has implemented quality reporting programs for home health agencies and skilled nursing facilities that are based on conditions of participation, and an end-stage renal disease (ESRD) Quality Incentive Program (76 FR 628 through 646) that links 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 CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries. Our goal is ultimately to align the clinical quality measure requirements of the Hospital OQR Program and various other programs, including the Hospital IQR Program, and the proposed ASC Quality Reporting Program, with the reporting requirements implemented under the Health Information Technology for Economic and Clinical Health (HITECH) Act, so that the burden of reporting can be reduced. In developing this and other quality reporting programs, as well as the Hospital Inpatient Value-Based Purchasing (Hospital Inpatient VBP) Program, we applied the following principles for the development and use of measures:

- Pay-for-reporting, public reporting, and value-based purchasing programs should rely on a mix of standards, processes, outcomes, and patient experience of care measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience of care measures. To the extent practicable and appropriate, outcome and patient experience of care measures should be adjusted for risk factors or other appropriate patient population or provider 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 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.

- The collection of information burden on providers should be minimized to the extent possible. To this end, we continuously seek to align our measures with the adoption of meaningful use standards for health information technology (HIT), so that data can be submitted and calculated via certified EHR technology with minimal burden.

- 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. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

We invite public comment on these principles.

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. Technical Specification Updates and Data Publication

a. Maintenance of Technical Specifications for Quality Measures

Technical specifications for each Hospital OQR measure 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 a subregulatory process for making updates to the technical specifications that we use to calculate Hospital OQR measures. This process is used when changes to the measure specifications are necessary due to changes in scientific evidence, treatment guidelines, or consensus among affected parties. Changes due to these reasons may not coincide with the timing of our regulatory actions, but nevertheless should be made so that the Hospital OQR measures are calculated based on the most up-

to-date scientific and consensus standards. We indicated that notification of technical changes to the measure specifications is made via the QualityNet Web site, http://www.QualityNet.org, and in the Hospital OQR Specifications Manual. The notification of changes to the measure technical specifications occurs no less than 3 months before any changes become effective for purposes of reporting under the Hospital OQR Program.

The Hospital OQR Specifications Manual is released every 6 months and addenda are released as necessary. This release schedule provides at least 3 months of advance notice for substantial 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 Hospital OQR 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 displayed on CMS Web sites such as the Hospital Compare Web site, http://www.hospitalcompare.hhs.gov, after a 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, 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. This approach is consistent with the approach taken under the Hospital IQR Program. Consistent with our current policy, we make Hospital OQR data publicly available whether or not the data have been validated for payment purposes.

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 would be notified via CMS listservs, CMS e-mail blasts, 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 IQR Program, including measures that we calculate using Medicare claims.

B. Proposed Revision to Measures Previously Adopted for the Hospital OQR Program for the CY 2012, CY 2013, and CY 2014 Payment Determinations

1. Background

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 adopted for the CY 2011 payment determination (74 FR 60637); 15 measures adopted for the CY 2012 payment determination (75 FR 72083 through 72084); 23 measures adopted for the CY 2013 payment determination (75 FR 72090); and 23 measures adopted for the CY 2014 payment determination (75 FR 72094). The table below also shows the 23 measures previously adopted for these payment determinations:

Hospital OQR Program Measures Previously Adopted for the CY 2011, CY 2012, CY 2013, and CY 2014* 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

Hospital OQR Program Measures Previously Adopted for the CY 2011, CY 2012, CY 2013, and CY 2014*** Payment Determinations
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 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- 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 **

* New measure adopted beginning with the CY 2012 payment determination.
** New measure adopted beginning with the CY 2013 payment determination.
*** All 23 measures were adopted for the CY 2014 payment determination.

2. Proposed Revision to Hospital OQR Program Measures Previously Adopted for the CY 2013 Payment Determination

In the CY 2011 OPPS/ASC final rule with comment period, we finalized the adoption of the chart-abstracted measure OP-22 – Left Without Being Seen (75 FR 72088 through 72089). This measure was endorsed (NQF # 0499) as part of an NQF project entitled "National Voluntary Consensus Standards for Emergency Care." This measure assesses the percentage of patients who leave the Emergency Department (ED) without being evaluated by qualified medical personnel, which is an indication of ED

overcrowding, and lack of timely access to care. We are proposing that beginning with the CY 2013 payment determination, hospitals would submit aggregate numerator and denominator counts once a year using a Web-based form available through the QualityNet Web site for this measure. This proposed process is different from that which is used to collect other chart-abstracted measures because it would not require hospitals to submit patient-level information for this measure, and would not require quarterly submission of data. We believe this proposed process will reduce the potential data collection and submission burden for this measure.

We are proposing that for the CY 2013 payment determination, data submission for this measure would occur between July 1, 2012 and August 15, 2012. We also are proposing that for the CY 2013 payment determination, the aggregate counts for the numerator (the total number of patients who left without being evaluated by a physician/advance practice nurse/physician's assistant) and the denominator (total number of patients who signed in to be evaluated for emergency services) would be submitted by hospitals and would span the time period from January 1, 2011 through December 31, 2011. We invite public comment on this proposed approach to data collection for OP-22 for the CY 2013 Hospital OQR Program and subsequent payment determinations, and on the time period to be assessed for this measure for the CY 2013 payment determination. The updated specifications for this measure will be made available in the July 2011 Hospital OQR Specifications Manual.

C. Proposed New Quality Measures for the CY 2014 and CY 2015 Payment Determinations

1. Considerations in Expanding and Updating Quality Measures under the Hospital OQR Program

In general, when selecting measures for the Hospital OQR Program, we take into account several considerations and goals. These include: (a) expanding the types of measures beyond process of care measures to include an increased number of outcome measures, efficiency measures, and patients' experience-of-care measures; (b) expanding the scope of hospital services to which the measures apply; (c) considering the burden on hospitals in collecting chart-abstracted data; (d) harmonizing the measures used in the Hospital OQR Program with other CMS quality programs to align incentives and promote coordinated efforts to improve quality; (e) seeking 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 data bases; and (f) weighing the relevance and utility of the measures compared to the burden on hospitals in submitting data under the Hospital OQR Program.

Specifically, we assign priority to quality measures that assess performance on: (a) conditions that result in the greatest mortality and morbidity in the Medicare population; (b) conditions that are high volume and high cost for the Medicare program; and (c) conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. We used and continue to use these criteria to

guide our decisions regarding what measures to add to the Hospital OQR Program measure set.

In the CY 2009 OPPS/ASC final rule with comment period, we adopted four claims–based quality measures that do not require a hospital to submit chart-abstracted clinical data (73 FR 68766). This supports our goal of expanding the measures for the Hospital OQR Program while minimizing the burden upon hospitals and, in particular, without significantly increasing the chart abstraction burden. In addition to claims-based measures, we are considering registries and EHRs as alternative ways to collect data from hospitals.

A registry is a collection of clinical data for purposes of assessing clinical performance, quality of care, and opportunities for quality improvement. Many hospitals submit data to and participate in existing registries. In addition, registries often capture outcome information and provide ongoing quality improvement feedback to registry participants. Instead of requiring hospitals to submit the same data to CMS that they are already submitting to registries, we could collect the data directly from the registries with the permission of the hospital, thereby enabling us to expand the Hospital OQR Program measure set without increasing the burden of data collection for those hospitals participating in the registries. The data that we would receive from registries would be used to calculate quality measures required under the Hospital OQR Program, and would be publicly reported like other Hospital OQR Program quality measures, encouraging improvements in the quality of care. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60633), we responded to public comments on such an approach.

In the CY 2009 OPPS/ASC final rule with comment period, we also stated our intention to explore mechanisms for data submission using EHRs (73 FR 68769). When we refer to the term Qualified EHR, we intend for it to have the same meaning as set forth by the Office of the National Coordinator for Health Information Technology (ONC) (45 CFR 170.102) which has adopted the statutory definition of Qualified EHR found in section 3000(13) of the Public Health Service Act. That section defines a Qualified EHR as "an electronic record of health-related information on an individual that -- (A) includes patient demographic and clinical health information, such as medical history and problem lists; and (B) has the capacity -- (i) to provide clinical decision support; (ii) to support physician order entry; (iii) to capture and query information relevant to health care quality; and (iv) to exchange electronic health information with, and integrate such information from other sources." Additionally, when we refer to the term, Certified EHR Technology, we intend for it to have the same meaning as set forth by the ONC at 45 CFR 170.102 as follows: "Certified EHR Technology" means (1) A complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary; or (2) a combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

Establishing a data submission mechanism using EHRs will require interoperability between EHRs and our data collection systems, additional infrastructure development on the part of hospitals and CMS, and the adoption of standards for the capturing, formatting, and transmission of data elements that make up the measures. However, once these activities are accomplished, the adoption of measures that rely on data obtained directly from EHRs would enable us to expand the Hospital OQR Program measure set with less cost and burden to hospitals. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60633 through 60634), we responded to public comments on such an approach.

Continuing to reduce our reliance on the chart-abstraction mechanism would allow us and hospital outpatient departments to devote available resources towards maximizing the potential of registries and EHRs for quality measurement reporting. Both mechanisms hold the promise of more sophisticated and timely reporting of clinical quality measures. Clinical data registries allow the collection of more detailed data, including outcomes. Registries can also provide feedback and quality improvement information based on reported data. Finally, clinical data registries can also receive data from EHRs, and therefore, serve as an alternative means to reporting clinical quality data extracted from an EHR.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72071 through 72174), we added new measures over a three year period for the CY 2012, CY 2013, and CY 2014 payment determinations. We believe this process will assist hospitals in planning, meeting future reporting requirements, and implementing quality improvement

efforts. We will also have more time to develop, align, and implement the infrastructure necessary to collect data on the measures and make payment determinations. The fact that we finalized measures for a three year period of time (for example, for the CY 2012, CY 2013 and CY 2014 payment determinations in the CY 2011 OPPS/ASC final rule with comment period) does not preclude us from proposing to adopt additional measures or changing the list of measures for these payment determinations through subsequent rulemaking cycles that affect these future payment determinations.

We have previously expanded the Hospital OQR Program measure set dramatically by adopting measures over several payment determinations in order to allow hospital outpatient departments adequate time to plan and implement the reporting of quality data for the CY 2012, CY 2013 and CY 2014 payment determinations. In this proposed rule, we are proposing to add new measures to the existing Hospital OQR measure set for the CY 2014 payment determination and are proposing to add new measures for the CY 2015 payment determination.

2. Proposed New Hospital OQR Program Quality Measures for the CY 2014 Payment Determination

As stated above, the CY 2014 measure set for the Hospital OQR Program currently contains 23 measures that we adopted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72094). In this proposed rule, we are proposing to adopt a number of additional measures for the CY 2014 measure set.

a. Proposed New National Healthcare Safety Network (NHSN) Healthcare Associated Infection (HAI) Measure for the CY 2014 Payment Determination: Surgical Site Infection (NQF #0299)

Healthcare Associated Infections (HAIs) is a topic area widely acknowledged by HHS, the Institute of Medicine (IOM), the National Priorities Partnership, and others as a high priority requiring measurement and improvement. HAIs are among the leading causes of death in the United States. CDC estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths.[1] It is estimated that more Americans die each year from HAIs than from auto accidents and homicides combined. HAIs not only put the patient at risk, but also increase the days of hospitalization required for patients and add considerable health care costs. HAIs are largely preventable through interventions such as better hygiene and advanced scientifically tested techniques for surgical patients. Therefore, many health care consumers and organizations are calling for public disclosure of HAIs, arguing that public reporting of HAI rates provides the information health care consumers need to choose the safest hospitals, and gives hospitals an incentive to improve infection control efforts. This proposed measure is currently collected by the National Healthcare Safety Network (NHSN) as part of State-mandated reporting and surveillance requirements for hospitals in some States. Additionally, data submission for this measure through EHRs may be possible in the near future.

[1] McKibben. L., Horan, T.: Guidance on public reporting of healthcare-associated infections: recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005; 33:217–26.

The NHSN is a secure, Internet-based surveillance system maintained and managed by the CDC, and can be utilized by all types of healthcare facilities in the United States, including acute care hospitals, long term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and long term care facilities. The NHSN is provided free of charge to hospitals. The NHSN enables healthcare facilities to collect and use data about HAIs, clinical practices known to prevent HAIs, the incidence or prevalence of multidrug-resistant organisms within their organizations, and other adverse events. Some States use the NHSN as a means for healthcare facilities to submit data on HAIs mandated through their specific State legislation. Currently, 21 States require hospitals to report HAIs using the NHSN, and the CDC supports more than 4,000 hospitals that are using NHSN.

Increasingly, more surgical procedures are being performed in hospital outpatient department settings and ASCs. Therefore, we have determined that this measure is "appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings" as required under section 1833(t)(17)(C)(i) of the Act. This proposed HAI measure assesses the percentage of surgical site infections occurring within 30 days after an NHSN-defined operative procedure if no implant is left in place or within one year if an implant is in place, and the infection appears to be related to the operative procedure. Infections are identified on original admission or upon readmission to the facility of original operative procedure within the relevant time frame (30 days for no implants; within 1 year for implants). The specifications for this proposed HAI measure can be found at http://www.cdc.gov/nhsn/psc.html.

We also believe that this measure meets the requirement under section 1833(t)(17)(C)(i) of the Act that measures selected for the Hospital OQR Program "reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities." This measure was NQF-endorsed in 2007 and was adopted by the Hospital Quality Alliance in 2008. We note that this measure also was adopted for the Hospital IQR Program beginning with the FY 2014 payment determination (75 FR 50211) and its adoption into the Hospital OQR Program would further our goal of aligning measures across programs where feasible.

We are proposing that submission of data for this proposed NHSN measure for the CY 2014 payment determination would relate to infection events occurring between January 1, 2013 and June 30, 2013. We are proposing that hospital outpatient departments use the existing NHSN infrastructure and protocols that already exist for this proposed measure to report it for Hospital OQR Program purposes. We invite public comment on our proposal to adopt this HAI measure into the Hospital OQR Program for the CY 2014 payment determination.

b. Proposed New Chart-Abstracted Measures for the CY 2014 Payment Determination

In the CY 2011 OPPS/ASC final rule with comment period, we stated that we would not finalize five proposed NQF-endorsed diabetes care measures because we were in the process of refining the chart-abstracted numerator definitions for these measures (75 FR 72091). We also stated that we intended to again propose to adopt these measures for the CY 2014 payment determination. We now are proposing to adopt these five

diabetes care measures for the CY 2014 payment determination as chart-abstracted measures. These five measures are: (1) Hemoglobin A1c Management (NQF #0059); (2) Diabetes Measure Pair: A. Lipid Management: Low Density Lipoprotein Cholesterol (LDL-C) < 130, B. Lipid Management: LDL-C < 100 (NQF #0064); (3) Diabetes: Blood Pressure Management (NQF #0061); (4) Diabetes: Eye Exam (NQF #0055); and (5) Diabetes: Urine Protein Screening (NQF #0062). We note that these five measures are electronically specified. We hope to be able to collect such information via EHRs in the future, and we solicit comments on using EHR for data collection in the future. In addition, we are proposing to adopt another new chart-abstracted measure, Cardiac Rehabilitation Patient Referral from an Outpatient Setting (NQF #0643), for the CY 2014 payment determination. Below are descriptions of each of these six proposed new chart-abstracted measures.

(1) Proposed Diabetes Measure: Hemoglobin A1c Management (NQF #0059)

In general, diabetes mellitus is a chronic disease that impacts the lives of a large portion of the population and consumes a significant amount of U.S. healthcare dollars. With the prevalence of diabetes in the Medicare-eligible population expected to double, costs are expected to increase almost fourfold to $171 million.[2] Uncontrolled diabetes often leads to biochemical imbalances that can lead to acute life-threatening events, such as diabetic ketoacidosis and hyperosmolar, or nonketotic coma. In patients with insulin-dependent diabetes, the risk of development or progression of retinopathy, nephropathy, and neuropathy can be reduced by 50 to 75 percent by intensive outpatient

[2] Huang, E.S., Basu, A., O'Grady, M., Capretta, J.C.: Projecting the future diabetes population size and related costs for the U.S. Diabetes Care. 2009;32 (12):2225-29.

treatment of hyperglycemia compared to conventional treatment. Early treatment may help slow or halt the progression of diabetic complications, and following the guidelines for screening may assist those patients with no outward sign of diabetic complications to be identified earlier through regular screening tests. Some guidelines recommend that the HgA1c level be tested during an initial assessment and in follow-up assessments which should occur at no longer than 3-month intervals.[3] Other guidelines recommend that the HgA1c level be tested at least twice a year in patients with stable glycemic control and who are meeting treatment goals, and quarterly in patients whose HgA1c level does not meet target glycemic goals.[4]

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities. Because this measure is NQF-endorsed, we believe that this measure meets the requirement of reflecting consensus among affected parties. However, we note that consensus among affected parties can be reflected through means other than NQF endorsement. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting, in which many patients with diabetes are treated.

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[3] The American Association of Clinical Endocrinologists Medical Guidelines for the Management of Diabetes Mellitus: The AACE System of Intensive Diabetes Self-Management -2002 Update.

[4] American Diabetes Association. Standards of Medical Care in Diabetes. Diabetes Care. 2008 Jan:31 (Suppl 1):S12-54.

Lower HgA1c levels are associated with reduced microvascular and neuropathic complications of diabetes. This NQF-endorsed measure measures the percentage of adult patients with diabetes aged 18-75 years with a most recent HgA1c level greater than 9 percent (poor control). The specifications for this measure are located in Appendix A (beginning page A-60) of the 2008 NQF Report titled "National Voluntary Consensus Standards for Ambulatory Care—Part 1" available at the following link: http://www.qualityforum.org/Publications/2008/03/National_Voluntary_Consensus_Standards_for_Ambulatory_Care%E2%80%93Part_1.aspx

Glycosylated hemoglobin (HgA1c) assay measures average blood glucose over the preceding two to three months, rather than just one point in time. HgA1c values fluctuate less frequently than fasting glucose values and give clinicians a better integrated view of the patient's average blood sugar over time. High HgA1c is a more reliable indicator of chronic high blood sugar. We invite public comment on this proposed measure.

(2) Proposed Diabetes Measure Pair: A. Lipid Management: Low Density Lipoprotein Cholesterol (LDL-C) <130, B. Lipid Management: LDL-C <100 (NQF #0064)

LDL-C measures the development of atherosclerotic plaque which increases the cardiac events risk for diabetic patients, who already face heart disease death rates that are about two to four times higher than these rates are for non-diabetic patients.[5] Improved dyslipidemia management helps to mitigate the risk for cardiovascular disease. Lipid-lowering therapy for diabetics has been a consistent recommendation in several

[5] American Diabetes Association. Standards of Medical Care in Diabetes. Diabetes Care. 2007 Jan;30 (Suppl 1):S8-15.

guidelines, prompted by randomized trials supporting statin therapy to lower the risk of cardiovascular involvement for this population. Despite the evidence basis and guideline support, only a minority of patients with diabetes are prescribed statin treatment or achieve target LDL-C goals.[6]

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities. Because this measure is NQF-endorsed, we believe that this measure meets the requirement of reflecting consensus among affected parties. However, we note that consensus among affected parties can be reflected through means other than NQF endorsement. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting which serve many patients with diabetes who often have high level of LDL-C.

Early treatment of hyperlipidemia as indicated by high level of LDL-C may help to slow or halt the progression of cardiovascular disease and impact the quality of the life of the diabetic patient, affecting the patient's life expectancy and decreasing costs involved in treating diabetic complications. This NQF-endorsed measure assesses: (i) the percentage of adult patients with diabetes aged 18-75 years whose most recent LDL-C test result was < 130 mg/dl; and (ii) the percentage of adult patients with diabetes aged 18-75 years whose most recent LDL-C test result during the measurement year was

[6] Das, S.R., Vaeth, P.A., Stanek, H.G., de Lemos, J.A., Dobbins, R.L., McGuire, D.K.: Increased cardiovascular risk associated with diabetes in Dallas County. Am Heart J 2006;151:1087-93.

< 100 mg/dl. The specifications for this measure are located in Appendix A (beginning page A-60) of the 2008 NQF Report titled "National Voluntary Consensus Standards for Ambulatory Care—Part 1" available at the following link: http://www.qualityforum.org/Publications/2008/03/National_Voluntary_Consensus_Standards_for_Ambulatory_Care%E2%80%93Part_1.aspx. We invite public comment on this proposed measure.

(3) Proposed Diabetes Measure: Blood Pressure Management (NQF #0061)

Blood pressure control reduces the risk of cardiovascular disease and microvascular complications in patients with diabetes. Well-controlled blood pressure impacts the quality of the life of the diabetic patient, affects the patient's life expectancy, and decreases the costs involved in treating diabetic complications.

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities. Because this measure is NQF-endorsed, we believe that this measure meets the requirement of reflecting consensus among affected parties. However, we note that consensus among affected parties can be reflected through means other than NQF endorsement. This measure is appropriate for measuring the quality of care in the hospital outpatient departments which serve many patients with diabetes and suffer from high blood pressure.

Early treatment of high blood pressure may help slow or halt the progression of kidney involvement and damage.[7] This NQF-endorsed measure measures the percentage of patient visits with blood pressure measurement recorded among all patients visits aged > 18 years with diagnosed hypertension. The specifications for this measure are located in Appendix A (beginning page A-60) of the 2008 NQF Report titled "National Voluntary Consensus Standards for Ambulatory Care—Part 1" available at the following link: http://www.qualityforum.org/Publications/2008/03/National_Voluntary_Consensus_Standards_for_Ambulatory_Care%E2%80%93Part_1.aspx. We invite public comment on this proposed measure.

(4) Proposed Diabetes Measure: Eye Exam (NQF #0055)

A dilated eye exam helps to detect the risk for vision-threatening diabetic retinopathy which is prevalent among people with diabetes. Data from the 2011 National Diabetes Fact Sheet shows that diabetes is the leading cause of new cases of blindness among adults aged 20–74 years.[8] However, dilated eye exams for diabetic patients can prevent retinopathy through early detection[9] and stereoscopic retinal photography is sometimes used to grade diabetic retinopathy severity.

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient

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[7] Centers for Disease Control and Prevention. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 20112007. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 20112008.

[8] Centers for Disease Control and Prevention. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 20112007. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 20112008.

[9] American Diabetes Association. Standards of medical care in diabetes. Diabetes Care. 2007 Jan;30 (Suppl 1):S8-15.

settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities. Because this measure is NQF-endorsed, we believe that this measure meets the requirement of reflecting consensus among affected parties. However, we note that consensus among affected parties can be reflected through means other than NQF endorsement. This measure is appropriate for measuring quality of care in the hospital outpatient departments which serve many patients with diabetes who are at risk for diabetic retinopathy.

This NQF-endorsed measure measures the percentage of adult patients with diabetes age 18 to 75 years who received a dilated eye exam or seven standard field stereoscopic photos with interpretation by an ophthalmologist or optometrist, or imaging to verify diagnosis from stereoscopic photos during the reporting year, or during the prior year, if the patient is at low risk for retinopathy. A patient is considered low risk if the patient has no evidence of retinopathy in the prior year. The specifications for this measure are located in Appendix A (beginning page A-60) of the 2008 NQF Report titled "National Voluntary Consensus Standards for Ambulatory Care—Part 1" available at the following link: http://www.qualityforum.org/Publications/2008/03/National_Voluntary_Consensus_Standards_for_Ambulatory_Care%E2%80%93Part_1.aspx. We invite public comment on this proposed measure.

(5) Proposed Diabetes Measure: Urine Protein Screening (NQF #0062)

Urine protein screening for microalbumin detects an abnormal amount of protein albumin leaks in the urine by the capillaries of the kidney. High levels of blood sugar in uncontrolled diabetes can cause damage to the capillaries in the kidneys. Diabetics accounted for 44 percent of new cases of kidney disease. In 2005, a total of 178,689 diabetics with ESRD were on dialysis or received a kidney transplant in the United States and Puerto Rico.[10] In 2009, MedPAC reported costs for the 330,000 Medicare recipients receiving dialysis treatment for ESRD at over $8 billion.[11]

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities. Because this measure is NQF-endorsed, we believe that this measure meets the requirement of reflecting consensus among affected parties. However, we note that consensus among affected parties can be reflected through means other than NQF endorsement. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient departments which serve many patients with diabetes who are at risk for kidney diseases.

Early urine screenings for microalbumin may prevent kidney disease from worsening to ESRD. This NQF-endorsed measure measures the percentage of adult

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[10] Centers for Disease Control and Prevention. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 2007. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2008.

[11] MedPAC. Outpatient dialysis service: assessing payment adequacy and updating payments. Report to the Congress: Medicare payment policy. 2009 Mar;131-56.

diabetic patients ages 18 – 75 years with at least one test for microalbumin during the measurement year or who had evidence of medical attention for existing nephropathy (diagnosis of nephropathy or documentation of microalbuminuria or albuminuria). The specifications for this measure are located in Appendix A (beginning page A-60) of the 2008 NQF Report titled "National Voluntary Consensus Standards for Ambulatory Care—Part 1" available at the following link: http://www.qualityforum.org/Publications/2008/03/National_Voluntary_Consensus_Standards_for_Ambulatory_Care%E2%80%93Part_1.aspx. We invite public comment on this proposed measure.

(6) Proposed Cardiac Rehabilitation Measure: Patient Referral from an Outpatient Setting (NQF #0643)

Cardiac rehabilitation improves the quality of life, reduces modifiable cardiovascular risk factors, enhances adherence to preventable medications, and lowers morbidity and mortality.[12] Despite these benefits, cardiac rehabilitation is significantly underutilized by patients with heart disease and there is significant geographical variation in referral rates and lower use in women, non-whites, older patients and patients on Medicaid.[13] A recent study of Medicare beneficiaries, using 70,040 matched pairs of patients hospitalized for coronary conditions or revascularization procedures, found that mortality rates were 21 percent to 34 percent lower in cardiac rehabilitation users

[12] Wenger, N.K.: Current status of cardiac rehabilitation. J. Am Coll Cardiol 2008; 51:1619-1631.
[13] Suaya, J.A., Shepard, D.S., Normand, S.L., et al.: Use of cardiac rehabilitation by Medicare beneficiaries after myocardial infarction or coronary bypass surgery. Circulation. 2007;116:1653-62

compared to nonusers.[14] Evidence from registries which include a cardiac rehabilitation performance measure indicated that only about 18 percent of eligible patients were referred to cardiac rehabilitation.[15] Under our regulations, 42 CFR 410.49, cardiac rehabilitation is covered for patients who have had one or more of the following: an acute myocardial infarction within the preceding 12 months, current stable angina, individuals who have undergone coronary bypass surgery, a percutaneous coronary intervention or coronary stenting, heart valve repair or replacement, or a heart-lung transplant.

In May 2010, the NQF endorsed two cardiac rehabilitation referral performance measures as part of the call for care coordination performance measures. These measures are: (1) Cardiac Rehabilitation: Patient Referral From an Inpatient Setting (NQF #0642) – The percentage of patients admitted to the hospital with a qualifying cardiovascular disease (CVD) event who are referred to an early outpatient cardiac rehabilitation/secondary prevention program; and (2) Cardiac Rehabilitation: Patient Referral From an Outpatient Setting (NQF #0643) – The percentage of patients evaluated in an outpatient setting who in the previous 12 months experienced an acute myocardial infarction or chronic stable angina or who have undergone coronary artery bypass (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery (CVS), or cardiac transplantation who have not already participated in an early outpatient cardiac rehabilitation/secondary prevention program for the qualifying event and who are referred to an early outpatient cardiac rehabilitation/secondary prevention program unless

[14] Suaya, J.A., Stason, W.B., Ades, P.A., et al.: Cardiac rehabilitation and survival in older coronary patients. J. Am Coll Cardiol. 2009;54:25-33.
[15] Chan, P.S., Oetgen, W.J., Buchanan, D., Mitchell, K. et al.: Cardiac performance measure compliance on outpatients: the American College of cardiology and National Cardiovascular data registry's PINNACLE (Practice Innovation and Clinical Excellence) program. J. Am Coll Cardiol 2010 56(1) 8-14)

there is a documented medical or patient oriented reason why a referral was not made. We are proposing to adopt the second (NQF #0643) of these measures for the CY 2014 Hospital OQR Program. The measure specifications are located in Appendix A (Pages A4 and A5) of the 2010 NQF consensus report entitled " Preferred Practices and Performance Measures for Measuring and Reporting Care Coordination" which is available at the following link:

http://www.qualityforum.org/Publications/2010/10/Preferred_Practices_and_Performance_Measures_for_Measuring_and_Reporting_Care_Coordination.aspx

This proposed measure targets patients who have experienced a qualifying cardiovascular event. These patients are commonly seen in hospital outpatient departments and, for this reason, we believe that the proposed measure is appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings as required under section 1833(t)(17)(C)(i) of the Act. The measure also is NQF-endorsed, and therefore meets the requirement that measures selected for the program "reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities" under section 1833(t)(17)(C)(i) of the Act.

We are proposing to adopt the NQF-endorsed Cardiac Rehabilitation Patient Referral from an Outpatient Setting measure for CY 2014 payment determination. The goal of this measure is to improve the delivery of cardiac care in order to reduce cardiovascular mortality and morbidity and optimize the health of patients suffering from CVD.

We invite public comment on this proposed measure.

c. Proposed New Structural Measures

For the CY 2014 payment determination, we are proposing to add two structural measures: 1) Safe Surgery Checklist Use; and 2) Hospital Outpatient Volume for Selected Outpatient Surgical Procedures. In general, structural measures assess the characteristics and capacity of the provider to deliver quality health care.

(1) Proposed Safe Surgery Checklist Use Measure

This proposed structural measure assesses whether a hospital outpatient department utilizes a Safe Surgery checklist that assesses whether effective communication and safe practices are performed during three distinct perioperative periods: (1) the period prior to the administration of anesthesia; (2) the period prior to skin incision; and (3) the period of closure of incision and prior to the patient leaving the operating room. The use of such checklists has been credited with dramatic decreases in preventable harm, complications and post-surgical mortality[16]. In November 2010, the New England Journal of Medicine (NEJM) published a study concluding that surgical complications were reduced by one-third, and mortality by nearly half, when a safe surgery checklist was used.[17]

We believe that effective communication and the use of safe surgical practices during surgical procedures will significantly reduce preventable surgical deaths and complications. For example, mistakes in surgery can be prevented by ensuring that the

[16] Haynes, A.B.; Weiser, T.G.; Berry, W.G. et. al (2009). "A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population.". New England Journal of Medicine. 360: 491-499.
[17] de Vries EN, Prins HA, Crolla RMPH, et al. Effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med 2010;363: 1928-37

correct surgery is performed on the correct patient and at the correct place on the patient's body.[18] A safe surgery checklist would also reduce the potential for human error, which we believe would increase the safety of the surgical environment.

The safe surgery checklists of which we are aware typically include safe surgery practices corresponding to three critical perioperative periods: the period prior to the administration of anesthesia, the period prior to skin incision, and the period of closure of incision and prior to the patient leaving the operating room. Some examples of safe surgery practices that can be performed during each of these three perioperative periods are shown in the table below:

First critical point (period prior to administering anesthesia)	**Second critical point (period prior to skin incision)**	**Third critical point (period of closure of incision and prior to patient leaving the operating room)**
● Verbal confirmation of patient identity ● Mark surgical site ● Check anesthesia machine/medication ● Assessment of allergies, airway and aspiration risk	● Confirm surgical team members and roles ● Confirm patient identity, procedure, and surgical incision site ● Administration of antibiotic prophylaxis within 60 minutes before incision ● Communication among surgical team members of anticipated critical events ● Display of essential imaging as appropriate	● Confirm the procedure ● Complete count of surgical instruments and accessories ● Identify key patient concerns for recovery and management of the patient

One example of a checklist that lists safe surgery practices during each of these three perioperative periods is the World Health Organization Surgical Safety Checklist, which was adopted by The World Federation of Societies of Anesthesiologists as an

[18] Hospital National Patient Safety Goals. The Joint Commission Accreditation Hospital Manual, 2011. http://www.jointcommission.org/standards_information/npsgs.aspx

international standard of practice. This checklist can be found at: http://www.who.int/patientsafety/safesurgery/ss_checklist/en/index.html.

The adoption of a structural measure that assesses Safe Surgery Checklist use would align our patient safety initiatives with those of several surgical specialty societies including: The American College of Surgeons' Nora Institute for Patient Safety, the American Society of Anesthesiologists, The Joint Commission, the National Association for Healthcare Quality and the Association of periOperative Registered Nurses (AORN). For this proposed structural measure, a hospital outpatient department would indicate whether or not it uses a safe surgery checklist for its surgical procedures that includes safe surgery practices during each of the three critical perioperative periods discussed above. The measure would assess whether the hospital uses a safe surgery checklist in the hospital outpatient department for surgical procedures, but would not require a hospital to report whether it uses a checklist in connection with any individual outpatient procedures.

The proposed Safe Surgery Checklist structural measure is not NQF-endorsed. However, we believe that consensus among affected parties can be reflected through means other than NQF endorsement including: consensus achieved during the measure development process; consensus shown through broad acceptance and use of measures; and consensus through public comment. The proposed safe surgery checklist measure assesses the adoption of a best practice for surgical care that is broadly accepted and in widespread use among affected parties. In addition to being adopted by The World Federal of Societies of Anesthesiologists, the use of a safe surgery checklist is one of the

safe surgery principles endorsed by the Council on Surgical and Perioperative Safety, which is comprised of the American Association of Nurse Anesthetists, American College of Surgeons, American Association of Surgical Physician Assistants, American Society of Anesthesiologists, American Society of PeriAnesthesia Nurses, AORN, and Association of Surgical Technologists. Two State agencies (Oregon, South Carolina), the Veterans Health Administration[19], numerous hospital systems, State hospital associations (such as California, and South Carolina), national accrediting organizations and large private insurers have endorsed the use of a safe surgery checklist as a best practice for reducing morbidity, mortality, and medical errors.[20, 21] Because the use of a safe surgery checklist is a widely accepted best practice for surgical care, we believe that the proposed structural measure of Safe Surgery Checklist use reflects consensus among affected parties. We also note that The Joint Commission has included safe surgery checklist practices among those to be used to achieve National Patient Safety Goals adopted for 2011 for surgeries performed in ambulatory settings and hospitals.

For CY 2014 payment determination, we are proposing that data collection for this structural measure for hospital outpatient departments will be from July 1, 2013 through August 15, 2013 for the time period January 1, 2012 through December 31, 2012. These data will be collected via a Web-based tool available on the QualityNet Web site that is currently employed for the collection of structural measures

[19] Neily, J; Mills, PD, Young-Xu, Y. (2010). "Association between implementation of a Medical Team Training Program and Surgical Mortality". JAMA. 304 (15): 1693-1700.
[20] Haynes, AB; Weiser, TG; Berry, WR et al (2009) "A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population". NEJM. 360:491-499.
[21] Birkmeyer, JD (2010) "Strategies for Improving Surgical Quality – Checklists and Beyond." NEJM. 363: 1963-1965.

for the Hospital IQR Program and the Hospital OQR Program. We invite public comments on our proposal to add this new structural measure to the CY 2014 Hospital OQR Program measure set.

(2) Proposed Hospital Outpatient Department Volume for Selected Outpatient Surgical Procedures Measure

There is substantial evidence in recent peer-reviewed clinical literature that volume of surgical procedures, particularly of high risk surgical procedures, is related to better patient outcomes, including decreased surgical errors and mortality[1], [2], [3]. This may be attributable to greater experience and/or surgical skill, greater comfort with and, hence, likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure. For this reason, the National Quality Forum has previously endorsed measures of total all-patient surgical volume for Isolated CABG and Valve Surgeries (NQF #0124), Percutaneous Coronary Intervention (PCI) (NQF #0165), Pediatric Heart Surgery (NQF #0340), Abdominal Aortic Aneurism Repair (NQF #357), Esophageal Resection (#0361), and Pancreatic Resection (NQF #0366). Additionally, many consumer-oriented Web sites that display health care quality information required to be reported under State law (California, New York, Texas, Washington, Florida, Illinois, Michigan, Oregon) and private organizations (Leapfrog Group, U.S. News & World Report) are reporting

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[1] Livingston, E.H.; Cao, J "Procedure Volume as a Predictor of Surgical Outcomes". JAMA. 2010;304(1):95-97.

[2] David R. Flum, D.R.; Salem, L.; Elrod, J.B.; Dellinger, E.P.; Cheadle, A. Chan, L. "Early Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures". *JAMA. 2005;294(15):1903-1908.*

[3] Schrag, D; Cramer, L.D.; Bach, P.B.; Cohen, A.M.; Warren, J.L.; Begg, C.B " Influence of Hospital Procedure Volume on Outcomes Following Surgery for Colon Cancer" *JAMA. 2000; 284 (23): 3028-3035.*

procedure volume, in addition to provider performance on surgical process (SCIP measures) and outcome measures (SSI, Patient Safety Indicators, and Mortality), in order to provide more context to consumers choosing a health care provider. The currently NQF-endorsed measures of procedure volume (noted above) relate to surgeries performed only in inpatient settings, and would not be applicable to the types of procedures approved to be performed in HOPDs and ASCs.

The table below, which shows the proportion of procedures during calendar year 2010 performed in hospital outpatient departments stratified by broad categories, reveals that most hospital outpatient procedures (99%) fall into one of 8 categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.

CY 2010 Hospital Outpatient Data	
Procedure Category	**% of Total Services**
Cardiovascular	75.50%
Chest	0.00%
Ear	0.20%
Endocrine	0.10%
Eye	1.70%
Gastrointestinal	5.70%
Genitourinary	2.70%
Hemic & Lymphatic	0.30%
Maternity	0.00%
Musculoskeletal	3.80%
Nervous System	2.80%
Radiology	0.10%
Respiratory	1.00%
Skin	6.20%
Total	100.00%

Because surgical volume is associated with better quality, and surgical procedures are performed in hospital outpatient departments, we believe that surgical volume is appropriate for measuring the quality of these eight categories of surgical procedures performed in an HOPD. For the CY 2014 payment determination, we are proposing that HOPDs would report all-patient volume data with respect to these eight categories between the dates July 1, 2013 and August 15, 2013 with respect to the time period January 1, 2012 through December 31, 2012. In other words, under this proposal, an HOPD would report its CY 2012 all-patient volume data for these eight categories of procedures during the 45 day window of July 1, 2013 to August 15, 2013. The table below lists the specific HCPCS codes for each of the 8 procedure categories for which hospitals would be required to report the all-patient volume data. Like the other structural measures in the Hospital OQR program, data on this proposed measure would be collected via an online Web-based tool that will be made available to HOPDs via the QualityNet Web site.

We invite public comment on this proposal.

In summary, for the CY 2014 payment determination, in addition to the 23 measures we previously adopted in the CY 2011 OPPS/ASC final with comment period, we are proposing to adopt 1 new NHSN HAI measure, 6 additional new chart-abstracted measures, and 2 new structural measures. With respect to the proposed surgical site infection HAI measure, HOPDs would be required to report the data to the NHSN beginning with January 1, 2013 to through June 30, 2013 infection events and would be

required to use the procedures set out by the NHSN. We are proposing that submission of data on the five proposed diabetes measures and the proposed cardiac rehabilitation measure would begin with first quarter CY 2013 (January 1, 2013 to March 31, 2013) encounters. With respect to the proposed structural measures, we are proposing that HOPDs submit data between July 1, 2013 and August 15, 2013 with respect to a calendar year 2012 reporting time period.

We invite public comments on these proposals for the CY 2014 payment determination. The proposed complete measure set for the Hospital OQR Program CY 2014 payment determination, including the measures we adopted in the CY 2011 OPPS/ASC final rule with comment period, is reflected in the table below.

CY 2014 Hospital OQR Program Measure Set Reflecting Measures Previously Adopted and the Proposed Addition of 1 NHSN HAI Measure, 6 Chart-Abstracted Measures, and 2 Structural Measures
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)*

CY 2014 Hospital OQR Program Measure Set Reflecting Measures Previously Adopted and the Proposed Addition of 1 NHSN HAI Measure, 6 Chart-Abstracted Measures, and 2 Structural Measures
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 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: Surgical Site Infection***
OP-25: Diabetes: Hemoglobin A1c Management ***
OP-26: Diabetes Measure Pair: A Lipid management: low density lipoprotein cholesterol (LDL-C) <130, B Lipid management: LDL-C <100 ***
OP-27: Diabetes: Blood Pressure Management ***
OP-28: Diabetes: Eye Exam***
OP-29: Diabetes: Urine Protein Screening ***
OP-30: Cardiac Rehabilitation Patient Referral From an Outpatient Setting ***
OP-31: Safe Surgery Checklist Use***

OP-32: 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

CY 2014 Hospital OQR Program Measure Set Reflecting Measures Previously Adopted and the Proposed Addition of 1 NHSN HAI Measure, 6 Chart-Abstracted Measures, and 2 Structural Measures	
Cardiovascular	33000 through 37999
Respiratory	30000 through 32999

* New measure for the CY 2012 payment determination.
** New measure for the CY 2013 payment determination.
*** Proposed new measure for the CY 2014 payment determination.

3. Proposed Hospital OQR Program Measures for the CY 2015 Payment Determination

a. Proposed Retention of CY 2014 Hospital OQR Measures for the CY 2015 Payment Determination

In general, unless otherwise specified, we retain measures from one payment determination to the next. Accordingly, we are proposing that all of the measures we finalize for the CY 2014 payment determination continue to be used for the CY 2015 payment determination. We invite public comment on this proposal.

b. Proposed New NHSN HAI Measure for the CY 2015 Payment Determination

For the measure set to be used for the CY 2015 payment determination, we are proposing to adopt an additional HAI measure entitled Influenza Vaccination Coverage among Healthcare Personnel (HCP) (NQF # 0431). This measure is currently collected by the CDC via the NHSN.

Rates of serious illness and death resulting from influenza and its complications are increased in high-risk populations such as persons over 50 years or under four years of age, and persons of any age who have underlying conditions that put them at an increased risk. HCP can acquire influenza from patients and can transmit influenza to

patients and other HCP. Many HCP provide care for, or are in frequent contact with, patients with influenza or patients at high risk for complications of influenza. The involvement of HCP in influenza transmission has been a long-standing concern.[22,23,24]

Vaccination is an effective preventive measure against influenza, and can prevent many illnesses, deaths, and losses in productivity.[25] HCP are considered a high priority for expanding influenza vaccine use. Achieving and sustaining high influenza vaccination coverage among HCP is intended to help protect HCP and their patients and reduce disease burden and healthcare costs. Results of several studies indicate that higher vaccination coverage among HCP is associated with lower incidence of nosocomial influenza.[26,27,28] Such findings have led some to call for mandatory influenza vaccination of HCP.[29,30,31,32, 33]

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[22] Maltezou, H.C., Drancourt, M.: Nosocomial influenza in children. Journal of Hospital Infection 2003; 55:83-91

[23] Hurley, J.C., Flockhart, S.: An influenza outbreak in a regional residential facility. Journal of Infection Prevention 2010; 11:58-61

[24] Salgado, C.D., Farr, B.M., Hall, K.K., Hayden, F.G.: Influenza in the acute hospital setting. The Lancet Infectious Diseases 2002; 2:145-155.

[25] Wilde, J.A., McMillan, J.A., Serwint, J., Butta, J., O'Riordan, M.A., Steinhoff, M.C.: Effectiveness of influenza vaccine in health care professionals: a randomized trial. The Journal of the American Medical Association 1999; 281:908-913.

[26] Salgado, C.D., Giannetta, E.T., Hayden, F.G., Farr, B.M.: Preventing influenza by improving the vaccine acceptance rate of clinicians. Infection Control and Hospital Epidemiology 2004; 25: 923-928.

[27] Potter, J., Stott, D.J., Roberts, M.A., et al.: Influenza vaccination of health-care workers in long-term-care hospitals reduces the mortality of elderly patients. Journal of Infectious Diseases 1997; 175:1-6.

[28] Hayward, A.C., Harling, R., Wetten, S., et al.: Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. British Medical Journal 2006; 333:1241-1246.

[29] Talbot, T.R., Bradley, S.F., Cosgrove, S.E., et al.: SHEA position paper: Influenza vaccination of healthcare workers and vaccine allocation for healthcare workers during vaccine shortages. Infection Control and Hospital Epidemiology 2005; 26:882-890

[30] American College of Physicians (ACP), ACP policy on influenza vaccination of health care workers. http://www.acponline.org/running_practice/quality_improvement/projects/adult_immunization/flu_hcw.pdf.

[31] Greene, L.R., Cain, T.A., Dolan, S.A. et al. : APIC position paper: influenza immunization of healthcare personnel. Association of Professionals in Infection Control (APIC). November 2008. http://www.apic.org/Content/NavigationMenu/PracticeGuidance/Topics/Influenza/APIC_Position_Paper_I

Until recently, vaccination coverage among HCP has been well below the national Healthy People 2010 target of 60 percent,[34] but preliminary data suggest 62 percent of HCP reported receiving seasonal influenza vaccine in 2009-2010.[35] Only 37 percent reported receiving the 2009 pandemic A/H1N1 vaccine.[36]

HCP refers to all personnel working in healthcare settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air.[37] HCP may include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the healthcare facility, and persons (for example, clerical, dietary, house-keeping, laundry, security, maintenance, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be

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nfluenza_11_7_08final_revised.pdfhttp://www.apic.org/Content/NavigationMenu/PracticeGuidance/Topics/Influenza/APIC_Position_Paper_Influenza_11_7_08final_revised.pdf.

[32] National Patient Safety Foundation (NPSF), Mandatory flu vaccinations for healthcare workers. Press Release, November 18, 2009. http://www.npsf.org/pr/pressrel/2009-11- 18.php.

[33] Infectious Diseases Society of America (IDSA), IDSA policy on mandatory immunization of health care workers against seasonal and 2009 H1N1 influenza. Infectious Diseases Society of America (IDSA). September 30, 2009. http://www.idsociety.org/HCWimmunization/.

[34] Walker, F.J., Singleton, J.A., Lu, P., Wooten, K.G., Strikas, R.A.: Influenza vaccination of healthcare workers in the United States, 1989-2002. Infection Control and Hospital Epidemiology 2006; 27:257-265.

[35] http://www.cdc.gov/mmwr/preview/mmwrhtml/rr55e209a1.htm Influenza Vaccination of Health-Care Personnel
Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices

[36] Centers for Disease Control and Prevention., Interim results: Influenza A (H1N1) 2009 and Monovalent Seasonal Influenza Vaccination Coverage Among Health-Care Personnel—United States August 2009-January 2010. Morbidity and Mortality Weekly Report (MMWR); 59:357-362. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5912a1.htm

[37] Adapted from: Pearson ML., Bridges CB., Harper SA., : Influenza vaccination of health-care personnel: Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). Morbidity and Mortality Weekly Report (MMWR) 2006; 55:1-16. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm

transmitted to and from HCP and patients. Settings in which HCP may work include, but are not limited to, acute care hospitals, long-term care facilities, skilled nursing facilities, rehabilitation centers, physicians' offices, urgent care centers, outpatient clinics, home health agencies, and emergency medical services.

Currently, four States have "offer" laws for influenza vaccination of HCP, meaning that vaccine must be offered to HCP by healthcare facilities; and three States (Alabama, California, and New Hampshire) have "ensure" laws for influenza vaccination of HCP, meaning that vaccination of non-immune HCP is mandatory in the absence of a specified exemption or refusal; and, additionally, numerous hospitals and other healthcare facilities have established policies requiring mandatory influenza vaccination of their HCP.[38]

Currently, no State requires that hospitals report this measure to NHSN. However, approximately 13 hospitals (including long term acute care and rehabilitation), outpatient hemodialysis centers, long term care facilities, and ambulatory surgical centers are currently reporting HCP immunization data to NHSN. In September 2009, CDC released the Healthcare Personnel Safety (HPS) Component of NHSN, which complements Patient Safety and Biovigilance components available in NHSN. The HPS Component replaced CDC's National Surveillance System for Health Care Workers (NaSH) and is comprised of two modules: the Blood/Body Fluid Exposure Module and the Influenza Vaccination and Management and Exposure Module.[39] Currently, participation in either module is voluntary. The current Influenza Vaccination and

[38] For additional information regarding healthcare facilities' influenza vaccine policies, please see: http://www.immunize.org/honor%2Droll/.http://www.immunize.org/honor%2Droll/.

[39] Available at: http://www.cdc.gov/nhsn/hps.htmlhttp://www.cdc.gov/nhsn/hps.html.

Management and Exposure Module may soon offer options for healthcare facilities to submit vaccination summary data. NHSN plans to partner with vendor-based surveillance systems to permit periodic data extractions into NHSN.

The modules feature basic, custom, and advanced analysis capabilities available in real-time, which allow individual healthcare facilities to compile and analyze their own data, as well as benchmark these results to aggregate NHSN estimates. The HPS Component can assist participating facilities in developing surveillance and analysis capabilities to permit the timely recognition of HCP safety problems and prompt interventions with appropriate measures. Influenza vaccination data submitted to CDC will ultimately capture regional trends on the yearly uptake of the vaccine, prophylaxis and treatment for healthcare personnel, as well as the elements within yearly influenza campaigns that succeed or require improvement. At the State and national levels, the HPS Component will aid in monitoring rates and trends.

Due to the significant impact of HCP influenza vaccination on patient outcomes, we believe this measure is appropriate for measuring the quality of care in hospital outpatient departments. Healthcare Personnel (HCP) Influenza Vaccination is one of the HAI measures that we proposed to adopt for the FY 2015 Hospital IQR Program in the FY 2012 IPPS/LTCH PPS proposed rule. This measure assesses the percentage of healthcare personnel who have been immunized for influenza during the flu season. The specifications for this measure are available at http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf

The proposed HCP Influenza Vaccination measure is NQF-endorsed for the hospital setting and applies to the hospital outpatient setting. Therefore, this measure meets the requirement for measure selection under section 1833(t)(17)(C)(i) of the Act. We are proposing to adopt the Influenza Vaccination Coverage among Healthcare Personnel measure that is collected by the CDC via the NHSN. The NHSN proposed reporting mechanism for this proposed HAI measure is discussed in greater detail in section XIV.C.2.a. of this proposed rule. Data submission for this NHSN proposed measure would relate to immunizations from October 1, 2013 through March 31, 2014 for the CY 2015 payment determination. We are proposing that hospital outpatient departments use the NHSN infrastructure and protocol to report the measure for Hospital OQR purposes. We invite public comment on our proposal to adopt this HAI measure into the Hospital OQR Program for the CY 2015 payment determination.

Proposed Hospital OQR Program Measure Set for the CY 2015 Payment Determination
OP-1: Median Time to Fibrinolysis
OP-2: Fibrinolytic Therapy Received Within 30 Minutes
OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP-4: Aspirin at Arrival
OP-5: Median Time to ECG
OP-6: Timing of Antibiotic Prophylaxis
OP-7: Prophylactic Antibiotic Selection for Surgical Patients
OP-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

Proposed Hospital OQR Program Measure Set for the CY 2015 Payment Determination
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 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: Surgical Site Infection (via NHSN)***
OP-25: Diabetes: Hemoglobin A1c Management ***
OP-26: Diabetes Measure Pair: A Lipid management: low density lipoprotein cholesterol (LDL-C) <130, B Lipid management: LDL-C <100 ***
OP-27: Diabetes: Blood Pressure Management ***
OP-28: Diabetes: Eye Exam***
OP-29: Diabetes: Urine Protein Screening ***
OP-30: Cardiac Rehabilitation Patient Referral From an Outpatient Setting ***
OP-31: Safe Surgery Checklist Use***

OP-32: 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

Proposed Hospital OQR Program Measure Set for the CY 2015 Payment Determination	
Skin	10000 through 19999, G0247, 0046T, 0268T, G0127, C9726, C9727
Genitourinary	50000 through 58999, 0193T, 58805
Cardiovascular	33000 through 37999
Respiratory	30000 through 32999
OP-33: Influenza Vaccination Coverage among Healthcare Personnel (HCP) ****	

* New measure for the CY 2012 payment determination.
** New measure for the CY 2013 payment determination.
*** Proposed new measure for the CY 2014 payment determination.
**** Proposed new measure for the CY 2015 payment determination.

D. Possible Quality Measures under Consideration for Future Inclusion in the Hospital OQR Program

The current measure set for Hospital OQR includes measures that assess imaging efficiency patterns, care transitions, and the use of HIT. We are proposing in this proposed rule to add measures to the CY 2014 and CY 2015 measure sets addressing diabetes care, HAIs, referrals for cardiac rehabilitation, and Safe Surgery Checklist use. Thus, the measures that we have previously adopted for the Hospital OQR Program, as well as the proposed measures being proposed in this proposed rule, address infection outcomes and infection control processes. In previous years' rulemakings, we have provided lists of measures that are under consideration for future adoption into the Hospital OQR measure set. Below is a list of potential measurement areas that we are considering for future Hospital OQR payment determinations (beginning with CY 2015) for which we are soliciting public comment. In particular, we seek comment on the inclusion of Patient Experience of Care Measures in the Hospital OQR measure set for a

future payment determination, such as existing Consumer Assessment of Healthcare Providers and Systems **(**CAHPS) surveys for clinicians/groups and the CAHPS Surgical Care Survey, sponsored and submitted by the American College of Surgeons (ACS) and the Surgical Quality Alliance (SQA).

We also intend to align the surgical safety measures across the HOPD and ASC settings and would seek to utilize comparable data to assess patient safety in these settings. We seek comment on the potential submission of such measures by HOPDs via quality codes submitted on claims in the future. We also seek comment on the inclusion of measures of Anesthesia related Complications in the Hospital OQR measurement set.

Measures and Measurement Topics Under Consideration for Future Hospital OQR Program Payment Determinations Beginning with CY 2015
Measures for future development:
Procedure Specific Measures
Colonoscopy and other Endoscopy measures
Cataract Surgery measures
Cancer Care
Adjuvant Chemotherapy is Considered or Administered within 4 Months of Surgery to Patients Under Age 80 with AJCC III Colon Cancer.
Adjuvant Hormonal Therapy for Patients with Breast Cancer
Needle Biopsy to Establish Diagnosis of Cancer Precedes Surgical Excision/Resection.
Heart Failure
Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
Heart Failure: Left Ventricular Ejection Fraction Assessment
Heart Failure: Combination Medical Therapy for Left Ventricular Systolic Dysfunction
Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction
Heart Failure: Counseling regarding Implantable Cardioverter-Defibrillator (ICD) Implantation for Patients with Left Ventricular Systolic Dysfunction on Combination Medical Therapy

Heart Failure: Patients with Left Ventricular Systolic Dysfunction on Combination Medical Therapy
Heart Failure: Symptom Management
Heart Failure: Symptom and Activity Assessment
Heart Failure: Patient Education
Heart Failure: Overuse of Echocardiography
Heart Failure: Post-Discharge Appointment for Heart Failure Patients
Surgical Safety
Patient Fall
Patient Burn
Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
Hospital Transfer/Admission
Patient Experience-of-Care
Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians/groups
CAHPS Surgical Care Survey
Anesthesia Related Complications
Death
Cardiac Arrest
Perioperative Myocardial Infarction
Anaphylaxis
Hyperthermia
Transfusion Reaction
Stroke, Cerebral Vascular Accident, or Coma following anesthesia
Visual Loss
Medication Error
Unplanned ICU admission
Patient intraoperative awareness
Unrecognized difficult airway
Reintubation
Dental Trauma
Perioperative aspiration
Vascular access complication, including vascular injury or pneumothorax
Pneumothorax following attempted vascular access or regional anesthesia
Infection following epidural or spinal anesthesia
Epidural hematoma following spinal or epidural anesthesia

High Spinal
Postdural puncture headache
Major systemic local anesthetic toxicity
Peripheral neurologic deficit following regional anesthesia
Infection following peripheral nerve block
Additional Measurement Topics
NQF Serious Reportable Events in Healthcare
Medication Reconciliation
Chemotherapy
Post-discharge follow up
Post-discharge ED visit within 72 hours
Breast cancer detection rate

We invite public comment on these measures and other topics that we might consider proposing to adopt beginning with the Hospital OQR Program CY 2015 payment determination. We also are seeking suggestions and rationales to support the adoption of measures and topics for the Hospital OQR Program which do not appear in the table above.

E. Proposed Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2012 Payment Update

1. Background

Section 1833(t)(17)(A) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), requires 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 under section 1833(t)(17) of the Act, 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 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, or market basket update, is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To implement the requirement to reduce the market basket update 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), and in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72099). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this CY 2012 OPPS/ASC proposed rule.

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2012

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 2012 annual payment update factor. For the CY 2012 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of $68.052 by the proposed full conversion factor of $69.420. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2012 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.

F. Extraordinary Circumstances Extension or Waiver for CY 2012 and Subsequent Years

In our experience, there have been times when hospitals have been unable to submit required quality data due to extraordinary circumstances that are not within their control. It is our goal to not penalize hospitals for such circumstances and we do not want to unduly increase their burden during these times. Therefore, in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60046 through 600647), we adopted a process for hospitals to request and for CMS to grant extensions or waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the hospital. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72103), we retained these procedures with some modifications. For CY 2012 and subsequent years, we are proposing to retain these procedures with one modification. We are proposing to extend these procedures to the submission of medical record documentation for purposes of complying with our validation requirement for the Hospital OQR Program.

Under this process, 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 and any other 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 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, to the CEO and any additional designated hospital personnel, notifying them that the hospital's request has been received;

(2) Provide a formal response to the CEO and any additional designated hospital personnel using the contact information provided in the request notifying them of our decision; and

(3) Complete our review of any CY 2012 request and communicate our response within 90 days following our receipt of such a request.

We note that we might also decide to grant waivers or extensions to hospitals that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, hurricane) affects an entire region or locale. If we make the determination to grant a waiver or extension to hospitals in a region or locale, we would communicate this decision to hospitals and vendors through routine communication channels, including but not limited to e-mails and notices on the QualityNet Web site.

We invite public comment on this proposal to retain our existing process for granting extraordinary circumstances extensions or waivers, and to extend this process to the submission of medical record documentation, for the Hospital OQR Program.

G. Proposed Requirements for Reporting of Hospital OQR Data for CY 2013 and Subsequent Years

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 the payment determination requirements for the CY 2012 payment update in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72099 through 72106).

With respect to the payment determinations for CY 2013 and subsequent years, we are proposing to implement the requirements listed below. Most of these requirements are the same as the requirements we implemented for the CY 2012 payment determination, with some proposed modifications.

1. Administrative Requirements for CY 2013 and Subsequent Years

To participate in the Hospital OQR Program, we are proposing that several administrative steps be completed. These steps are the same as those we finalized for the CY 2012 payment determination and would require the hospital to:

- Identify a QualityNet security administrator who follows the registration process located on the QualityNet Web site (http://www.QualityNet.org) and submits the information to the appropriate CMS-designated contractor. All CMS-designated contractors would be identified on the QualityNet Web site. The same person may be the QualityNet security administrator for both the Hospital IQR Program and the Hospital OQR Program. Based on our experience, we believe that the QualityNet security administrator typically fulfills a variety of tasks related to the hospital's ability to participate in the Hospital OQR Program, such as: creating, approving, editing and/or terminating QualityNet user accounts within the organization; monitoring QualityNet usage to maintain proper security and confidentiality measures; and serving as a point of contact for information regarding QualityNet and the Hospital OQR Program. However, the main purpose of the QualityNet

Administrator is to serve as a contact for security purposes. Because of CMS information systems security requirements, the hospital would be required to maintain a current QualityNet security administrator for as long as the hospital participates in the program. While only a single QualityNet security administrator would be required for program purposes, we suggest to hospitals that it may be beneficial to have more than one QualityNet security administrator for back-up purposes.

- Register with QualityNet, regardless of the method used for data submission.
- Complete and submit an online participation form if this form (or a paper Notice of Participation form) has not been previously completed, if a hospital has previously withdrawn, or if the hospital acquires a new CCN. For Hospital OQR Program purposes, hospitals that share the same CCN would be required to complete a single online participation form. At this time, the participation form for the Hospital OQR Program is separate from the participation form required for the Hospital IQR Program and completing a form for each program is required. Agreeing to participate includes acknowledging that the data submitted to the CMS-designated contractor would be submitted to CMS, shared with one or more other CMS contractors that support the implementation of the Hospital OQR Program, and be publicly reported.

We are proposing to retain the procedures and update the deadlines for submitting the participation form which we established in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100):

Hospitals with Medicare acceptance dates on or after January 1 of the year prior to the annual payment update affected: For the CY 2013 and subsequent years payment updates, we are proposing that any hospital that has a Medicare acceptance date on or after January 1 of the year prior to the annual payment update affected (for example, 2012 would be the year prior to the affected CY 2013 annual payment update), including a new hospital and hospitals that have merged, must submit a completed participation form no later than 180 days from the date identified as its Medicare acceptance date on the CMS Certification and Survey Provider Enhanced Reporting (CASPER) system. Hospitals typically receive a package notifying them of their new CCN after they receive their Medicare acceptance date. The Medicare acceptance date is the earliest date that a hospital can receive Medicare payment for the services that it furnishes. Completing the participation form would include supplying the name and address of each hospital campus that shares the same CCN.

The use of the Medicare acceptance date as beginning the timeline for Hospital OQR Program participation allows us to monitor more effectively hospital compliance with the requirement to complete a participation form because a hospital's Medicare acceptance date is readily available to CMS through its data systems. In addition, providing an extended time period to register for the program would allow newly functioning hospitals sufficient time to get their operations fully functional before having to collect and submit quality data.

We are aware that Medicare acceptance dates may be back-dated. In that event, we would consider a hospital's request to allow additional time to elect to participate.

Hospitals with Medicare acceptance dates before January 1 of the year prior to the affected annual payment update: For the CY 2013 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, 2012 would be the year prior to the affected CY 2013 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 March 31 of the year prior to the affected annual payment update. We are proposing a deadline of March 31, because we believe it would give hospitals sufficient 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 data for first quarter of the year's services. This requirement would apply to all hospitals whether or not the hospital billed for payment under the OPPS.

For the CY 2013 and subsequent years payment updates, we are proposing that any Hospital OQR participating hospital that wants to withdraw may do so at any time from January 1 to November 1 of the year prior to the affected annual payment update. A hospital that withdraws during this time period for any annual payment update would not be able to later sign up to participate for that payment update, would receive a 2.0 percentage point reduction to its OPD fee schedule increase factor for that year, and would be required to submit a new participation form in order to participate in any future year of the Hospital OQR Program. We note that once a hospital has submitted a participation form, it is considered to be an active Hospital OQR Program participant

until such time as the hospital submits a withdrawal form to CMS or is designated as closed in the CMS CASPER system.

We invite public comment on these proposed Hospital OQR Program administrative requirements for the CY 2013 and subsequent years' payment determinations.

2. Form, Manner, and Timing of Data Submission for CY 2013 and Subsequent Years

We are proposing 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:

a. Proposed CY 2013 and CY 2014 Data Submission Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS

With respect to the proposed chart-abstracted measures for which hospitals would submit data directly to CMS, we are proposing for CY 2013 and CY 2014 that participating hospitals submit chart-abstracted data for each applicable quarter by the deadline posted on the QualityNet Web site; there must be no lapse in data submission. For the CY 2013 program, we are proposing that the applicable quarters would be as follows: 3rd quarter CY 2011, 4th quarter CY 2011, 1st quarter CY 2012, and 2nd quarter CY 2012. Hospitals that did not participate in the CY 2012 Hospital OQR Program, but would like to participate in the CY 2013 Hospital OQR Program, and that have a Medicare acceptance date on the CASPER system before January 1, 2012, would begin data submission with respect to 1st quarter CY 2012 encounters using the 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, 2012, data submission must begin with the first full quarter following the submission of a completed online participation form.

For the CY 2014 program, we are proposing that the applicable quarters for previously finalized measures would be as follows: 3rd quarter CY 2012, 4th quarter CY 2012, 1st quarter CY 2013, and 2nd quarter CY 2013. With respect to our proposed measures (5 Diabetes measures and 1 Cardiac Rehabilitation measure), the applicable quarters would be 1st quarter CY 2013 and 2nd quarter CY 2013. Hospitals that did not participate in the CY 2013 Hospital OQR Program, but would like to participate in the CY 2014 Hospital OQR Program, and that have a Medicare acceptance date on the CASPER system before January 1, 2013, would begin data submission with respect to 1st quarter CY 2013 encounters using the CY 2014 measure set that was finalized in the CY 2013 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.

We are proposing that hospitals must submit all required data according to the data submission schedule that is made available on the QualityNet Web site (https://www.QualityNet.org). This Web site meets or exceeds all current HIPAA requirements. 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 2012

(January-March, 2012) would be on or around August 1, 2012. The actual submission deadlines would be posted on the http://www.QualityNet.org Web site.

We are proposing that hospitals submit chart-abstracted data to the OPPS Clinical Warehouse using either the CMS Abstraction and Reporting Tool for Outpatient Department (CART-OPD) measures or the tool of a third-party vendor that meets the measure specification requirements for data transmission to QualityNet.

We are proposing that hospitals must collect Hospital OQR data from outpatient hospital encounters to which the required measures apply. In previous rulemakings, we have utilized various terms for describing the unit of care for outpatient hospital reporting, including encounter, episode, episode of care, and discharge. We note that for outpatient hospital services, the term encounter is explicitly used and defined in the Medicare Benefit Policy Manual (Pub. 100-02), Chapter 6, Section 20.3, which states "A hospital outpatient 'encounter' is a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient." For Medicare outpatient services, the terms episode and episode of care also are used. When discussing inpatient services, the Medicare Benefit Policy Manual specifically refers to discharges; the term encounter is not used in reference to inpatient services. Thus, for Hospital OQR, we are examining encounters, episodes, or episodes of care and would use these terms in connection with the Hospital OQR Program.

We will make every effort to ensure that data elements common to both inpatient and outpatient settings are defined consistently for purposes of quality reporting (such as "time of arrival").

We are proposing that hospitals must submit quality data using the CCN under which the care was furnished.

To be accepted into the OPPS Clinical Warehouse and to meet data submission requirements, data submissions, at a minimum, must be timely, complete, and accurate. Data submissions are considered to be "timely" when data are successfully accepted into the OPPS Clinical Warehouse on or before the reporting deadline. A "complete" submission would be determined based on whether the data satisfy the sampling criteria that are published and maintained in the Hospital OQR Specifications Manual, and must correspond to both the aggregate number of encounters submitted by a hospital and the number of Medicare claims the hospital submits for payment; requirements for utilizing the option of sampling are discussed below.

We strongly recommend that hospitals review OPPS Clinical Warehouse feedback reports and the Hospital OQR Provider Participation Reports that are accessible through their QualityNet accounts. These reports enable hospitals to verify whether the data they or their vendors submitted were accepted into the OPPS Clinical Warehouse and the date/time that such acceptance occurred. We also note that irrespective of whether a hospital submits data to the OPPS Clinical Warehouse itself or uses a vendor to complete the submissions, the hospital is responsible for ensuring that Hospital OQR requirements are met.

b. Eligibility to Voluntarily Sample and Proposed Data Submission Exception for Low Patient Volume for CY 2013 and Subsequent Years

If a hospital has a sufficiently large number of eligible encounters with respect to a measure, the hospital has the option to sample those encounters and submit data only for these sampled encounters, rather than submitting data on all of the eligible encounters. This sampling scheme, which includes the minimum number of encounters that a hospital must have in order to sample, is set out in the Hospital OQR Specifications Manual at least 3 months in advance of each data submission deadline. We note that sampling is not required and hospitals may submit more cases than the minimum set by our sampling scheme and may submit up to all of their cases if they desire to do so. We changed the notification timeframe for this sampling scheme to at least 3 months from at least 4 months to be consistent with the Hospital OQR Specifications Manual release schedule. If a hospital chooses to sample for a particular quarter, the hospital must meet the sampling requirements for the required chart-abstracted measures that quarter.

In addition, to reduce the burden on hospitals that treat a low number of patients but otherwise meet the submission requirements for a particular quality measure, we are proposing to continue our policy that hospitals that have five or fewer encounters (both Medicare and non-Medicare) for any measure included in a measure topic in a quarter would not be required to submit patient level data for the entire measure topic for that quarter. Even if hospitals would not be required to submit patient level data because they have five or fewer encounters (both Medicare and non-Medicare) for any measure included in a measure topic in a quarter, we note that they may voluntarily do so.

c. Proposed Population and Sampling Data Requirements Beginning with the CY 2013 Payment Determination and for Subsequent Years

During the past three years of the Hospital OQR Program, the submission of population and sampling data was not required, though hospitals could submit, on a voluntary basis, the aggregate numbers of outpatient encounters which are eligible for submission under the Hospital OQR Program and sample size counts. These aggregated numbers of outpatient encounters represent the number of outpatient encounters in the universe of all possible cases eligible for data reporting under the Hospital OQR Program. For the CY 2012 payment update, we proposed, but did not adopt, a policy to require submission of this population and sample size data.

We are now proposing that beginning with the CY 2013 payment determination, hospitals must submit 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.

Under this proposal, a hospital would submit on a quarterly basis an aggregate population and sample size count with respect to each measure regardless of whether any patients met the inclusion criteria for the measure population. For example, if a hospital did not treat any patients who met the inclusion criteria for a specific measure, the hospital would still be required to submit a zero for its quarterly aggregate population and sample count to meet the requirement.

Our analysis of third quarter CY 2010 outpatient hospital submitted data shows that for hospitals that submitted abstracted data for encounters, at least 99 percent of

these providers voluntarily reported both population and sampling data. Data completeness was also assessed by comparing reported Medicare cases to submitted claim counts, minimum encounter count thresholds based on reported population sizes, and minimum sample size thresholds based on reported population sizes. We found that less than 10 percent of hospitals differed significantly in their Medicare self-reported encounters versus Medicare claim counts in the Clinical Warehouse, and less than 20 percent did not meet case count or sample size minimum thresholds. Based upon this analysis, we believe that hospitals have had sufficient time to become familiar with Hospital OQR data reporting and have developed data systems necessary to support this proposed requirement; in fact recent data suggest that the vast majority of hospitals have done so.

We are proposing that the deadlines for the reporting of aggregate numbers of outpatient hospital encounters and sample size counts would be the same as those for reporting data for chart–abstracted measures, and these deadlines would be posted on the data submission schedule that would be available on the QualityNet Web site. Hospitals would be permitted to submit this information prior to the deadline; this would allow us to advise hospitals regarding their incomplete submission status as appropriate and give hospitals sufficient time to make appropriate revisions before the data submission deadline.

We plan to use the aggregate population and sample size data to assess data submission completeness to the OPPS Clinical Warehouse and adherence to sampling requirements for Medicare and non-Medicare patients.

d. Proposed Claims-Based Measure Data Requirements for the CY 2013 and CY 2014 Payment Determinations

For the claims-based measures, we are proposing to calculate 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. For the CY 2013 and CY 2014 payment updates, we would utilize paid Medicare FFS claims for services furnished from January 1, 2010 to December 31, 2010 and January 1, 2011 to December 31, 2011, respectively.

e. Proposed Structural Measure Data Requirements for the CY 2013 and CY 2014 Payment Determinations

For the CY 2013 payment determination, we are proposing that hospitals would be required to submit data on the structural measures, including OP-17: Tracking Clinical Results between Visits, between July 1, 2012 and August 15, 2012 with respect to the time period of January 1, 2011 to December 31, 2011.

As discussed above, we are proposing to adopt two new structural measures for the CY 2014 payment determination, OP-31: Safe Surgery Checklist Use, and OP-32: Hospital Outpatient Department Volume for Selected Outpatient Surgical Procedures. We are proposing that for the CY 2014 payment determination, hospitals would 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.

f. Proposed Data Submission Deadlines for the Proposed NHSN HAI Surgical Site Infection Measure for the CY 2014 Payment Determination

As discussed above, we are proposing to adopt a new HAI measure for the CY 2014 payment determination: surgical site infection. We are proposing to use the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of this measure to NHSN. We refer readers to the CDC's NHSN Web site (http://www.cdc.gov/nhsn) for detailed data submission and reporting procedures. We believe that these procedures are feasible because they are already widely used by over 4,000 hospitals reporting HAI data to the NHSN. Our proposal seeks to reduce hospital burden by aligning CMS data submission and reporting procedures with NHSN procedures currently used by hospitals, including hospitals complying with 28 State HAI reporting requirements. The submission timeframes for the CY 2014 payment determination that we are proposing to use for the proposed HAI measure are shown below. Hospitals would be required to submit their quarterly data to the NHSN for Hospital OQR purposes according to the schedule shown in the table below (any updates to this schedule made by CMS will be posted on the QualityNet Web site).

Proposed Submission Timeframe for the Proposed Surgical Site Infection Measure for the CY 2014 Payment Determination		
CY 2013 Infection Events	**CDC-NHSN Collection and Quarterly Report**	**Final Submission Deadline for Hospital OQR Program CY 2014 Payment Determination**
Q1 (Jan 1 to Mar 31, 2013)	January 31st to August 1st	August 1, 2013
Q2 (Apr 1 to Jun 30, 2013)	April 30th to November 1st	November 1, 2013

Hospitals would have until the Hospital OQR final submission deadline to submit their quarterly data to NHSN. After the final Hospital OQR Program submission deadline has occurred for each CY 2013 quarter to be used toward the CY 2014 payment determination, we will obtain the hospital-specific calculations generated by the NHSN for the Hospital OQR Program.

g. Proposed Data Submission Requirements for OP-22, ED-Patient Left Without Being Seen, for the CY 2013 and CY 2014 Payment Determinations

With respect to OP-22: ED-Patient Left Without Being Seen, we are proposing that hospitals would be required to submit data once for each of the CY 2013 and CY 2014 payment determinations via a Web-based tool located on the QualityNet Web site. For the CY 2013 payment determination, hospitals would be required to submit data between July 1, 2012 and August 15, 2012 with respect to the time period from January 1, 2011 to December 31, 2011. For the CY 2014 payment determination, hospitals would be required to submit data between July 1, 2013 and August 15, 2013 with respect to the time period of January 1, 2012 to December 31, 2012.

We invite public comment on these proposals for data collection and submission requirements.

3. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS: Proposed Data Validation Approach for the CY 2013 Payment Determination

a. Randomly Selected Hospitals

Similar to our approach for the CY 2012 payment determination (75 FR 72103 through 72106), we are proposing to validate chart-abstracted data submitted directly to CMS from randomly selected hospitals for the CY 2013 payment determination. To reduce hospital burden and to facilitate our efforts to reallocate resources in the event that we finalize the targeting proposal discussed below, for the CY 2013 payment determination, we are proposing to reduce the number of randomly selected hospitals from 800 to 450. We have found that hospitals are consistently reporting high accuracy rates for chart-abstracted measures and that variation among hospitals is relatively low. We believe that this low level of variation between hospitals will allow us to reduce the sample size while not diminishing our ability to make statistical inferences from the sample. Thus, we believe that we can safely reduce sample size and still have sufficient case numbers for purposes of validation. Because these 450 hospitals will be selected randomly, every Hospital OQR Program participating hospital will be eligible each year for validation selection. To be eligible for random selection for validation, a hospital must be coded as open in the OSCAR system at the time of selection and must have submitted at least 10 encounters to the OPPS Clinical Warehouse during the data collection period for the CY 2013 payment determination. We are proposing this 10

encounter minimum so that we have a sufficient sample size for calculating a statistically valid validation score.

b. Proposed Use of Targeting Criteria for Data Validation Selection for CY 2013

(1) Background

In the CY 2011 OPPS/ASC proposed rule (75 FR 46381), we stated that we were considering building upon what we proposed as a validation approach for the Hospital OQR Program. We noted that we were considering, in addition to selecting a random sample of hospitals for validation purposes, selecting targeted hospitals based on criteria designed to measure whether the data these hospitals have reported raises a concern regarding data accuracy. Because hospitals had gained little experience with validation under the Hospital OQR at that time, we noted that we were considering this approach for possible use beginning with the CY 2013 payment determination. Examples of targeting criteria suggested for inclusion:

- Abnormal data patterns identified such as consistently high Hospital OQR measure denominator exclusion rates resulting in unexpectedly low denominator counts;
- Whether a hospital had previously failed validation;
- Whether a hospital had not been previously selected for validation for 2 or more consecutive years;
- Whether a hospital had low submitted case numbers relative to population sizes; or
- Whether a hospital had any extreme outlier values for submitted data elements.

We invited comment on whether, in addition to random sampling for validation, we should use targeted validation and, if so, what criteria for targeting we should adopt.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72106) we responded to the comments we received and noted that for the CY 2013 payment determination, Hospital OQR Program data reporting will have been completed for four payment determinations: CYs 2009, 2010, 2011, and 2012. Further, hospitals will have had the opportunity to learn from the validation process. We also stated that we intended to propose to implement validation targeting criteria for CY 2013 and subsequent years in the CY 2012 OPPS/ASC proposed rule.

(2) Proposed Targeting Criteria for Data Validation Selection for CY 2013

In addition to proposing to randomly selecting 450 hospitals for validation, we are proposing to select up to an additional 50 hospitals based upon targeting criteria. A hospital could be 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. We are proposing to define an "outlier value" for purposes of this targeting as a measure value that appears to deviate markedly from the measure values for other hospitals. For a normally distributed variable, nearly all values of the variable lie within 3 standard deviations of the mean; very few values lie past the 3 standard deviation mark. One definition of an outlier is a value that exceeds this threshold.[40] In order to target very

[40] Ruan, Da, Chen, Guoguing, Kerre, Etienne E., and Wets, Geert, (2010), Intelligent Data Mining: Techniques and Applications, Studies in Computational Intelligence, Vol. 5, Page 318.

extreme values, we are proposing to target hospitals that greatly exceed this threshold; such extreme values strongly suggest that data submitted is inaccurate. Specifically, we are proposing to select hospitals for validation if their measure value for a measure is greater than 5 standard deviations from the mean, placing the expected occurrence of such a value outside of this range at 1 in 1,744,278. If more than 50 hospitals meet either of the above targeting criteria, then up to 50 would be selected randomly from this pool of hospitals.

c. Encounter Selection

For each selected hospital (random or targeted), we are proposing 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 supporting medical record documentation that corresponds to the encounter.

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: 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 measured hospital as well as at a national level; and 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 hospitals per year will selected.

For all selected hospitals, we will 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 are proposing to validate data for April 1, 2011 to March 31, 2012 encounters as this provides a full year of the most recent data possible to use for purposes of completing the validation in time to make the CY 2013 payment determinations.

d. Validation Score Calculation

For the CY 2013 payment determination, we are proposing to use the validation calculation approach finalized for the CY 2012 payment determination 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.

To receive the full OPPS OPD fee schedule increase factor for CY 2013, 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 payment determination (75 FR 72105). We also are proposing to utilize the same medical record documentation submission procedures that we also finalized for the CY 2012 payment determination (75 FR 72104) with one modification; we are proposing to shorten the time period given to hospitals to submit medical record documentation to the CMS contractor from 45 calendar days to 30 calendar days. This proposed change in submission timeframe will align the process with requirements in 42 CFR 476.78(b)(2), which allow 30 days for chart submission in the context of QIO review. We are proposing this deadline of 30 days also to reduce the time for data validation completion to increase timeliness of providing hospitals with feedback on their abstraction accuracy.

4. Additional Data Validation Conditions under Consideration for CY 2014 and Subsequent Years

We continue to consider building upon our validation approach of targeting hospitals to address data quality concerns and to ensure that our payment decisions are made using accurate data. Thus, we are requesting public comment on the following additional targeting criteria to select hospitals for validation:

● Whether a hospital that was open under its current CCN and had not been selected for validation in the previous 3 years. This is consistent with validation targeting criteria we recently proposed to implement for the CY 2015 Hospital IQR Program (76 FR 25920 through 25921).

● Whether a hospital had submitted a low number of encounters relative to population sizes; or

● Whether a hospital reported significant numbers of "Unable to Determine" data elements.

We welcome public comment on these proposals, and are specifically interested in receiving public comments on definitions of what low numbers relative to population sizes and what would constitute significant numbers of "Unable to Determine" data elements.

H. Proposed Hospital OQR Reconsideration and Appeals Procedures for CY 2013 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. 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 modification.

We are proposing to continue this process for the CY 2013 payment determination and subsequent years. Under this proposed 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 2013 payment determination, the request must be submitted by February 3, 2013) and must contain the following information:

  - oo Hospital CCN.

  - oo Hospital Name.

  - oo 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.

  - oo 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.

oo CEO and any additional designated hospital personnel contact information, including name, e-mail address, telephone number, and mailing address (must include physical address, not just a post office box).

oo 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 may not 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). We are proposing that hospitals would submit this documentation to a designated CMS contractor which would have authority to review patient level information. We would 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 would 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 note that, consistent with our policy for CY 2012 reconsiderations, reconsideration request forms would not need to be signed by the hospital's CEO.

Following receipt of a request for reconsideration, CMS would--

- Provide an e-mail acknowledgement, using the contact information provided in the reconsideration request, to the CEO and any additional designated hospital personnel notifying them that the hospital's request has been received.

- Provide a formal response to the hospital CEO and any additional designated hospital personnel, using the contact information provided in the reconsideration request, notifying the hospital of the outcome of the reconsideration process.

We intend to complete any reconsideration reviews and communicate the results of these determinations within 90 days following the deadline for submitting requests for reconsideration.

We also propose to apply the same policies that we finalized for the CY 2012 payment determination 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 would 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 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 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 would initially be limited to determining whether the medical documentation submitted in response to the designated CMS contractor's request was the correct documentation. If we determine that the hospital did submit the correct medical documentation, we would abstract the data elements and compute a new validation score for the encounter. If we conclude that the hospital did not submit the correct medical record documentation, we would not further consider the hospital's request.

- If a hospital requests reconsideration on the basis that it disagrees with a determination that it did not submit the requested medical record documentation to the CMS contractor within the proposed 30 calendar day timeframe, our review would initially be limited to determining whether the CMS contractor received the requested medical record documentation within 30 calendar days, and whether the hospital received the initial medical record request and reminder notice. If we determine that the CMS contractor timely received paper copies of the requested medical record documentation, we would abstract data elements from the medical record documentation submitted by the hospital and compute a validation score for the hospital. If we determine that the hospital received two letters requesting medical documentation but did not submit the requested documentation within the 30 calendar day period, we would not further consider the hospital's request.

If a hospital is dissatisfied with the result of a Hospital OQR reconsideration decision, the hospital would be able to file an appeal under 42 CFR Part 405, Subpart R (PRRB appeal).

We invite public comment on our proposed CY 2013 Hospital OQR Program reconsideration and appeals procedures.

I. 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 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 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. We also anticipate such a transition for hospital outpatient measures, although likely somewhat after the transition for hospital inpatient measures. This is a result of the fact that the clinical quality measures in the EHR Incentive Program currently are primarily aligned with the Hospital IQR Program, rather than the Hospital OQR Program. 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 measures based on clinical record data.

J. 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs

1. Background

Under section 4102(a) of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5), eligible hospitals and CAHs may qualify for incentive payments if they successfully demonstrate meaningful use of certified EHR technology. The final rule for the Medicare EHR Incentive Program (75 FR 44314) established the Stage 1 criteria for meaningful use, which include, among other requirements, that eligible hospitals and CAHs report clinical quality measures (CQMs) to CMS, in addition to meeting other objectives and measures described in the final rule. The final rule also requires that for the 2012 payment year and subsequent years, an eligible hospital or CAH using certified EHR technology must submit information on the specified clinical quality measures electronically. However, for the 2011 payment year, eligible hospitals and CAHs are required to submit CQM results as calculated by certified EHR technology through attestation, rather than submit the information electronically. In the final rule (75 FR 44380), we also stated that we anticipated that we would have completed the necessary steps to have the capacity to receive information on CQMs electronically for the 2012 payment year. However, we also acknowledged that if we do not have the capacity to accept electronic reporting of CQMs in 2012, consistent with

sections 1848(o)(2)(B)(ii) and 1886(n)(3)(B)(ii) of the Act, we would continue to rely on attestation for reporting CQMs as a requirement for demonstrating meaningful use of certified EHR technology for the 2012 payment year.

We also stated in the final rule that, with respect to electronic submission of information on clinical quality measures, certified EHR technology will be required to transmit calculated clinical quality measure results under the PQRI 2009 Registry XML specification. We noted that this was the only such standard that the certified EHR technology would be able to support based on the standards that have been adopted for certified EHR technology (75 FR 44435; see also 45 CFR 170.205(f)).

Since the publication of the final rule, we have determined that it is not feasible to receive electronically the information necessary for clinical quality measure reporting based solely on the use of PQRI 2009 Registry XML Specification content exchange standard as is required for certified EHR technology. This is because the specification is tailored to the elements required for 2009 PQRI Registry XML submission, rather than constituting a more generic standard. As a result, we are proposing to modify the requirement that clinical quality measure reporting must be done electronically. Specifically, we are proposing that for the 2012 payment year and subsequent years, eligible hospitals and CAHs may continue to report clinical quality measure results as calculated by certified EHR technology by attestation, as for the 2011 payment year. Alternatively, for the 2012 payment year, eligible hospitals and CAHs would be able to participate in the proposed FY 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs (Electronic Reporting Pilot) which is

further described below. We are proposing to revise our regulations at §495.8(b)(2)(ii) and proposing to add §495.8(b)(2)(vi) that would reflect these proposals for reporting CQMs through attestation and the Electronic Reporting Pilot.

2. Proposed Electronic Reporting Pilot

Section 1886(n)(3)(B)(ii) of the Act provides authority for the Secretary to accept information on CQMs electronically on a pilot basis. For payment year 2012, we are proposing that eligible hospitals and CAHs participating in the Medicare EHR Incentive Program may meet the CQM reporting requirement of the EHR Incentive Program for payment year 2012 by participating in the proposed Electronic Reporting Pilot. We are proposing that participation in this Electronic Reporting Pilot would be voluntary and that eligible hospitals and CAHs may continue to attest to the results of CQMs calculated by certified EHR technology as they did for the 2011 payment year.

We would encourage participation in the proposed Electronic Reporting Pilot in view of our desire to adequately pilot electronic submission of CQMs and to move to a system of reporting where eligible hospitals and CAHs can qualify for CQM reporting for both the Hospital IQR and Hospital OQR Programs, and the EHR Incentive Program. We strongly encourage eligible hospitals and CAHs to participate in the proposed Electronic Reporting Pilot as it provides opportunities to test the interoperability and functionality of the certified EHR technology that they have implemented. We believe that the participation of eligible hospitals and CAHs in the proposed Electronic Reporting Pilot would help advance EHR-based reporting in the Hospital IQR and Hospital OQR Programs.

Eligible hospitals and CAHs would need to be registered in order to participate in the proposed Electronic Reporting Pilot. Eligible hospitals and CAHs wishing to participate in the proposed Electronic Reporting Pilot for the CQMs would register by indicating their desire and intent to participate in the proposed Electronic Reporting Pilot as part of the attestation process for the Medicare EHR Incentive Program. We are proposing that eligible hospitals and CAHs that participate in the proposed Electronic Reporting Pilot and meet its submission requirements would satisfy the requirements for reporting clinical quality measures under the Medicare EHR Incentive Program. Such eligible hospitals and CAHs would therefore not need to attest to the results of clinical quality measures calculated by certified EHR technology. As described below, for the purpose of the proposed Electronic Reporting Pilot, CMS would calculate the results of the clinical quality measures for eligible hospitals and CAHs based on patient level data submitted for Medicare patients. The proposed Electronic Reporting Pilot would require eligible hospitals and CAHs to submit information on the same 15 CQMs that were listed in Table 10 of the final rule (75 FR 44418 through 44420) for the Medicare and Medicaid EHR Incentive Programs and such information would be obtained from the certified EHR technology used by the eligible hospital or CAH.

We are proposing that electronic submission of the 15 CQMs through this proposed Electronic Reporting Pilot would be sufficient to meet the core objective for reporting CQMs for the Medicare EHR Incentive Program for the 2012 payment year. Since the reporting of CQMs is only one of the 14 core meaningful use objectives for eligible hospitals and CAHs for the Medicare EHR Incentive Program, an eligible

hospital or CAH that chooses to participate in the proposed Electronic Reporting Pilot would still be required to meet and attest to the other core and menu set objectives and their associated measures using the attestation module for the program on the CMS Web site.

After the eligible hospital or CAH had attested and CMS has received electronic submission of the CQMs from an eligible hospital or CAH participating in the proposed Electronic Reporting Pilot, CMS would determine whether the eligible hospital or CAH has successfully met all the requirements for the Medicare EHR Incentive Program. We expect this determination would be made within 2 months after the end of the payment year and not later than November 30, 2013. Eligible hospitals and CAHs who do not meet the reporting requirements through the Electronic Reporting Pilot may meet such requirement through attestation. We are proposing that eligible hospitals and CAHs, alternatively, may attest, but still participate in the proposed Electronic Reporting Pilot.

3. CQM Reporting under the Proposed Electronic Reporting Pilot

Under §495.6(f)(9), we require Medicare eligible hospitals and CAHs (which would include those participating in the proposed Electronic Reporting Pilot) to successfully report hospital clinical quality measures to CMS in the manner specified by CMS. We are proposing that eligible hospitals and CAHs participating in the proposed Electronic Reporting Pilot must submit CQM data on all 15 CQMs listed in Table 10 of the final rule (75 FR 44418 through 44420) to CMS, via a secure portal based on data obtained from the eligible hospital or CAH's certified EHR technology.

In the final rule for the Medicare and Medicaid EHR Incentive Programs, we stated that we will require eligible hospitals and CAHs to report aggregate-level CQM data (75 FR 44432). However, we note that for the purpose of the proposed Electronic Reporting Pilot, we are proposing that eligible hospitals and CAHs participating in the proposed Electronic Reporting Pilot would submit patient-level CQM data for Medicare patients only. Aside from requiring attestation to other objectives/measures based on data for all patients, specifically, we are proposing that eligible hospitals and CAHs participating in the proposed Electronic Reporting Pilot would: (1) submit CQM data on Medicare patients only; (2) submit Medicare patient-level data from which CMS may calculate CQM results using a uniform calculation process, rather than aggregate results calculated by the eligible hospital or CAH's certified EHR technology; (3) submit one full Federal fiscal year of CQM data, regardless of the eligible hospital or CAH's year of participation in the Medicare and Medicaid EHR Incentive Programs; and (4) use electronic specifications for transmission as specified by CMS which we expect would be Level 1 QRDA.

As noted previously, for the proposed Electronic Reporting Pilot, CQM data on which the eligible hospital or CAH's submission is based must be obtained from certified EHR technology. However, the functionality of reporting these CQMs to CMS will not rely on the certification process. Eligible hospitals and CAHs participating in the proposed Electronic Reporting Pilot would report CQMs based on a pilot measurement period of one full Federal fiscal year (October 1, 2011 through September 30, 2012), regardless of whether the eligible hospital or CAH is in its first year of participation in

the Medicare and Medicaid EHR Incentive Programs. The period for submitting information on CQMs under the proposed Electronic Reporting Pilot would be October 1, 2012 through November 30, 2012, which is the 60 days following the close of the measurement period. The CQM reporting format would be as specified by CMS, which we expect would be Quality Data Reporting Architecture (QRDA) Level 1. We would offer a test period beginning July 1, 2012, which would allow eligible hospitals, CAHs, or their designee to submit CQM reports to CMS with the requirements that would be used in the proposed Electronic Reporting Pilot. The test period would remain open. Additional details including educational materials about participation in the proposed Electronic Reporting Pilot would be provided on the QualityNet Web site at http://www.qualitynet.org.

We invite public comment on the proposed Electronic Reporting Pilot discussed above.

K. Proposed ASC Quality Reporting Program

1. Background

Section 109(b) of the MIEA TRHCA amended section 1833(i) of the Act by re-designating clause (iv) as clause (v) and adding new clause (iv) to paragraph (2)(D) and by adding new paragraph (7). Section 1833(i)(2)(D)(iv) of the Act authorizes, but does not require, the Secretary to 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)." Section 1833(i)(7)(A) of the Act states that the Secretary may provide that any ASC that does not submit quality measures to the

Secretary in accordance with paragraph (7) 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 a reduction for one year cannot be taken into account in computing any annual increase factor for a subsequent year.

Section 1833(i)(7)(B) of the Act provides that, "[e]xcept as the Secretary may otherwise provide," the hospital outpatient quality data provisions of subparagraphs (B) through (E) of section 1833(t)(17) of the Act shall apply to ASCs in a similar manner to the manner in which they apply under these paragraphs to hospitals under the Hospital OQR Program and any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ASC, the setting of an ASC, or services of an ASC, respectively. Section 1833(t)(17)(B) of the Act requires that hospitals submit quality data in a form and manner, and at a time, that the Secretary specifies.

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities. Section 1833(t)(17)(C)(ii) of the Act allows the Secretary to select measures that are the same as (or a subset of) the measures for which data are required to be submitted under the Hospital IQR Program. Section 1833(t)(17)(D) of the Act gives the Secretary the authority to replace measures or indicators as appropriate, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown

not to represent the best clinical practice. Section 1833(t)(17)(E) of the Act requires the Secretary to establish procedures for making data submitted under the Hospital OQR Program available to the public. Such procedures include providing hospitals with the opportunity to review their data before these data are released to the public. For a more detailed discussion of the provisions in §1833(t)(17) of the Act, please see section XIV.A.3.b. of this proposed rule.

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 requirements, such as public reporting of quality measures. However, in these rules, we indicated that we intended to implement the provisions of section 109(b) of the MIEA-TRHCA in the future.

In preparation for proposing an ASC quality reporting program, in the CY 2011 OPPS/ASC proposed rule, we solicited public comment on the following measures under consideration for ASC quality data reporting: (1) Patient Fall in the ASC; (2) Patient Burn; (3) Hospital Transfer/Admission; (4) Wrong Site, Side, Patient, Procedure, Implant; (5) Prophylactic IV Antibiotic Timing; (6) Appropriate Surgical Site Hair Removal; (7) Surgical Site Infection (SSI); (8) Medication Administration Variance

(MAV); (9) Medication Reconciliation; and (10) VTE Measures: Outcome/Assessment/Prophylaxis (75 FR 46383).

In addition to preparing to propose implementation of an ASC quality reporting program, the Department developed a plan to implement a value-based purchasing (VBP) program for payments under the Medicare program 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 have recently 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 contains this plan. This report is found on our Web site at: http://www.cms.gov/ASCPayment/downloads/C_ASC_RTC%202011.pdf. Currently, we do not have express statutory authority to implement an ASC VBP Program. Should there be legislation to authorize CMS to implement an ASC VBP program, we will develop the program and propose it through rulemaking.

In this proposed rule, we are proposing to implement the ASC Quality Reporting Program beginning with the CY 2014 payment determination, with data collection beginning in CY 2012 for most of the measures to be used for the CY 2014 payment determination.

2. ASC Quality Reporting Program Measure Selection

a. Proposed Timetable for Selecting ASC Quality Measures

We are proposing to adopt measures for three CY payment determinations for the ASC Quality Reporting Program in this rulemaking. Therefore, in this proposed rule, we

are proposing to adopt measures for the CYs 2014, 2015, and 2016 payment determinations. To the extent that we finalize some or all of the measures for future payment determinations, we would not be precluded from proposing to adopt additional measures or changing the list of measures for future payment determinations through annual rulemaking cycles so that we may address changing program needs arising from new legislation or from changes in HHS and CMS priorities. Under this approach, in the CY 2013 or CY 2014 rulemaking cycle, we could propose any additions or revisions to the measures we adopted in the CY 2012 rulemaking cycle for the CY 2014 payment determination or for future payment determinations. This is consistent with our approach to proposing measures for multiple payment determinations for the Hospital IQR and Hospital OQR Programs. We believe this proposed process will assist ASCs in planning, meeting future reporting requirements, and implementing quality improvement efforts. We also would have more time to develop, align, and implement the infrastructure necessary to collect data on the measures and make payment determinations. This flexibility would enable us to adapt the program to support changes in HHS and CMS priorities and any new legislative requirements. We invite public comments on this proposal.

b. Considerations in the Selection of Measures for the ASC Quality Reporting Program

Section 1833(i)(7)(B) of the Act states that §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 at 1833(t)(17)(C)(i) of the Act state that measures developed shall "be

appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities."

In selecting proposed measures for the ASC Quality Reporting 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 ASC quality reporting 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, the Hospital IQR Program, the Physician Quality Reporting System, and reporting requirements implemented under the HITECH Act 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 we have noted in 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.

In developing this and other quality reporting programs, as well as the Hospital Inpatient VBP Program, we applied the following principles for the development and use

of measures. We invite public comment on these principles in the ASC quality reporting context.

- Pay-for-reporting, public reporting, and value-based purchasing programs should rely on a mix of standards, process, outcomes, and patient experience of care measures, including measures of care transitions and changes in patient functional status. 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.

- The collection of information should minimize the burden on providers/ suppliers to the extent possible. To this end, we will continuously seek to align our measures with the adoption of meaningful use standards for HIT, so that data can be submitted and calculated via certified EHR technology with minimal burden.

- To the extent practicable and feasible, and within the scope of our statutory authorities for various quality reporting and value-based purchasing programs, measures used by CMS should be endorsed by a national, multi-stakeholder organization.

Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

We believe that ASC facilities are similar, insofar as the delivery of surgical and related nonsurgical services, to HOPDs. Similar standards and guidelines can be applied between hospital outpatient departments and ASCs with respect to surgical care improvement, given that many of the same surgical procedures are provided in both settings. Measure harmonization assures that comparable care in different 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. In general, our goal is to adopt harmonized measures that assess the quality of care given across settings and providers/suppliers and to use the same measure specifications based on clinical evidence and guidelines for the care being assessed regardless of provider/supplier type or setting. This harmonization goal is also supported by a commenter to the CY 2011 OPPS/ASC proposed rule, who recommended CMS align ASC quality measures with State and other Federal requirements (75 FR 72109).

Our CY 2014 measure proposals for ASCs align closely with those discussed in the Report to Congress entitled "Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan" and with those proposed for future consideration in the CY 2011 OPPS/ASC proposed rule (75 FR 46383). Furthermore, the measures that we are proposing for ASCs fall into the parameter of our stated framework for the ASC Quality Reporting Program, discussed above. The initial measure set that we are

proposing for the CY 2014 payment determination addresses outcome measures and infection control process measures. Six of the eight initial measures that we are proposing for the CY 2014 payment determination are recommended by the ASC Quality Collaborative (ASC QC) and are NQF-endorsed. The seventh measure that we are proposing is appropriate for measuring ambulatory surgical care, is NQF-endorsed, is currently in use in the Physician Quality Reporting System, and is similar to a measure that is being utilized in the Hospital OQR program, and therefore aligns across settings in which outpatient surgery is performed. We are proposing collecting these seven measures via "quality data codes" to be placed on Part B claims submitted by ASCs for Medicare fee-for-service patients beginning January 1, 2012. The eighth measure we are proposing for the ASC Quality CY 2014 payment determination is an outcome measure of Surgical Site Infection (SSI) to be submitted in 2013 via the CDC's National Healthcare Safety Network (NHSN). Similarly, hospital inpatient departments will begin reporting this measure to the CDC under the Hospital IQR Program in 2012, and we are also currently proposing in this rule that hospital outpatient departments begin reporting this measure to the CDC under the Hospital OQR Program in 2013. Thus, this measure would be aligned across quality reporting programs for facilities performing surgery.

3. Proposed ASC Quality Measures for the CY 2014 Payment Determination

a. Proposed Claims-Based Measures Requiring Submission of Quality Data Codes (QDCs) beginning January 1, 2012

We are proposing to adopt seven NQF-endorsed claims-based measures, six of which were developed by the ASC QC. The ASC QC is a cooperative effort of

organizations and companies formed in 2006 with a common interest in ensuring that ASC quality data is measured and reported in a meaningful way. Stakeholders in the ASC QC include ASC corporations, ASC associations, professional societies and accrediting bodies that focus on ASC quality and safety. The ASC QC initiated a process of standardizing ASC quality measure development through evaluation of existing nationally endorsed quality measures to determine which could be directly applied to the outpatient surgery facility setting. The ASC QC in its ASC Quality Measure Implementation Guide version 1.4 states that "it focused on outcomes and processes that ASC facilities could influence or impact, outcomes that ASC facilities would be aware of given their limited contact with the patient, and outcomes that would be understandable and important to key stakeholders in ASC care, including patients, providers and payers."

The ASC QC developed and pilot-tested five facility-level measures (Patient Burn; Patient Fall in the ASC; Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; Hospital Transfer/Admission, and Prophylactic IV Antibiotic Timing) for feasibility and usability. On November 15, 2007, these five measures were endorsed by the NQF. On September 25, 2008, a sixth ASC QC-developed facility-level measure, "Appropriate Surgical Site Hair Removal" was NQF-endorsed as "Ambulatory Surgery Patients with Appropriate Method of Hair Removal." Of the six ASC QC measures, the Prophylactic IV Antibiotic Timing and Ambulatory Surgery Patients with Appropriate Method of Hair Removal measures are infection control process measures, and the rest are outcome measures. All six of these measures were listed as under

consideration in the CY 2011 OPPS/ASC proposed rule (75 FR 46383). We are proposing these six measures for use in the CY 2014 payment determination.

The seventh claims-based measure we are proposing for the CY 2014 payment determination is Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin. This measure was developed by the American Medical Association's (AMA's) Physician Consortium for Performance Improvement, a national, diverse, physician-led group that identifies, develops, and promotes implementation of evidence-based clinical performance measures that reflect best practices. This measure is NQF-endorsed. It is an infection control process measure and is currently adopted in the Hospital IQR Program and Physician Quality Reporting System (PQRS).

We are proposing to collect all seven measures using the claims-based quality data codes (QDCs) data collection mechanism. We are proposing to require ASCs to report on ASC claims a quality data code (QDC) to be used for reporting quality data. We are proposing that an ASC would need to add a QDC to any claim involving a proposed claims-based quality measure. CMS is in the process of developing QDCs for each proposed claims-based quality measure. The QDC will be a CPT Category II code or a HCPCS Level II G-code if an appropriate CPT code is not available. More information on the QDCs that will be associated with the proposed quality measures will be provided in the CY 2012 OPPS/ASC final rule with comment period. Additionally, CMS is proposing to create a new ASC payment indicator "M5" (Quality measurement code used for reporting purposes only; no payment made) for assignment to the QDC to clarify that no payment is associated with the QDC for that claim. If one or more of these

measures are finalized as proposed, an ASC would need to begin submitting these QDCs on any Medicare Part B claims pertaining to the measures on January 1, 2012.

For the first six measures listed, the ASC QC measures specifications can be found at http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf . [41] For the seventh measure, the specifications can be found on the PQRS Web site at: http://www.cms.gov/apps/ama/license.asp?file=/pqrs/downloads/2011_PhysQualRptg_MeasureSpecificationsManual_033111.pdf.

These seven proposed measures are discussed in more detail below:

(1) Patient Burns (NQF #0263)

The ASC Quality Measures: Implementation Guide Version 1.4 states that every patient receiving care in an ASC setting has the potential to experience a burn during an episode of care, given the multitude of factors that could pose risks for patient burns in the surgical and procedural settings. The Guide cited a recent publication from the ECRI Institute that relates an increased risk of burns associated with newer electrosurgical devices due to their application of higher electrical current for longer time intervals. Other common sources of burns in a surgical setting include chemical and thermal sources, and radiation, scalds, and fires. Clinical practice guidelines for reducing the risk of burns have been established by the American Society of Anesthesiologists (ASA) and Association of Operating Room Nurses (AORN).

This NQF-endorsed measure assesses the percentage of ASC admissions experiencing a burn prior to discharge. The NQF-endorsed specifications for ASC QC

[41] ASC Quality Measures: Implementation Guide Version 1.4, ASC Quality Collaboration, December 2010.

measure can be found at: http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf. The ASC QC in their ASC Quality Measure Implementation Guide version 1.4 defines a "burn" for purposes of this measure as "[u]nintended tissue injury caused by any of the six recognized mechanisms: scalds, contact, fire, chemical, electrical or radiation (e.g., warming devices, prep solutions, and electrosurgical unit or laser)." We believe that this measure would allow stakeholders to develop a better understanding of the incidence of these events and further refine means to ensure prevention.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe that this measure is appropriate to measure quality in ASCs since they serve surgical patients who may face the risk of burns during ambulatory surgical procedures. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

We invite public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012. While the NQF-endorsed specification for this measure includes all

ASC admissions, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated in recent exchanges that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients that are part of the broader population to which the measure applies. If finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

(2) Patient Fall (NQF #0266)

Falls, particularly in the elderly, can cause injury and loss of functional status, and falls in healthcare settings can be prevented through assessment of risk, care planning, and patient monitoring. Healthcare settings are being called upon to report patient falls and to take steps to reduce the risk of falls. The ASC QC indicates in their ASC quality measure implementation guide the use of anxiolytics, sedatives, and anesthetic agents may put patients undergoing outpatient surgery at increased risk for falls. Guidelines and best practices for the prevention of falls, and management of patients after falls have been made available by the Agency for Healthcare Research and Quality (http://www.ahrq.gov/qual/transform.htm), and the National Center for Patient Safety (http://www.patientsafety.gov).

This NQF-endorsed measure assesses the percentage of ASC admissions experiencing a fall in the ASC. The NQF-endorsed specifications for this ASC QC measure can be found at: http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf. The ASC QC in their ASC Quality Measure Implementation Guide version 1.4 defines a "fall" as "a sudden, uncontrolled, unintentional, downward displacement of the body to the ground or other object, excluding falls resulting from violent blows or other purposeful actions", which is consistent with the definition set forth by the National Center for Patient Safety.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe that this measure is appropriate to measure quality in ASCs because it was specifically developed to measure quality of surgical care furnished by ASCs, as measured by patient falls. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is NQF-endorsed.

We invite public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC

services furnished for Medicare fee-for-service beneficiaries from January 1, 2012 through December 31, 2012. While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated in recent exchanges that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients that are part of the broader population to which the measure applies. If finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

(3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)

Surgeries and procedures performed on the wrong site/side, and wrong patient can result in significant impact on patients, including complications, serious disability or death. While the prevalence of such serious errors may be rare, such events are considered serious reportable events, and are included in the NQF's Serious Reportable Events in Healthcare 2006 Update.[42] The Joint Commission (a not-for-profit organization that accredits and certifies health care organizations and programs in the US) has issued a

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42 http://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare%E2%80%932006_Update.aspx

Universal Protocol to prevent such serious surgical errors.[43] The proposed NQF-endorsed measure assesses the percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant. The ASC QC in their ASC Quality Measures: Implementation Guide Version 1.4 defines "wrong" as "not in accordance with intended site, side, patient, procedure or implant." The NQF-endorsed specifications for this ASC QC measure can be found at: http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe that this measure is appropriate to measure quality in ASCs because the measure assesses the quality of surgical care provided in ASCs as measured by the percentage of surgical errors. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

We invite public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC

[43] Joint Commission. Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery. Available at http://www.jointcommission.org/standards_information/up.aspx. Last accessed December 14, 2010.

services furnished for Medicare patients from January 1, 2012 through December 31, 2012. While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated in recent exchanges that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients that are part of the broader population to which the measure applies. If finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

(4) Hospital Transfer/Admission (NQF #0265)

The transfer or admission of a surgical patient from an outpatient setting to an acute care setting can be an indication of a complication, serious medical error, or other unplanned negative patient outcome. While acute intervention may be necessary in these circumstances, a high rate of such incidents may indicate suboptimal practices or patient selection criteria. The proposed NQF-endorsed measure assesses the rate of ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC. The ASC QC defines "hospital transfer/admission" as "any transfer/admission from an ASC directly to an acute care hospital, including hospital emergency room."

The NQF-endorsed specifications for this ASC QC measure can be found at: http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf. The ASC QC believes that this "measure would allow ASCs to assess their guidelines for procedures performed in the facility and patient selection if transfers/admissions are determined to be at a level higher than expected. If commonalities are found in patients who are transferred or admitted, guidelines may require revision."

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate to measure quality in ASCs because it assesses outpatient surgical care quality in the form of the rate of surgical outpatients needing acute care interventions. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

We invite public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012. While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate these

measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients that are part of the broader population to which the measure applies. If finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

(5) Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264)

Timely preoperative administration of intravenous antibiotics to surgical patients is an effective practice in reducing the risk of developing a surgical site infection, which in turn is associated with reduced health care burden and cost, and better patient outcomes. [44] [45] [46] The measurement of timely antibiotic administration for surgical patients is occurring in the Hospital IQR Program, Hospital OQR Program and the Physician Quality Reporting System. The NQF-endorsed ASC QC measure assesses the rate of ASC patients who received IV antibiotics ordered for surgical site infection prophylaxis on time. The NQF-endorsed specifications for this ASC QC measure can be

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[44] Classen, D. et al.: The timing of prophylactic administration of antibiotics and the risk of surgical wound infection. NEJM. 1992;326(5):281-286.

[45] Silver, A. et al.: Timeliness and use of antibiotic prophylaxis in selected inpatient surgical procedures. The Antibiotic Prophylaxis Study Group. Am J Surg. 1996;171(6):548-552.

[46] Dounis, E., Tsourvakas, S., Kalivas, L., and Giamacellou, H.: Effect of time interval on tissue concentrations of cephalosporins after tourniquet inflation. Highest levels achieved by administration 20 minutes before inflation. Acta Orthop Scand. 1995;66(2):158-60.

found at:

http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf.

The ASC QC measure implementation guide defines "antibiotic administered on time" as "[a]ntibiotic infusion … initiated within one hour prior to the time of the initial surgical incision or the beginning of the procedure (e.g., introduction of endoscope, insertion of needle, inflation of tourniquet) or two hours prior if vancomycin or fluoroquinolones are administered." The measure also defines "prophylactic antibiotic" as "an antibiotic prescribed with the intent of reducing the probability of an infection related to an invasive procedure. For purposes of this measure, the following antibiotics are considered prophylaxis for surgical site infections: Ampicillin/sulbactam, Aztreonam, Cefazolin, Cefmetazole, Cefotetan, Cefoxitin, Cefuroxime, Ciprofloxacin, Clindamycin, Ertapenem, Erythromycin, Gatifloxacin, Gentamicin, Levofloxacin, Metronidazole, Moxifloxacin, Neomycin and Vancomycin." All prophylactic IV antibiotics administered for surgical site infection would need to have their infusion initiated within the one hour time frame, except for vancomycin or fluoroquinolones, where infusion must be initiated within the two hours time frame. The ASC QC Guide states that "[i]n cases involving more than one antibiotic, all antibiotics must be given within the appropriate time frame in order for the case to meet criteria." The timing of the antibiotic starts at the time the antibiotic is initiated with a preoperative order.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop

measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate to measure quality in ASCs because it assesses the quality of care for surgical patients in an outpatient setting as measured by timely antibiotic administration. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

We invite public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDCs data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012. While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated in recent exchanges that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients that are part of the broader population to which the measure applies. If finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B

claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

(6) Ambulatory Surgery Patients with Appropriate Method of Hair Removal (NQF #0515)

The ASC QC[47] cited evidence that "[r]azors can cause microscopic cuts and nicks to the skin, not visible to the eye. Use of razors prior to surgery increases the incidence of wound infection when compared to clipping, depilatory use or no hair removal at all."[48] A 1999 guideline issued by the CDC suggests that if hair must be removed from a surgical site, that it preferably be done with clippers rather than razors in order to minimize cuts and nicks to the skin which may increase the risk of a surgical site infection [49] In 2002, the Association of Operating Room Nurses published similar guidelines for appropriate hair removal.[50] While a similar measure is being considered for retirement from the Hospital IQR Program because it displays a high degree of performance with little variability or room for improvement, we believe that there is significant, variability in practice and level of adherence to this guideline in outpatient surgical settings such as ASCs is not known, and accordingly, this measure is still appropriate for use in the ASC setting. We are proposing to adopt the NQF-endorsed measure to capture the percentage of ASC admissions with appropriate surgical site hair removal. The NQF-endorsed specifications for this ASC QC measure can be found at:

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[47] ASC QC Quality measures: Implementation Guide version 1.4. ASC Quality Collaboration. December 2010.

[48] Seropian, R., Reynolds, B.M.: Wound infections after preoperative depilatory versus razor preparation. Am J Surg.1971 Mar;121(3):251-4.

[49] http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf

[50] Association of Operating Room Nurses. Recommended practices for skin preparation of patients. AORN J. 2002 Jan;75(1):184-7.

http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate to measure quality in ASCs because it assesses quality of surgical care performed in ASCs, as measured by appropriate surgical site hair removal. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it was developed by the ASC QC and is endorsed by the NQF.

We invite public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012. While the NQF-endorsed specification for this measure includes all ASC admissions, our proposal to use information submitted on claims to calculate these measures that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF indicated in recent exchanges that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure

specification is an appropriate application of the NQF-endorsed measure to a subset of patients that are part of the broader population to which the measure applies. If finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of CY 2014 payment determination.

(7) Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin (NQF #0268)

Surgical outcomes are affected by the selection of appropriate antibiotics. Current guidelines indicate that first or second generation cephalosporins are effective for prevention of surgical site infections in most cases. The goal of this proposed measure is to ensure safe, cost-effective, broad spectrum antibiotics are used as a first line prophylaxis unless otherwise indicated. This measure was developed by the AMA's Physician Consortium for Performance Improvement, a national, diverse, physician-led group that identifies, develops, and promotes implementation of evidence-based clinical performance measures that reflect best practices. This measure received NQF-endorsement under a 2008 project entitled "Hospital Care: Specialty Clinician Performance Measures," and it assesses the percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for cefazolin or cefuroxime for antimicrobial prophylaxis. While we recognize that this measure is not specifically endorsed for the ASC setting, we believe that this measure is highly relevant for use in ASCs because it assesses adherence to best practices for use of prophylactic antibiotics

for outpatient surgical patients. Accordingly, we propose to adopt an application of this NQF-endorsed measure for use in the ASC Quality Reporting Program. The measure specifications for this proposed measure can be found at: http://www.cms.gov/pqrs/downloads/2011_PhysQualRptg_MeasuresGroups_SpecificationsManual_033111.pdf?agree=yes&next=Accept.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate for measurement of quality care in an ASC because it specifically assesses quality care, as measured by adherence to best practices for prophylactic antibiotics provided for outpatient surgical patients. It is not feasible or practicable to adopt an NQF-endorsed measure of prophylactic antibiotic selection specifically for ASCs because there is no such NQF-endorsed measure. We note that section 1833(t)(17) of the Act does not require that each measure we adopt for the ASC Quality Reporting Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the ASC Quality Reporting Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt

measures that are not NQF-endorsed or measures that have not been endorsed for the ASC setting.

The proposed adoption of this measure in the ASC Quality Reporting Program also is consistent with our goal to align measures across settings, as it is also used in the Physician Quality Reporting System, and a similar measure (NQF #0528) has been implemented in the Hospital OQR Program and the Hospital IQR Program.

We invite public comment on our proposal to adopt this measure for the CY 2014 payment determination using the claims-based QDC data collection mechanism for ASC services furnished for Medicare patients from January 1, 2012 through December 31, 2012. While the NQF-endorsed specification for this measure includes all surgical patients, our proposal to use information submitted on claims to calculate these measures requires that we restrict the measure population to the population for which CMS receives claims. Therefore, for this program, we would need to calculate the measures based on claims submitted for ASC services furnished to Medicare fee-for-service beneficiaries. NQF has indicated in recent exchanges that our proposal to use Medicare Part B claims submitted by ASCs to calculate the measure consistently with the measure specification is an appropriate application of the NQF-endorsed measure to a subset of patients that are part of the broader population to which the measure applies. If finalized, ASCs would need to place QDCs relevant to this measure on Medicare Part B claims beginning January 1, 2012 in order to report this measure for purposes of the CY 2014 payment determination.

b. Surgical Site Infection Rate (NQF #0299)

HAIs are among the leading causes of death in the United States. CDC estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths.[51] It is estimated that more Americans die each year from HAIs than from auto accidents and homicides combined. HAIs not only put the patient at risk, but also increase the days of hospitalization required for patients and add considerable health care costs. HAIs are largely preventable for surgical patients through application of perioperative best practices such as those listed in the CDC's SSI prevention guidelines. Therefore, many health care consumers and organizations are calling for public disclosure of HAIs, arguing that public reporting of HAI rates provides the information health care consumers need to choose the safest hospitals, and gives hospitals an incentive to improve infection control efforts. This proposed measure is currently collected by the National Healthcare Safety Network (NHSN) as part of State-mandated reporting and surveillance requirements for hospitals in some States. Additionally, data submission for this measure through EHRs may be possible in the near future.

This measure is NQF-endorsed and we are also proposing to adopt it for the CY 2014 Hospital OQR Program. It also has been adopted for the FY 2014 Hospital IQR Program. Because we are proposing the same measure for Hospital OQR program in this rule, we refer readers to the discussion of this measure in section XIV.C.2.a. of this proposed rule. The measure specifications can be found at

[51] McKibben. L., Horan, T.: Guidance on public reporting of healthcare-associated infections: recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005;33:217–26.

http://www.cdc.gov/nhsn/psc.html. The NQF describes this measure as the "percentage of surgical site infection events occurring within thirty days after the operative procedure if no implant is left in place, or [within] one year if an implant is in place in patients who had an NHSN operative procedure performed during a specified time period and the infection appears to be related to the operative procedure."

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. Increasingly, surgical procedures are being performed in hospital outpatient department settings and ASCs. We believe this measure is appropriate for measuring quality of care in ASCs because it applies to outcomes for surgical patients undergoing procedures that are performed in ASCs. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is endorsed by the NQF. The proposed adoption of this measure in the ASC Quality Reporting Program also is consistent with our goal to align measures across settings because we have proposed this measure for the Hospital OQR Program for CY 2014 payment determination and have previously adopted it for Hospital IQR Program for the FY 2014 payment determination. Therefore, we are proposing to adopt the Surgical Site Infection Rate measure that is

collected by the CDC via the NHSN for the ASC Quality Reporting Program for the CY 2014 payment determination.

Data submission for this measure for the CY 2014 payment determination would begin with infection events occurring on or after January 1, 2013 through June 30, 2013. The proposed reporting mechanism for this proposed HAI measure via the NHSN is discussed in greater detail in section XIV.C.2.a. of this proposed rule. We invite public comment on this proposed measure and the reporting mechanism.

In summary, we are proposing to adopt 7 claims-based measures using the QDC data collection mechanism, and one NHSN HAI measure of Surgical Site Infection Rate for a total of eight measures for ASCs for the CY 2014 payment determination. We believe the proposal falls within our stated framework for the ASC Quality Reporting Program. For the CY 2014 payment determination, we are proposing that data submission for the claims-based measures begin on January 1, 2012 and end December 31, 2012. For the CY 2014 payment determination, we are proposing that data submission for the NHSN-based SSI measure begin with infection events occurring between January 1, 2013 and June 30, 2013. This proposed measure is currently collected by the NHSN as part of State-mandated reporting and surveillance requirements for hospitals in some States.

The NHSN is a secure, Internet-based surveillance system maintained and managed by the CDC, and can be utilized by all types of healthcare facilities in the United States, including acute care hospitals, long term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ASCs, and long term care

facilities. The NHSN reporting infrastructure is provided free of charge to healthcare providers/suppliers to access and use for reporting data regarding healthcare safety and infections. The NHSN enables healthcare facilities to collect and use data about HAIs, clinical practices known to prevent HAIs, the incidence or prevalence of multidrug-resistant organisms within their organizations, and other adverse events. Some States use the NHSN as a means for healthcare facilities to submit data on HAIs mandated through their specific State legislation. We invite public comments on our proposals. The proposed measures for ASCs for the CY 2014 payment determination are listed below with the ASC prefix:

ASC Program Measurement Set Proposed for the CY 2014 Payment Determination (Data submission to occur in 2012 and 2013)
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: Ambulatory Surgery Patients with Appropriate Method of Hair Removal*
ASC-7: Selection of Prophylactic Antibiotic First OR Second Generation Cephalosporin*
ASC-8: Surgical Site Infection Rate**

* Data submission proposed to begin in CY 2012.
**Data submission proposed to begin in CY 2013.

4. Proposed ASC Quality Measures for CY 2015 Payment Determination

a. Retention of Measures Adopted for the CY 2014 Payment Determination in the CY 2015 Payment Determination

In general, unless we otherwise specify in the retirement section of a rule, we propose to retain measures from one CY payment determination to another. We are proposing to retain the eight measures we are proposing to adopt for the CY 2014 payment determination, if they are finalized in the CY 2012 OPPS/ASC final rule with comment period, for the CY 2015 payment determination. We invite public comments on this proposal.

b. Proposed Structural Measures for the CY 2015 Payment Determination

For the CY 2015 payment determination, we are proposing to adopt two structural measures: Safe Surgery Checklist Use, and ASC Facility Volume Data on Selected ASC Surgical Procedures. We discuss these proposals below.

(1) Safe Surgery Checklist Use

A sound surgery safety checklist could minimize the most common and avoidable risks endangering the lives and well-being of surgical patients. The purpose of this proposed structural measure is to assess whether ASCs are using a safe surgery checklist that covers effective communication and helps ensure that safe practices are being performed at three critical perioperative periods: prior to administration of anesthesia, prior to incision, and prior to the patient leaving the operating room. The use of such checklists has been credited with dramatic decreases in preventable harm, complications

and post-surgical mortality[52]. In November 2010, the New England Journal of Medicine published a study concluding that surgical complications were reduced by one-third, and mortality by nearly half, when a safe surgery checklist was used.[53]

We believe that effective communication and the use of safe surgical practices during surgical procedures will significantly reduce preventable surgical deaths and complications. Some examples of safe surgery practices that can be performed during each of these three perioperative periods are shown in the table below:

First critical point (prior to administering anesthesia)	Second critical point(prior to skin incision)	Third critical point (prior to patient leaving the operating room)
● Verbal confirmation of patient identity ● Mark surgical site ● Check anesthesia machine/medication ● Assessment of allergies, airway and aspiration risk	● Confirm surgical team members and roles ● Confirm patient identity, procedure, and surgical incision site ● Administration of antibiotic prophylaxis within 60 minutes before incision ● Communication among surgical team members of anticipated critical events ● Display of essential imaging as appropriate	● Confirm the procedure ● Complete count of surgical instruments and accessories ● Identify key patient concerns for recovery and management of the patient

For example, mistakes in surgery can be prevented by ensuring that the correct surgery is performed on the correct patient and at the correct place on the patient's body.[54] A safe surgery checklist would also reduce the potential for human error, which would increase the safety of the surgical environment. An example of a checklist that

[52] Haynes, A.B.; Weiser, T.G.; Berry, W.G. et. al (2009). "A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population". New England Journal of Medicine. 360: 491-499.
[53] de Vries EN, Prins HA, Crolla RMPH, et al. Effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med 2010;363: 1928-37
[54] Hospital National Patient Safety Goals. The Joint Commission Accreditation Hospital Manual, 2011. http://www.jointcommission.org/standards_information/npsgs.aspx

employs safe surgery practices at each of these three perioperative periods is the World Health Organization Surgical Safety Checklist, which was adopted by The World Federation of Societies of Anesthesiologists as an international standard of practice. This checklist can be found at: http://www.who.int/patientsafety/safesurgery/ss_checklist/en/index.html.

The adoption of a structural measure that assesses Safe Surgery Checklist Use would align our patient safety initiatives with those of several surgical specialty societies including: the American College of Surgeons' Nora Institute for Patient Safety, the American Society of Anesthesiologists, The Joint Commission, the National Association for Healthcare Quality and the AORN. The measure would assess whether the ASC uses a safe surgery checklist in general, and would not require an ASC to report whether it uses a checklist in connection with any individual procedures.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. This measure is appropriate for the measurement of quality of care furnished by ASCs because it pertains to best practices for surgeries, and ASCs perform ambulatory surgeries. It also reflects consensus among affected parties. As stated in section XIV.C.2.c.1 of this proposed rule, we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including

consensus achieved during the measure development process; consensus shown through broad acceptance and use of measures; and consensus through public comment. The proposed safe surgery checklist measure assesses the adoption of a best practice for surgical care that is broadly accepted and in widespread use among affected parties. In addition to being adopted by The World Federation of Societies of Anesthesiologists, the use of a safe surgery checklist is one of the safe surgery principles endorsed by the Council on Surgical and Perioperative Safety[55], which is comprised of the American Association of Nurse Anesthetists, the American College of Surgeons, the American Association of Surgical Physician Assistants, the American Society of Anesthesiologists, the American Society of PeriAnesthesia Nurses, AORN, and the Association of Surgical Technologists. Two State agencies (Oregon, South Carolina), the Veterans Health Administration[56], numerous hospital systems, State hospital associations (such as California and South Carolina), national accrediting organizations and large private insurers have endorsed the use of a safe surgery checklist as a best practice for reducing morbidity, mortality, and medical errors.[57, 58] Because the use of a safe surgery checklist is a widely accepted best practice for surgical care, we believe that the proposed structural measure of Safe Surgery Checklist Use reflects consensus among affected parties. We also note that The Joint Commission has included safe surgery checklist practices among those to be used to achieve National Patient Safety Goals adopted for

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[55] http://www.cspsteam.org/safesurgerychecklist/safesurgerychecklist.html
[56] Neily, J; Mills, PD, Young-Xu, Y. (2010). "Association between implementation of a Medical Team Training Program and Surgical Mortality". JAMA. 304 (15): 1693-1700.
[57] Haynes, AB; Weiser, TG; Berry, WR et al (2009) "A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population". NEJM. 360:491-499.
[58] Birkmeyer, JD (2010) "Strategies for Improving Surgical Quality – Checklists and Beyond." NEJM. 363: 1963-1965.

2011 for surgeries performed in ambulatory settings and hospitals[59]. The Safe Surgery Checklist Use structural measure is not NQF-endorsed, and there is no NQF-endorsed measure of safe surgery checklist use despite the broad acceptance and widespread endorsement of this practice. Therefore, it is not feasible or practicable to adopt an NQF-endorsed measure of safe surgery checklist use because there is no such NQF-endorsed measure. We note that section 1833(t)(17) of the Act does not require that each measure we adopt for the ASC Quality Reporting Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the ASC Quality Reporting Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures. We note that the proposed adoption of this measure in the ASC Quality Reporting Program is consistent with our goal to align measures across settings because we are also proposing the same measure for the Hospital OQR Program for CY 2014 payment determination.

For the CY 2015 payment determination, we are proposing that data collection for this structural measure for ASCs would begin on July 1, 2013 and end on August 15, 2013 for the entire time period from January 1, 2012 through December 31, 2012. In other words, an ASC would report whether their facility employed a safe surgery checklist that covered each of the three critical perioperative periods for the entire calendar year of 2012 during the 45-day window from July 1 through August 15, 2013. The information for this structural measure would be collected

[59] http://www.jointcommission.org/standards_information/npsgs.aspx

via an online Web-based tool that will be made available to ASCs via the QualityNet Web site. This collection mechanism is also used to collect structural measures and other information for other programs, specifically for the Hospital IQR and Hospital OQR programs.

We invite public comments on our proposal to add this new structural measure to the ASC quality measurement set and the submission process for the CY 2015 payment determination.

(2) ASC Facility Volume Data on Selected ASC Surgical Procedures

There is substantial evidence in recent peer-reviewed clinical literature that volume of surgical procedures, particularly of high risk surgical procedures, is related to better patient outcomes, including decreased surgical errors and mortality.[60, 61, 62] This may be attributable to greater experience and/or surgical skill, greater comfort with and hence likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure. For this reason, the National Quality Forum has endorsed measures of total all-patient surgical volume for Isolated CABG and Valve Surgeries (NQF #0124), Percutaneous Coronary Intervention (PCI) (NQF #0165), Pediatric Heart Surgery (NQF #0340), Abdominal Aortic Aneurism Repair (NQF #357), Esophageal Resection (#0361), and Pancreatic Resection (NQF #0366). Additionally, many consumer-oriented Web sites reporting

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[60] Livingston, E.H.; Cao, J "Procedure Volume as a Predictor of Surgical Outcomes". JAMA. 2010;304(1):95-97.

[61] David R. Flum, D.R.; Salem, L.; Elrod, J.B.; Dellinger, E.P.; Cheadle, A. Chan, L. "Early Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures". *JAMA. 2005;294(15):1903-1908.*

[62] Schrag, D; Cramer, L.D.; Bach, P.B.; Cohen, A.M.; Warren, J.L.; Begg, C.B " Influence of Hospital Procedure Volume on Outcomes Following Surgery for Colon Cancer" *JAMA. 2000; 284 (23): 3028-3035.*

health care quality information sponsored by States (California, New York, Texas, Washington, Florida, Illinois, Michigan, Oregon) and private organizations (Leapfrog Group, U.S. News & World Report) are reporting procedure volume, in addition to provider performance on surgical process (SCIP measures) and outcome measures (SSI, Patient Safety Indicators, and Mortality), because it provides beneficial performance information to consumers choosing a health care provider,. The currently NQF-endorsed measures of procedure volume (noted above) relate to surgeries only performed in inpatient settings, and would not be applicable to the types of procedures approved to be performed in HOPDs and ASCs.

The recently issued Report to Congress entitled "Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan" included an analysis of CY 2009 ASC claims for Medicare beneficiaries. When stratified by specialty category, CMS identified six procedure categories that historically constitute 98.5 percent of the total volume of procedures performed in ASCs: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, and Genitourinary. We are proposing that ASCs submit all patient volume data on these six broad categories of surgical procedures as a structural measure to be used for the ASC Quality Reporting Program CY 2015 payment determination. In section XIV.C.2.c.(2) of this proposed rule, we are also proposing that HOPDs submit similar all patient volume data for eight broad procedure categories.

Structural measures assess whether a provider/facility possesses conditions for the care of patients that are associated with better quality. Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary,

except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. Because surgical volume is associated with better quality, and surgical procedures are performed in ASCs, we believe that surgical volume is appropriate for measuring the quality of these six categories of surgical procedures performed in ASCs. We have previously established for other programs that we believe consensus among affected parties can be reflected through various means including widespread use among industry stakeholders. We believe that the ASC Facility Volume Data on Selected ASC Surgical Procedures structural measure reflects consensus among affected parties as being associated with quality of surgical care because of recent evidence published in well-respected and widely circulated peer-reviewed clinical literature, and because of its widespread reporting among States and private stakeholders on Web sites featuring quality information. Because the current volume measures are endorsed for inpatient procedures, many of which are not performed in outpatient settings such as ASCs, it is not feasible or practicable to utilize NQF endorsed measures of volume for ASCs. Further, section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act, which contains this requirement, applies to the ASC Quality Reporting Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures. For the CY 2015 payment determination, we are proposing that ASCs would report these data with respect to these six categories between the dates

July 1, 2013 and August 15, 2013 with respect to the time period January 1, 2012 through December 31, 2012. In other words, under this proposal, an ASC would report its CY 2012 all-patient volume data for these six categories of procedures during the 45-day window of July 1 to August 15, 2013. The table below lists the HCPCS codes for which hospitals would be required to report all-patient volume data. Like the structural measures in the Hospital OQR program, data on this proposed measure would be collected via an online Web-based tool that will be made available to ASCs via the QualityNet Web site. This collection mechanism is also used to collect structural measures and other information for other programs (Hospital IQR and Hospital OQR). We invite public comment on this proposal.

In summary, for the CY 2015 payment determination, we are proposing to retain the eight measures proposed for the CY 2014 payment determination, if they are adopted in the final rule with comment period, and to add two structural measures. We invite public comments on these proposals for the CY 2015 payment determination. The proposed measures for ASCs for CY 2015 payment determination are listed below:

Proposed ASC Program Measurement Set for the CY 2015 Payment Determination
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: Ambulatory Surgery Patients with Appropriate Method of Hair Removal
ASC-7: Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin
ASC-8: Surgical Site Infection Rate

Proposed ASC Program Measurement Set for the CY 2015 Payment Determination	
ASC-9: Safe Surgery Checklist Use*	
ASC-10: ASC Facility Volume Data on Selected ASC 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

*New proposed measures for CY 2015 payment determination.

5. Proposed ASC Quality Measures for the CY 2016 Payment Determination

a. Retention of Measures Adopted for the CY 2015 Payment Determination in the CY 2016 Payment Determination

In general, unless otherwise specified in the retirement section of a rule, we propose to retain measures from one CY payment determination to the next. We are proposing to retain the ten measures we are proposing to adopt for the CY 2015 payment determination, if they are finalized in an OPPS/ASC final rule with comment period, for the CY 2016 payment determination. We invite public comment on this proposal.

b. Proposed HAI Measure: Influenza Vaccination Coverage among Healthcare Personnel (HCP) (NQF #0431)

The Influenza Vaccination among Healthcare Personnel measure assesses the percentage of healthcare personnel who have been immunized for influenza during the flu

season. The specifications for this measure are available at http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf.

For the ASC CY 2016 payment determination, we are proposing to adopt this NQF-endorsed HAI measure. We also are proposing to adopt this measure for the Hospital OQR Program for the CY 2015 payment determination. We refer readers to the discussion in section XIV.C.3.b. of this proposed rule for a detailed description of this measure.

Read together, section 1833(i)(7)(B) of the Act and section 1833(t)(17)(C)(i) of the Act require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by ASCs, that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. We believe this measure is appropriate for measuring quality of care in ASCs due to the significant impact of HCP influenza vaccination on the spread of influenza among patients. Furthermore, we believe that this measure meets the consensus requirement and the requirement that it be set forth by a national consensus building entity because it is endorsed by the NQF.

We are proposing that ASCs use the NHSN infrastructure and protocol to report the measure for ASC Quality Reporting Program purposes. Collection of data via the NHSN for this measure will begin with immunizations from October 1, 2013 to March 31, 2014 for the CY 2016 payment determination. We invite public comment on our

proposal to adopt this HAI measure into the ASC Quality Reporting Program for the CY 2016 payment determination.

In summary, for the CY 2016 payment determination, we are proposing to retain the ten measures that we adopt for the CY 2015 payment determination (if these proposals are finalized in a final rule) and to add one NHSN HAI measure. The proposed measures for ASCs for the CY 2016 payment determination are listed below:

Proposed ASC Program Measurement Set for the CY 2016 Payment Determination	
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: Ambulatory Surgery Patients with Appropriate Method of Hair Removal	
ASC-7: Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin	
ASC-8: Surgical Site Infection Rate	
ASC-9: Safe Surgery Checklist Use	
ASC-10: ASC Facility Volume Data on Selected ASC 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

Proposed ASC Program Measurement Set for the CY 2016 Payment Determination
ASC- 11: Influenza Vaccination Coverage among Healthcare Personnel *

*New proposed measure for CY 2016 payment determination.

6. ASC Measure Topics for Future Consideration

Below is a list of future measurement areas that we are considering for future ASC Quality Reporting Program payment determinations for which we seek comment.

In particular, we seek comment on the inclusion of Patient Experience of Care Measures in the ASC Quality Reporting Program measure set for a future payment determination, such as existing Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians/groups and the CAHPS Surgical Care Survey, sponsored and submitted by the American College of Surgeons (ACS) and the Surgical Quality Alliance (SQA). We also, in particular, seek comment on the inclusion of procedure-specific measures for cataract surgery, colonoscopy and endoscopy, and for measures of Anesthesia Related Complications in the ASC Quality Reporting Program measure set.

Measures and Measurement Topics under Consideration for Future Payment Determinations
Patient Experience of Care:
Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians/groups
CAHPS Surgical Care Survey
Procedure Specific Measures
Colonoscopy and other Endoscopy measures
Cataract Surgery measures
Anesthesia Related Complications:
Death
Cardiac Arrest
Perioperative Myocardial Infarction

Measures and Measurement Topics under Consideration for Future Payment Determinations
Anaphylaxis
Hyperthermia
Transfusion Reaction
Stroke, Cerebral Vascular Accident, or Coma following anesthesia
Visual Loss
Medication Error
Unplanned ICU admission
Patient intraoperative awareness
Unrecognized difficult airway
Reintubation
Dental Trauma
Perioperative aspiration
Vascular access complication, including vascular injury or pneumothorax
Pneumothorax following attempted vascular access or regional anesthesia
Infection following epidural or spinal anesthesia
Epidural hematoma following spinal or epidural anesthesia
High Spinal
Postdural puncture headache
Major systemic local anesthetic toxicity
Peripheral neurologic deficit following regional anesthesia
Infection following peripheral nerve block
Additional Future Measurement Topics:
NQF Serious Reportable Events in Healthcare
Medication administration variance
Medication reconciliation
Venous thromboembolism measures: outcome/assessment/prophylaxis.
Presence of Physician during Entire Recovery Period
Post-discharge follow up
Post-discharge ED visit within 72 hours

We invite public comment on these quality measures and measurement topics so that we may consider proposing to adopt them for future ASC Quality Reporting Program payment determinations beginning with the CY 2015 payment determination. We also

are seeking suggestions for additional measures and rationales for the ASC Quality Reporting Program that are not listed in the table above.

7. Technical Specification Updates and Data Publication

a. Maintenance of Technical Specifications for Quality Measures

We are proposing to provide technical specifications, and in some cases, links to technical specifications hosted on external third party Web sites, for the ASC Quality Reporting Program measure in a Specifications Manual, to be posted after publication of the CY 2012 OPPS/ASC final rule with comment period, on the CMS QualityNet Web site at http://www.QualityNet.org. Currently, the specifications for the proposed ASC measures for the CY 2014, CY 2015 and CY 2016 payment determinations, with the exception of the two structural measures, can be found at: http://www.ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf; http://www.cms.gov/apps/ama/license.asp?file=/pqrs/downloads/2011_PhysQualRptg_MeasureSpecificationsManual_033111.pdf; http://www.cdc.gov/nhsn/psc.html; and http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf. The specifications for the two structural measures are included in the discussion above and in the table of measures proposed for the CY 2015 payment determination.

We are proposing to maintain the technical specifications for the measures adopted for the ASC quality reporting program by updating this Specifications Manual and including detailed instructions and calculation algorithms as appropriate. In some

cases where the specifications are available elsewhere, we may include links to Web sites hosting technical specifications. We currently use this same process for Hospital OQR Program measures, as discussed above in section XIV.A.3.a. of this proposed rule. We are proposing to follow the same technical specification maintenance process for the ASC Quality Reporting Program measures and we invite public comments on this proposal.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established a subregulatory process for updates to the technical specifications that we use to calculate Hospital OQR Program measures. This process is used when changes to the measure specifications are necessary due to changes in scientific evidence or other substantive changes, thereby giving CMS the option to seek re-endorsement of that measure. We note that NQF endorsement of an OQR measure is not required under sections 1833(i)(2)(D)(iv), (i)(7) or (t)(17) of the Act. The legal standard for adopting Hospital OQR measures is consensus among affected parties, and to the extent feasible and practicable, measures that are set forth by a consensus building entity. The legal standard for adopting ASC measures is this same standard, except as the Secretary may otherwise provide. Changes of this nature to measures adopted for the ASC Quality Reporting Program may not coincide with the timing of our regulatory actions, but nevertheless require inclusion in the measure specifications so that measures are calculated based on the most up-to-date scientific standards and, in some instances, consensus standards.

For the Hospital OQR Program, we indicated that notification of changes to the measure specifications is available on the QualityNet Web site,

http://www.QualityNet.org, and in the Hospital OQR Program Specifications Manual and would occur no less than 3 months before any changes become effective for purposes of reporting under the Hospital OQR Program. The Hospital OQR Program Specifications Manual is released every 6 months and addenda are released as necessary providing at least 3 months of advance notice for substantial changes such as changes to ICD-9, CPT, NUBC, and HCPCS codes, and at least 6 months notice for substantive changes to data elements that would require significant systems changes. We are proposing to follow the same subregulatory process for the ASC Quality Reporting Program for updates to the technical specifications. We invite public comments on this proposal.

b. Publication of ASC Quality Reporting 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. These requirements under section 1833(t)(17)(E) of the Act also apply to the ASC Quality Reporting Program except as the Secretary may otherwise provide. We are proposing to make data that an ASC has submitted for the ASC Quality Reporting Program available on a CMS Web site after providing ASCs an opportunity to preview the data to be made public. We are proposing that these data would be displayed at the CMS Certification Number (CCN) level. Publishing this information encourages beneficiaries to work with their doctors and ASCs to discuss the quality of care ASCs provide to patients, thereby providing an additional incentive to ASCs to improve the

quality of care that they furnish. We intend to propose more detail on the publication of data in a later rulemaking. We solicit public comment on these proposed processes of making ASC quality data available to the public.

8. Proposed Requirements for Reporting of ASC Quality Data for the CY 2014 Payment Determination

To participate in the ASC Quality Reporting Program for the CY 2014 payment determination, we are proposing that ASCs must meet data collection and data submission requirements. We intend to propose administrative requirements, data validation and data completeness requirements, reconsideration and appeals processes, and CY 2015 payment determination reporting requirements in the CY 2013 OPPS/ASC proposed rule with comment period.

a. Proposed Data Collection and Submission Requirements for the Proposed Claims-Based Measures

We are proposing that, to be eligible for the full CY 2014 ASC annual payment update, ASCs would be required to submit complete data on individual quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims. For the CY 2014 payment determination, we are proposing to utilize Medicare fee-for-service ASC claims for services furnished between January 1, 2012 and December 31, 2012.

We are proposing to consider an ASC as participating in the ASC Quality Reporting Program for CY 2014 payment determination if the ASC includes QDCs specified for the program on their CY 2012 claims relating to the proposed measures if

finalized. As no determinations will be made affecting payment until the CY 2014 annual payment update, we are proposing this approach as to reduce ASC burden. We intend to provide additional details regarding participation notification and other administrative requirements in CY 2013 rulemaking.

We are proposing that data completeness for claims-based measures would 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 claim. We intend to propose how we will assess data completeness for claims-based measures in the CY 2013 OPPS/ASC proposed rule. We request public comment on these proposals and are specifically interested in receiving public comment on what constitutes complete data in regard to our proposed ASC claims-based measures utilizing QDCs and methods to assess completeness.

b. Proposed Data Submission Deadlines for the Proposed Surgical Site Infection Rate Measure

As discussed above, we are proposing to adopt a HAI measure, Surgical Site Infection Rate, for the CY 2014 payment determination. We are proposing to use the data submission and reporting standard procedures that have been set forth by the CDC for NHSN participation in general and for submission of this measure to NHSN. We refer readers to the CDC's NHSN Web site (http://www.cdc.gov/nhsn) for detailed data submission and reporting procedures. Our proposal seeks to reduce ASC burden by aligning CMS data submission and reporting procedures with NHSN procedures

currently utilized by healthcare providers and suppliers. The submission timeframes for the CY 2014 payment determination that we are proposing to use for the proposed Surgical Site Infection Rate measure are shown below. ASCs must submit their quarterly data to NHSN for ASC Quality Data Reporting purposes within the date intervals shown in the table below (any updates to this schedule will be posted on the QualityNet Web site).

Proposed Submission Timeframe for the Proposed Surgical Site Infection Rate Measure for the CY 2014 Payment Determination		
CY 2013 Infection Events	**CDC-NHSN Collection and Quarterly Report**	**Final Submission Deadline for ASC Quality Reporting CY 2014 Payment Determination**
Q1 (Jan 1 to Mar 31, 2013)	January 31st to August 1st	August 1, 2013
Q2 (Apr 1 to Jun 30, 2013)	April 30th to November 1st	November 1, 2013

We request public comments on these proposals.

XV. Proposed Changes to Whole Hospital and Rural Provider Exceptions to the Physician Self-Referral Prohibition: Exception for Expansion of Facility Capacity; and Proposed Changes to Provider Agreement Regulations Relating to Patient Notification Requirements

A. Background

Section 1877 of the Act, also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain "designated health services" (DHS) payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing

another individual, entity, or third party payer) for those DHS furnished as a result of a prohibited referral. The Act establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions that pose no risk of program or patient abuse.

Section 1877(d) of the Act sets forth additional exceptions related to ownership or investment interests held by a physician (or an immediate family member of a physician) in an entity that furnishes DHS. Section 1877(d)(2) of the Act provides an exception for ownership or investment interests in rural providers. In order for an entity to qualify for the exception, the DHS must be furnished in a rural area (as defined in section 1886(d)(2) of the Act) and substantially all of the DHS furnished by the entity must be furnished to individuals residing in a rural area. Section 1877(d)(3) of the Act provides an exception, known as the "whole hospital" exception, for ownership or investment interests in a hospital located outside of Puerto Rico, provided that the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

B. Changes Made by the Affordable Care Act

1. Provisions Relating to Exceptions to Ownership and Investment Prohibition (Section 6001(a) of the Affordable Care Act)

Section 6001(a) of the Affordable Care Act amended the whole hospital and rural provider exceptions to impose additional restrictions on physician ownership or investment in hospitals. The statute defines a "physician owner or investor" in a hospital as a physician or immediate family member of a physician who has a direct or indirect

ownership or investment interest in a hospital. We will refer to hospitals with such "physician owners or investors" as "physician-owned hospitals."

We addressed section 6001(a) of the Affordable Care Act in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71800). In §411.362, we implemented most of the requirements of section 6001(a) of the ACA, including patient safety requirements. In sections XV.B.2. and C. of this proposed rule, we address the process for a hospital to request an exception to the prohibition on expansion of facility capacity under section 6001(a)(3) of the Affordable Care Act. In section D. of this proposed rule, we address related patient notification requirements in the provider agreement regulations.

2. Provisions of Section 6001(a)(3) of the Affordable Care Act

The amended whole hospital and rural provider exceptions provide that a hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). Section 6001(a)(3) of the Affordable Care Act added new section 1877(i)(3)(A)(i) of the Act to set forth that the Secretary shall establish and implement an exception process to the prohibition on expansion of facility capacity. Referrals are prohibited if made by physician owners or investors after facility expansion and prior to the Secretary granting an exception. Exceptions for expanding facility capacity will protect only those referrals

made after the exception is granted. In this proposed rule, we set forth proposed regulations for this process at §411.362(c) and related definitions at §411.362(a).

The proposed regulations at §411.362(c) set forth the process for a hospital to request an exception. Proposed new §411.362(c)(2) outlines the requirements for an applicable hospital request and §411.362(c)(3) outlines the requirements for a high Medicaid facility request. These terms are defined at sections 1877(i)(3)(E) and 1877(i)(3)(F) of the Act. The statute is clear that an applicable hospital may apply for an exception up to once every 2 years. Using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we are proposing to interpret the statute to impose the same 2-year frequency limit to apply also to high Medicaid facilities as discussed in section XV.C.2. of this proposed rule.

We are proposing to set forth the elements required for a complete request for an exception under proposed new §411.362(c)(4). The opportunity for community input (required by section 1877(i)(3)(A)(ii) of the Act) and timing of a complete request are described in proposed §411.362(c)(5). Under proposed §411.362(c)(5), we are proposing to provide an opportunity for individuals and entities in the community in which the hospital is located to provide input with respect to the hospital's request for an exception. For purposes of this proposed rule, when the statute refers to an "application," we use the term "request."

Because section 1877(i)(3)(D) of the Act provides that any increase in the number of operating rooms, procedure rooms, and beds for which a hospital is licensed pursuant to being granted an exception may occur only in facilities on the hospital's main campus,

we are proposing a definition of the "main campus of the hospital" at §411.362(a), as discussed below. Additionally, we are proposing a definition of the "baseline number of operating rooms, procedure rooms, and beds" for purposes of section 1877(i)(3)(C)(ii) of the Act.

Section 1877(i)(3)(H) of the Act provides that the Secretary shall publish the final decision with respect to an application in the **Federal Register** no later than 60 days after receiving a complete application. Under section XV.C.4. of this proposed rule, below, we discuss our proposal for publishing decisions in the **Federal Register** as well as on the CMS Web site.

Under section 1877(i)(3)(A) of the Act, the Secretary must promulgate regulations concerning the process for a hospital to apply for an exception by January 1, 2012, and implement this process on February 1, 2012. We anticipate an effective date of January 1, 2012, for these proposed regulations. Below, we set out our proposals related to the exception process in greater detail.

C. Proposed Changes Relating to the Process for an Exception to the Prohibition on Expansion of Facility Capacity

In order to conform our regulations to the amendments made to the rural provider and whole hospital exceptions by section 6001(a)(3) of the Affordable Care Act, we are proposing to add two definitions in §411.362(a) and a new §411.362(c) to establish the process by which an applicable hospital or high Medicaid facility may request an exception to the prohibition on expansion of facility capacity. We are proposing to define the terms "baseline number of operating rooms, procedure rooms, and beds" and

"main campus of the hospital." The process we are proposing sets forth the relevant data sources and the elements of a complete request for an exception.

1. Applicable Hospital

Below we separately discuss each of the statutory criteria that a hospital must satisfy to qualify as an "applicable hospital." We are proposing the processes by which a hospital can determine whether it satisfies each criterion. The proposed data requirements for each criterion are further discussed in each section below.

We are proposing that data from the CMS Healthcare Cost Report Information System (HCRIS) be used to determine whether a hospital satisfies the inpatient admission, bed capacity, and bed occupancy criteria. We currently consider HCRIS to contain a sufficient amount of data for a particular fiscal year if HCRIS contains data from at least 6,100 hospitals for that fiscal year. Therefore, we are proposing that HCRIS must contain data from at least 6,100 hospitals for a particular year in order for that year's data to be used under the exception process. If HCRIS does not contain sufficient data for that year, data from the most recent year(s) that satisfy the threshold should be used.

CMS will post the average percent of total inpatient Medicaid admissions per county, the average bed capacity per State, the national average bed capacity, and the average bed occupancy per State on the CMS Web site at: http://www.cms.gov/physicianselfreferral/85_physician_owned_hospitals.asp. Hospitals can access these data to assess whether they satisfy the respective criteria to qualify as an applicable hospital. CMS will make a reasonable effort to ensure that the data contained

in HCRIS are correct and complete at the time of disclosure. We are soliciting public comment on proposing and justifying alternative data sources other than HCRIS that could result in more accurate determinations as to whether a hospital satisfies the relevant criteria.

a. Percentage Increase in Population

Section 1877(i)(3)(E)(i) of the Act provides that an applicable hospital means a hospital that is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the application date) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by the Bureau of the Census.

To determine the percentage increase in population in the county and State in which the hospital is located, we are proposing at §411.362(c)(2)(i) that the hospital use population estimates provided by the Bureau of the Census. If the hospital is located in an area referred to by the Bureau of the Census as a county equivalent area, such as an independent city, borough, or census area, the hospital should use the Bureau of the Census estimates for the county equivalent area in which it is located. For the remainder of this subsection, "county" refers to both a county and a county equivalent area.

We recognize that the Bureau of the Census may not provide county and State population size estimates that are current as of the date that a hospital submits its request for an exception. We are proposing that a hospital should use only the most recent estimates available to perform the necessary calculations. For example, if a hospital submits a request for an exception in 2012, but the most recent year for which the Bureau

of the Census has estimates is 2010, the hospital should perform the necessary calculations using estimates for years 2010 and 5 years prior.

We are proposing also that the hospital use county and State population estimates for the same years. For example, if a hospital submits a request for an exception in 2012 and the most recent year for which the Bureau of the Census has State and county population estimates is 2011 and 2010, respectively, the hospital should perform the necessary calculations using estimates for years 2010 and 5 years prior. We are proposing to review a request based on the population estimates available as of the date that a hospital submits its request even if the Bureau of the Census updates its estimates after the hospital submits its request and prior to our decision.

b. Inpatient Admissions

Section 1877(i)(3)(E)(ii) of the Act provides that an applicable hospital means a hospital that has an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located. We are proposing at §411.362(c)(2)(ii) to require hospitals to calculate inpatient admissions using filed hospital cost report discharge data. We are proposing that, in calculating the hospital's annual percent of total Medicaid inpatient admissions, the hospital should divide the number of discharges for the year that are paid for under Medicaid by the total number of discharges for the year paid for by any governmental or private payor. We are soliciting public comment on other data sources that could be used to provide an accurate estimate

of the annual percent of total Medicaid inpatient admissions for the applicable hospital and for all hospitals in the same county.

The statute does not specify the number of years for which the hospital's annual percent of total inpatient admissions under Medicaid must be equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located. We are proposing at §411.362(c)(2)(ii) that a hospital must satisfy this criterion for each of the 3 most recent fiscal years for which data are available as of the date the hospital submits a request. We invite public comment on whether 3 years of data are sufficient to indicate a legitimate need by the hospital to increase its number of operating rooms, procedure rooms, and beds and, if not, how many years of data we should consider in evaluating a request for an exception.

We are proposing at §411.362(c)(2)(ii) that the hospital would estimate its annual percentage of total inpatient admissions under Medicaid. The hospital would reference its own filed cost reports for the 3 most recent fiscal years for which data are available. We are proposing that we would review a request based on the data available as of the date the hospital submits its request. We plan to issue guidance to further address the process for a hospital to estimate its annual percentage of total inpatient admissions under Medicaid. The guidance will also explain how CMS will determine and provide the average percentages of inpatient admissions under Medicaid for each county.

c. Nondiscrimination

Section 1877(i)(3)(E)(iii) of the Act provides that an applicable hospital does not discriminate against beneficiaries of Federal health care programs and does not permit

physicians practicing at the hospital to discriminate against such beneficiaries. We are proposing to incorporate this requirement at §411.362(c)(2)(iii) of the regulations.

d. Bed Capacity

Section 1877(i)(3)(E)(iv) of the Act provides that an applicable hospital means a hospital that is located in a State in which the average bed capacity in the State is less than the national average bed capacity. The statute does not specify a time period over which a State's average bed capacity must be less than the national average bed capacity. We are proposing at §411.362(c)(2)(iv) that the State average bed capacity must be less than the national average bed capacity for each of the 3 most recent fiscal years for which data are available as of the date that a hospital submits its request. We invite public comment on whether 3 years of data are sufficient to indicate a legitimate need by the hospital to increase its number of operating rooms, procedure rooms, and beds and, if not, how many years of data we should consider in evaluating any request for an exception.

Under our proposed process, CMS would use filed hospital cost reporting data to determine State and national average bed capacities. We plan to issue guidance explaining how CMS will determine and provide the average bed capacities. We are proposing that we would review a request based on the data available as of the date a hospital submits its request.

e. Bed Occupancy

Section 1877(i)(3)(E)(v) of the Act provides that an applicable hospital means a hospital that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located. The statute does not specify

the time period over which the hospital's average bed occupancy rate must be greater than the State average bed occupancy rate. We are proposing at §411.362(c)(2)(v) that the hospital's bed occupancy rate must be greater than the State average bed occupancy rate for each of the 3 most recent fiscal years for which data are available as of the date that a hospital submits its request. We invite public comment on whether 3 years of data are sufficient to indicate a legitimate need by the hospital to increase the number of its operating rooms, procedure rooms, and beds and, if not, how many years of data we should consider in evaluating any request for an exception.

We are proposing at §411.362(c)(2)(v) that the hospital use filed hospital cost reporting data to calculate its own average bed occupancy rate. We plan to issue guidance explaining how the hospital can calculate its bed occupancy rate. The guidance would also explain how CMS will determine and provide the State bed occupancy rates. We are proposing that we would review a request based on the data available as of the date that the hospital submits its request.

2. High Medicaid Facility

Below we separately discuss each of the statutory criteria that a hospital must satisfy to qualify as a "high Medicaid facility." We are proposing the processes by which a hospital can determine whether it satisfies each criterion. The proposed data requirements for each criterion are further discussed in the sections below.

As discussed in section XV.C.1. of this proposed rule, we currently consider HCRIS to contain a sufficient amount of data for a particular fiscal year once HCRIS contains data from at least 6,100 hospitals for that year. Therefore, we are proposing that

HCRIS must contain data from at least 6,100 hospitals for a particular year in order for that year's data to be used under the exception process. If HCRIS does not contain sufficient data for that year, data from the most recent year(s) that satisfies the threshold should be used.

a. Number of Hospitals in County

Section 1877(i)(3)(F)(i) of the Act provides that a high Medicaid facility means a hospital that is not the sole hospital in a county. We are proposing to incorporate this requirement into the regulations at §411.362(c)(3)(i).

b. Inpatient Admissions

Section 1877(i)(3)(F)(ii) of the Act provides that a high Medicaid facility means a hospital that, with respect to each of the 3 most recent years for which data are available, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located. We are proposing to incorporate this requirement at §411.362(c)(3)(ii) of the regulations.

We are proposing at § 411.362(c)(3)(ii) that the hospital estimate its annual percentages of total inpatient admissions under Medicaid for each of the 3 most recent fiscal years for which data are available. We also are proposing that the hospital estimate the annual percentage of such admissions for all other hospitals located in the county in which the hospital is located for each of the 3 most recent fiscal years for which data are available. We are proposing that we would review a request based on the data available as of the date that the hospital submits its request.

We are proposing to require the applicant hospital to use filed hospital cost reporting discharge data as a proxy for inpatient admissions under Medicaid. CMS will post the data necessary for a hospital to calculate the annual percentage of total inpatient admissions under Medicaid for all other hospitals located in the county in which the hospital is located on the CMS Web site at: http://www.cms.gov/physicianselfreferral/85_physician_owned_hospitals.asp. We plan to issue guidance that further describes the process for hospitals to estimate inpatient admissions under Medicaid.

c. Nondiscrimination

Section 1877(i)(3)(F)(iii) of the Act provides that a high Medicaid facility does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. We are proposing to incorporate this requirement at §411.362(c)(3)(iii) of the regulations.

3. Procedure for Submitting a Request

We are not creating an application form that a hospital must complete to apply for an exception to the prohibition on expansion of facility capacity. Rather, we are proposing that a hospital submit to CMS a request that includes the information and documentation set forth in proposed §411.362(c)(4)(ii).

We are proposing that each request must include: (i) the name and address, National Provider Identification number(s) (NPI), Tax Identification Number(s) (TIN), and CMS Certification Number(s) (CCN) of the hospital; (ii) the county in which the hospital is located; and (iii) the name, title, address, and daytime telephone number of a

contact person who will be available to discuss the request with CMS on behalf of the hospital. Each request must include a clear statement as to whether the hospital is requesting an exception as an applicable hospital or a high Medicaid facility. We are proposing that each request submitted by a hospital must include a clear explanation of how it satisfies the criteria using the information discussed in sections XV.C.1. or 2. of this proposed rule. This includes performing, recording, and submitting all calculations necessary to submit a complete request. The hospital's request must state that it does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. Finally, we encourage hospitals to clearly label all documentation submitted with a request and indicate the criteria for which the documentation provides supporting information.

We are proposing at §411.362(c)(4)(ii)(E) that each request must include documentation supporting the hospital's calculation of the hospital's baseline number of operating rooms, procedure rooms, and beds as defined at section 1877(i)(3)(C)(iii) of the Act; the hospital's number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of the date that the hospital submits its request; and the additional number of operating rooms, procedure rooms, and beds by which the hospital requests to expand.

Finally, we are proposing at §411.362(c)(4)(iii) that each request must include a certification signed by an authorized representative of the hospital attesting that all of the information provided is true and correct to the best of his or her knowledge and belief.

We are proposing at §411.362(c)(4)(i) that a hospital must either mail an original and one copy of its request to CMS or submit its request electronically. If a hospital submits its request electronically, the hospital must also submit an original, hard copy of the required certification.

4. Community Input

Section 1877(i)(3)(A)(ii) of the Act provides that individuals and entities in the community in which the applicable hospital is located shall have an opportunity to provide input on the applicable hospital's request for an exception to the prohibition against facility expansion. We are proposing to incorporate this provision in proposed §411.362(c)(5) of the regulations. We are proposing that the community input must take the form of written comments. In addition, using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we are proposing that individuals and entities in the community in which a high Medicaid facility is located may have the same opportunity to submit written comments.

We are proposing at §411.362(c)(5) that a hospital must disclose on any public Web site for the hospital that it is requesting an exception. The notice should be accessible to the public and should remain posted from the time a request is submitted to CMS until a decision is finalized by CMS. Once CMS has received the statements, certifications, and documentation required for a hospital's request, CMS will report that the hospital is requesting an exception on the CMS Hospital Listserv and will post the hospital's request for an exception on the CMS Web site. For specific information on how to subscribe to the CMS Hospital Listserv, please access the CMS Web site at

http://www.cms.gov/MLNProducts/downloads/MailingLists_FactSheet.pdf. In addition, we are proposing that a notice of the hospital's request will be published in the **Federal Register**. We are proposing at §411.362(c)(5) to allow individuals and entities in the community 30 days from the date of the notice's publication in the **Federal Register** to submit written comments.

Examples of community input include documentation demonstrating that the hospital does not satisfy one or more of the data criteria or that the hospital discriminates against beneficiaries. These are examples only; we are not restricting the types of community input that may be submitted. We are proposing at §411.362(c)(5) that written comments must be submitted by mail or electronically to CMS.

We are proposing at §411.362(c)(5)(i) that we will consider a request complete if CMS does not receive any written comments during the 30-day period after notice of the hospital's request is published in the **Federal Register**.

If CMS receives written comments, CMS will notify the hospital in writing. We are proposing at §411.362(c)(5)(ii) to allow the hospital 30 days after CMS notifies the hospital of the written comments to submit information and documentation that rebut the written comments. We will consider the request complete at the end of the 30-day period provided for the hospital's rebuttal, regardless of whether the hospital submits additional information or documentation. We reserve the right to perform our own calculations based on a review of the material submitted and of information generally available to CMS.

5. Permitted Increase

Section 1877(i)(3)(C)(i) of the Act provides that a hospital granted an exception from the Secretary may increase the number of operating rooms, procedure rooms, and beds for which the hospital is licensed above its baseline number of operating rooms, procedure rooms, and beds. If the hospital has been granted a previous exception from the Secretary, the hospital may increase above the number of operating rooms, procedure rooms, and beds for which the hospital is licensed after application of the most recent increase under such an exception.

a. Amount of Permitted Increase

Section 1877(i)(3)(C)(ii) of the Act provides that the Secretary shall not permit an increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed to the extent such increase would result in the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed exceeding 200 percent of the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital. We are proposing to incorporate this provision at §411.362(c)(6)(i) of the regulations.

Using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we are proposing to similarly limit the increase in the number of operating rooms, procedure rooms, and beds for which a high Medicaid facility may request an exception. We are soliciting public comment on whether the proposed limit would be sufficient to balance the intent of the general prohibition on expansion with the purpose of the

exception process to provide the opportunity to expand in areas where a sufficient need for access to high Medicaid facilities is demonstrated.

A hospital must determine its baseline facility capacity to ensure that an expansion is within the limits set forth at section 1877(i)(3)(C)(ii) of the Act and to submit a complete request. Section 1877(i)(3)(C)(iii) of the Act defines the "baseline number of operating rooms, procedure rooms, and beds" as the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed as of [March 23, 2010] (or, in the case of a hospital that did not have a provider agreement in effect as of such date but does have such an agreement in effect on December 31, 2010, the effective date of such provider agreement). We are proposing to incorporate this definition, with the clarification that it also applies to high Medicaid facilities, at §411.362(a) of the regulations.

b. Location of Permitted Increase

Section 1877(i)(3)(D) of the Act provides that any increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed may occur only in facilities on the main campus of the applicable hospital. We are proposing to incorporate this provision at proposed §411.362(c)(6)(ii) of the regulations. We are proposing to define the term "main campus" as the term "campus" is defined at §413.65(a)(2). Using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we are proposing that, with respect to high Medicaid facilities, the limitation on expansion of hospital capacity, as set forth at section 1877(i)(1)(B) of the Act,

similarly applies to the number of operating rooms, procedure rooms, and licensed beds on the "campus" of the high Medicaid facility.

6. Decisions

Section 1877(i)(3)(H) of the Act states that the Secretary shall publish in the Federal Register the final decision with respect to an application for an exception to the prohibition against facility expansion not later than 60 days after receiving a complete application. We are proposing to codify this provision at §411.362(c)(7). To facilitate access to decisions, we are proposing to post our decisions on the CMS Web site as well. The posted information will include the hospital's name, address, county, and our final decision. If an exception is granted under this section, we will also post the number of operating rooms, procedure rooms, and beds by which the hospital may expand under the granted exception. We believe that posting decisions on the CMS Web site will enable us to inform the public and the affected community of our decisions in a timely manner and in a centralized location.

7. Limitation on Review

Section 1877(i)(3)(I) of the Act provides that there shall be no administrative or judicial review of the process, either under section 1869, section 1878, or otherwise. We incorporated this limitation on review at proposed §411.362(c)(8) of the regulations. We interpret this limitation on review to mean that CMS' decision with respect to whether a hospital qualifies for an exception is not reviewable.

8. Frequency of Request

Section 1877(i)(3)(B) of the Act provides that the exception process shall permit an applicable hospital to apply for an exception up to once every 2 years. We are incorporating this provision at § 411.362(c)(1). Using our authority under sections 1871 and 1877 of the Act, we similarly are proposing to permit a high Medicaid facility to submit a request for an exception up to once every 2 years from the date of a CMS decision on the hospital's most recent request. We are proposing to consider the date of a CMS decision to be the date of the letter sent to the requesting party.

D. Proposed Changes Related to Provider Agreement Regulations on Patient Notification Requirements

Section 1866 of the Act states that a provider of services shall be qualified to participate in the Medicare program and shall be eligible for Medicare payments if it files a Medicare provider agreement and abides by the requirements applicable to Medicare provider agreements. These requirements are incorporated in our existing regulations at 42 CFR Part 489, Subparts A and B (Provider Agreements and Supplier Approval). Section 5006 of the Deficit Reduction Act of 2005 mandated the Secretary to develop a strategic and implementing plan to address certain issues with respect to physician ownership of specialty hospitals. As part of that plan, we used our authority under sections 1866, 1820(e)(3), and 1861(e)(9) of the Act (as well as our general rulemaking authority under sections 1102 and 1871 of the Act) to impose certain additional requirements on physician-owned hospitals as part of their provider agreements. These new requirements were established in the FY 2008 IPPS final rule with comment period

(72 FR 47385 through 47391) and the FY 2009 IPPS final rule (73 FR 48686 through 48688).

Specifically, we added a new provision to require that all hospitals and CAHs: (1) furnish all patients written notice at the beginning of their inpatient hospital stay or outpatient service if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week; and (2) describe how the hospital or CAH will meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present in the hospital or CAH. These requirements are codified at §489.20(w). The requirements of §§489.20(u) and (w) were made applicable to both inpatient hospital stays and outpatient services because, as we stated in the FY 2008 IPPS final rule with comment period, these provisions are in the interest of the health and safety of all individuals who receive services in these institutions. The notice requirements are intended to permit individuals to make more informed decisions regarding their treatment.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72251), we stated that we saw no reason to treat the safety of hospital inpatients differently than hospital outpatients, and, thus, applied these patient safety requirements to hospital inpatients and outpatients. We continue to believe that both hospital inpatients and outpatients should receive these disclosures prior to admission. However, after hospitals in general informed us that it would be unduly burdensome to provide disclosures to <u>all</u> outpatients, and hospitals with emergency departments reported the individual notice requirement makes the registration process more cumbersome and time-consuming than

is desirable in the emergency department setting, we revisited this issue. We have reconsidered the patient safety requirements related to patient notification of physician presence, and in this proposed rule, we are proposing that hospital outpatients would need to receive such disclosures only where the risk of an emergency or the length of the outpatient visit make their situations more like that of hospital inpatients. Under this proposal, disclosures would be required only for those outpatients receiving observation services, surgery, or any other procedure requiring anesthesia. Signage would be required for hospital outpatients in the emergency department, as we recognize the merit of finding a less cumbersome manner to provide the required notice in this setting. Other hospital outpatient encounters are relatively short and, in many cases, scheduled in advance. The risk of emergency is relatively low in most of these scheduled encounters. As a result, we believe the safety of these particular hospital outpatients would not be compromised in any way if hospitals were not required to provide disclosures in these circumstances.

In this proposed rule, we are proposing to revise paragraph (w)(1) of §489.20 to reduce the categories of outpatients who must be notified if a hospital does not have a physician on site 24 hours per day/7 days per week. We are proposing that only those outpatients who receive observation services, surgery, or services involving anesthesia, must receive such written notice. We believe this change would reduce burden, but ensure that notice goes to those categories of patients who are more likely to find themselves in a situation where a physician is not present when an emergency develops. (We note that we are not making any changes to similar patient safety requirements for

physician-owned hospitals at §411.362(b)(5)(i).) We are proposing to add a provision that notice would be required at the beginning of a planned or unplanned inpatient stay or outpatient visit, and we provide explanation of when a planned or unplanned stay or visit begins. We are proposing to add a provision to state that an unplanned stay or visit begins at the earliest point at which the patient presents to the hospital. The current regulation describes when a stay or visit begins by referring to the time when a package of information is provided regarding scheduled preadmission testing and registration for a planned hospital admission or outpatient service. However, many admissions to the hospital are unplanned admissions of patients who present on an unscheduled visit to the emergency department. Therefore, it was necessary to clarify when we considered such unplanned stays or visits begin.

We are proposing to add a new paragraph (w)(2) to §489.20 (existing paragraph (w)(2) would be redesignated as discussed below) that would require a hospital that is a main provider that has one or more remote locations of a hospital or satellites to make the determination of whether notice is required separately at each location providing inpatient services. We are proposing to use the terms "main provider," "remote location of a hospital," and "satellite" as these terms are defined at §413.65(a)(2), §412.22(h), or §412.25(e), as applicable. We are proposing that notice would be required for all applicable patients, that is, all inpatients and applicable outpatients, at each location at which inpatient services are furnished and at which a doctor of medicine or doctor of osteopathy is not present 24 hours per day/7 days per week. We are proposing to move language that is currently in paragraph (w)(1) to a new paragraph (w)(3), governing the

content of the written notice. We are proposing to redesignate existing paragraph (w)(2), which requires the hospital to receive a signed acknowledgment from the patient who has received a notice that the patient understands that a physician may not be present during all hours in which services are furnished to the patient, as paragraph (w)(4) and to revise the redesignated paragraph. We are proposing to add a provision to state that, before providing an outpatient service to an outpatient for whom a notice is required, the hospital must receive the signed acknowledgment. This revision would make this requirement consistent with our proposed revisions to paragraph (w)(1) limiting the notice requirement to certain categories of outpatients.

We are proposing to add a new paragraph (w)(5) which would require every hospital that has a dedicated emergency department in which a doctor of medicine or doctor of osteopathy is not present 24 hours per day/7 days per week to post a notice conspicuously in a place or places likely to be noticed by all individuals entering the dedicated emergency department. "Dedicated emergency department" would have the meaning found in existing §489.24(b) of the regulations. We would require the notice to state that the hospital does not have a doctor of medicine or doctor of osteopathy present in the hospital 24 hours per day/7 days per week, and to indicate how the hospital will meet the needs of any patient with an emergency medical condition, as that term is defined in §489.24(b), at a time when no doctor of medicine or doctor of osteopathy is present within the hospital. In the event that there is a decision to admit a patient from the emergency department as an inpatient, the individualized written disclosure and acknowledgment would have to be made at the time the patient is admitted.

XVI. Additional Proposals for the Hospital Value-Based Purchasing (Hospital VBP) Program

A. Hospital VBP Program

1. Legislative Background

Section 3001(a) of the Affordable Care Act added section 1886(o) to the Act. This section requires the Secretary to establish a hospital inpatient value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital Inpatient Value-Based Purchasing Program (Hospital VBP Program) to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction of 1.0 percent to the FY 2013 base operating DRG payment amount for each discharge, as required by section 1886(o)(7)(B)(i) of the Act.

Section 1886(o)(1)(C) of the Act provides that the Hospital VBP Program applies to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act), but excludes from the definition of the term "hospital," with respect to a fiscal year: (1) a hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act (the Hospital IQR Program) for such fiscal year; (2) a hospital for which, during the performance period for the fiscal year, the Secretary cited deficiencies that pose

"immediate jeopardy" to the health or safety of patients; and (3) a hospital for which there are not a minimum number (as determined by the Secretary) of measures for the performance period for the fiscal year involved, or for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for such fiscal year.

2. Overview of the Hospital Inpatient VBP Program Final Rule

We recently issued the Hospital Inpatient VBP Program Final Rule, which implemented the Hospital VBP Program gram under section 1886(o) of the Act (76 FR 26490 through 26547). The Hospital Inpatient VBP Program Final Rule was developed based on extensive research we conducted on hospital value-based purchasing, including research that formed the basis of a 2007 report we submitted to Congress, entitled "Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program." This report is available on our Web site (https://www.cms.gov/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf) and takes into account input from stakeholders and other interested parties.

As described more fully in the Hospital Inpatient VBP Program Final Rule, we adopted for the FY 2013 Hospital VBP Program 13 measures that we have already adopted for the Hospital IQR Program, categorized into two domains (76 FR 26495 through 26511). We grouped 12 clinical process of care measures into a clinical process of care domain, and placed the HCAHPS survey measure into a patient experience of care domain. We adopted a 3-quarter performance period from July 1, 2011 through

March 31, 2012 for these measures (76 FR 26494 through 26495). To determine whether a hospital meets the proposed performance standards for these measures, we will compare each hospital's performance during this performance period to its performance during a 3-quarter baseline period from July 1, 2009 through March 31, 2010 (76 FR 26493 through 26495).

We also finalized a methodology for assessing the total performance of each hospital based on performance standards under which we will score each hospital based on achievement and improvement ranges for each applicable measure. We will calculate a Total Performance Score for each hospital by combining the greater of the hospital's achievement or improvement points for each measure to determine a score for each domain, weighting each domain score (for the FY 2013 Hospital VBP Program, the weights will be clinical process of care = 70 percent, patient experience of care = 30 percent), and adding together the weighted domain scores. We will convert each hospital's Total Performance Score into a value-based incentive payment using a linear exchange function. We refer readers to the Hospital Inpatient VBP Program Final Rule for further explanation of the details of the FY 2013 Hospital VBP Program (76 FR 26490 through 26547).

For FY 2014, we adopted 13 outcome measures comprised of 3 mortality measures, 2 AHRQ composite measures, and 8 hospital-acquired condition (HAC) measures (76 FR 26511). These measures are discussed fully in the Hospital Inpatient VBP Program Final Rule (76 FR 26510 through 26511). These finalized outcome measures for FY 2014 are set forth below.

Finalized Outcome Measures for the FY 2014 Hospital VBP Program	
Mortality Measures (Medicare Patients)	
	● Acute Myocardial Infarction (AMI) 30-day mortality rate
	● Heart Failure (HF) 30-day mortality rate
	● Pneumonia (PN) 30-day mortality rate
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) Composite Measures	
	● Complication/patient safety for selected indicators (composite)
	● Mortality for selected medical conditions (composite)
Hospital Acquired Condition Measures	
	● Foreign Object Retained After Surgery
	● Air Embolism
	● Blood Incompatibility
	● Pressure Ulcer Stages III & IV
	● Falls and Trauma: (Includes: Fracture, Dislocation, Intracranial Injury, Crushing Injury, Burn, Electric Shock)
	● Vascular Catheter-Associated Infection
	● Catheter-Associated Urinary Tract Infection (UTI)
	● Manifestations of Poor Glycemic Control

3. Proposed Additional FY 2014 Hospital VBP Program Measures

For the FY 2014 Hospital VBP Program, we are proposing to retain all 13 of the clinical process of care and patient experience of care measures that we adopted for the FY 2013 Hospital VBP Program. We also are proposing to add one measure to the clinical process of care domain: SCIP-Inf-9: Postoperative Urinary Catheter Removal on Postoperative Day 1 or 2. This measure was specified for the Hospital IQR Program beginning with FY 2011 and subsequent payment determination years (74 FR 43869 through 43870), and information about the measure first appeared on Hospital Compare in December 2010. Thus, we believe that this measure meets the requirement in section 1886(o)(2)(C)(i) of the Act to be included in the Hospital VBP Program because it has been specified for the Hospital IQR Program and will have been displayed on Hospital

Compare for at least one year before the applicable performance period begins. In addition, SCIP-Inf-9 is NQF-endorsed (#453).

The measure is relevant for the Hospital VBP Program because it assesses a practice that reduces Catheter Associated Urinary Tract Infection (CAUTI), and improves patient safety, which is highlighted as one of the Institute of Medicine's six quality aims along with effectiveness, patient-centeredness, timeliness, efficiency, and equity. SCIP-Inf-9 is one of the NQF-endorsed SCIP infection prevention measures; these measures are referenced as a whole among the metrics listed in the HHS Action Plan to Prevent HAIs. This Action Plan can be found at the following Web site: http://www.hhs.gov/ash/initiatives/hai/actionplan/. Furthermore, this measure meets other criteria considered for measure selection for the Hospital VBP Program, such as not being "topped-out" and displaying meaningful variability among hospitals. Therefore, we believe it would be a meaningful measure to include in the Hospital VBP Program.

The table below lists the clinical process of care and patient experience of care measures we are proposing to adopt for the FY 2014 Hospital VBP Program. We note that these measures are currently NQF-endorsed and we will continue to monitor these measures to ensure that they reliably measure hospital quality, for example, ensuring that, among other things, these measures are not "topped-out," and their measurement criteria remain endorsed by NQF and/or are otherwise appropriate. To the extent we determine that these measures are topped-out, we may choose not to finalize them.

Proposed Clinical Process of Care and Patient Experience of Care Measures for the FY 2014 Hospital VBP Program	
Clinical Process of Care Measures	
Measure ID	**Measure Description**
Acute myocardial infarction	
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival
Heart Failure	
HF-1	Discharge Instructions
Pneumonia	
PN-3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient
Healthcare-associated infections	
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose
SCIP-Inf-9	Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2
Surgeries	
SCIP-Card-2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period
SCIP-VTE-1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery
Patient Experience of Care Measures	
Measure ID	**Measure Description**
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey*

*Proposed dimensions of the HCAHPS survey for use in the FY 2014 Hospital VBP Program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge Information and Overall Rating of Hospital.

We invite public comment on these proposals.

4. Proposed Minimum Numbers of Cases and Measures for the Outcome Domain for the FY 2014 Hospital VBP Program

a. Background

Section 1886(o)(1)(C)(ii)(III) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for the fiscal year. Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year. In the Hospital Inpatient VBP Program Final Rule, we adopted 13 outcome measures for the FY 2014 Hospital VBP Program (76 FR 26511), but we did not adopt a minimum number of cases for such measures to apply to hospitals, nor did we adopt a minimum number of measures necessary for the outcome domain to be included in the Total Performance Score.

Under section 1886(o)(1)(C)(iii) of the Act, in determining the minimum number of reported measures and cases under sections 1886(o)(1)(C)(ii)(III) and (IV), the Secretary must conduct an independent analysis of what minimum numbers would be appropriate. As described in the Hospital Inpatient VBP Final Rule (76 FR 26528 through 26529), to fulfill this requirement, we commissioned Brandeis University to perform an independent analysis that examined technical issues concerning the minimum number of cases per measure and the minimum number of measures per hospital for clinical process of care measures needed to derive reliable domain scores. Based on that

analysis, we finalized our policy to exclude any clinical process of care measures for which a hospital reported fewer than 10 cases, and to exclude from the Hospital VBP Program any hospital to which fewer than 4 of the clinical process of care measures applied. We also finalized our proposal to exclude any hospital reporting fewer than 100 HCAHPS surveys during the performance period (76 FR 26529 through 26531).

To determine the minimum numbers of measures and cases that should be required for the outcome domain, we again commissioned Brandeis University to perform an independent analysis. This analysis examined hospital performance on the 13 finalized outcome measures using data from the proposed baseline periods (discussed below) for the FY 2014 Hospital VBP Program. As we did to analyze the reliability of scores in the clinical process of care domain, different minimum numbers of cases and measures were tested to determine the combination of minimum numbers of cases and measures that would lead to reliable scores in the outcome domain while allowing the maximum number of hospitals to be scored for the Hospital VBP Program. Concurrent with the Brandeis analysis, we contracted with researchers at Mathematica Policy Research (Mathematica) to explore the minimum number of cases a hospital would need to report for each individual outcome measure.

b. Proposed Minimum Number of Cases for Mortality Measures, AHRQ Composite Measures, and HAC Measures

The analyses by Brandeis and Mathematica determined that in order to receive a score on a mortality measure, the hospital would need to report a minimum of 10 cases, and in order to receive a score on an AHRQ composite measure, a hospital would need to

report a minimum of 3 cases. Consistent with these analyses, we are proposing that these case minimums would apply for the FY 2014 Hospital VBP Program.

Mathematica also examined the minimum number of cases a hospital would need to report in order to receive a reliable score on each HAC measure. Along with reliability concerns, when conducting this analysis, Mathematica also took into consideration our view, more fully explained in section XVI.A.6.d. of this proposed rule, that the incidence of HACs raises significant safety and quality concerns for patients and for the Medicare program. Therefore, we believe that a hospital should be held accountable when HACs occur in all instances in order to protect and promote patient safety. Mathematica concluded that a minimum of one Medicare claim would be sufficient to compute an accurate score on each HAC measure, and in accordance with this conclusion, we are proposing that hospitals be evaluated based on the presence or absence of HAC occurrences, regardless of the number of Medicare cases a hospital treats, as long as the hospital submits at least one Medicare claim during the performance period. As we discuss further below, we anticipate that all participating hospitals will submit at least one Medicare claim during the performance period, which would be sufficient for the hospitals to receive a score on seven of the eight HAC measures.

c. Proposed Minimum Numbers of Measures for Outcome Domain

Brandeis researchers also analyzed the reliability of the outcome domain scores for hospitals depending upon the total number of outcome measures on which they reported. The analysis showed that the data provide a meaningful and sufficiently reliable indication of outcomes for hospitals in the outcome domain as long as the

hospitals submit the minimum number of cases (discussed above) on each of 11 outcome measures for FY 2014. Specifically, the analysis found that using at least 11 outcome measures per hospital provided sufficiently comparable reliability of hospitals' scores in the outcome domain (particularly in terms of rank ordering relative to other hospitals) as compared with what hospitals' scores would have been if they had reported on more outcome measures. Brandeis concluded that this 11 measure minimum could be comprised of the 8 HAC measures, together with 3 measures comprised of any combination of the 3 mortality measures and the 2 AHRQ composite measures.

We note that, in conducting its analysis, Brandeis evaluated how the outcome domain score would be affected if a hospital reported all eight finalized HAC measures. However, one of these HAC measures, Foreign Object Retained After Surgery, will not apply to a very small subset of hospitals that do not perform surgeries. Taking this into account, as well as our own further analysis which shows that the reliability of the outcome domain score would not be significantly different as a statistical matter, we are proposing that the minimum number of measures a hospital would need to report in order to receive a score on the outcome domain is 10, comprised of 7 of the 8 HAC measures (all but the Foreign Object Retained After Surgery measure), along with 3 other measures comprised of any 3 of the other outcome measures (for example, 2 AHRQ composite measures and 1 mortality measure, or 3 mortality measures). We believe that this proposal is consistent with the conclusions reached by Brandeis. In addition, from an inclusiveness standpoint, we believe that a 10 measure minimum will maximize hospital participation in the FY 2014 Hospital VBP Program.

Furthermore, because we believe that every domain is an important component of an accurate Total Performance Score, we are proposing that, in order for a hospital to receive a Total Performance Score and be included in the FY 2014 Hospital VBP Program, the hospital must have enough cases and measures to report on all finalized domains. This proposed requirement should not impose any new barrier to hospitals or greatly reduce the number of hospitals in the FY 2014 Hospital VBP Program as compared to the FY 2013 Hospital VBP Program, when hospitals will only be scored on clinical process of care and patient experience of care measures. This is because, as stated above, an analysis of the existing data shows that virtually all hospitals participating in the FY 2014 Hospital VBP Program will report on a sufficient number of cases and measures to receive outcome domain scores in addition to the clinical process and patient experience domain scores for FY 2014.

We invite public comment on the proposed minimum numbers of cases and measures required for the FY 2014 Hospital VBP Program. We also invite public comment on the proposed requirement that hospitals must report on all four domains (if finalized) to receive a Total Performance Score for the FY 2014 Hospital VBP Program.

5. Proposed Performance Periods and Baseline Periods for FY 2014 Measures

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program for a fiscal year that begins and ends prior to the beginning of such fiscal year.

a. Proposed Clinical Process of Care Domain and Patient Experience of Care Domain Performance Period and Baseline Period

For the FY 2014 Hospital VBP Program, we are proposing a 9-month (3-quarter) performance period from April 1, 2012 to December 31, 2012 for the clinical process of care and patient experience of care domain measures. As described in the Hospital Inpatient VBP Final Rule (76 FR 26494 through 26495), due to various statutory deadlines and other challenges we faced in implementing the FY 2013 Hospital VBP Program in a timely fashion, we adopted a 3-quarter performance period for the clinical process of care and patient experience of care domains for the FY 2013 payment determination. We have stated our intent to move to a 12-month performance period when feasible. While a 12-month performance period is not yet feasible for FY 2014, we believe that this proposed 3-quarter performance period will allow us to notify hospitals of the amount of their value-based incentive payment at least 60 days before the start of FY 2014. It would also allow us to consider selecting CY 2013, a 12-month performance period, as the performance period for the FY 2015 Hospital VBP Program. In addition, this proposed performance period for FY 2014 would begin immediately after the end of the FY 2013 performance period, provide reliable performance information, and ensure that incentive payments can be made beginning with October 1, 2013 discharges.

As we explained in the Hospital Inpatient VBP Program Final Rule (76 FR 26485), we believe that baseline data should be used from a comparable 9-month (3-quarter) period. Therefore, we are proposing April 1, 2010 to December 31, 2010 as

the baseline period for these proposed measures for FY 2014. We invite public comment on these proposals.

b. Proposed Outcome Domain Performance Periods and Baseline Periods

In the Hospital Inpatient VBP Program proposed rule, we proposed an 18-month performance period of July 1, 2011 to December 31, 2012 and an 18-month baseline period of July 1, 2008 to December 31, 2009 for the three mortality outcome measures currently specified under the Hospital IQR Program (MORT-30-AMI, MORT-30-HF, MORT-30-PN). In response to public comment and for reasons discussed in the Hospital Inpatient VBP Program Final Rule (76 FR 26494), we adopted a 12-month performance period of July 1, 2011 to June 30, 2012 and a 12-month baseline period of July 1, 2009 to June 30, 2010 for these measures.

In the Hospital Inpatient VBP Program Final Rule, we stated that we would begin the performance period for the proposed HAC and AHRQ measures 1 year after such measures were included on Hospital Compare. Because all the finalized HAC and AHRQ measures were included on Hospital Compare on March 3, 2011, we finalized March 3, 2012 as the start of the performance period for these measures in the Hospital Inpatient VBP Program Final Rule (76 FR 26494 through 26495). We stated in the Hospital Inpatient VBP Program Final Rule (76 FR 26495) that we would propose the end performance period date for these measures in this proposed rule.

In order for the HAC and AHRQ measures to be scored for the FY 2014 Hospital VBP Program, the performance period for these measures would need to end by the fourth quarter of FY 2012 to allow us sufficient time to collect and process the necessary

claims data. We note that this time period needs to be longer for HAC and AHRQ measures than for clinical process and patient experience measures, which are based on chart-abstracted data and surveys rather than claims. Claims data require at least three months following a given calendar quarter to process and necessitate two additional months to complete measure calculation, including risk adjustment, statistical modeling, quality assurance, programming, and generating reports on patient-level data, which is provided to hospitals.

Therefore, we are proposing to adopt a nearly 7-month performance period for the HAC and AHRQ measures for FY 2014 by selecting September 30, 2012 as the end of the performance period. While we would prefer to use a 12-month performance period, analysis of existing data indicates that a 7-month performance period would provide sufficiently robust values on these critical measures.

As stated above, because we believe that a comparable period should be selected for the baseline data, we are proposing to set March 3, 2010 to September 30, 2010 as the baseline period for the proposed HAC and AHRQ measures for the FY 2014 Hospital VBP Program. We invite public comment on these proposals.

The following tables include all proposed and finalized baseline and performance periods for the FY 2013 and FY 2014 program years.

FY 2013 Hospital VBP Program Baseline and Performance Periods		
Domain	Baseline Period	Performance Period
Clinical Process	July 1, 2009 – March 31, 2010	July 1, 2011 – March 31, 2012

FY 2013 Hospital VBP Program Baseline and Performance Periods		
Patient Experience	July 1, 2009 – March 31, 2010	July 1, 2011 – March 31, 2012

FY 2014 Hospital VBP Program Baseline and Performance Periods		
Domain	Baseline Period	Performance Period
*Clinical Process**	April 1, 2010 - December 31, 2010	April 1, 2012 - December 31, 2012
*Patient Experience**	April 1, 2010 - December 31, 2010	April 1, 2012 - December 31, 2012
*Efficiency**	May 15, 2010 – 90 days prior to February 14, 2011	May 15, 2012 – February 14, 2013
Outcomes • Mortality • HAC* • AHRQ*	• July 1, 2009 – June 30, 2010 • March 3, 2010 – September 30, 2010 • March 3, 2010 – September 30, 2010	• July 1, 2011 – June 30, 2012 • March 3, 2012 - September 30, 2012 • March 3, 2012 – September 30, 2012

**Proposed*

6. Proposed Performance Standards for the FY 2014 Hospital VBP Program

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established and announced not later than 60 days before the beginning of the performance period for the fiscal year involved, as required by section 1886(o)(3)(C) of

the Act. Achievement and improvement standards are discussed more fully in the Hospital Inpatient VBP Program Final Rule (76 FR 26511 through 26513). In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement.

(1) Mortality Measures

In the Hospital Inpatient VBP Program Final Rule, we finalized the achievement performance standard (achievement threshold) for each of the proposed FY 2014 Hospital VBP Program mortality measures at the median of hospital performance (50th percentile) during the applicable baseline period. We also finalized the improvement performance standard (improvement threshold) for each mortality measure at each specific hospital's performance on each measure during the baseline period of July 1, 2009 to June 30, 2010 (76 FR 26511 through 76 FR 26512). In addition, we finalized the precise achievement thresholds for these mortality measures (76 FR 26513), as shown below:

Achievement Thresholds for the FY 2014 Hospital VBP Program Mortality Outcome Measures (Displayed as Survival Rates)			
Mortality Outcome Measures			
Measure ID	**Measure Description**	**Performance Standard (Achievement Threshold)**	**Benchmark**
MORT-30-	Acute Myocardial	0.8477	0.8673

Achievement Thresholds for the FY 2014 Hospital VBP Program Mortality Outcome Measures (Displayed as Survival Rates)			
AMI	Infarction (AMI) 30-Day Mortality Rate		
MORT-30-HF	Heart Failure (HF) 30-Day Mortality Rate	0.8861	0.9042
MORT-30 PN	Pneumonia (PN) 30-Day Mortality Rate	0.8818	0.9021

(2) Proposed Medicare Spending Per Beneficiary Measure

In section IV.B.3.b.(2)(A) of the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25927), we proposed to calculate a ratio of the Medicare spending per beneficiary amount for each hospital to the median Medicare spending per beneficiary amount across all hospitals during the performance period. We proposed to set the achievement threshold at the median Medicare spending per beneficiary ratio across all hospitals during the performance period. The proposed value of the achievement performance standard (achievement threshold) for the Medicare Spending per Beneficiary measure would be 1.0. This would be the middle ratio, or the Medicare spending per beneficiary for the median hospital divided by the median Medicare spending per beneficiary for all hospitals.

Likewise, in section IV.B.3.b.(2)(B) of the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25927 through 25928), we proposed to set the improvement performance standard (improvement threshold) for the proposed Medicare spending per beneficiary measure at the hospital's own Medicare spending per beneficiary ratio, as calculated during the proposed baseline period. We also proposed to set the achievement performance benchmark at the mean of the lowest decile of Medicare spending per beneficiary ratios during the performance period, and that the improvement benchmark

would be equal to the achievement performance benchmark for the performance period, which is the mean of the lowest decile of Medicare spending per beneficiary ratios. We refer readers to the FY 2012 IPPS/LTCH proposed rule for a complete discussion of these proposals.

b. Proposed Clinical Process of Care and Patient Experience of Care FY 2014 Performance Standards

As discussed in section XVI.B.5.a. of this proposed rule, we are proposing to adopt a 9-month (3-quarter) performance period of April 1, 2012 to December 31, 2012 for the clinical process of care and patient experience of care measures for the FY 2014 Hospital VBP Program. To set achievement and improvement performance standards for these proposed measures for the FY 2014 Hospital VBP Program, we are proposing to use the same approach adopted in the Hospital Inpatient VBP Program Final Rule. That approach, as well as our rationale for adopting it, is explained in detail at 76 FR 26511 through 76 FR 26513. We are proposing to set the achievement performance standard (achievement threshold) for each proposed measure at the median of hospital performance (50th percentile) during the proposed baseline period of April 1, 2010 through December 31, 2010. We also are proposing to set the improvement performance standard (improvement threshold) for each of the proposed measures at each specific hospital's performance on the applicable measure during the proposed baseline period of April 1, 2010 through December 31, 2010. We are proposing to set each benchmark for each measure as the mean of the top decile performance of applicable hospitals during the proposed baseline period. We invite public comment on these proposals.

We set out proposed achievement performance standards for the proposed clinical process of care and patient experience of care measures using the applicable baseline period data in the table below.

Proposed Achievement Performance Standards for Proposed FY 2014 Clinical Process of Care and Patient Experience of Care Measures			
Measure ID	**Measure Description**	**Performance Standard (Achievement Threshold)**	**Benchmark**
Process of Care Measures			
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0.8066	0.9630
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0.9344	1.0000
HF-1	Discharge Instructions	0.9266	1.0000
PN-3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital	0.9730	1.0000
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient	0.9446	1.0000
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0.9807	1.0000
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients	0.9813	1.0000
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time	0.9663	0.9996
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose	0.9634	1.0000
SCIP-Inf-9	Postoperative Urinary Catheter Removal on Post	0.9286	0.9989

Proposed Achievement Performance Standards for Proposed FY 2014 Clinical Process of Care and Patient Experience of Care Measures			
Measure ID	**Measure Description**	**Performance Standard (Achievement Threshold)**	**Benchmark**
	Operative Day 1 or 2		
SCIP-Card-2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period	0.9565	1.0000
SCIP-VTE-1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered	0.9462	1.0000
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery	0.9492	0.9983
Patient Experience of Care Measure			
HCAHPS			
	Communication with Nurses	75.79%	84.99%
	Communication with Doctors	79.57%	88.45%
	Responsiveness of Hospital Staff	62.21%	78.08%
	Pain Management	68.99%	77.92%
	Communication about Medicines	59.85%	71.54%
	Hospital Cleanliness & Quietness	63.54%	78.10%
	Discharge Information	82.72%	89.24%
	Overall Rating of Hospital	67.33%	82.55%

c. AHRQ Measures

For the reasons we have discussed in the Hospital Inpatient VBP Program Final rule (76 FR 26514), we are proposing to set the achievement performance standard (achievement threshold) for each AHRQ composite measure at the median of hospital performance (50th percentile) during the proposed baseline period of March 3, 2010 to September 30, 2010. We are proposing to set the benchmark for each AHRQ composite measure at the mean of the top decile of hospital performance during the proposed baseline period of March 3, 2010 to September 30, 2010. We also are proposing to set the improvement performance standard (improvement threshold) for each of the proposed measures at each specific hospital's performance on the applicable measure during the proposed baseline period of March 3, 2010 to September 30, 2010.

d. HAC Measures

We adopted eight HAC measures in the Hospital Inpatient VBP Final Rule. For each of these eight HAC measures, at least one quarter of hospitals achieved a 100 percent rating based on administrative data for all IPPS hospitals participating in the Hospital IQR Program for Medicare discharges from October 1, 2008 through June 30, 2010 (that is, they do not have any reportable HAC occurrences). In addition, based on the administrative data from October 1, 2008 through June 30, 2010, at least one half of all hospitals achieved a measure rate of 100 percent on six of the eight HAC measures (Foreign Object Retained After Surgery; Air Embolism; Blood Incompatibility; Pressure Ulcer Stages III and IV; Catheter-Associated UTI; Manifestations of Poor Glycemic Control). Accordingly, the achievement threshold for these measures would be

zero if we proposed to set performance standards for each individual measure using the same methodology that we finalized with respect to the mortality measures.

We believe that the HAC measures are extremely important in promoting patient safety, improving quality of care, and reducing costs. According to a 2010 HHS Office of the Inspector General report, entitled "Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries" (http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf), an estimated 13.5 percent of hospitalized Medicare beneficiaries experienced adverse events during their hospital stays. We believe that all the finalized HAC measures assess the presence of conditions and outcomes that are reasonably preventable if high quality care is furnished to the Medicare beneficiary. We also believe that the incidence of HACs in general raises major patient safety issues for Medicare beneficiaries. Outcome measures, including HAC outcome measures, are widely regarded by the provider community as strongly indicative of the quality of medical care and as integral to reporting and improving quality and patient safety. Therefore, we believe it is important to include HAC outcome measures in the Hospital VBP Program.

For these reasons, we are proposing that our topped-out policy would not apply to the HAC measures. We also are proposing to treat the eight individual HAC measures as a single aggregate HAC score for purposes of scoring, and believe that this approach will enable us to calculate meaningful distinction among hospitals and variation in hospital performance. In addition, this aggregation of the scores for the HAC measures ensures that the HAC measures do not unduly outweigh the remainder of the measures in the outcome domain. Accordingly, in taking into account our HAC policy and reliability

concerns, we are proposing to set achievement performance standards, benchmarks, and improvement performance standards based on hospital combined performance on seven or eight HAC measures, as applicable, during the proposed performance or baseline period. Because certain hospitals will report on only seven of the eight HAC measures, we are proposing separate standards for hospital performance depending on whether the hospitals report on seven or eight HAC measures. As discussed more fully below, we are also proposing to score hospital performance on the HAC measures by combining hospital performance scores on each of the HAC measures to calculate a single, aggregate HAC score for this purpose.

As finalized in the Hospital Inpatient VBP Program Final Rule (76 FR 26514), we are proposing to set the achievement performance standard (achievement threshold) for the HAC aggregate score for those hospitals that report on all eight of the HAC measures at the median of hospital performance (50th percentile) of those hospitals reporting on all eight of the HAC measures during the proposed baseline period of March 3, 2010 to September 30, 2010. We are proposing to set the achievement performance standard (achievement threshold) for the HAC aggregate score for those hospitals that report on seven of the HAC measures at the median of hospital performance (50th percentile) on only those seven measures for those hospitals reporting on either seven or eight of the HAC measures during the proposed baseline period of March 3, 2010 to September 30, 2010.

We are proposing to set the benchmark for the HAC aggregate score for those hospitals that report on all eight of the HAC measures at the mean of the top decile of

hospital performance for those hospitals reporting on all eight HAC measures during the proposed baseline period of March 3, 2010 to September 30, 2010. We are proposing to set the benchmark for the HAC aggregate score for those hospitals that report on seven of the HAC measures at the mean of the top decile of hospital performance on only those sevenmeasures for hospitals reporting on either seven or eight of the HAC measures during the proposed baseline period of March 3, 2010 to September 30, 2010.

We also are proposing to set the improvement performance standard (improvement threshold) for the HAC aggregate score at each specific hospital's performance during the proposed baseline period of March 3, 2010 to September 30, 2010, whether the hospitals report on seven or eight HAC measures. Please see below for further discussion of the aggregate HAC scoring methodology.

We note that the performance standards for the HAC aggregate score are displayed in the table below as a score composed of all eight individual HAC measures. We recognize that all hospitals report on seven of these individual measures, and nearly all (about 95 percent) of hospitals report all eight. However, a small number of hospitals do not report on the Foreign Object Removal after Surgery HAC measure. We believe that any numerical differences between the HAC performance standards for hospitals reporting on seven of eight HAC measures compared to the standards for hospitals reporting on all eight HAC measures will be statistically insignificant. However, we intend to provide updated performance standards in the CY 2012 OPPS/ASC final rule with comment period for those hospitals only reporting on seven of the eight HAC measures.

We invite public comment on the proposed methodology for setting performance standards for the aggregate HAC score for HAC measures finalized for the FY 2014 Hospital VBP Program. We specify the proposed performance standards for the aggregate HAC score (all eight measures) and AHRQ measures using the proposed baseline period data in the table below. We note that, for both AHRQ and HAC measures, a lower value represents better performance on the measures. Thus, a "perfect" score on each measure would be a 0.00.

Proposed Achievement Performance Standards for FY 2014 HAC* and AHRQ Measures			
Outcome Measures			
Measure ID	**Measure Description**	**Performance Standard (Achievement Threshold)**	**Benchmark**
HACs**	Hospital Acquired Conditions per 1,000 (aggregated)	0.00109	0.0000
AHRQ Composite	Complication/patient safety for selected indicators (composite)	0.4006	0.2754
AHRQ Composite	Mortality for selected medical conditions (composite)	0.7542	0.6130

* Finalized HACs for use in the FY 2014 Hospital VBP Program include: Foreign Object Retained After Surgery, Air Embolism, Blood Incompatibility, Pressure Ulcer Stages III & IV, Falls and Trauma, Vascular Catheter Associated Infections, Catheter Associated Urinary Tract Infection, and Manifestations of Poor Glycemic Control.

** HAC performance standards were calculated using data from hospitals reporting on 8 HAC measures. The final rule will include the performance standards for hospitals reporting on seven HAC measures.

7. Proposed FY 2014 Hospital VBP Program Scoring Methodology

a. Proposed FY 2014 Domain Scoring Methodology

In the Hospital Inpatient VBP Program Final Rule, we adopted a methodology for scoring all clinical process of care, patient experience of care, and outcome measures. As noted in the Hospital Inpatient VBP Program Final Rule, this methodology outlines an approach that we believe is well-understood by patient advocates, hospitals and other stakeholders because it was developed during a year-long process that involved extensive stakeholder input, and was presented by us in a report to Congress. Further, we have conducted extensive research on a number of other scoring models for the Hospital VBP Program to ensure a high level of confidence in the scoring methodology (76 FR 26514). In addition, we believe that, for simplicity and consistency of the Hospital VBP Program, it is important to score hospitals under the same methodology for subsequent fiscal years, with appropriate modifications to accommodate new domains and measures. Therefore, we are proposing to use the same scoring methodology for these measures in the FY 2014 Hospital VBP Program, with the changes discussed below for HAC measures. We also refer readers to discussion of the proposed Medicare Spending per Beneficiary measure in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25927 through 25928). We invite public comment on this proposal.

b. Proposed HAC Measures Scoring Methodology

We are proposing to score the HAC measures using an aggregated HAC rate based on the unweighted average of the rates of the individual HAC measures. However, as explained above, we are aware that hospitals may only report on seven of the eight

finalized HAC measures. This is because some hospitals do not perform surgeries, and therefore would not submit eligible claims that would be the basis for the Foreign Object Retained After Surgery HAC measure. The remaining seven HAC measures would apply to all hospitals, however, because all hospitals that participate in the Hospital VBP Program will submit eligible claims for these measures. We also anticipate that most hospitals will report on all eight of the individual HAC measures because most hospitals that participate in the Hospital VBP Program perform surgeries and would submit eligible surgical claims that would be the basis for the Foreign Object Retained After Surgery HAC measure. Accordingly, we are proposing that the aggregate HAC score for each hospital be calculated as the equally-weighted average of the rates on all HAC measures for which the hospital reports Medicare claims, which will most often be an equally-weighted average of the rates on all eight measures, but may be scores on seven of the HAC measures. As stated above, the HAC aggregate score will be calculated if a hospital submits at least one Medicare claim during the performance period. For example, if a hospital submits one or more Medicare claims during the performance period, and those claims do not indicate any HAC occurrences, the hospital will receive a perfect score on all applicable HAC measures. The aggregate HAC rate would then be used to assign points in accordance with the proposed performance standards discussed above to calculate an individual hospital's aggregate HAC achievement and improvement scores. The single aggregate HAC score would be the greater of the hospital's achievement or improvement score. The hospital's aggregate HAC score would be combined with the hospital's score on other outcome measures to derive an outcome

domain score, with the aggregate HAC score weighted equally with the other outcome measures in the domain. We note that in assigning points for this aggregate HAC score, lower aggregate HAC scores represent better performance. We believe our proposed aggregate scoring methodology for HAC measures allows us to meaningfully score hospitals on these critical patient safety measures.

We welcome public comment on this proposal.

8. Ensuring HAC Reporting Accuracy

For the FY 2013 Hospital VBP Program, the validation process we adopted for the Hospital IQR Program will ensure that the Hospital VBP data are accurate (76 FR 26537 through 26538). In addition, Medicare Administrative Contractors (MACs) review claims to ensure that accurate Medicare payments are made. This claims review ensures that HAC data included on the claims are accurately reported both for the Hospital IQR Program and the Hospital VBP Program. In addition, we are considering proposing to adopt additional targeting to assess the accuracy of HAC data reported on claims. Specifically, we are considering targeting a subset of hospitals that report zero or an aberrantly low percentage of HACs on Medicare fee-for-service IPPS claims relative to the overall national average of HACs.

This consideration is supported by our analysis of HAC rates calculated using data from Medicare fee-for-service claims from October 1, 2008 through June 30, 2010. We publicly released these rates in March 2011, and they can be found on our Web site at: http://www.cms.gov/HospitalQualityInits/06_HACPost.asp#TopOfPage. This analysis revealed a range in hospital-reporting of the eight HACs from a low of 0.0001

percent (that is, 1 discharge out of every 100,000 applicable discharges) of hospital inpatient discharges (23 discharges) reporting a blood incompatibility, to a high of 0.0564 percent (that is, 56.4 discharges out of every 100,000 applicable discharges) reporting Falls and Trauma. According to this analysis, however, these HAC rates appear to be underreported occurrences when compared to similar HAI measures. For example, the Catheter Associated Urinary Tract Infection (CAUTI) measure rate was 5.4 percent, or 54 out of every 1,000 eligible discharges, as reported in the AHRQ 2008 National Healthcare Quality Report. This rate is more than 125 times greater than the national HAC reported CAUTI rate of 0.317 out of every 1,000 eligible discharges. While we recognize that definitional differences in the measures might contribute to this rate difference, we also believe that underreporting of HAC claims data contributed to this difference. It is important to note that the 5.4 percent CAUTI rate was calculated using medical record documentation as a data source and a random sample of Medicare beneficiaries for acute care hospital stays, as discussed in a separate Federal report about healthcare quality (AHRQ 2008 National Healthcare Quality Report). We note that this analysis is exploratory in nature, and we cannot definitively conclude any systematic underreporting by any particular hospitals. Nonetheless, we believe that this analysis provides sufficient information for CMS to consider development of a HAC validation process to assess potential underreporting by hospitals and ensure accurate reporting among all hospitals reporting HACs on Medicare claims. Our goal is to improve quality and patient safety through accurate reporting of hospital quality data and accurately linking quality to payment in the Hospital VBP Program. We strive to ensure accurate

reporting, and we believe that validating a random subset of hospitals that report an aberrantly low number of HACs would strengthen our overall effort to link value to quality. We welcome public comments regarding our consideration of a HAC validation process. We also note that we intend to take appropriate action if we discover systematic underreporting of HAC and other adverse event information, including, where appropriate, reporting such instances to the HHS Office of the Inspector General for its review.

9. Proposed Domain Weighting for FY 2014 Hospital VBP Program

For the FY 2013 Hospital VBP Program, we adopted a weighting scheme that weights the clinical process of care domain at 70 percent of the Total Performance Score, and weights the patient experience of care domain at 30 percent. However, the addition of the outcome domain and the proposed addition of an efficiency domain necessitate the adoption of a different domain weighting scheme than we adopted for the FY 2013 Hospital VBP Program. We discuss below the factors we considered in determining the appropriate weight to propose for each domain in the FY 2014 Hospital VBP Program.

As we have previously stated, we believe that the patient's experience associated with receiving inpatient services in a hospital is important in determining the hospital's overall quality of care for purposes of the Hospital VBP Program. However, we also believe that a majority of the Total Performance Score should be based on the objective data submitted by hospitals on the measures selected for the Hospital VBP Program. Thus, as we finalized for the FY 2013 Hospital VBP Program, we are proposing to weight the patient experience of care domain at 30 percent for the FY 2014 Hospital VBP

Program. We believe that this weighting proposal appropriately incentivizes hospitals to provide patient-centered care across the full spectrum of their services. As we stated in the Hospital Inpatient VBP Program Final Rule (76 FR 26491), we believe that domains need not be given equal weight, and that over time, scoring methodologies should be weighted more towards outcomes, patient experience of care and functional status measures (measures assessing physical and mental capacity, capability, well-being and improvement). Consistent with this policy and our analysis showing that many of the clinical process of care measures are nearly topped-out, we are proposing to reduce the weighting for the clinical process of care domain to 20 percent. We also are proposing to weight the outcome domain at 30 percent of the Total Performance Score for the FY 2014 Hospital VBP Program. Because we believe that scoring hospitals on outcome measures will improve treatment outcomes and patient safety, we intend to propose increasing the weighting for the outcome domain in subsequent fiscal years as more outcome measures become available.

As we indicated in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25927 through 25928), we believe that efficiency is an important component of improving outcomes, the patient experience of care and the overall quality of care provided to Medicare beneficiaries in the inpatient hospital setting. However, we also recognize the importance of clinical quality based upon industry standards of care and the patients' experience of care. Accordingly, we are proposing to weight the efficiency domain at 20 percent of the Total Performance Score for the FY 2014 Hospital VBP Program.

Therefore, we are proposing the following domain weights for the FY 2014 Total Performance Score: outcome domain = 30 percent; clinical process of care domain = 20 percent; patient experience of care domain = 30 percent; and efficiency domain = 20 percent. Under this proposed weighting scheme, the clinical care-related domains (process of care and outcome domains) would, together, constitute 50 percent of the total performance score (20 percent for clinical process of care and 30 percent for outcome), the patient experience of care domain would constitute 30 percent, and the efficiency domain would constitute 20 percent. We believe that this proposed weighting scheme will hold hospitals accountable for all aspects of patient care, including clinical outcomes and efficiency.

We invite public comment on the proposed weighting of the four proposed domains to be used in the calculation of the Total Performance Score for the FY 2014 Hospital VBP Program.

B. Proposed Review and Correction Process under the Hospital VBP Program

1. Background

Section 1886(o)(10)(A)(i) of the Act requires the Secretary to make information available to the public regarding individual hospital performance in the Hospital VBP Program, including: (1) performance of the hospital on each measure that applies to the hospital; (2) the performance of the hospital with respect to each condition or procedure; and (3) the hospital's Total Performance Score. To meet this requirement, we stated our intention in the Hospital Inpatient VBP Program Final Rule to publish hospital scores with respect to each measure, each hospital's condition-specific score (that is, the

performance score with respect to each condition or procedure, for example, AMI, HF, PN, and SCIP), each hospital's domain-specific score, and each hospital's Total Performance Score on Hospital Compare (76 FR 26534 through 26536). We intend to make proposals related to making this information publicly available in future rulemaking.

Section 1886(o)(10)(A)(ii) of the Act requires the Secretary to ensure that each hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to each hospital under section 1886(o)(10)(A)(i) of the Act prior to such information being made public.

For the FY 2013 Hospital VBP Program, the finalized measures consist of chart-abstracted clinical process of care measures and a patient experience of care measure. We are proposing that hospitals will have an opportunity to review and correct chart-abstracted data and patient experience data through the processes discussed below. We intend to make additional proposals regarding the review and correction of outcome measures, efficiency measures, and domain, condition, and Total Performance Scores in future rulemaking.

2. Proposed Review and Corrections of Data Submitted to the QIO Clinical Warehouse on Chart-Abstracted Process of Care Measures and Measure Rates

We are proposing that the process utilized to give hospitals an opportunity to review and correct data submitted on the Hospital IQR Program chart-abstracted measures also be used to allow hospitals to correct data and measure rates on chart-abstracted measures for the Hospital VBP Program. Under this proposed process,

hospitals would continue to have the opportunity to review and correct data they submit on all Hospital IQR Program chart-abstracted measures, whether or not the measure is adopted as a measure for the Hospital VBP Program. We are proposing to use the Hospital IQR Program's data submission, review, and correction processes, which will allow for review and correction of data on a continuous basis as it is being submitted for the Hospital IQR Program, which in turn would allow hospitals to correct data and measure rates used to calculate the Hospital VBP Program Total Performance Score for those hospitals that participate in both programs. We believe this process would satisfy the requirement in section 1886(o)(10)(A)(ii) of the Act to allow hospitals to review and submit corrections for one of the pieces of information that will be made public with respect to each hospital – the measure rates for chart-abstracted measures. For hospitals that do not participate in the Hospital IQR Program but do participate in the Hospital VBP Program, such as Maryland hospitals, we intend to make proposals regarding how those hospitals will be able to review and correct their Hospital VBP data in future rulemaking.

Under the Hospital IQR Program, hospitals currently have an opportunity to submit, review, and correct any of the chart-abstracted information submitted to the QIO Clinical Warehouse for the full 4 ½ months following the last discharge date in a calendar quarter. (We note that in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25915), we proposed to reduce the submission period from 4½ months to 104 days.) Hospitals can begin submitting data on the first discharge day of any reporting quarter. Hospitals are encouraged to submit data early in the submission schedule so that they can identify

errors and resubmit data before the quarterly submission deadline. Users are able to view and make corrections to the data that they submit within 24 hours of submission. The data are populated into reports that are updated nightly with all data that have been submitted and successfully processed for the previous day. Hospitals are able to view a report each quarter which shows the numerator, denominator and percentage of total for each Clinical Measure Set and Strata. That report contains the hospital's performance on each measure set/strata submitted to the QIO Clinical Warehouse. The numerator is the number of cases that satisfies the conditions of the performance measure, and a denominator is the number of successfully accepted cases in the measure population evaluated by the performance measure. The percentage of total is calculated by using the numerator divided by the denominator multiplied by 100. This measure rate is the same as the Hospital VBP measure rate.

We believe that 4 ½ months is sufficient time for hospitals to be able to submit, review data, make corrections to the data, and view their percentage of total, or measure rate, on each Clinical Measure Set/Strata for use in both the Hospital IQR and Hospital VBP Programs. Additionally, because this process is familiar to most hospitals, use of this existing framework reduces the burden that could have been placed on hospitals that participate in the Hospital IQR Program if they had to learn a new process for submitting data for the Hospital VBP Program. Following the period in which hospitals can review and correct data and measure rates for chart-abstracted measures as specified above, we propose that hospitals will have no further opportunity to correct such data or measure rates.

We are proposing that once the hospital has an opportunity to review and correct data related to chart-abstracted measures submitted in the Hospital IQR Program, we will consider that the hospital has been given the opportunity to review and correct this data and measure rates for purposes of the Hospital VBP Program, and these measure rates will be used to calculate domain, condition, and Total Performance Scores for the Hospital VBP Program without further review and correction. We invite public comment on this proposal.

3. Proposed Review and Correction Process for Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Data

We are proposing a "two-phase" process for the review and correction of HCAHPS data. Under this proposed process, hospitals would have the opportunity to review and correct data they submitted on all HCAHPS Hospital IQR Program items in the first phase, whether or not such items or combination of items are adopted as HCAHPS dimensions for the Hospital VBP Program. In the second phase, hospitals would have the opportunity to review the patient-mix and mode adjusted HCAHPS scores (details on the HCAHPS adjustment process may be found at: http://www.hcahpsonline.org/files/Final%20Draft%20Description%20of%20HCAHPS%20Mode%20and%20PMA%20with%20bottom%20box%20modedoc%20April%2030,%202008.pdf) on dimensions that we will use to score hospitals under the Hospital VBP Program to determine whether they believe CMS calculated their scores on these dimensions correctly. We believe that this proposal for a two-phase review process will expedite hospital review and correction of data. We also believe that this proposal will

improve quality of care because hospitals will be able to timely review their HCAHPS scores and respond efficiently in improving patient care to address areas of weakness reflected in their scores. We are not proposing to release any patient level data to the public. This proposed review process would only grant each hospital the authority to review and correct the hospital's patient-level data.

a. Phase One: Review and Correction of HCAHPS Data Submitted to the QIO Clinical Warehouse

For the first phase of the HCAHPS review and correction process, we proposed to reduce the HCAHPS submission deadline under the Hospital IQR Program by one week in order to create a 1-week period for hospitals to review and correct their HCAHPS data. We included this proposal to reduce the submission deadline in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25916). Currently, hospitals have approximately 14 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse. Under this proposal, hospitals would have approximately 13 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse and a 1-week period to review and correct that data. During the 13-week submission period, hospitals would be able to resubmit their data to make corrections to the patient-level records. The 1-week review and correction period would occur immediately after the 13-week data submission deadline.

The proposed 1-week review and correction period would allow hospitals to provide missing data or replace incorrect data in the data files they have submitted to the QIO Clinical Warehouse. The 1-week review and correction period will allow hospitals

to identify any issues with the data they had submitted in the 13-week submission period. Hospitals will have the opportunity to review frequency distributions of all of their submitted data items, which include hospital summary information, patient administrative data, and patient survey responses, and resubmit their HCAHPS data files to correct identified issues during the 1-week review and correction period. We define the term "review and correct" to mean that hospitals can correct their existing data records, but not add new data records. Accordingly, hospitals would not be allowed to add new patient-level records or remove existing patient-level records during the review and correction period. Following the conclusion of the 1-week review and correction period, hospitals would not be allowed to review, correct, or submit additional HCAHPS data for the applicable calendar quarter.

b. Phase Two: Review and Correction of HCAHPS Scores for the Hospital VBP Program

In the second phase of the proposed HCAHPS review and correction process, hospitals would be given the opportunity to review their scores on the HCAHPS items that will be used in the Hospital VBP Program. These HCAHPS scores are constructed after the data that hospitals had submitted have been analyzed to identify and remove incomplete surveys and after adjustments for the effects of patient-mix and survey mode have been applied. (Details on the HCAHPS adjustment process may be found at: http://www.hcahpsonline.org/files/Final%20Draft%20Description%20of%20HCAHPS%20Mode%20and%20PMA%20with%20bottom%20box%20modedoc%20April%2030,%202008.pdf.) Hospitals would have approximately 1 week to examine their HCAHPS

dimension scores for the applicable Hospital VBP Program performance period. A participating hospital would have the opportunity to question CMS if the hospital believes its scores were miscalculated. We would respond to a hospital's inquiries by checking the calculation and, if necessary, recalculating the hospital's HCAHPS scores. In this proposed second phase of the HCAHPS review and correction process, hospitals would not be allowed to change or submit new HCAHPS data or delete existing data. Their right to correct information during this period would be limited to reviewing their HCAHPS dimension scores and notifying CMS of any errors in its calculation of those scores. We intend to propose the procedural aspects of the second phase of the proposed HCAHPS review and correction process in the FY 2013 IPPS/LTCH PPS proposed rule. In summary, for the chart-abstracted and patient experience of care measures, we are proposing that existing procedures for submission, review, and correction related to chart-abstracted measures under the Hospital IQR Program, coupled with the proposed two phase review of HCAHPS scores discussed above, would constitute an opportunity for review and correction of measure data and measure rates under the Hospital VBP Program. Because these procedures give hospitals the opportunity to review and correct the data and/or measure rates, such data and measure rates may be used to calculate domain, condition, and Total Performance Scores for the Hospital VBP Program. We intend to make proposals related to making this information publicly available, and to make additional proposals regarding the review and correction of outcome measures, efficiency measures, and domain, condition, and Total Performance Scores in future rulemaking. We invite public comment on these proposals.

XVII. Files Available to the Public via the Internet

In the past, a majority of the Addenda to which we referred throughout the preamble of the OPPS/ASC proposed and final rules appeared in the printed version of the **Federal Register** as part of the annual rulemakings. However, beginning with this CY 2012 proposed rule, the Addenda of the proposed and final rules will be published and available only via the Internet on the CMS Web site. We note that our existing regulations at §§416.166(b), 416.171(b), and 416.173 provide for the annual publication of the covered surgical procedures and the payment rates under the ASC payment system in the **Federal Register**. In this proposed rule, we are proposing to revise these three regulations to reflect the option of annually publishing the Addenda containing the covered surgical procedures and payment rates under the ASC payment system via the Internet on the CMS Web site.

To view the Addenda of the CY 2012 OPPS/ASC proposed rule pertaining to the CY 2012 proposed payments under the OPPS, go to the CMS Web site at: http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD and select "1525-P" from the list of regulations. All Addenda for this proposed rule are contained in the zipped folder entitled "2012 OPPS NPRM Addenda" at the bottom of the page.

To view the Addenda of the CY 2012 OPPS/ASC proposed rule pertaining to the CY 2012 proposed payments under the ASC payment system, go to the CMS Web site at: http://www.cms.gov/ASCPayment/ASCRN/ and select "1525-P" from the list of regulations. All Addenda for this proposed rule are contained in the zipped folder entitled "Addendum AA, BB, DD1, and DD2" at the bottom of the page.

A. Information in Addenda Related to the Proposed CY 2012 Hospital OPPS

Addenda A and B provide various data pertaining to the proposed CY 2012 payment for items and services under the OPPS. Specifically, Addendum A includes a list of all proposed APCs to be payable under the OPPS, including the proposed scaled relative weights, the proposed national unadjusted payment rates, the proposed national unadjusted copayments, and the proposed minimum unadjusted copayments for each APC that we are proposing for CY 2012. Addendum B includes a list of all active HCPCS codes, including the proposed APC assignments, the proposed scaled relative weights, the proposed national unadjusted payment rates, the proposed national unadjusted copayments, the proposed minimum unadjusted copayments, and the proposed payment status indicators and proposed comment indicators for CY 2012 OPPS.

For the convenience of the public, we also are including on the CMS Web site a table that displays the HCPCS code data in Addendum B sorted by APC assignment, identified as Addendum C.

Addendum D1 defines the proposed payment status indicators that we are proposing to use in Addenda A and B. Addendum D2 defines the proposed comment indicators that are used in Addendum B. Addendum E lists the HCPCS codes that are proposed to be only payable to hospitals as inpatient procedures and that are not payable under the OPPS for CY 2012. Addendum L contains the proposed out-migration wage adjustment for CY 2012. Addendum M lists the HCPCS codes that are proposed to be members of a composite APC and identifies the proposed composite APC to which each

is assigned. This addendum also identifies the proposed status indicator for each HCPCS code and a proposed comment indicator if there is a proposed change in the code's status with regard to its membership in the composite APC. Each of the HCPCS codes included in Addendum M has a single procedure payment APC, listed in Addendum B, to which it is assigned when the criteria for assignment to the composite APC are not met. When the criteria for payment of the code through the composite APC are met, one unit of the composite APC payment is paid, thereby providing packaged payment for all services that are assigned to the composite APC according to the specific I/OCE logic that applies to the APC. We refer readers to the discussion of composite APCs in section II.A.2.e. of this proposed rule for a complete description of the proposed composite APCs.

Addendum N, "Proposed Bypass Codes for Creating 'Pseudo' Single Procedure Claims for CY 2012 OPPS," contains a list of the HCPCS codes that we are proposing to use to create "pseudo" single claims from multiple procedure claims so that the most claims data can be used to set median costs for the CY 2012 OPPS. We refer readers to section II.A.1.b. of this proposed rule for a full discussion of the use of this file in the proposed 2012 OPPS ratesetting process. Addendum N contains the following elements for the proposed CY 2012 bypass codes: (1) HCPCS code; (2) short descriptor; (3) overall bypass indicator; and (4) an indicator if the code was not used as a bypass code in ratesetting activities prior to this CY 2012 proposed rule. The addendum was previously issued as a table (usually Table 1) in the preamble of the applicable proposed or final rule. We are issuing it as an addendum in this proposed rule because it is lengthy

and users can better analyze the file if it is furnished in Excel format on the CMS Web site.

B. Information in Addenda Related to the Proposed CY 2012 ASC Payment System

Addenda AA and BB provide various data pertaining to the proposed CY 2012 payment for the covered surgical procedures and covered ancillary services for which ASCs may receive separate payment. Addendum AA lists, for CY 2012, the proposed ASC covered surgical procedures, whether the procedure is proposed to be subject to multiple procedure discounting, the proposed comment and payment indicators for each procedure, and the proposed payment weights and rates for each procedure. Addendum BB displays, for CY 2012, the proposed ASC covered ancillary services, the proposed comment and payment indicators for each service, and the proposed payment weights and rates for each service.

Addendum DD1 defines the proposed payment indicators that are used in Addenda AA and BB. Addendum DD2 defines the proposed comment indicators that are used in Addenda AA and BB.

To view the Addenda that pertain to the list of proposed surgical procedures to be excluded from Medicare payment if furnished in ASCs, go to the CMS Web site at: http://www.cms.gov/ASCPayment/ASCRN/ and select "1525-P" from the list of regulations. The proposed excluded ASC procedures are contained in the zipped folder titled "Addendum EE" at the bottom of the page. The proposed excluded procedures listed in Addendum EE are surgical procedures that are assigned to the OPPS inpatient list, are not covered by Medicare, are reported using a CPT unlisted code, or have been

determined to pose a significant safety risk to a Medicare beneficiary when performed in an ASC or for which standard medical practice dictates that the beneficiary typically requires active medical monitoring and care at midnight following the procedure.

The Medicare Physician Fee Schedule (MPFS) data files are located at the CMS Web site at: http://www.cms.gov/PhysicianFeeSched/.

The links to all of the FY 2012 IPPS proposed wage index-related tables (that are used for the CY 2012 OPPS) are accessible on the CMS Web site at: http://www.cms.gov/AcuteInpatientPPS/WIFN.

XVIII. 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. Requirements in Regulation Text

This proposed rule contains the following proposed information collection requirements specified in the regulatory text:

1. ICRs Regarding Basic Commitments of Providers (§489.20)

Section 489.20(w) contains a physician presence disclosure requirement that requires disclosure when a doctor of medicine or a doctor of osteopathy is not onsite 24 hours per day, 7 days per week. The burden associated with the physician presence disclosure requirement is the time and effort necessary for each hospital and CAH to develop a standard notice to furnish to its patient, obtain the required patients signatures, and maintain a copy in the patient's medical record. Although this requirement is subject to the PRA, the associated burden is approved under OMB control number 0938-1034.

Our proposed amendment to §489.20(w) would require that, for hospitals and CAHs that are not physician owned, the existing physician presence disclosure requirement regarding outpatient services would apply only to outpatients receiving observation services, surgery, and procedures requiring anesthesia. The burden associated with this requirement would be greatly reduced and includes revisions to the time and effort necessary for each hospital and CAH to revise and disseminate the existing standard notice to its patients. The requirements in §489.20(w) apply to all hospitals as defined in §489.24(b). We estimate that there are approximately 2,597 hospitals and CAHs that may not have a doctor or medicine or a doctor of osteopathy

onsite at all times. We estimate that it will take each hospital or CAH 4 hours to develop or amend and review a disclosure form on a one-time basis, 30 seconds to make each disclosure, another 30 seconds to obtain the patient's signature, and an additional 30 seconds to include a copy of the notice in the patient's medical record. We estimate that on average each hospital or CAH that is subject to the disclosure requirement will make 1966 disclosures per year. The estimated annual burden associated with developing an amended form, obtaining patient signatures, and copying and recording the form is 137,872 hours at a cost of approximately $2,551,148.

2. ICRs Regarding Exceptions Process Related to the Prohibition of Expansion of Facility Capacity (§411.362)

As discussed in section XV. of this proposed rule, our proposed new §411.362(c) would establish and implement a process under which an applicable hospital or high Medicaid facility may apply for an exception to the prohibition on expansion of facility capacity. A physician-owned hospital would be allowed to request an exception under proposed §411.362(c) by providing information to CMS regarding the hospital's baseline number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of March 23, 2010, and specifying the increase in the number of operating rooms, procedure rooms and beds it is requesting under the exceptions process. In addition, the hospital would have to provide supporting documentation to CMS regarding the criteria it must satisfy. We estimate that 265 physician-owned hospitals would request an exception. We estimate that it would take each hospital 8 hours and 17.5 minutes to complete the request process at the cost of $417.74 for each hospital. Overall, the annual

burden for this process is estimated at approximately 2,153 hours at the cost of approximately $110,707. These estimates do not include time or cost burden estimates for hospitals to read and provide rebuttal statements in response to community input comments, which is included in the proposed regulation, and the associated time and costs for the hospital to send them to CMS. Due to the voluntary nature of this criterion, time and cost burden estimates would be difficult to anticipate as this is an unknown variable.

PROPOSED REVISED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation Section(s)	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§489.20	0938-1034	2,597	1,966	0.019	137,872*	18.50	2,551,148	0	2,551,148
§411.362	0938-New	265	265	8.29	2,153	51,42	110,707	0	110,707
Total		2,862	2,231		140,025				2,661,855

* Represents the revised burden estimate associated with the requirement. It does not reflect the burden currently approved under OCN 0938-1034.

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 document. The following is a discussion of those requirements.

1. Hospital Outpatient Quality Reporting (Hospital OQR) Program

As previously stated in section XIV. of this proposed rule, 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) for a detailed discussion of 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 must 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 and expires 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 lab 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.

The 23 measures that we adopted in the CY 2011 OPPS/ASC final rule with comment period to be used for the CY 2012 through CY 2014 payment determinations are listed in the table below.

Hospital OQR Program Measurement Set Adopted in the CY 2011 OPPS/ASC Final Rule with Comment Period to be Used for the CY 2012, CY 2013, and CY 2014 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 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 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

b. Additional Proposed Hospital OQR Program Measures for CY 2014

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 this CY 2012 OPPS/ASC

proposed rule, we are proposing to add, for the CY 2014 payment determination, 6 chart-abstracted measures, 2 structural measures (including hospital outpatient volume data for selected outpatient surgical procedures), and 1 HAI surgical site infection measure. Thus, for the CY 2014 payment determination, we are proposing that there would be a total of 32 measures. The complete proposed measure set we are proposing for the CY 2014 payment determination, including measures we have previously adopted, is shown below.

Proposed CY 2014 Hospital OQR Program Measure Set Reflecting Measures Previously Adopted and the Proposed Additions
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 Patients**

Proposed CY 2014 Hospital OQR Program Measure Set Reflecting Measures Previously Adopted and the Proposed Additions
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 Before 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: Surgical Site Infection***
OP-25: Hemoglobin A1c Poor Control in Diabetic Patients ***
OP-26: Low Density Lipoprotein (LDL-C) Control in Diabetic Patients ***
OP-27: High Blood Pressure Control in Diabetic Patients ***
OP-28: Dilated Eye Exam in Diabetic Patients ***
OP-29: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients ***
OP-30: Cardiac Surgery Referral***
OP-31: Safety Surgery Checklist***
OP-32: Hospital Outpatient Department Volume for Selected Outpatient Surgical Procedures***

*New measure for the CY 2012 payment determination.
**New measure for the CY 2013 payment determination.
***Proposed new measure for the CY 2014 payment determination.

We will calculate the claims-based measures using Medicare FFS claims data and do not require additional hospital data submissions, and we are using the same data submission requirements related to the chart-abstracted abstracted quality measures that are submitted directly to CMS that we used for the CY 2011 and CY 2012 payment determinations. For the structural measures, including the collection of all-patient volume for selected outpatient procedures; hospitals will enter data into a Web-based collection tool during a specified collection period once annually. For the collection of HAI data, we are proposing that hospitals would use the NHSN infrastructure and protocol to report the measure for Hospital OQR Program purposes. The NHSN is a

Web-based reporting tool hosted by CDC and is provided free of charge to hospitals. Under the Hospital OQR Program requirements, hospitals must complete and submit a notice of participation form for the Hospital OQR Program if they 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 (including those previously adopted and those currently proposed) is the time and effort associated with completing the notice of participation form, collecting and submitting the data on the 32 measures. For the chart-abstracted measures where data is submitted directly to CMS, 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 (including the OP-22 measure for which we are proposing that data be submitted via a Web-based tool rather than via an electronic file) we estimate it will take 35 minutes per sampled case. Based upon the data submitted for the CY 2011 payment determination and our estimates for the additional proposed measures, we estimate there will be a total of 1,307,510 cases per year, approximately 409 cases per year per respondent. The estimated annual burden associated with the submission requirements for these chart-abstracted measures is 762,278 hours (1,307,510 cases per year x 0.583 hours per case).

For the structural measures, excluding the proposed 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 this measure 1,603 hours (3,200 hospitals x 0.167 hours per hospital x 3 structural measures per hospital).

For the collection of data for the proposed HAI Surgical Site Infection measure, we estimate that approximately 1,200 hospitals are participating in the Hospital OQR Program, but are not currently submitting HAI data to the NHSN. Based upon burden estimates associated with the collection of NHSN data currently approved under OCN: 0920-0666, we estimate that additional annual burden associated with this proposed measure will be 17,269 hours (0.533 hr per response x estimated 27 responses per hospital x 1,200 hospitals).

For the proposed 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 proposed requirement would 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 534 hours (3,200 hospitals x 0.167 hours per hospital).

c. Proposed Hospital OQR Program Measures for CY 2015

For the CY 2015 payment determination, we are proposing to retain the requirement that hospitals must complete and submit a notice of participation form for the Hospital OQR Program. For the CY 2015 payment determination, we also are

proposing to retain the measures used for CY 2014 payment determination (including, if adopted, the measures proposed in this proposed rule) and to add one additional HAI measure, Healthcare Personnel (HCP) Influenza Vaccination. Achieving and sustaining high influenza vaccination coverage among HCP is intended to help protect HCP and their patients and reduce disease burden and healthcare costs.

For the CY 2015 payment determination, the burden associated with these proposed requirements is the time and effort associated with completing the notice of participation form, collecting and submitting the data on the proposed measures, and collecting and submitting proposed all-patient volume data for selected outpatient surgical procedures. For the proposed 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 proposed 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 payment determination and our estimates for the additional proposed measures, we estimate there will be a total of 1,307,510 cases per year, approximately 409 cases per year per respondent. The estimated annual burden associated with the aforementioned proposed submission requirements for the proposed chart-abstracted data is 762,278 hours (1,307,510 cases per year x 0.583 hours per case). For the proposed 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 this proposed measure 1,603 hours (3,200 hospitals x 0.167 hours per hospital x 3 structural measures per hospital).

For the proposed collection of HAI data, we estimate that approximately 1,200 hospitals are participating in the Hospital OQR Program, but are not currently submitting HAI data to the NHSN. We base our burden estimates upon burden estimates associated with the collection of NHSN data currently approved under OCN: 0920-0666. For the proposed Surgical Site Infection HAI measure, we estimate that hospitals will incur an additional burden of 17,269 hours (0.533 hours per response x an estimated 27 responses per hospital x 1,200 hospitals).

For the proposed collection of HCP Influenza Vaccination HAI measure data, we estimate that hospitals will incur an additional burden of 14,400 hours (2.0 hours per response x an estimated 6 responses per hospital x 1,200 hospitals).

For the proposed 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 proposed 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 proposed measure 534 hours (3,200 hospitals x 0.167 hours per hospital).

We invite public comment on the burden associated with these proposed information collection requirements.

3. Proposed Hospital OQR Program Validation Requirements for CY 2013

In this proposed rule, we are proposing to retain most of the requirements related to data validation for CY 2013 that we adopted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72103 through 72106) for CY 2012, with some revisions. While these requirements are subject to the PRA, they are currently approved under OCN: 0938-1109 and expire October 31, 2013.

Similar to our approach for the CY 2012 Hospital IQR Program payment determination (75 FR 72103 through 72106), we are proposing to validate data from randomly selected hospitals for the CY 2013 payment determination, but we are proposing to reduce the number of hospitals from 800 to 450. 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 72106, respectively), we discussed additional data validation conditions under consideration for CY 2013 and subsequent years. In this proposed rule, we are proposing to select for validation, up to 50 additional hospitals based upon targeting criteria.

For each selected hospital, we would randomly select up to 48 patient episodes of care 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 proposed CY 2013 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 proposed data submission requirements. To comply with the proposed requirements, we estimate each hospital must submit up to 48 cases for the affected year for review. We are proposing that selected hospitals comply with these requirements per 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 proposed data validation process for CY 2013 is approximately 6,000 hours.

We also are proposing to reduce the deadline from 45 days to 30 days for hospitals to submit requested medical record documentation to a CMS contractor to support our validation process. This proposal may create an additional administrative burden for hospitals selected for validation. However, this proposed deadline is in line with our QIO regulations at §476.78 and the total burden would be the time required to comply with the requirements for copying and mailing in a 30-day period 12 charts for each of four quarters for CY 2013.

We invite public comment on the burden associated with these proposed 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. We are proposing to continue this process for the CY 2013 payment determination. 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. ASC Quality Reporting Program

In this proposed rule, we are proposing to adopt seven claims-based measures for collection beginning in CY 2012 and one NHSN HAI measure of Surgical Site Infection for collection beginning in CY 2013. These measures would be used for the CY 2014 payment determination. We are proposing to collect quality measure data for the seven claims-based measures by using Quality Data Codes (QDCs) placed on submitted claims beginning with services furnished from January 1, 2012 through December 31, 2012. Data collection for the HAI measure would begin with infection events occurring on or after January 1, 2013 through June 30, 2013. The eight proposed 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)
- Ambulatory Surgery Patients with Appropriate Method of Hair Removal (NQF #0515)
- Selection of Prophylactic Antibiotic: First OR Second Generation Cephalosporin(NQF #0268)
- Surgical Site Infection Rate (NQF #0299)

Approximately 71 percent of ASCs participate in Medical Event Reporting, which includes reporting on the first four proposed 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).

The remaining proposed claims-based measures concern surgical procedures. We estimate the burden associated with submitting QDCs for these measures to be 465,703 hours (5,577,280 claims per year x 50 percent of claims requiring quality data code information x 0.167 hours per claim). We refer readers to the HHS Report to Congress: Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan,

available at the Web site: https://www.cms.gov/ASCPayment/downloads/C_ASC_RTC%202011.pdf as the source for the number of ASCs and number of claims per year to calculate ASC burden estimates.

For the collection of the Surgical Site Infection HAI data, we are proposing that ASCs would use the NHSN infrastructure and protocol to report the measure for ASC Quality Reporting Program purposes discussed above.

For the Surgical Site Infection HAI measure, we estimate that it will require ASCs an additional 8,275 hours (0.533 hours per response x an estimated 3 responses per ASC x 5,175 ASCs). We base the time per response for our burden estimate on burden estimates associated with the collection of NHSN data currently approved under OCN: 0920-0666, and the number of ASCs from to the HHS Report to Congress: Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan, available at the Web site: https://www.cms.gov/ASCPayment/downloads/C_ASC_RTC%202011.pdf.

For CY 2015 payment determination, we are proposing to retain the eight measures we are proposing to adopt for CY 2014 payment determination (if they are adopted) and we are proposing to add two structural measures.

For the structural measures, we are proposing that ASCs would 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 x 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 x 0.167 hours per ASC).

For the CY 2016 payment determination, we are proposing to retain the ten measures we are proposing to adopt for the CY 2015 payment determination (if they are adopted) , and are proposing to add one structural measure, Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

We estimate that each participating ASC will spend 10 minutes per year to collect and submit the data via a Web-based tool, making the estimated annual burden associated with this proposed measure 864 hours (5,175 ASCs x 0.167 hours per ASC).

6. Proposed 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and CAHs

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 2012 Medicare EHR Incentive Program Electronic Reporting Pilot) to successfully report hospital clinical quality measures (CQMs) to CMS in the manner specified by CMS. Although we are proposing that eligible hospitals and CAHs may continue to attest CQMs in 2012, they may also choose to participate in the proposed 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Hospitals and

CAHs. We are proposing that eligible hospitals and CAHs participating in the 2012 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 portal based on data obtained from the eligible hospital's 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 2012 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 Managers to submit the CQM information on their behalf. We estimate the cost burden for an eligible hospital or CAH to submit the CQMs and hospital quality requirements is $29.64 (0.5 hour x $59.27 (mean hourly rate for computer and information systems managers based on the 2010 Bureau of Labor Statistics) and the total estimated annual cost burden for all eligible hospitals and CAHs to submit the required CQMs is $145,889 ($29.64 x 4,922 hospitals and CAHs). We are soliciting public comments on the estimated numbers of eligible hospitals and CAHs that may registered for the Medicare EHR Incentive Program Electronic Reporting Pilot that would submit the CQM information via the proposed Electronic Reporting Pilot in FY 2012. We also

invite public comments on the type of personnel or staff that would mostly likely submit on behalf of eligible hospitals and CAHs.

7. Additional Topics

In addition to seeking OMB approval for the proposed information collection requirements associated with the Hospital OQR Program, we are seeking public comment on several issues that may ultimately affect the burden associated with the Hospital OQR Program. Specifically, in this proposed rule, we are proposing to retain measures for the CY 2015 payment determinations, adopt new measures for the CY 2014 and CY 2015 payment determinations, and we are seeking comments on other possible measures under consideration for adoption into the Hospital OQR Program. We also are soliciting public comments on collecting chart-abstracted data for one measure for the CY 2013 payment determination via a Web-based tool, and on the continued use of an extraordinary circumstance extension or waiver for reporting quality data, and additional data validation conditions that we are considering adopting beginning with the CY 2014 payment determination.

We also are seeking public comment on our proposals for an ASC Quality Reporting Program for the ASC payment determinations for CYs 2014, 2015 and 2016.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at http://www.cms.hhs.gov/Paperwork@cms.hhs.gov, or call the Reports Clearance Office at 410-786-1326.

We invite public comments on these potential information collection requirements.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, (CMS–1525–P)

Fax: (202) 395–6974; or

E-mail: OIRA_submission@omb.eop.gov.

XIX. 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.

XX. 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 Congressional Review Act (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. 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 the proposed rule. We are soliciting public comments on the Regulatory Impact Analysis provided.

2. Statement of Need

This proposed rule requests public comment on the CMS proposal to update the Medicare hospital outpatient prospective payment rates and the ambulatory surgical center prospective payment rates for CY 2012. The proposed rule is necessary to enable CMS to acquire and consider the public comments on the proposed changes to payment policies and payment rates for services furnished by hospitals and CMHCs to outpatients

for CY 2012. 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. In addition, we must review the clinical integrity of payment groups and weights at least annually.

This proposed rule also requests public comment on the CMS proposal to update the ASC payment rates for CY 2012. The proposed rule is necessary to enable CMS to acquire and consider public comments on the proposed changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC for CY 2012. Because the ASC payment rates are based on the OPPS relative weights for the majority of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS weights. In addition, because the services provided in ASCs are identified by HCPCS codes which are reviewed and revised either quarterly or annually, depending on the HCPCS codes, 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 often than every 2 years.

Section 1833(t)(17) of the Act requires that subsection (d) hospitals that fail to meet quality reporting requirements under the Hospital OQR Program to incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor. In section

XIV. of this proposed rule, we are proposing additional policies affecting the Hospital OQR Program for CY 2013, CY 2014, and CY 2015 that hospitals would have to meet in order to receive the full OPD fee schedule increase factor. We are soliciting public comments on these proposed additional policies.

In this proposed rule, to further implement section 6001(a)(3) of the Affordable Care Act, we set forth the proposed process for a hospital to request an exception to the prohibition on expansion of facility capacity under the whole hospital and rural provider exceptions to the physician self-referral prohibition. We also set forth a related proposal for amendments to the patient safety requirements in the provider agreement regulations. We are soliciting public comments on these proposed changes.

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital VBP Program to hospitals for discharges occurring on or after October 1, 2012. In this proposed rule, we are proposing to add one chart-abstracted measure for the FY 2014 payment determination under the Hospital Inpatient VBP Program. We are soliciting public comments on this proposed additional measure.

Section 109(b) of the MIEA TRHCA states that the Secretary may implement a quality reporting system for ASCs in a manner so as to provide for a reduction of 2.0 percentage point s in any annual update with respect to the year involved, for failure to report on quality measures. In this proposed rule, we are proposing to establish an ASC Quality Reporting Program with the collection of seven quality measures beginning in CY 2012.

3. Overall Impacts for Proposed OPPS and ASC Provisions

We estimate that the effects of the proposed OPPS provisions that would be implemented by this proposed rule 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 OPPS for CY 2012 compared to CY 2011 to be approximately $3.285 billion. Because this proposed rule for the OPPS is "economically significant" as measured by the $100 million threshold and also a major rule under the Congressional Review Act, we have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this rulemaking. Table 51 of this proposed rule displays the redistributional impact of the proposed CY 2012 changes on OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the effects of the proposed ASC provisions that would be implemented by this proposed rule for the ASC payment system would result in expenditures exceeding $100 million in any one 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 2012 compared to CY 2011 to be approximately $224 million. Because this proposed rule for the ASC payment system is "economically significant" as measured by the $100 million threshold and also a major rule under the Congressional Review Act, we have prepared a regulatory impact analysis of changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this rulemaking. Table 52 and Table 53 of this

proposed rule display the redistributional impact of the CY 2012 proposed changes on ASC payment, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Detailed Economic Analyses

a. Effects of Proposed OPPS Changes in This Proposed Rule

We are proposing to update the OPPS payment rates and to revise several OPPS payment policies for CY 2012. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the 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. In addition, we must review the clinical integrity of payment groups and weights at least annually. Consistent with our historical proactice in this proposed rule, we are proposing to update the conversion factor and the wage index adjustment for hospital outpatient services furnished beginning January 1, 2012, as we discuss in sections II.B. and II.C., respectively, of this proposed rule. We discuss our implementation of section 10324 of the Affordable Care Act, as amended by HCERA, authorizing a wage index of 1.00 for certain frontier States. We also are proposing to revise the relative APC payment weights using claims data for services furnished on and after January 1, 2010, through and including December 31, 2010, and updated cost report information. We are proposing to continue the current payment adjustment for rural SCHs, including EACHs. Finally, we list the

19 drugs and biologicals in Table 26 of this proposed rule that we are proposing to remove from pass-through payment status for CY 2012.

Under this proposed rule, we estimate that the update change to the conversion factor and other adjustments (but not including the effects of outlier payments, pass-through estimates, and the application of the frontier State wage adjustment for CY 2012), would increase total OPPS payments by 1.5 percent in CY 2012. The proposed changes to the APC weights, the changes to the wage indices, the 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 are budget neutral. However, these proposed updates would change the distribution of payments within the budget neutral system as shown in Table 51 below and described in more detail in this section. We also estimate that the total proposed change in payments between CY 2011 and CY 2012, considering all payments, including proposed changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment outside of budget neutrality, in addition to the application of the proposed OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F) and 1833(t)(3)(G) of the Act, would increase total estimated OPPS payments by 1.5 percent.

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2012 policy changes on various hospital groups. We post on the CMS Web site our hospital-specific estimated payments for CY 2012 with the other supporting

documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS Web site at: http://www.cms.hhs.gov/HospitalOutpatientPPS/. At the Web site, select "regulations and notices" from the left side of the page and then select "CMS-1525-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 51 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A.2. of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the proposed individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we do not make adjustments for future changes in variables such as service volume, service mix, or number of encounters. As we have done in previous rules, we are soliciting public comment and information about the anticipated effects of our proposed changes on providers and our methodology for estimating them.

(2) Estimated Effects of This Proposed Rule on Hospitals

Table 51 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. As discussed in section II.F. of this proposed rule, we are proposing to extend an adjustment to certain cancer hospitals under section 3138 of the Affordable Care Act. Because these hospitals would continue to be eligible to receive hold harmless payments (under our standard policy), we now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs, and we also include a column that shows the impact on other hospitals of the proposed budget neutral cancer adjustment.

We present separate impacts for CMHCs in Table 51 because CMHCs are paid only for partial hospitalization services and CMHCs are a different provider type from hospitals. In CY 2011, 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 2012, we are proposing to continue this APC payment structure and to base payment fully on the median costs calculated using claims and cost report data for the type of provider for which rates are being set, that is, hospital or CMHC. We display the impact on CMHCs of this proposed policy below, and we discuss the impact on hospitals as part of our discussion of the impact of proposed changes on hospitals for CY 2012.

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor set under the methodology in the statute.

The distributional impacts presented do not include assumptions about changes in volume and service mix. Section 1833(t)(3)(C)(iv) of the Act provides that, for purposes of this subparagraph subject to paragraph (17) and subparagraph (F) of this paragraph, 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. The proposed market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket in this discussion, is 2.8 percent. However, section 1833(t)(3)(F)(i) of the Act reduces that 2.8 percent by the proposed productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act which we propose to be 1.2 percentage points (which is theMFP adjustment for FY 2012 as proposed in the FY 2012 IPPS / LTCH proposed rule), and section 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act further reduce the amount by 0.1 percentage point, resulting in the OPD fee schedule increase factor of 1.5 percent, which we are proposing to use in the calculation of the CY 2012 OPPS proposed conversion factor. We refer readers to section II.B. of this proposed rule for a detailed discussion of the calculation of the conversion factor and the source of its components. 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 into the CY 2012 estimates in Table 51.

Table 51 shows the estimated redistribution of hospital and CMHC payments among providers as a result of APC reconfiguration and recalibration; wage indices and the rural adjustment; the combined impact of the APC recalibration, wage and rural

adjustment effects, and the OPD fee schedule increase factor update to the conversion factor; the effect of the proposed budget neutral adjustment to payments made to the 11 cancer hospitals that meet the classification criteria in section 1886(d)(1)(B)(v) of the Act; the frontier State wage index adjustment; and, finally, estimated redistribution considering all proposed payments for CY 2012 relative to all payments for CY 2011, including the impact of changes in estimated outlier payments, and changes to the pass-through payment estimate. We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are not proposing to make any changes to the policy for CY 2012. Because the proposed updates to the conversion factor (including the update of the OPD fee schedule increase factor, that is, the proposed IPPS market basket amount less the productivity adjustment required by section 1833(t)(3)(F)(i) of the Act and less the adjustment required by sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act; the subtraction of the estimated cost of the cancer adjustment; the subtraction of the estimated cost of the rural adjustment; and the subtraction of 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 2011 and CY 2012 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed OPPS rates for CY 2012 would have a positive effect for providers paid under the OPPS, resulting in a 1.5 percent estimated increase in Medicare payments. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs suggest that these proposed changes would result in a 1.1 percent estimated increase in Medicare payments to all other hospitals.

To illustrate the impact of the proposed CY 2012 changes, our analysis begins with a baseline simulation model that uses the final CY 2011 weights, the FY 2011 final IPPS wage indices that include reclassifications, and the final CY 2011 conversion factor. Column 2 in Table 51 shows the independent effect of the proposed changes resulting from the reclassification of services among APC groups and the recalibration of APC weights, based on 12 months of CY 2010 OPPS hospital claims data and the most recent cost report data. We modeled the effect of the proposed APC recalibration changes for CY 2012 by varying only the weights (the final CY 2011 weights versus the proposed CY 2012 weights calculated using the service mix and volume in the CY 2010 claims used for this proposed rule) and calculating the percent difference in weight. Column 2 also reflects the effect of the proposed changes resulting from the APC reclassification and recalibration changes and any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the proposed changes in the relative magnitude of payment weights.

Column 3 reflects the independent effects of the proposed updated wage indices, including the proposed 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 6. 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 2012. We modeled the independent effect of updating the wage indices by varying only the wage indices, holding APC relative weights, service mix, and the rural adjustment constant and using the proposed CY 2012 scaled weights and a CY 2011 conversion factor that included a budget neutrality adjustment for the effect of changing the wage indices between CY 2011 and CY 2012.

Column 4 demonstrates the independent effect of the proposed cancer hospital payment adjustment. For CY 2012 we are proposing to make additional payment to raise each cancer hospital's payment to cost ratio (PCR) to the weighted average PCR for all other hospitals paid under the OPPS. We are proposing to accomplish this by adjusting each cancer hospital's OPPS payment by the percentage difference between their individual PCR (without TOPs) and the weighted average PCR of the other hospitals paid under the OPPS. This results in an increase in estimated payments to cancer hospitals of 38.8 percent compared to the estimated payment that would have been made under the OPPS to these hospitals as a class in CY 2011, but does not represent the estimated net increase in payment to cancer hospitals for CY 2012. After accounting for TOPs that we estimate cancer hospitals would no longer receive as a result of increased payment under the OPPS, the net increase in estimated payment to cancer hospitals for CY 2012 would be approximately 9 percent.

Column 5 demonstrates the combined "budget neutral" impact of proposed APC recalibration (that is, Column 2), the wage index update (that is, Column 3), as well as the impact of updating the conversion factor with the OPD fee schedule increase factor, the proposed 2.8 percent hospital market basket update less the multifactor productivity adjustment required by section 1833(t)(3)(F)(i) of the Act which we are proposing to be 1.2 percentage points, and less the 0.1 percentage point reduction required by sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(ii) of the Act, which resulted in an OPD fee schedule increase factor of 1.5 percent). We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the weights and wage indices for each year, and using a CY 2011 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indices.

Column 6 demonstrates the cumulative impact of the proposed budget neutral adjustments from Columns 2 through 4, and the OPD fee schedule increase factor of 1.5 percent reflected in Column 5, combined with the non-budget neutral frontier State wage index adjustment, discussed in section II.C.1. of this proposed rule. This differs from Column 5 solely based on application of the proposed nonbudget neutral frontier Stage wage index adjustment.

Column 7 depicts the full impact of the proposed CY 2012 policies on each hospital group by including the effect of all the proposed changes for CY 2012 (including the APC reconfiguration and recalibration shown in Column 2) and comparing them to all estimated payments in CY 2011. Column 7 shows the combined budget neutral effects of Columns 2 through 4, plus the impact of the frontier State wage index

adjustment; the proposed change to the fixed-dollar outlier threshold from $2,025 to $2,100 as discussed in section II.G. of this proposed rule; the change in the hospital OQR payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIV.E. 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 107 hospitals that failed to meet the OQR reporting requirements for the full CY 2011 update (and assumed, for modeling purposes, to be the same number for CY 2012), we included 30 hospitals in our model because they had both CY 2010 claims data and recent cost report data. We estimate that the cumulative effect of all proposed changes for CY 2012 would increase payments to all providers by 1.5 percent for CY 2012. We modeled the independent effect of all changes in Column 7 using the final weights for CY 2011 and the proposed weights for CY 2012. We used the final conversion factor for CY 2011 of $68.876 and the proposed CY 2012 conversion factor of $69.420 discussed in section II.B. of this proposed rule in this model.

Column 7 also contains simulated outlier payments for each year. We used the charge inflation factor used in the FY 2012 IPPS/LTCH PPS proposed rule of 9.08 percent (1.0908) to increase individual costs on the CY 2010 claims, and we used the most recent overall CCR in the April 2011 Outpatient Provider-Specific File (OPSF) (76 FR 26025). Using the CY 2010 claims and a 4.44 percent charge inflation factor, we currently estimate that outlier payments for CY 2011, using a multiple threshold of 1.75 and a fixed-dollar threshold of $2,025 should be approximately 1.1 percent of total

payments. Outlier payments of 1.1 percent are incorporated in the CY 2011 comparison in Column 6. We used the same set of claims and a charge inflation factor of 9.08 percent (1.0908) and the CCRs in the April 2011 OPSF, with an adjustment of 0.9850, to reflect relative changes in cost and charge inflation between CY 2010 and CY 2012, to model the CY 2012 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $2,100.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 51 shows the total number of facilities (4,141), including designated cancer and children's hospitals and CMHCs for which we were able to use CY 2010 hospital outpatient and CMHC claims to model CY 2011 and CY 2012 payments, by classes of hospitals. We excluded all hospitals for which we could not accurately estimate CY 2011 or CY 2012 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 (3,879) 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 200 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: Proposed APC Changes Due to Reassignment and Recalibration

This column shows the combined effects of the proposed reconfiguration, recalibration, and other policies (such as setting payment for separately payable drugs and biologicals at ASP+4 percent with an accompanying reduction in the amount of cost associated with packaged drugs and biologicals and changes in payment for PHP services). Overall, we estimate that proposed changes in APC reassignment and recalibration across all services paid under the OPPS would increase payments to urban hospitals by 0.2 percent. We estimate that both large and other urban hospitals would experience an increase of 0.2 percent, all attributable to recalibration. We estimate that urban hospitals billing fewer than 21,000 lines for OPPS services would experience decreases ranging from 0.2 percent to 5.5 percent. The decrease of 5.5 percent for urban hospitals billing fewer than 5,000 lines per year is attributable to the decline in the proposed payment for APC 0034 (Mental Health Services Composite), for which the payment rate is proposed to be set at the payment rate for APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs). Urban hospitals billing 21,000 or more lines for OPPS services would experience increases of 0.1 to 0.5 percent. Overall, we estimate that rural hospitals would experience an increase of 0.2 percent as a result of changes to the APC structure. We estimate that rural hospitals of all bed sizes

would experience increases of 0.1 to 0.5 percent as a result of the proposed APC recalibration. We estimate that rural hospitals that report fewer than 5,000 lines for OPPS services would experience a decrease of 1.2 percent, while rural hospitals that report 5,000 or more lines for OPPS services would experience an increase of 0.1 to 0.9 percent in payment as a result of proposed APC recalibration.

Among teaching hospitals, we estimate that the impact resulting from APC recalibration would include a decrease of 0.1 percent for major teaching hospitals and an increase of 0.3 for minor teaching hospitals and nonteaching hospitals.

Classifying hospitals by type of ownership suggests that voluntary, proprietary, and governmental hospitals would experience no change or estimated increases of 0.1 to 0.3 percent as a result of the proposed APC recalibration. Finally, we estimate that hospitals for which DSH payments are not available would experience a decrease of 7.5 to 7.7 percent. Hospitals for which DSH is not available furnish a large number of psychiatric services and we believe that the proposed decline in payment for APC 0176 is the cause for this estimated decline in payment.

Column 3: Proposed New Wage Indices and the Effect of the Rural Adjustment

This column estimates the impact of applying the proposed FY 2012 IPPS wage indices for the CY 2012 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 Columns 6 and 7. We are proposing to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2012, 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 adjustment. Overall, we estimate that urban hospitals would experience no change from CY 2011 to CY 2012, and that rural hospitals would experience decreases of 0.2 to 0.4 percent as a result of the updated wage indices. We estimate that hospitals located in urban New England, Middle Atlantic, West North Central, West South Central, and Puerto Rico regions would experience increases of 0.1 to 0.5 percent while other urban regions would experience no change or decreases of 0.2 to 0.7 percent. Hospitals in urban New England are expected to see an increase of 3.8 percent as a result of the implementation of the rural floor. See section II.C. for more information. We estimate that hospitals in rural West North Central, West South Central, and Pacific States would experience increases of 0.1 to 0.5 percent, respectively, while other rural regions would experience decreases from 0.2 to 0.7 percent.

Column 4: Proposed Cancer Hospital Payment Adjustment

This column estimates the budget neutral impact of applying the proposed hospital-specific CY 2012 cancer adjustment authorized by section 3138 of the Affordable Care Act, which would result in an estimated aggregate increase in OPPS payments to dedicated cancer hospitals of 38.8 percent for the CY 2012 OPPS. After accounting for TOPs that we estimate would no longer be made, the net impact would result in an increase in payment to these hospitals of approximately 9 percent. We estimate that all other hospitals would experience a decrease of 0.6 to 0.7 percent in

CY 2012 as result of the adjustment to payments to the cancer hospitals under this proposed payment adjustment.

Column 5: All Proposed Budget Neutrality Changes Combined with the Proposed OPD Fee Schedule Increase

We estimate that, for most classes of hospitals, the addition of the proposed OPD fee schedule increase factor of 1.5 percent would mitigate the negative impacts created by the budget neutrality adjustments made in Columns 2 and 3. While all other classes of hospitals would receive an increase after the update is applied to the budget neutrality adjustments, urban hospitals that bill fewer than 11,000 lines and rural hospitals that report fewer than 5,000 lines would experience decreases. In particular, urban hospitals that report fewer than 5,000 lines would experience a cumulative decrease, after application of the proposed OPD fee schedule increase factor and the budget neutrality adjustments, of 4.3 percent, largely as a result of the proposed decrease in payment for APC 0034 (Mental Health Services Composite). OPPS payment for APC 0034 is proposed to continue being set to the payment rate of APC 0176 (Level II Partial Hospitalization (4 or more services) for hospital-based PHPs), which experienced a decline based on updated cost report and hospital claims data.

Overall, we estimate that these proposed changes would increase payments to urban hospitals by 1.1 percent. We estimate that large urban hospitals and "other" urban hospitals would also experience an increase of 1.1 percent. We estimate that rural hospitals would experience a 0.8 percent increase as a result of the proposed OPD fee schedule increase factor and other budget neutrality adjustments.

Among teaching hospitals, we estimate that the observed impacts resulting from the proposed OPD fee schedule increase factor and other budget neutrality adjustments would include an increase of 1.2 percent for major teaching hospitals and an increase of 1.0 percent for minor teaching hospitals.

Classifying hospitals by type of ownership suggests that proprietary hospitals would experience an estimated increase of 0.7 percent, while voluntary hospitals would experience an estimated increase of 1.2 percent and government hospitals would experience an estimated increase of 0.6 percent.

Column 6: Proposed Frontier State Wage Index Adjustment

This column shows the impact of all budget neutrality adjustments, application of the proposed 1.5 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 changes reflected in Column 4). In general, we estimate that all facilities would experience a combined increase of 1.6 percent and that all hospitals would experience a combined increase of 1.1 percent. Hospitals in the rural Mountain region would experience an increase of 2.3 percent, most of which is attributable to the proposed frontier State wage adjustment. Similarly, hospitals in both the urban and rural West North Central region would experience an increase of 1.8 percent, most of which is attributable to the proposed frontier State wage adjustment.

Column 7: All Proposed Changes for CY 2012

Column 7 compares all proposed changes for CY 2012 to estimated final payment for CY 2011, including the proposed changes in the outlier threshold, payment reductions for hospitals that failed to meet the OQR reporting requirements, and the difference in pass-through estimates that are not included in the combined percentages shown in Column 5. This column includes estimated payment for a few hospitals receiving reduced payment because they did not meet their hospital outpatient quality measure reporting requirements; however, we estimate that the anticipated change in payment between CY 2011 and CY 2012 for these hospitals would be negligible. (We further discuss the estimated impacts of hospitals' failure to meet these requirements below in section XX.A.4.d. of this proposed rule.) Overall, we estimate that facilities would experience an increase of 1.5 percent under this proposed rule in CY 2012 relative to total spending in CY 2011. The projected 1.5 percent increase for all facilities in Column 7 of Table 51 reflects the proposed 1.5 percent OPD fee schedule increase factor, less 0.00 percent for the change in the pass-through estimate between CY 2011 and CY 2012, less 0.06 percent for the difference in estimated outlier payments between CY 2011 (1.06 percent) and CY 2012 (1.0 percent), less 0.09 percent due to the section 508 wage adjustment, plus 0.10 percent due to the 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 is 1.5 percent after rounding.

We estimate that the combined effect of all proposed changes for CY 2012 would increase payments to urban hospitals by 1.2 percent. We estimate that large urban

hospitals would experience a 1.1 percent increase, while "other" urban hospitals would experience an increase of 1.2 percent. We estimate that urban hospitals that bill less than 5,000 lines of OPPS services would experience a decrease of 4.2 percent, largely attributable to the proposed decline in payment for APC 0034 (Mental Health Services Composite). We estimate that urban hospitals that bill 11,000 or more lines of OPPS services would experience increases between 0.6 percent and 1.5 percent, while urban hospitals that report between 5,000 and 10,999 lines would experience a decrease of 0.8 percent.

Overall, we estimate that rural hospitals would experience a 0.9 percent increase as a result of the combined effects of all proposed changes for CY 2012. We estimate that rural hospitals that bill less than 5,000 lines of OPPS services would experience a decrease of 0.7 percent and that rural hospitals that bill 5,000 or more lines of OPPS services would experience increases ranging from 0.8 to 1.7 percent.

Among teaching hospitals, we estimate that the impacts resulting from the combined effects of all proposed changes would include an increase of 1.2 percent for major teaching hospitals and 1.1 percent for minor teaching hospitals and non-teaching hospitals.

In our analysis, we have also stratified hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would receive an increase of 1.3 percent, proprietary hospitals would receive an increase of 0.8 percent, and governmental hospitals would experience an increase of 0.7 percent.

(3) Estimated Effects of This Proposed Rule on CMHCs

The last line of Table 51 demonstrates the isolated impact on CMHCs. In CY 2011, CMHCs are paid under four APCs for services under the OPPS: APC 0172 (Level I Partial Hospitalization (3 services) for CMHCs); APC 0173 (Level II Partial Hospitalization (4 or more services) for CMHCs); 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 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 2012, we are proposing to continue the four APC provider-specific structure we adopted for CY 2011 and to base payment fully on the cost data for the type of provider furnishing the service. We modeled the impact of this APC policy assuming that CMHCs would 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 2010 claims data used for this CY 2012 OPPS/ASC proposed rule. We excluded days with one or two 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 0172 and APC 0173 for CMHCs both decline in CY 2012 due to CMHC cost data for partial hospitalization services provided by CMHCs, we estimate that there would be a 34.2 percent decrease in payments to CMHCs due to these APC policy changes (shown in Column 2).

Column 3 shows that the estimated impact of adopting the proposed CY 2012 wage index values have no influence on payments to CMHCs. Column 4 shows that CMHCs would receive a 0.7 percent reduction as a result of the proposed cancer hospital adjustment. We note that all providers paid under the OPPS, including CMHCs, would receive a proposed 1.5 percent OPD fee schedule increase factor. Column 5 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2012 and the proposed CY 2012 wage index updates, results in an estimated decrease of 33.2 percent. Column 6 shows that adding the frontier State wage adjustment results in no change to the cumulative 33.2 percent decrease. Column 7 shows that adding the proposed changes in outlier and pass-though payments would result in a 33.1 percent decrease in payment for CMHCs that reflects all proposed changes for CY 2012.

The impact of the changes to hospital payment rates for partial hospitalization services is reflected in the impact of all proposed changes on hospitals. The impact of the decline in payment for APC 0034 appears most notably in small urban hospitals that furnish primarily outpatient psychiatric services.

All providers paid under the OPPS would receive a proposed 1.5 percent OPD fee schedule increase factor under this policy. Combining this proposed OPD fee schedule increase factor with proposed changes in APC policy for CY 2012, the proposed CY 2012 wage index updates, and with proposed changes in outlier and pass-through payments, we estimate that the combined impact on hospitals within the OPPS system

would be a 1.5 percent increase in total payment for CY 2012. Table 51 presents the estimated impact of the proposed changes to the OPPS for CY 2012.

TABLE 51.—ESTIMATED IMPACT OF THE CY 2012 PROPOSED CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENTS SYSTEM

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Number of Hospitals	APC Recali-bration	New Wage Index and Rural Adjust-ment	New Cancer Hospital Payment Adjust-ment	Comb (cols 2, 3,4) with Market Basket Update	Comb (col 5) with Frontier Wage Index Adjust-ment	All Changes
ALL FACILITIES *	4,141	0.0	0.0	0.0	1.5	1.6	1.5
ALL HOSPITALS	3,879	0.2	0.0	-0.6	1.0	1.1	1.1
(excludes hospitals permanently held harmless and CMHCs)							
URBAN HOSPITALS	2,928	0.2	0.0	-0.6	1.1	1.2	1.2
LARGE URBAN	1,592	0.2	0.0	-0.7	1.1	1.1	1.1
(GT 1 MILL.)							
OTHER URBAN	1,336	0.2	0.0	-0.6	1.1	1.3	1.2
(LE 1 MILL.)							
RURAL HOSPITALS	951	0.2	-0.3	-0.7	0.8	1.0	0.9
SOLE COMMUNITY	385	0.1	-0.2	-0.6	0.8	1.3	0.9
OTHER RURAL	566	0.3	-0.4	-0.7	0.8	0.8	0.9
BEDS (URBAN)							
0 - 99 BEDS	1,007	-0.1	0.1	-0.7	0.8	0.9	0.8
100-199 BEDS	856	0.4	0.1	-0.7	1.3	1.4	1.3
200-299 BEDS	445	0.4	0.1	-0.7	1.3	1.5	1.4
300-499 BEDS	417	0.2	-0.1	-0.6	1.0	1.0	1.0
500 + BEDS	203	0.0	0.1	-0.6	1.0	1.0	1.1
BEDS (RURAL)							
0 - 49 BEDS	340	0.2	-0.1	-0.7	0.9	1.1	1.0
50- 100 BEDS	364	0.1	-0.3	-0.6	0.6	0.9	0.7
101- 149 BEDS	140	0.5	-0.2	-0.7	1.1	1.3	1.2
150- 199 BEDS	60	0.2	-0.4	-0.7	0.6	1.2	0.7
200 + BEDS	47	0.1	-0.3	-0.6	0.8	0.8	0.8
VOLUME (URBAN)							
LT 5,000 Lines	611	-5.5	0.4	-0.7	-4.3	-4.2	-4.2

	5,000 - 10,999 Lines	146	-1.5	-0.1	-0.7	-0.8	-0.6	-0.8
	11,000 - 20,999 Lines	255	-0.2	-0.1	-0.7	0.6	0.6	0.6
	21,000 - 42,999 Lines	490	0.5	-0.1	-0.7	1.2	1.2	1.2
	42,999 - 89,999 Lines	738	0.5	0.1	-0.7	1.5	1.5	1.5
	GT 89,999 Lines	688	0.1	0.0	-0.6	1.0	1.1	1.1
	VOLUME (RURAL)							
	LT 5,000 Lines	71	-1.2	-0.2	-0.7	-0.7	1.4	-0.7
	5,000 - 10,999 Lines	81	0.9	0.1	-0.7	1.8	1.9	1.7
	11,000 - 20,999 Lines	184	0.3	-0.3	-0.7	0.8	1.0	0.8
	21,000 - 42,999 Lines	286	0.4	-0.3	-0.7	0.9	1.2	1.0
	GT 42,999 Lines	329	0.1	-0.3	-0.6	0.7	0.9	0.8
	REGION (URBAN)							
	NEW ENGLAND	150	0.0	3.8	-0.6	4.6	4.6	4.4
	MIDDLE ATLANTIC	351	0.1	0.1	-0.6	1.1	1.1	1.0
	SOUTH ATLANTIC	452	0.3	-0.6	-0.7	0.6	0.6	0.7
	EAST NORTH CENT.	469	0.3	-0.6	-0.6	0.6	0.6	0.6
	EAST SOUTH CENT.	184	0.4	-0.7	-0.6	0.5	0.5	0.7
	WEST NORTH CENT.	193	0.1	0.1	-0.6	1.1	1.8	1.3
	WEST SOUTH CENT.	489	0.3	0.3	-0.7	1.4	1.4	1.5
	MOUNTAIN	202	0.2	0.0	-0.6	1.0	1.4	1.2
	PACIFIC	390	0.0	-0.2	-0.7	0.7	0.7	0.8
	PUERTO RICO	48	0.3	0.5	-0.7	1.6	1.6	1.7
	REGION (RURAL)							
	NEW ENGLAND	26	-0.5	-0.5	-0.6	-0.1	-0.1	0.1
	MIDDLE ATLANTIC	68	0.2	-0.2	-0.6	0.9	0.9	1.0
	SOUTH ATLANTIC	162	0.4	-0.2	-0.7	1.0	1.0	1.1
	EAST NORTH CENT.	126	0.2	-0.7	-0.7	0.4	0.4	0.3
	EAST SOUTH CENT.	172	0.6	-0.6	-0.7	0.8	0.8	0.9
	WEST NORTH CENT.	101	-0.4	0.2	-0.6	0.7	1.8	1.0
	WEST SOUTH CENT.	201	0.4	0.1	-0.7	1.3	1.3	1.3
	MOUNTAIN	66	0.2	-0.6	-0.6	0.5	2.3	0.5
	PACIFIC	29	0.1	0.5	-0.6	1.5	1.5	1.7
	TEACHING STATUS							
	NON-TEACHING	2,891	0.3	-0.1	-0.7	1.0	1.1	1.1
	MINOR	699	0.3	-0.1	-0.6	1.0	1.2	1.1
	MAJOR	289	-0.1	0.4	-0.6	1.2	1.2	1.2
	DSH PATIENT PERCENT							
	0	7	-0.7	0.0	-0.7	0.1	0.1	0.3
	GT 0 - 0.10	343	0.2	0.2	-0.7	1.2	1.3	1.3
	0.10 - 0.16	359	0.4	-0.4	-0.7	0.8	0.9	0.8
	0.16 - 0.23	733	0.3	0.0	-0.7	1.1	1.3	1.1

0.23 - 0.35	1,037	0.3	0.0	-0.6	1.2	1.3	1.2
GE 0.35	789	0.1	0.1	-0.6	1.0	1.0	1.2
DSH NOT AVAILABLE **	611	-7.5	0.5	-0.7	-6.2	-6.2	-6.1
URBAN TEACHING/DSH							
TEACHING & DSH	901	0.2	0.1	-0.6	1.1	1.2	1.2
NO TEACHING/DSH	1,446	0.4	-0.1	-0.7	1.2	1.2	1.3
NO TEACHING/NO DSH	6	-0.7	0.0	-0.7	0.1	0.1	0.3
DSH NOT AVAILABLE**	575	-7.7	0.6	-0.7	-6.3	-6.3	-6.2
TYPE OF OWNERSHIP							
VOLUNTARY	2,060	0.3	0.1	-0.6	1.2	1.3	1.3
PROPRIETARY	1,259	0.0	-0.1	-0.7	0.7	0.8	0.8
GOVERNMENT	560	0.1	-0.4	-0.6	0.6	0.6	0.7
CMHCs	200	-34.2	0.0	-0.7	-33.2	-33.2	-33.1
Cancer Hospitals	11	0.2	0.6	38.8	41.5	41.5	37.8

Column (1) shows total hospitals and/or CMHCs.

Column (2) shows the impact of proposed changes resulting from the reclassification of HCPCS codes among APC groups and the proposed recalibration of APC weights based on CY 2010 hospital claims data.
Column (3) shows the proposed budget neutral impact of updating the wage index by applying the FY 2012 hospital inpatient wage index. See section II.C. for discussion of the estimated increase in payments to urban New England hospitals

Column (4) shows the proposed budget neutral estimated impact within the OPPS of applying a proposed cancer hospital adjustment to all OPPS services. However, we note that after accounting for the TOPs that we estimate cancer hospitals would no longer receive, the proposed net increase in payment to cancer hospitals would be approximately 9 percent.
Column (5) shows the impact of all proposed budget neutrality adjustments and the proposed addition of the 1.5 percent OPD fee schedule increase factor (2.8 percent reduced by 1.2 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 (6) shows the proposed non-budget neutral impact of applying the frontier State wage adjustment, after application of the CY 2012 proposed OPD fee schedule increase factor.

Column (7) shows the proposed additional adjustments to the conversion factor resulting from a proposed change in the pass-through estimate and adds proposed outlier payments. This column also shows the expiration of section 508 wages on September 30, 2011 and the application of the proposed frontier State wage adjustment for CY 2012.

*These 4,141 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.

(4) Estimated Effect of This Proposed Rule 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 2011 OPPS, the national unadjusted copayment is $228.76, and the minimum unadjusted copayment is $215.24, 20 percent of the national unadjusted payment rate of $1,076.14. For CY 2012, the proposed national unadjusted copayment for APC 0037 is $225.55, a decline from the copayment in effect for CY 2011. The proposed minimum unadjusted copayment for APC 0037 is $213.25 or 20 percent of the proposed CY 2012 national unadjusted payment rate for APC 0037 of $1,066.25. The proposed minimum unadjusted copayment would decline because the CY 2011 payment rate for APC 0037 would decline for CY 2012. For further discussion on the calculation of the proposed national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this proposed rule. We note that the proposed rural hospital and cancer hospital payment adjustments would result in corresponding increases in the beneficiary copayment, where those payment adjustments are applied. In all cases, the statute limits beneficiary liability for copayment for a procedure to the hospital inpatient deductible for the applicable year. The CY 2011 hospital inpatient deductible is $1,132 (75 FR 68799 through 68800). The CY 2012 hospital inpatient deductible was not known at the time this proposed rule was developed.

In order to better understand the impact of changes in copayment on beneficiaries, we modeled the percent change in total copayment liability using CY 2010 claims. We estimate, using the claims of the 4,141 hospitals and CMHCs on which our modeling is based, that total beneficiary liability for copayments would increase as an overall percentage of total payments, from 22.0 percent in CY 2011 to 22.1 percent in CY 2012 due largely to changes in service mix.

(5) Effects on Other Providers

The relative weights and payment amounts established under the OPPS affect the payments made to ASCs as discussed in section XIII. of this proposed rule. No types of providers other than hospitals and ASCs are affected by the changes we are proposing in this proposed rule.

(6) Effects on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be $3.285 billion in additional program payments for OPPS services furnished in CY 2012. 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 under section XX.A.4.a.(4). of this proposed rule.

(7) Alternatives Considered

Alternatives to the changes we are proposing to make and the reasons for our selected alternatives are discussed throughout this proposed rule. Some of the major

issues discussed in this proposed rule and the alternatives considered are discussed below.

● Alternatives Considered for Payment of the Acquisition and Pharmacy Overhead Costs of Drugs and Biologicals That Do Not Have Pass-Through Status

We are proposing that, for CY 2012, the OPPS would make payment for separately payable drugs and biologicals at ASP+4 percent, and this payment would continue to represent combined payment for both the acquisition and pharmacy overhead costs of separately payable drugs and biologicals. In addition, because we are proposing to continue to make a pharmacy overhead adjustment for CY 2012, we believe it is appropriate to account for inflation that has occurred since the overhead redistribution amount of $200 million was applied in CY 2011. Therefore, as discussed in further detail in section V.B.3. of this proposed rule, we believe that approximately $161 million of the estimated $705 million in pharmacy overhead cost currently attributed to coded packaged drugs and biologicals with an ASP and $54 million of the estimated $502 million in pharmacy overhead cost currently attributed to coded and uncoded packaged drugs and biologicals without an ASP should, instead, be attributed to separately payable drugs and biologicals to provide an adjustment for the pharmacy overhead costs of these separately payable products. As a result, we also are proposing to reduce the cost of packaged drugs and biologicals that is included in the payment for procedural APCs to offset the proposed $215 million adjustment to payment for separately payable drugs and biologicals. We are proposing that any redistribution of pharmacy overhead cost that may arise from CY 2012 final rule claims data would occur only from some drugs and

biologicals to other drugs and biologicals, thereby maintaining the estimated total cost of drugs and biologicals under the OPPS.

We considered two alternatives for payment of the acquisition and pharmacy overhead costs of drugs and biologicals that do not have pass-through status for CY 2012. The first alternative we considered, but are not proposing, is to compare 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 (70 FR 68642), but without redistribution of estimated pharmacy overhead costs. Under this methodology without redistribution, using April 2011 ASP information and costs derived from CY 2010 OPPS claims data, we estimated the combined acquisition and overhead costs of separately payable drugs and biologicals to be ASP-2 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 188 percent of ASP. We did not choose this alternative because we believe that this analysis indicates that our standard drug payment methodology has 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 and the one we are proposing for CY 2012 is to continue our pharmacy overhead redistribution methodology and proposing to apply an inflation allowance and redistribute $215 million in overhead costs from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals which would result in a payment for non-pass-through separately payable drugs and biologicals at ASP+4 percent, which would continue to represent a combined payment for both the acquisition costs of separately payable drugs and biologicals and the pharmacy overhead costs applicable to these products. We also are proposing to reduce the cost of packaged drugs and biologicals that is included in the payment for procedural APCs to offset the $215 million adjustment to payment for separately payable drugs and biologicals, resulting in payment for packaged drugs and biologicals of ASP+123 percent under our proposal.

We chose this alternative because we believe that it provides the most appropriate redistribution of pharmacy overhead costs associated with drugs and biologicals, based on the analyses discussed in section V.B.3. of this proposed rule.

- Proposed OPPS Payment Adjustment for Certain Cancer Hospitals

Section 3138 of the Affordable Care Act instructs the Secretary to conduct a study to determine if outpatient costs, including the cost of drugs and biologicals, incurred by

cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to ambulatory classification groups exceed the costs incurred by other hospitals furnishing services under this subsection (section 1833(t) of the Act). Further, section 3138 of the Affordable Care Act provides that if the cancer hospitals' costs with respect to APC groups are determined to be greater than the costs of other hospitals paid under the OPPS, the Secretary shall provide an appropriate budget neutral payment adjustment to reflect these higher costs.

As discussed in detail in section II. F. of this proposed rule, using the claims and cost report data that we used under the modeled proposed CY 2011 OPPS, we constructed our traditional provider-level database of costs, modeled payments, units, service mix, wage index and other provider information that we typically use to establish class adjustments under the OPPS. We observed that cancer hospitals were more costly with respect to APC groups than other hospitals paid under the OPPS, having a standardized cost per discounted unit of $150.12 compared to a standardized cost per discounted unit of $94.14 for all other hospitals.

Having reviewed the cost data from the standard analytic database and determined that cancer hospitals are more costly with respect to APC groups than other hospitals within the OPPS system, we are proposing a payment adjustment for cancer hospitals for CY 2012 based on a comparison of costliness relative to payments using cost report data. Specifically, our proposed adjustment is as follows: If a hospital described in section 1886(d)(1)(B)(v) of the Act has a PCR (as determined by the Secretary) that is less than the weighted average PCR of other hospitals furnishing services under section 1833(t) of

the Act (as determined by the Secretary) (Target PCR) for covered hospital outpatient department services (except pass-through devices defined in section 419.66), the payment adjustment is the percentage difference between the PCR of the hospital and the Target PCR. The CY 2012 proposed rule cost report data indicated a cancer hospital weighted average PCR of 0.647 (range = 0.56 to 0.82) and a weighted average PCR for all other hospitals equal to 0.901. Our proposed adjustment would result in an estimated 39.3 percent aggregate increase in budget neutral payments to cancer hospitals. For a cancer hospital with an individual PCR that is above the weighted average PCR of other hospitals furnishing services under the OPPS, we are proposing a zero percent adjustment for services furnished on and after January 1, 2012.

We considered three alternatives for the proposed OPPS payment adjustment for certain cancer hospitals. The first alternative we considered, but are not proposing, is to use our standard payment regression model instead of cost report data to identify an appropriate payment adjustment for cancer hospitals. We used this approach in our CY 2006 OPPS final rule with comment period to establish the 7.1 percent payment adjustment for rural SCHs (70 FR 68556 through 68561). However, in constructing our analysis of cancer hospitals' costs relative to other hospitals, we considered whether our standard analytical approach would lead to valid results. The analyses presented in the CY 2006 OPPS proposed and final rules were designed to establish an adjustment for a large class of rural hospitals. In contrast, section 3138 of the Affordable Care Act is specifically limited to identifying an adjustment for 11 cancer hospitals to the extent that their costs with respect to APC groups exceeded the costs incurred by other hospitals

furnishing services under section 1833(t) of the Act. With such a small sample size (11 out of approximately 4,000 hospitals paid under the OPPS), we were concerned that the standard explanatory and payment regression models used to establish the rural hospital adjustment would lead to imprecise estimates of payment adjustments for this small group of hospitals. Further, section 3138 of the Affordable Care Act specifies explicitly that cost comparisons between classes of hospitals must include the cost of drugs and biologicals. In our CY 2006 analysis of rural hospitals, we excluded the cost of drugs and biologicals in our model because the extreme units associated with proper billing for some drugs and biologicals can bias the calculation of a service mix index, or volume weighted average APC relative weight, for each hospital (70 FR 42698). Therefore, we chose not to pursue our standard combination of explanatory and payment regression modeling to determine a cancer hospital adjustment.

The second alternative we considered, but are not proposing, is to provide the same adjustment to all cancer hospitals based on the difference between the weighted average PCR for all cancer hospitals (0.647) and the weighted average PCR for all other hospitals (0.901). This class adjustment, instead of a hospital specific adjustment, would provide a 39.3 percent payment increase for each cancer hospital. Because this alternative did not seem equitable to other hospitals furnishing services under OPPS as it would result in a PCR for most cancer hospitals that is higher the weighted average PCR of other hospitals furnishing services under OPPS and a much larger budget neutrality adjustment, we did not propose this alternative.

The third alternative we considered, and the one we are proposing for CY 2012, is to provide a hospital specific payment adjustment to cancer hospitals that have a PCR that is less than the weighted average PCR of other hospitals furnishing services under the OPPS, for covered hospital outpatient department services (except pass-through devices) furnished on and after January 1, 2012, based on the percent difference between each cancer hospital's PCR and the weighted average PCR of other OPPS hospitals using the most recent cost report data. For cancer hospitals with an individual PCR that is above the weighted average PCR of other hospitals furnishing services under the OPPS, we are proposing a zero percent adjustment for services furnished on and after January 1, 2012. For purposes of calculating a proposed adjustment, we chose to rely on this straightforward assessment of payments and costs from the cost report data because of the concerns outlined above with respect to the small number of hospitals, and because of the challenges associated with accurately including drug and biological costs in our standard regression models. We believe that an appropriate adjustment would redistribute enough payments from other hospitals paid under the OPPS to the cancer hospitals to give cancer hospitals a PCR that is comparable to the average PCR for other hospitals paid under the OPPS.

● Alternatives Considered for the Supervision of Hospital Outpatient Therapeutic Services

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72012), we stated our intent to develop through our CY 2012 rulemaking an independent review process that enables the agency to request, with stakeholder input, advisory

recommendations regarding the appropriate supervision level for individual outpatient therapeutic services. We considered three alternatives with regard to the nature of the advisory recommendations regarding the appropriate supervision level for individual outpatient therapeutic services.

The first alternative we considered but are not proposing is to use an existing body other than the APC Panel such as the Relative Value Scale Update Committee to make recommendations to CMS with regard to the level of supervision that would be required for outpatient therapeutic services. We did not choose a different existing body because we did not believe there was an alternative that had an appropriate balance of subject matter expertise or that would be able to furnish the appropriate advice.

The second alternative we considered but are not proposing is to establish a new non-advisory body such as a Technical Expert Panel. We did not propose to establish a new entity because currently we have no funding to do so. Moreover, it is not clear that the resources of a new body are necessary for the supervision deliberations, especially once initial determinations are made regarding key services. Also, we believe it is important to obtain advice that carries the weight of a Federal advisory recommendation.

The third alternative we considered, and the one we selected, is to propose to establish the Federal Advisory APC Panel as an independent review body that would evaluate individual outpatient therapeutic services for potential assignment by CMS of general (lower) or personal (higher) supervision. We are proposing to amend the APC Panel charter to render the Panel more appropriate for this task by expanding its scope to include the topic of supervision. We also are proposing to add two to four members to

the Panel who would be representative of CAHs, so that all types of hospitals who are subject to the supervision rules for payment would be represented in developing the Panel's recommendations. We are proposing to use the standard APC Panel protocols with respect to frequency of meetings and receiving requests for evaluation of services. We believe it is important to obtain advice that carries the weight of a Federal advisory recommendation, because it may have greater legitimacy both with stakeholders and with CMS compared to the opinions of other types of groups. The APC Panel has a long and excellent history of providing valuable advice to CMS with regard to the clinical issues associated with the APC groupings of hospital outpatient therapeutic services under the OPPS, and we believe that extension of the function of the Panel to providing advice on supervision of individual hospital outpatient therapeutic services will result in both full consideration of the views of all types of hospitals and the best possible clinical decisions with respect to the level of supervision that should be required as a condition of Medicare payment.

b. Effects of Proposed ASC Payment System Changes in This Proposed Rule

On August 2, 2007, we published in the **Federal Register** the final rule for the revised ASC payment system, effective January 1, 2008 (72 FR 42470). In that final rule, we adopted the methodologies to set payment rates for covered ASC services to implement the revised payment system so that it would be designed to result in budget neutrality as required by section 626 of Pub. L. 108-173; established that the OPPS relative payment weights would be the basis for payment and that we would update the system annually as part of the OPPS rulemaking cycle; and provided that the revised

ASC payment rates would be phased in over 4 years. During the 4-year transition to full implementation of the ASC payment rates, payments for surgical procedures performed in ASCs that were on the CY 2007 ASC list of covered surgical procedures were made using a blend of the CY 2007 ASC payment rate and the ASC payment rate calculated according to the ASC standard ratesetting methodology for the applicable transitional year. In CY 2009, we paid ASCs using a 50/50 blend, in which payment was calculated by adding 50 percent of the CY 2007 ASC rate for a surgical procedure on the CY 2007 ASC list of covered surgical procedures and 50 percent of the CY 2009 ASC rate calculated according to the ASC standard ratesetting methodology for the same procedure. For CY 2010, we transitioned the blend to a 25/75 blend of the CY 2007 ASC rate and the CY 2010 ASC payment rate calculated according to the ASC standard ratesetting methodology. In CY 2011, we are paying ASCs for all covered surgical procedures, including those on the CY 2007 ASC list, at the ASC payment rates calculated according to the ASC standard ratesetting methodology.

ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII. of this proposed rule, we set the proposed CY 2012 ASC relative payment weights by scaling CY 2012 ASC relative payment weights by the ASC scalar of 0.9373. The estimated effects of the updated relative payment weights on payment rates during this second year of full implementation of the ASC payment rates calculated according to the ASC standard ratesetting methodology are varied and are reflected in the estimated payments displayed in Tables 52 and 53 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system, which is the consumer price index for all urban consumers (CPI-U), be reduced by the 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 multi-factor 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). We calculated the proposed CY 2012 ASC conversion factor by adjusting the CY 2011 ASC conversion factor by 1.0003 to account for changes in the pre-floor and pre-reclassified hospital wage indices between CY 2011 and CY 2012 and by applying the proposed CY 2012 MFP-adjusted CPI-U of 0.9 percent (2.3 percent CPI-U minus a productivity adjustment of 1.4 percent percentage points). The proposed CY 2012 ASC conversion factor is $42.329.

(1) Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2012 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service mix between CY 2010 and CY 2012 with precision. We believe that the net effect on Medicare expenditures resulting from the proposed CY 2012 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 This Proposed Rule on Payments to 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 2012 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 2012 update to the revised ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2010 claims data. Table 52 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2011 payments to estimated CY 2012 payments, and Table 53 shows a comparison of estimated CY 2011 payments to estimated CY 2012 payments for procedures that we estimate would receive the most Medicare payment in CY 2012.

Table 52 shows the estimated effects on aggregate proposed Medicare payments under the revised 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 52.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped or 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 2011 ASC Payments were calculated using CY 2010 ASC utilization (the most recent full year of ASC utilization) and CY 2011 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2011 ASC payments.

- Column 3—Estimated CY 2012 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that would be attributable to updates to proposed ASC payment rates for CY 2012 compared to CY 2011.

As seen in Table 52, we estimate that the proposed update to ASC rates for CY 2012 would result in a 0 percent decrease in aggregate payment amounts for eye and

ocular adnexa procedures, a 1 percent increase in aggregate payment amounts for digestive system procedures, and a 2 percent increase in aggregate payment amounts for nervous system procedures.

Generally, for the surgical specialty groups that account for less ASC utilization and spending, we estimate that the payment effects of the CY 2012 update are variable. For instance, we estimate that, in the aggregate, payment for genitourinary system procedures and hemic & lymphatic systems procedures would increase by 5 percent and 4 percent, respectively, whereas auditory system procedures and cardiovascular system procedures would decrease by 5 percent and 4 percent, respectively, under the proposed CY 2012 rates.

An estimated increase in aggregate payment for the specialty group does not mean that all procedures in the group would experience increased payment rates. For example, the estimated modest increase for CY 2012 for genitourinary system procedures is likely due to an increase in the ASC payment weight for some of the high volume procedures, such as CPT code 50590 (Fragmenting of kidney stone) where estimated payment would increase by 25 percent for CY 2012.

Also displayed in Table 52 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. Payment for New Technology Intraocular Lenses (NTIOLs) is captured under this category. Because the NTIOL class for reduced spherical aberration expired on February 26, 2011, and a new NTIOL class was not approved during CY 2011

rulemaking, we redistributed the estimated payment dedicated to separately paid NTIOLs in CY 2011 while the NTIOL class was active to other services for CY 2012. Therefore, we estimate that aggregate payments for these items and services would decrease by 30 percent for CY 2012.

TABLE 52.—ESTIMATED IMPACT OF THE PROPOSED CY 2012 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2012 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2011 ASC Payments (in Millions) (2)	Estimated CY 2012 Percent Change (3)
Total	$3,400	1%
Eye and ocular adnexa	$1,435	0%
Digestive system	$689	1%
Nervous system	$454	2%
Musculoskeletal system	$420	2%
Genitourinary system	$150	5%
Integumentary system	$132	1%
Respiratory system	$43	0%
Cardiovascular system	$32	-4%
Ancillary items and services	$29	-30%
Auditory system	$11	-5%
Hematologic & lymphatic systems	$5	4%

Table 53 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 2012. The table displays 30 of the procedures receiving the greatest estimated CY 2011 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2011 program payment.

- Column 1–HCPCS code.

- Column 2–Short Descriptor of the HCPCS code.

- Column 3–Estimated CY 2011 ASC Payments were calculated using CY 2010 ASC utilization (the most recent full year of ASC utilization) and the CY 2011 ASC payment rates. The estimated CY 2011 payments are expressed in millions of dollars.

- Column 4–Estimated CY 2012 Percent Change reflects the percent differences between the estimated ASC payment for CY 2011 and the estimated payment for CY 2012 based on the proposed update.

As displayed in Table 53, 21 of the 30 procedures with the greatest estimated aggregate CY 2011 Medicare payment are included in the 3 surgical specialty groups that are estimated to account for the most Medicare payment to ASCs in CY 2011, specifically eye and ocular adnexa, digestive system, and nervous system surgical groups. Consistent with the estimated payment effects on the surgical specialty groups displayed in Table 52 the estimated effects of the proposed CY 2012 update on ASC payment for individual procedures shown in Table 53 are varied.

The ASC procedure for which the most Medicare payment is estimated to be made in CY 2011 is the cataract removal procedure reported with CPT code 66984 (Cataract surg w/iol 1 stage). We estimate that the proposed update to the ASC rates would result in a 0 percent change for this procedure in CY 2012. The estimated payment effects on two of the other three eye and ocular adnexa procedures included in Table 53 are slightly more significant. We estimate that the payment rate for CPT code 66821 (After cataract laser surgery) would increase by 2 percent and payment for CPT code 67042 (Vit for macular hole) would increase by 3 percent.

We estimate that the proposed payment rates for all of the digestive system procedures included in Table 53 would change by -3 to +3 percent in CY 2012. During the previous 4-year transition to the revised ASC payment system, payment for most of the high volume digestive system procedures decreased each year because, under the previous ASC payment system, the payment rates for many high volume endoscopy procedures were almost the same as the payments for the procedures under the OPPS.

The estimated effects of the proposed CY 2012 update on the nine nervous system procedures for which the most Medicare ASC payment is estimated to be made in CY 2011 would be variable. Our estimates indicate that the proposed CY 2012 update would result in payment increases of 2 to 3 percent for 6 of the 9 procedures and result in a 1 to 5 percent decrease for the other 3 nervous system procedures. The nervous system procedure for which we estimate a negative effect on CY 2012 payments is CPT code 63650 (Implant neuroelectrodes) which is expected to have payment decrease of 5 percent.

The estimated payment effects for most of the remaining procedures listed in Table 53 would be positive. For example, the payment rate for musculoskeletal CPT codes 26055 (Incise finger tendon sheath) is estimated to increase 4 percent over the CY 2011 payment rates. Musculoskeletal procedures are expected to account for a greater percentage of CY 2012 Medicare ASC spending as we estimate that payment for procedures in that surgical specialty group would increase under the revised payment system in CY 2012.

TABLE 53.--ESTIMATED IMPACT OF THE PROPOSED CY 2012 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code* (1)	Short Descriptor (2)	Estimated CY 2011 ASC Payments (in millions) (3)	Estimated CY 2012 Percent Change (4)
66984	Cataract surg w/iol, 1 stage	$1,083	0%
43239	Upper GI endoscopy, biopsy	$158	-3%
45380	Colonoscopy and biopsy	$133	2%
45378	Diagnostic colonoscopy	$100	2%
45385	Lesion removal colonoscopy	$87	2%
66982	Cataract surgery, complex	$79	0%
62311	Inject spine l/s (cd)	$66	2%
64483	Inj foramen epidural l/s	$66	2%
66821	After cataract laser surgery	$56	2%
15823	Revision of upper eyelid	$41	0%
64493	Inj paravert f jnt l/s 1 lev	$40	2%
63650	Implant neuroelectrodes	$38	-5%
G0105	Colorectal scrn; hi risk ind	$32	3%
29881	Knee arthroscopy/surgery	$31	0%
29826	Shoulder arthroscopy/surgery	$31	2%
64721	Carpal tunnel surgery	$30	2%
29827	Arthroscop rotator cuf repr	$27	2%
29880	Knee arthroscopy/surgery	$26	0%
63685	Insrt/redo spine n generator	$26	-1%
G0121	Colon ca scrn not hi rsk ind	$25	3%
45384	Lesion remove colonoscopy	$24	2%
43235	Uppr gi endoscopy, diagnosis	$23	-3%
52000	Cystoscopy	$20	1%
28285	Repair of hammertoe	$19	0%
64622	Destr paravertebrl nerve l/s	$19	3%
64590	Insrt/redo pn/gastr stimul	$16	-1%
62310	Inject spine c/t	$16	2%
26055	Incise finger tendon sheath	$16	4%
50590	Fragmenting of kidney stone	$15	25%
67042	Vit for macular hole	$14	3%

*Note that HCPCS codes proposed for deletion for CY 2012 are not displayed in this table.

The previous ASC payment system served as an incentive to ASCs to focus on providing procedures for which they determined Medicare payments would support their continued operation. We note that, historically, the ASC payment rates for many of the most frequently performed procedures in ASCs were similar to the OPPS payment rates for the same procedures. Conversely, procedures with ASC payment rates that were substantially lower than the OPPS rates were performed least often in ASCs. We believed that the revised ASC payment system would encourage greater efficiency in ASCs and would promote significant increases in the breadth of surgical procedures performed in ASCs because it distributes payments across the entire spectrum of covered surgical procedures based on a coherent system of relative weights that are related to the clinical and facility resource requirements of those procedures.

The CY 2010 claims data that we used to develop the proposed CY 2012 ASC payment system relative payment weights and rates reflect the third year of utilization under the revised payment system. Although the changes in the claims data are not large, the data reflect increased Medicare ASC spending for procedures that were newly added to the ASC list in CY 2008. Our estimates based on CY 2010 data indicate that for CY 2012 there would be especially noticeable increases in spending for the hematologic and lymphatic systems compared to the previous ASC payment system.

(3) Estimated Effects of This Proposed Rule on Beneficiaries

We estimate that the proposed CY 2012 update to the ASC payment system would be generally positive for beneficiaries with respect to the new procedures that we are adding to the ASC list of covered surgical procedures and for those that we are

designating as office-based for CY 2012. 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, ASC payment rates under the revised payment system are lower than payment rates for the same procedures under the OPPS; therefore, the beneficiary coinsurance amount under the ASC payment system almost always would 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 would 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 2012, the beneficiary coinsurance amount would be no greater than the beneficiary coinsurance in the physician's office.

(4) Alternatives Considered

Alternatives to the changes we are proposing to make 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 Office-Based Procedures

According to our final policy for the revised 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, 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 revised ASC payment system.

In developing this proposed rule, we reviewed CY 2010 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 2011 OPPS/ASC final rule with comment period (75 FR 72036 through 72038). Based on that review, and as discussed in section XIII.C.1.b. of this proposed rule, we are proposing to newly designate 10 surgical procedures as permanently office-based and proposing to make temporary office-based designations for 8 procedures in CY 2012 that were designated as temporarily office-based for CY 2011. 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 ten procedures we are proposing to designate as permanently office-based and the eight procedures we are proposing to designate as temporarily office-based at an ASC payment rate calculated according to the standard ratesetting methodology of the revised ASC payment system. We did not select this alternative because our analysis of the data and our clinical review indicated that all 10 procedures we are proposing to designate as permanently office-based, as well as the 8 procedures that we are proposing 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 10 procedures we are proposing to designate as permanently office-based and the 8 procedures we are proposing 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 2012 is to designate 10 additional procedures as permanently office-based for CY 2012 and to designate 8 procedures as temporarily office-based in CY 2012 that were designated as temporarily office-based for CY 2011. We chose this alternative because our claims data

and clinical review indicate that these procedures could be considered to be predominantly performed in physicians' offices. We believe that designating these procedures as office-based, which results in the CY 2012 ASC payment rate for these procedures potentially being capped at the CY 2012 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. Accounting Statements and Tables

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf), we have prepared two accounting statements to illustrate the impacts of this proposed rule. The first accounting statement, Table 54 below, illustrates the classification of expenditures for the CY 2012 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2012 OPD fee schedule increase shown in this proposed rule, based on the FY 2012 President's Budget. The second accounting statement, Table 55 below, illustrates the classification of expenditures associated with the 0.9 percent proposed CY 2011 update to the revised ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs in the FY 2012 President's Budget. Lastly, both tables classify all estimated impacts as transfers.

TABLE 54.--ACCOUNTING STATEMENT: CY 2012 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2011 TO CY 2012 ASSOCIATED WITH THE PROPOSED CY 2012 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$0.5 billion
From Whom to Whom	Federal Government to outpatient hospitals and other providers who received payment under the hospital OPPS
Total	$0.5 billion

TABLE 55.--ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2011 TO CY 2012 AS A RESULT OF THE PROPOSED CY 2012 UPDATE TO THE REVISED ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$26 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$26 million

d. Effect of Proposed Requirements for the Hospital Outpatient Quality Reporting (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), and section XVI. of the CY 2011 OPPS/ASC final rule with comment period (75 FR72064 through 72110), we discussed our 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 CY 2012-2014, respectively. In section XIV. of this proposed rule, we are

proposing additional policies affecting the Hospital OQR Program for CY 2013, CY 2014, and CY 2015.

We determined that 107 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor for CY 2011. Most of these hospitals (over 90 of the 107) received little or no OPPS payment on an annual basis and did not participate in the Hospital OQR Program. We estimate that 120 hospitals may not receive the full OPD fee schedule increase factor in CY 2012. 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 2013, CY 2014 and 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 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 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 this proposed rule, we are proposing 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 the CY 2011 and CY 2012 payment determinations, and under our proposal for 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.

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 2013. Therefore, we are unable to estimate the number of hospitals that would fail the validation documentation submission requirement for the proposed CY 2013 payment update.

The validation requirements for CY 2011, CY 2012, and the validation requirement proposed for CY 2013 would result in result in medical record documentation for approximately 7,300 cases for CY 2011, 9,600 cases per quarter for CY 2012, and approximately 6,000 cases per quarter for CY 2013, respectively, being submitted to a designated CMS contractor. We would 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 the CY 2011 and CY 2012 payment determinations, and proposed for the CY 2013 payment determination, respectively, we would have expenditures of approximately $16,060 for CY 2011, $21,120 per quarter for CY 2012, and approximately $13,200 per quarter for CY 2013. Again, as we would pay for the data collection effort, we believe that a requirement for medical record documentation for 7,300 total cases for CY 2011, a maximum of 12 cases per quarter for 800 hospitals for CY 2012, and a maximum of 12 cases per quarter for up to 500 hospitals for CY 2013 represents a minimal burden to Hospital OQR Program participating hospitals.

In previous years, medical record documentation was requested by a CMS contractor and hospitals were given 45 days from the date of the request to submit the requested documentation. In section XIV.G.3.d. of this proposed rule, for the CY 2013 payment determination, we are proposing to reduce the time from 45 days to 30 days for hospitals to submit requested medical record documentation to meet our validation requirement; this may create an additional administrative burden. The total burden would

be a maximum of 12 charts for each of the four quarters that must be copied and mailed within a 30-day period after the end of each quarter. We are proposing this deadline of 30 days to align the process with requirements in 42 CFR 476.78(b)(2), which allows 30 days for chart submission in the context of QIO review and to reduce the time for data validation completion to increase timeliness of providing hospitals feedback on their abstraction accuracy.

e. Effects of Proposed Changes to Physician Self-Referral Regulations

Section 6001(a) of the Affordable Care Act amended the whole hospital and rural provider exceptions (sections 1877(d)(2) and (d)(3) of the Act, respectively) to impose additional restrictions on physician ownership or investment in hospitals. The amended whole hospital and rural provider exceptions provide that a hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). Section 6001(a)(3) of the Affordable Care Act added new section 1877(i)(3)(A)(i) of the Act to set forth that the Secretary shall establish and implement an exception process to the prohibition on expansion of facility capacity.

Most physician-owned hospitals are unable to qualify for the ownership and investment exception at section 1877(d)(1) of the Act. Section 1877(d)(1) of the Act provides an exception for ownership or investment in publicly traded securities in a corporation where there is stockholder equity exceeding $75 million at the end of the

corporation's most recent fiscal year or on average during the previous 3 fiscal years; or the ownership involves mutual funds in a company that has assets greater than $75 million. Studies by the OIG and GAO have concluded that physician-owned hospitals tend to be smaller and are unable to meet the $75 million threshold.

The proposed regulations at §411.362(c) set forth the proposed process for a hospital to request an exception to the prohibition on expansion of facility capacity. Proposed new §411.362(c)(2) outlines the requirements for an applicable hospital request and §411.362(c)(3) outlines the requirements for a high Medicaid facility request. Our proposed regulations would require each hospital desiring an exception to access certain data and make estimates based on that data to determine if the hospital meets the relevant criteria. For example, a hospital would be required to access data furnished by the CMS Healthcare Cost Report Information System (HCRIS) and by the Bureau of the Census, in addition to referencing data from the hospital's individual cost reports and making certain estimates on the basis of its cost report data. We believe the impact of these requirements on affected hospitals would be minimal.

Our proposed regulations would require each hospital requesting an exception to provide documentation supporting its calculations to demonstrate that it satisfies the relevant criteria. Our proposed regulations would further require each hospital to provide documentation to support information related to its number of operating rooms, procedure rooms, and beds. This information would include, for example, the number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of the date that the hospital submits a request for an exception. Each hospital would also be

required to provide a detailed explanation regarding whether and how it satisfies each of the relevant criteria. We believe physician-owned hospitals would be minimally affected by these requirements.

Our proposed regulations would require each hospital requesting an exception to disclose on a public Web site for the hospital that it is requesting an exception. Our proposed regulations would require each hospital to certify that it does not discriminate and does not permit physicians to discriminate against beneficiaries of Federal health care programs. In addition, under our proposed regulations, if CMS were to receive input from the community related to a particular hospital's request for an exception, the hospital may submit a rebuttal statement in response to input from the community. We believe the impact of these requirements on physician-owned hospitals would be minimal.

We believe our proposals would affect a relatively small number of physician-owned hospitals. We estimate that 265 physician-owned hospitals are eligible to apply for an exception. We believe accurately estimating the number of hospitals choosing to request an exception would be impracticable. Further, we are not aware of any existing data or projections that may produce an estimate with reasonable certainty. As a result, we are choosing to estimate that each of the 265 eligible hospitals will request an exception in order to avoid underestimating the potential impact. We are not aware of any data that may indicate the potential increase in operation rooms, procedure rooms, or beds pursuant to exceptions potentially approved. We also have no data or projections

that may help estimate the number of physicians that would be affected by this proposed rule as a result of their ownership interests in hospitals.

The proposed requirements concerning the criteria and process for hospitals seeking an exception to the prohibition on expansion of facility capacity are consistent with the physician self-referral statute and regulations and the current practices of most hospitals. Thus, our proposed requirements would present a negligible impact on physician-owned hospitals. Physician-owned hospitals would bear costs associated with requesting an exception to the prohibition on facility expansion. In part because hospitals are currently undertaking the costs of producing a cost report, we believe that the cost of referencing the required data and making the required estimates would be negligible. In addition, we believe the costs of providing supporting documentation, certifying nondiscrimination against beneficiaries of Federal health care programs, and submitting other required information necessary to request an exception to CMS would be minimal.

We believe that beneficiaries may be positively impacted by these proposed provisions. Specifically, an increase in operating rooms, procedure rooms, and beds may augment the volume or nature of services offered by physician-owned hospitals. An expansion in the number of hospital beds may also permit additional inpatient admissions and overnight stays. Increased operating rooms, procedure rooms, and beds may result in improved access to health care facilities and services. We believe that our proposals are necessary to conform our regulations to the amendments to section 1877 of the Act. We also believe the proposed regulations would help minimize anticompetitive behavior that

can affect the decision as to where a beneficiary receives health care services and would possibly enhance the services furnished.

In this proposed rule, we are soliciting public comments on each of the issues outlined above that contain estimates of the costs and benefits of the proposed rule.

f. Effects of Proposed Changes to Provider Agreement Regulations on Patient Notification Requirements

In section XV.D. of this proposed rule, we discuss our proposal concerning the requirement that all hospitals and critical access hospitals must furnish written notice to their patients at the beginning of their hospital stay or outpatient visit if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week, and that the notice must indicate how the hospital will meet the medical needs of any patient who develops an emergency medical condition at a time when there is no physician present in the hospital. In this proposed rule, we are proposing to modify the provider agreement regulations to reduce the categories of outpatients who must be notified if hospital does not have a doctor of medicine or doctor of osteopathy on site 24 hours per days/7 days per week. We are proposing that only those outpatients who receive observation services, surgery, or services involving anesthesia must receive written notice. We are not making any changes to our patient safety requirements for physician-owned hospitals at §411.362(b)(5)(i). We continue to believe that patients should be made aware of whether or not a doctor of medicine or a doctor of osteopathy is present in the hospital at all times, and the hospital's plans to address patient's emergency medical conditions when a doctor of medicine or a doctor of osteopathy is not present.

We believe our proposed changes to the provider agreement regulations would result in only a minor change in the number of hospitals that are subject to the disclosure requirements, specifically those multicampus hospitals that currently have 24 hour per day, seven day per week presence of a doctor of medicine or a doctor of osteopathy on one, but not all of their campuses with inpatient services. We anticipate that very few multicampus hospitals would fall into this category. Rather, the primary impact of the proposed regulation would be to change the number of annual written disclosures given by hospitals to patients. We believe the cost of implementing these provisions borne by hospitals would be limited to a one-time cost associated with completing minor revisions to portions of the hospitals policies and procedures related to patient admission and registration, as well as providing written notification to patients and affected staff. Therefore, we do not believe that these proposed changes will have any significant economic impact on hospitals.

We do not anticipate that our proposals will have a significant economic impact on a substantial number of physicians, other health care providers and suppliers, or the Medicare or Medicaid programs and their beneficiaries. Specifically, we believe that this proposed rule will affect mostly hospitals, physicians, and beneficiaries. The proposed changes concerning the disclosure of the presence of a doctor of medicine or a doctor of osteopathy in hospitals is consistent with the physician self-referral statute and regulations as well as the current practices of most hospitals. Thus, our physician presence disclosure proposal would present a negligible economic impact on the hospital.

Overall, we believe that beneficiaries will be positively impacted by these provisions. Specifically, disclosure of physician presence equips patients to make informed decisions about where they elect to receive care. Our proposal makes no significant change that has the potential to impede patient access to health care facilities and services. In fact, we believe that our proposal will help minimize anti-competitive behavior that can affect the decision as to where a beneficiary receives health care services and possibly the quality of the services furnished.

g. Effects of Additional Proposed Hospital VBP Program Requirements

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital VBP Program to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction to the FY 2013 base operating MS–DRG payment amount for each discharge of 1 percent, as required by section 1886(o)(7)(B)(i) of the Act. The applicable percentage for FY 2014 is 1.25 percent, for FY 2015 is 1.5 percent, for FY 2016 is 1.75 percent, and for FY 2017 and subsequent years is 2 percent. In section XVI.A.3. of this proposed rule, we are proposing additional requirements for the FY 2014 Hospital VBP Program. Specifically, we are proposing to add one chart-abstracted measure to the Hospital VBP measure set for the FY 2014 payment determination. Because this additional measure is chart-abstracted and is required for the Hospital IQR Program, its inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program.

h. Effects of the Proposed EHR Reporting Pilot

Under section XIV.J. 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 2012 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 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.

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 Web site at http://sba.gov; choose "Contracting" and select "Table of Small Business Size Standards" in PDF or Excel.

In addition, section 1102(b) of the Social Security 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 fewer than 100 beds. We estimate that this proposed rule may have a significant impact on approximately 704 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 $135 million. This proposed rule would not mandate any requirements for State, local, or tribal governments, nor would it affect private sector costs.

D. Conclusion

The changes we are proposing would affect all classes of hospitals paid under the OPPS and would affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2012. Table 51 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 1.5 percent increase in payments for all services paid under the OPPS in CY 2012, after considering all proposed changes to APC reconfiguration and recalibration, as well as the proposed OPD fee schedule increase factor, wage index changes, including the proposed frontier State wage index adjustment, estimated payment for outliers, and changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience significant gains and others would experience modest losses in OPPS payments in CY 2012. Specifically, we estimate that the 11 dedicated cancer hospitals that met the classification criteria in section 1883(d)(1)(B)(v) of the Act, as a class, would receive an increase in payments under the OPPS of 38.8 percent for CY 2012, although after accounting for the TOPs that we estimate they would no longer receive due to increased payments under the OPPS, the net increase in payment to these hospitals would be approximately 9 percent. In contrast, we estimate that CMHCs would see an overall decrease in payment of 33.1 percent as a result of the proposed full transition in CY 2012 to payment rates for partial hospitalization services at CMHCs based on cost report and claims data submitted by CMHCs.

The proposed updates to the ASC payment system for CY 2012 would affect each of the approximately 5,000 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 that are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the revised payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 52 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted CPI-U update of 0.9 percent proposed for CY 2012.

XXI. 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 would 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 51 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 1.5 percent under this proposed rule. While we do not know the number of ASCs with government ownership, we anticipate that it is small. We believe that the proposed provisions related to

payments to ASCs in CY 2012 would not affect payments to any ASCs owned by government entities.

The analyses we have provided in section XX.A. of this proposed rule, in conjunction with the remainder of this document, demonstrates 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 and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, 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, Incorporation by reference, 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 410--SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation for Part 410 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Section 410.27 is amended by—

a. Revising the section heading.

b. Revising paragraph (a).

c. In paragraph (b), removing the cross-reference "§410.168" and adding in its place the cross-reference "§410.29".

d. In paragraph (c), removing the cross-reference "§410.168" and adding in its place the cross-reference "subpart G of Part 424 of this chapter".

e. Redesignating paragraphs (d) through (f) as paragraphs (e) through (g), respectively.

f. Adding a new paragraph (d).

The revisions and addition read as follows:

§410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service, which are defined as all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals that cannot be self-administered, if—

(1) They are furnished—

(i) By or under arrangements made by the participating hospital or CAH, except in the case of a SNF resident as provided in §411.15(p) of this subchapter;

(ii) As an integral although incidental part of a physician's or nonphysician practitioner's services;

(iii) In the hospital or CAH or in a department of the hospital or CAH, as defined in §413.65 of this subchapter; and

(iv) Under the direct supervision (or other level of supervision as specified by CMS for the particular service) of a physician or a nonphysician practitioner as specified in paragraph (g) of this section, subject to the following requirements:

(A) For services furnished in the hospital or CAH, or in an outpatient department of the hospital or CAH, both on and off-campus, as defined in §413.65 of this subchapter, "direct supervision" means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of

the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed;

(B) Certain therapeutic services and supplies may be assigned either general supervision or personal supervision. When such assignment is made, g*eneral supervision* means the definition specified at §410.32(b)(3)(i), and *personal supervision* means the definition specified at §410.32(b)(3)(iii);

(C) Nonphysician practitioners may directly supervise services that they may personally furnish in accordance with State law and all additional requirements, including those specified in §§410.71, 410.73, 410.74, 410.75, 410.76, and 410.77;

(D) For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§410.47 and 410.49, respectively; and

(E) For *nonsurgical extended duration therapeutic services (extended duration services)*, which are hospital or CAH outpatient therapeutic services that can last a significant period of time, have a substantial monitoring component that is typically performed by auxiliary personnel, have a low risk of requiring the physician's or appropriate nonphysician practitioner's immediate availability after the initiation of the service, and are not primarily surgical in nature, Medicare requires a minimum of direct supervision during the initiation of the service which may be followed by general supervision at the discretion of the supervising physician or the appropriate nonphysician practitioner. "Initiation" means the beginning portion of the nonsurgical extended duration therapeutic service which ends when the patient is stable and the supervising

physician or the appropriate nonphysician practitioner determines that the remainder of the service can be delivered safely under general supervision.

(2) In the case of partial hospitalization services, also meet the conditions of paragraph (e) of this section.

* * * * *

(d) Rules on emergency services furnished to outpatients in a foreign country are specified in subpart H of Part 424 of this chapter.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

3. The authority citation for Part 411 continues to read as follows:

Authority: Secs. 1102, 1860D-1 through 1860D-42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w-101 through 1395w-152, 1395hh and 1395nn).

4. Section 411.362 is amended by—

a. Adding in paragraph (a) definitions of "baseline number of operating rooms, procedure rooms, and beds" and "main campus of the hospital" in alphabetical order.

b. Revising paragraph (b)(2).

c. Adding paragraph (c).

The revision and additions read as follows:

§411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) * * *

Baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure rooms, and beds for which the applicable hospital or high Medicaid facility is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of such date, but does have a provider agreement in effect on December 31, 2010, the date of effect of such agreement).

Main campus of the hospital means "campus" as defined at § 413.65(a)(2).

* * * * *

(b) * * *

(2) Prohibition on facility expansion. The hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital is licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement), unless an exception is granted pursuant to paragraph (c) of this section.

* * * * *

(c) Criteria for an individual hospital seeking an exception to the prohibition on facility expansion.

(1) General. An applicable hospital or high Medicaid facility may request an exception from the prohibition on facility expansion up to once every 2 years from the date of a CMS decision on the hospital's most recent request.

(2) Criteria for applicable hospital. An applicable hospital is a hospital that satisfies all of the following criteria:

(i) Population increase. Is located in a county that has a percentage increase in population that is at least 150 percent of the percentage increase in population of the State in which the hospital is located during the most recent 5-year period for which data are available as of the date that the hospital submits its request. To calculate State and county population growth, a hospital must use Bureau of the Census estimates.

(ii) Medicaid inpatient admissions. Has an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located for each of the 3 most recent fiscal years for which data are available as of the date that the hospital submits its request. A hospital must use filed hospital cost report discharge data to estimate its annual percent of total inpatient admissions under Medicaid.

(iii) Nondiscrimination. Does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(iv) Average bed capacity. Is located in a State in which the average bed capacity in the State is less than the national average bed capacity for each of the 3 most recent fiscal years for which data are available as of the date that the hospital submits its request.

(v) Average bed occupancy. Has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located for each of the 3 most recent fiscal years for which data are available as of the date that the

hospital submits its request. A hospital must use filed hospital cost report data to determine its average bed occupancy rate.

(3) Criteria for high Medicaid facility. A high Medicaid facility is a hospital that satisfies all of the following criteria:

(i) Sole hospital. Is not the sole hospital in the county in which the hospital is located.

(ii) Medicaid inpatient admissions. With respect to each of the 3 most recent fiscal years for which data are available as of the date the hospital submits its request, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located. A hospital must use filed hospital cost report discharge data to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for every other hospital located in the county in which the hospital is located.

(iii) Nondiscrimination. Does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(4) Procedure for submitting a request. (i) A hospital must either mail an original and one copy of the written request to CMS or submit the request electronically to CMS. If a hospital submits the request electronically, the hospital must mail an original hard copy of the signed certification set forth in paragraph (c)(4)(iii) of this section to CMS.

(ii) A request must include the following information:

(A) The name, address, National Provider Identification number(s) (NPI), Tax Identification Number(s) (TIN), and CMS Certification Number(s) (CCN) of the hospital requesting an exception.

(B) The county in which the hospital requesting an exception is located.

(C) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with CMS on behalf of the hospital.

(D) A statement identifying the hospital as an applicable hospital or high Medicaid facility and a detailed explanation with supporting documentation regarding whether and how the hospital satisfies each of the criteria for an applicable hospital or high Medicaid facility. The request must state that the hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(E) Documentation supporting the hospital's calculations of its baseline number of operating rooms, procedure rooms, and beds; the hospital's number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of the date that the hospital submits a request for an exception; and the additional number of operating rooms, procedure rooms, and beds by which the hospital requests to expand.

(iii) A request must include the following certification signed by an authorized representative of the hospital: "With knowledge of the penalties for false statements provided by 18 U.S.C. 1001, I certify that all of the information provided in the request and all of the documentation provided with the request is true and correct to the best of

my knowledge and belief." An authorized representative is the chief executive officer, chief financial officer, or other comparable officer of the hospital.

(5) Community input and timing of complete request. Upon submitting a request for an exception and until the hospital receives a CMS decision, the hospital must disclose on any public Web site for the hospital that it is requesting an exception. Individuals and entities in the hospital's community may provide input with respect to the hospital's request no later than 30 days after CMS publishes notice of the hospital's request in the **Federal Register**. Such input must take the form of written comments. The written comments must be either mailed or submitted electronically to CMS.

(i) If CMS does not receive written comments from the community, a request will be deemed complete at the end of the 30-day period.

(ii) If CMS receives written comments from the community, the hospital has 30 days after CMS notifies the hospital of the written comments to submit a rebuttal statement. A request will be deemed complete at the end of this 30-day period regardless of whether the hospital submits a rebuttal statement.

(6) A permitted increase under this section—

(i) May not exceed 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and

(ii) May occur only in facilities on the hospital's main campus.

(7) Publication of final decisions. Not later than 60 days after receiving a complete request, CMS will publish the final decision in the **Federal Register**.

(8) Limitation on review. There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the process under this section (including the establishment of such process).

PART 416—AMBULATORY SURGICAL SERVICES

5. The 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).

6. Section 416.166 is amended by revising paragraph (b) to read as follows:

§416.166 Covered surgical procedures.

* * * * *

(b) General standards. Subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the Internet on the CMS Web site that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

* * * * *

7. Section 416.171 is amended by revising paragraphs (b) and (d) to read as follows:

§416.171 Determination of payment rates for ASC services.

* * * * *

(b) Exception. The national ASC payment rates for the following items and services are not determined in accordance with paragraph (a) of this section but are paid an amount derived from the payment rate for the equivalent item or service set under the payment system established in part 419 of this subchapter as updated annually in the **Federal Register** and/or via the Internet on the CMS Web site.

* * * * *

(d) Limitation on payment rates for office-based surgical procedures and covered ancillary radiology services. Notwithstanding the provisions of paragraph (a) of this section, for any covered surgical procedure under §416.166 that CMS determines is commonly performed in physicians' offices or for any covered ancillary radiology service, excluding those listed in paragraphs (d)(1) and (2) of this section, the national unadjusted ASC payment rates for these procedures and services will be the lesser of the amount determined under paragraph (a) of this section or the amount calculated at the nonfacility practice expense relative value units under § 414.22(b)(5)(i)(B) of this subchapter multiplied by the conversion factor described in § 414.20(a)(3) of this subchapter.

(1) The national unadjusted ASC payment rate for covered ancillary radiology services that involve certain nuclear medicine procedures will be the amount determined under paragraph (a) of this section.

(2) The national unadjusted ASC payment rate for covered ancillary radiology services that use contrast agents will be the amount determined under paragraph (a) of this section.

* * * * *

8. Section 416.173 is revised to read as follows:

§416.173 Publication of revised payment methodologies and payment rates.

CMS publishes annually, through notice and comment rulemaking in the **Federal Register** and/or via the Internet on the CMS Web site, the payment methodologies and payment rates for ASC services and designates the covered surgical procedures and covered ancillary services for which CMS will make an ASC payment and other revisions as appropriate.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

9. 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), and1395hh).

10. Section 419.32 is amended by:

a. Revising paragraph (b)(1)(iv)(A).

b. Removing the word “and” that appears at the end of paragraph (b)(1)(iv)(B)(1).

c. Removing the period and adding “; and” in its place at the end of paragraph (b)(1)(iv)(B)(2).

d. Adding a new paragraph (b)(1)(iv)(B)(3).

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 hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, reduced by the factor(s) specified in paragraph (b)(1)(iv)(B) of this section.

(B) * * *

(3) For calendar year 2012, a multifactor productivity adjustment (as determined by CMS) and 0.1 percentage point.

* * * * *

11. Section 419.43 is amended by adding paragraph (i) to read as follows:

§419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(i) Payment adjustment for certain cancer hospitals.—(1) General rule. CMS provides for a payment adjustment for covered hospital outpatient department services furnished on or after January 1, 2012, by a hospital described in section 1886(d)(1)(B)(v) of the Act.

(2) Amount of payment adjustment. The amount of the payment adjustment under paragraph (i)(1) of this section is determined by the Secretary as follows:

(i) If a hospital described in section 1886(d)(1)(B)(v) of the Act has a payment-to-cost ratio (as determined by the Secretary) that is less than the weighted average payment-to-cost ratio of other hospitals furnishing services under section 1833(t) of the Act (as determined by the Secretary) (referred to as the target payment-to-cost ratio), for covered hospital outpatient department services except pass-through devices as defined in §419.66, the payment adjustment is the percentage difference between the payment-to-cost ratio of the hospital and the target payment-to-cost ratio.

(ii) If a hospital described in section 1886(d)(1)(B)(v) of the Act has a payment-to-cost ratio (as determined by the Secretary) that is less than the weighted average payment-to-cost ratio of other hospitals furnishing services under section 1866(t) of the Act (as determined by the Secretary) (referred to as the target payment –to-cost ratio), for pass-through devices as defined in §419.66, the payment adjustment is zero percent.

(iii) If a hospital described in section 1886(d)(1)(B)(v) of the Act has a payment-to-cost ratio (as determined by the Secretary) that is greater than the target

payment–to-cost ratio (as determined by the Secretary), for covered hospital outpatient department services, the payment adjustment is zero percent.

(3) Budget neutrality. CMS establishes the payment adjustment under paragraph (i)(1) of this section in a budget neutral manner.

12. Section 419.70 is amended by revising paragraphs (d)(2) introductory text and (d)(6) to read as follows:

§419.70 Transitional adjustments to limit decline in payments.

* * * * *

(d) * * *

(2) Temporary treatment for small rural hospitals on or after January 1, 2006. For covered hospital outpatient services furnished in a calendar year from January 1, 2006, through December 31, 2011, 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, and 2011 if the hospital—

* * * * *

(6) Temporary treatment for sole community hospitals on or after January 1, 2010, and through December 31, 2011. For covered hospital outpatient services furnished on or after January 1, 2010, through December 31, 2011, 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 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.

* * * * *

PART 489--PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

13. The authority citation for Part 489 continues to read as follows:

Authority: Secs. 1102, 1819, 1820(e), 1861, 1864(m), 1866, 1869, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh).

14. Section 489.20 is amended by revising paragraph (w) to read as follows:

§489.20 Basic commitments.

* * * * *

(w)(1) In the case of a hospital as defined in §489.24(b), to furnish written notice to all patients at the beginning of their planned or unplanned inpatient hospital stay or at the beginning of any planned or unplanned outpatient visit for observation, surgery or any other procedure requiring anesthesia, if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week, in order to assist the patients in making informed decisions regarding their care, in accordance with § 482.13(b)(2) of this subchapter. For purposes of this paragraph, a planned hospital stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for

inpatient care or outpatient service. An unplanned hospital stay or outpatient visit begins at the earliest point at which the patient presents to the hospital.

(2) In the case of a hospital that is a main provider and has one or more remote locations of a hospital or one or more satellites, as these terms are defined in § 413.65(a)(2), § 412.22(h), or § 412.25(e) of this chapter, as applicable, the determination is made separately for the main provider and each remote location or satellite whether notice to patients is required. Notice is required at each location at which inpatient services are furnished at which a doctor of medicine or doctor of osteopathy is not present 24 hours per day, 7 days per week.

(3) The written notice must state that the hospital does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the hospital will meet the medical needs of any patient who develops an emergency medical condition, as defined in § 489.24(b), at a time when there is no doctor of medicine or doctor of osteopathy present in the hospital.

(4) Before admitting a patient or providing an outpatient service to outpatients for whom a notice is required, the hospital must receive a signed acknowledgment from the patient stating that the patient understands that a doctor of medicine or doctor of osteopathy may not be present during all hours services are furnished to the patient.

(5) Each dedicated emergency department, as that term is defined in § 489.24(b), in a hospital in which a doctor of medicine or doctor of osteopathy is not present 24 hours per day, 7 days per week must post a notice conspicuously in a place or places likely to be noticed by all individuals entering the dedicated emergency department. The posted

notice must state that the hospital does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the hospital will meet the medical needs of any patient with an emergency medical condition, as defined in § 489.24(b), at a time when there is no doctor of medicine or doctor of osteopathy present in the hospital.

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

15. 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).

16. Section 495.8 is amended by revising paragraph (b)(2)(ii) and adding paragraph (b)(2)(vi) to read as follows:

§495.8 Demonstration of meaningful use criteria.

* * * * *

(b) * * *

(2) * * *

(ii) Reporting clinical quality information. For § 495.6(f)(9) "Reporting hospital clinical quality measures to CMS or, in the case of Medicaid eligible hospitals, the States," report the hospital quality measures selected by CMS to CMS (or in the case of Medicaid eligible hospitals, the States) in the form and manner specified by CMS (or in the case of Medicaid eligible hospitals, the States).

* * * * *

(vi) Exception for Medicare eligible hospitals and CAHs for FY 2012--Participation in the Medicare EHR Incentive Program Electronic Reporting Pilot. In order to satisfy the clinical quality measure reporting objective in § 495.6(f)(9), aside from attestation, a Medicare eligible hospital or CAH may participate in the Medicare EHR Incentive Program Electronic Reporting Pilot.

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CMS-1525-P

(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 24, 2011

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Donald M. Berwick,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: June 28, 2011

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Kathleen Sebelius,

Secretary.

BILLING CODE 4120-01-P

[FR Doc. 2011-16949 Filed 07/01/2011 at 4:15 pm; Publication Date: 07/18/2011]